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FIFTH JUDICIAL DISTRICT COURT
BEAVERHEAD COUNTY
FILED
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BY

MONTANA FIFTH JUDICIAL DISTRICT COURT,
BEAVERHEAD COUNTY

CV-17-50-Bu-SEH

TRINA HEALTH OF MONTANA LLC, HAROLD LARON BRIGGS, BARRY BRIGGS, and HAROLD L. GROGAN, Plaintiffs, -vs- HEALTH CARE SERVICE CORPORATION d/b/a BLUE CROSS AND BLUE SHIELD OF MONTANA, Defendant.	Cause No. DV-17-14044 Judge: Honorable Luke Berger **PETITION FOR DECLARATORY JUDGMENT AND APPLICATION FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF**

Plaintiffs Trina Health of Montana LLC ("Trina"), Harold LaRon ("Ron") Briggs, Barry Briggs, and Harold L. Grogan (the individual plaintiffs collectively referred to hereafter as the "Patients" and "Plaintiff Patients", and all Plaintiffs collectively referred to as the "Plaintiffs"), by and through their undersigned counsel of record, file this *Petition for Declaratory Judgment and Application for Preliminary and Permanent Injunctive Relief* ("*Petition*"):

GENERAL ALLEGATIONS

1. This Petition is brought pursuant to §27-8-101, et seq., MCA, which statutory sections constitute the applicable portion to this action of the Uniform Declaratory Judgments Act, and pursuant to §27-19-201, et seq., MCA, which Montana statutes govern petitions for injunctive relief.

2. The jurisdiction of this court is invoked pursuant to Title 27, Chapter 8, MCA (Uniform Declaratory Judgments Act); and Title 27, Chapter 19, MCA. (Injunctions).

3. The violations alleged herein have occurred and will continue to occur in Beaverhead County, Montana; therefore, venue is proper in this Court. Section 25-2-121, MCA.

4. Plaintiff Ron Briggs is a resident of the State of Montana who resides in Dillon, Montana and is a patient who was receiving life-saving Artificial Pancreas Treatment® using the Microburst Insulin Infusion® treatment process ("APT/MII") at the Trina clinic in Dillon, Montana; therefore, Plaintiff Ron Briggs has standing to bring this action.

5. Plaintiff Ron Briggs received APT/MII at the Trina Health of Arizona clinic, and, after having his life saved as a result of such treatment, Ron Briggs organized Trina Health of Montana LLC, in his hometown of Dillon, Montana, because he was physically and financially unable to continue traveling out-of-state to receive APT/MII.

6. Trina Health of Montana LLC ("Trina") is a Montana limited liability company licensed by the Montana Department of Health and Human Services as a primary care outpatient clinic, and Trina is the exclusive APT/MII licensee in the state of Montana. Trina's clinic and principal place of business is in located in Dillon, Montana, and Patients began receiving APT/MII from Trina after Trina opened its doors to patients on September 28, 2015.

7. In order to treat patients covered by Blue Cross and Blue Shield of Montana,

Trina hired a physician and a nurse practitioner who obtained and maintained preferred provider status with Blue Cross and Blue Shield of Montana ("Covered Providers").

8. Plaintiff Barry Briggs is a resident of the State of Montana who resides in Dillon, Montana and is a patient who was receiving life-saving APT/MII at the Trina clinic in Dillon, Montana; therefore, Plaintiff Barry Briggs has standing to bring this action.

9. Plaintiff Harold L. Grogan is a resident of the State of Montana who resides in Dillon, Montana and is a patient who was receiving life-saving APT/MII at the Trina clinic in Dillon, Montana; therefore, Plaintiff Harold L. Grogan has standing to bring this action.

10. Defendant is a division of Health Care Service Corporation, a Mutual Legal Reserve Company, a foreign profit corporation, which entity is registered as a corporation in the State of Illinois and registered in the state of Montana as Blue Cross and Blue Shield of Montana ("BCBSMT").

11. As a Health Insurer in Montana, BCBSMT issued Plaintiff Ron Briggs a Blue Preferred Gold PPO-010 policy (January 1, 2017), Plaintiff Barry Briggs a Blue Preferred Gold PPO-104 policy (January 1, 2017), and issued Plaintiff Harold L. Grogan a Blue Preferred Gold PPO-104 policy, (January 1, 2017). All such policies contained the same coverage, exclusions and definitions related to diabetes treatment. **Exhibit 1, 001-107; Exhibit 2, 108-224 and Exhibit 3, 225-343**, respectively.

12. The Plaintiff Patients have each maintained their BCBSMT insurance policies in full force and effect for the entire time that they received APT/MII at Trina.

13. APT/MII is a diabetes treatment provided by Trina employed Covered Providers, which included office visits and medical supplies necessary to provide the medically necessary treatment.

14. Trina and its employed Covered Providers are required by applicable state and federal law to submit insurance claims that accurately reflect the billing codes for the treatment that is provided to Patients.

15. Currently, there is no specific single billing code designated for the processes necessary to provide the APT/MII; therefore, Trina submitted claims to BCBSMT for the APT/MII provided by using the appropriate covered outpatient billing codes ("covered APT/MII codes"), which are currently as follows:

Procedure Code	Procedure Code Description
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS/DX 1ST>1 HOUR
96366	IV INFUSION THERAPY/PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP
99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
J1815	INJECTION, INSULIN, PER 5 UNITS

16. Defendant BCBSMT paid the claims on the covered APT/MII codes submitted by Trina under the Plaintiff Patients' respective BCBSMT policies, from the time that Trina began treating patients, on September 28, 2015, through the approximate date of April 12, 2017.

17. On or about April 12, 2017, BCBSMT commenced denying Patients' claims for APT/MII, and BCBSMT sent cease and desist letters ("cease and desist letters") to the Trina clinic and to two of the Covered Providers employed by Trina (a final cease and desist letter was sent to the third Trina employed Covered Provider on April 19, 2017), demanding that Trina discontinue billing APT/MII under the covered APT/MII codes; demanding that Trina

discontinue billing under the individual codes applicable to APT/MII; and directing Trina to bill APT/MII under HCPS G9147 ("G9147"). **Exhibit 4, 344-391.** G9147 is the code for Outpatient Intravenous Insulin Treatment ("OIVIT"), and OIVIT is a procedure which is not reimbursed by BCBSMT. **Exhibit 4, at 345, 357, 369 and 381.**

18. BCBSMT based its position in its cease and desist letters on the Health Care Services Corporation ("HCSC") Medical Policy MED201.028 ("MED201.028") entitled Chronic Intermittent Intravenous Insulin Therapy (["]CIIIT["]), dated 05-15-2016, **Exhibit 5, 392-400**; however, HCSC's MED201.028 was not adopted by BCBSMT until June 1, 2017. **Exhibit 6, 401-406.**

19. Upon receipt of the cease and desist letters, Trina directed its Covered Providers to discontinue billing BCBSMT for APT/MII, and Trina ceased treating BCBSMT insureds until Trina could determine how to address the inaccurate statements and inappropriate directives related to BCBSMT-related billing contained in the cease and desist letters.

20. Since April 24, 2017, Patients have been unable to receive APT/MII in Dillon, or anywhere else in Montana, and the health of each of Patients has drastically deteriorated and continues to deteriorate on a daily basis as a result of not being able to receive APT/MII.

21. On July 28, 2017, Plaintiffs' Montana counsel of record sent an objection to BCBSMT's cease and desist letters ("Letter of Objection"). **Exhibit 7, 407-442.**

22. On August 28, 2017, BCBSMT, in a letter signed by Christopher Herriges, responded to Plaintiffs' Letter of Objection. **Exhibit 8, 443-470.**

23. On September 13, 2017, Plaintiffs' Montana counsel sent a letter to BCBSMT challenging Mr. Herriges' conclusions; providing information showing that APT/MII is not a CIIIT-type treatment; providing medically-based information to support the fact that APT/MII is

substantially different from a CIIIT-type treatment; and requesting that BCBSMT (1) detail the objective medical standards used by BCBSMT to support its conclusion that APT/MII is "synonymous" with or "substantially similar" to CIIT-type treatments and (2) detail why BCBSMT insists that it is medically appropriate for APT/MII to be billed under the OIVIT code G9147. **Exhibit 9, 471-509.**

24. On October 6, 2017, BCBSMT responded, by letter from Mr. Herriges, and BCBSMT reiterated the contractual basis upon which BCBSMT asserts that APT/MII should be excluded from coverage. **Exhibit 10, 510-543.**

25. In the October 6, 2017 letter, Mr. Herriges also stated:

> "[m]y intention in addressing the billing codes was merely to confirm that even if APT (CIIIT, OIVIT, etc.) was not itself a covered procedure or service, our Medical Policy envisions that providers could nevertheless bill certain subsidiary services or supplies (e.g. 94681, 96365, 96366, etc.) rendered in conjunction with APT, that may themselves otherwise be covered services/supplies, and which your clients were already billing prior to the April 2017 cease and desist letters." **See Exhibit 10, at 513.**

26. Mr. Herriges' statement clearly contradicts the cease and desist letters, and, upon information and belief, all subsidiary service or supply codes listed by Mr. Herriges, along with any other similar codes, would be excluded by BCBSMT, if those codes were to be submitted to BCBSMT in conjunction with G9147.

27. Until this billing/coding controversy and coverage dispute is resolved with BCBSMT, Trina cannot treat Patients with the life-saving APT/MII.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF –

APT/MII CODES ARE COVERED BY PATIENTS' BCBSMT PLANS

28. This claim for relief incorporates paragraphs 1 through 27 as if specifically set

forth herein.

29. Patients' BCBSMT Plans define the term "**BENEFIT**" as "Services, supplies and medications that are provided to a Member and covered under this "Member Guide as a Covered Medical Expense or Dental Service," as to Ron Briggs' Plan and "Contract as Covered Medical Expense," as to Barry Briggs' and Harold L. Grogan's Plan. **See Exhibit 1, at 91; Exhibit 2, at 197 and Exhibit 3, at 315,** respectively.

30. In the "**BENEFITS**" section the Plaintiffs BCBSMT Plans ("Plans"), the Plans detail Patients' covered benefits, including, but not limited to the following service/supply benefits for diabetes related treatment:

a. "**DIABETES TREATMENT (OFFICE VISIT)** Services and supplies for the treatment of diabetes provided during an office visit. For additional Benefits related to the treatment of diabetes, e.g., surgical services and medical supplies, refer to that specific Benefit.." **See Exhibit 1, at 51; Exhibit 2, at 167 and Exhibit 3, at 285**, respectively.

. . .

b. "**MEDICAL SUPPLIES**" The following supplies for use outside of a Hospital:
1. Supplies for insulin pumps, syringes and related supplies for conditions such as diabetes.
2. Injection aids, visual reading and urine test strips, glucagon emergency kits for treatment of diabetes…"
Medical Supplies are covered only when:
1. Medically Necessary to treat condition for which Benefits are payable.
2. Prescribed by a Covered Provider." **See Exhibit 1, at 55; Exhibit 2, at 171-172 and Exhibit 3, at 289-290**, respectively.

. . .

c. **OFFICE VISITS** Covered services provided in a Covered Provider's office during a Professional Call…Visits are limited to one visit per day per provider." **See Exhibit 1, at 56; Exhibit 2, at 173 and Exhibit 3, at 291**, respectively.

31. Because G9147 is not the specific procedure code for APT/MII, Trina billed the services/supplies rendered as part of APT/MII, individually, under the appropriate APT/MII codes, as detailed in ¶15, above.

32. Prior to BCBSMT determining APT/MII was excluded as detailed in the cease and desist letters, BCBSMT paid Trina for the individually coded service/supplies under the APT/MII codes for the treatment Trina provided to Patients.

33. At no time has BCBSMT asserted that the individually coded APT/MII codes for services/supplies were not covered under Patients' Plans.

34. BCBSMT has a contractual obligation to cover Benefits provided for under Plaintiffs' Plans as billed using the individually coded APT/MII codes.

35. Patients' BCBSMT Plans define "**CONTRACT"** as "[t]his Group Contract, the Group application and any amendments, endorsements, riders, or modifications made to the Contract made to it by The Plan. The Group Contract is issued to the employer," as to Ron Briggs' Plan and "[t]his Contract, the Member's application and any amendments, endorsements, riders, or modifications made by The Plan," as to Barry Briggs' and Harold L. Grogan's Plan. **See Exhibit 1, at 93; Exhibit 2, at 198 and Exhibit 3, at 316**, respectively.

36. BCBSMT has not asserted any application, amendment, endorsement, rider or modifications that would permit BCBSMT to deny coverage for the APT/MII codes as a Covered Medical Expense to Patients, or any other similarly situated patient.

37. Patients' BCBSMT Plan defines "**COVERED MEDICAL EXPENSE"** as:

> "Expenses incurred for Medically Necessary services, supplies and medications that are based on the Allowable Fee and:
> **1.** Covered under the Member Contract [Group Plan, as to Ron Briggs Plan];
> **2.** In accordance with Medical Policy; and
> **3.** Provided to the Member by and/or ordered by a covered provider for the diagnosis or treatment of an illness or injury or in providing maternity care.
> In order to be considered a Covered Medical Expense, the Member must be charged for such services, supplies and medications. **See Exhibit 1, at 93; Exhibit 2, at 198-199 and Exhibit 3, at 316-317**, respectively.

38. BCBSMT has not asserted that the individual APT/MII codes are not a covered medical expense; instead, BCBSMT has asserted, and continues to assert, that APT is "synonymous" with or "substantially similar" to OIVIT and/or CIIIT, which BCBSMT alleges are treatments excluded from coverage. **See Exhibit 8, 443-470 and Exhibit 10, 510-543.** (emphasis added)

SECOND CLAIM FOR RELIEF –

APT/MII IS NOT OIVIT OR CIIIT

39. This claim for relief incorporates paragraphs 1 through 38 as if specifically set forth herein.

40. On page 2 of the cease and desist letters, BCBSMT relies on MED201.028 to support its position that CIIIT is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT." **See Exhibit 4, at 345, 357, 369 and 381.**

41. The cease and desist letters go on to state that "[t]he 2017 HCPCS Level II manual lists HCPCS G9147 as, [']Outpatient 'Intravenous' Insulin Treatment['] (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures." **See Exhibit 4, at 345, 357, 369 and 381.**

42. Additionally, in BCBSMT's letter of August 28, 2017, Mr. Herriges stated that:

> "You are correct in your letter that there is not a specific CPT to code for APT. However, because G9147 is the code designated by CMS for CIIIT claims and because CIIIT and APT are synonymous or substantially similar, BCBSMT was correct in its cease and desist letters to instruct your client to use G9147 when coding claims for APT." **Exhibit 8, at 445.**

43. On September 13, 2017, Plaintiffs' Counsel provided the medical process information to clearly show that APT is not OIVIT and neither is it "synonymous" with or "substantially similar" to OIVIT or CIIIT, as defined by BCBSMT in its Medical Policy MED201.028. **Exhibit 9, at 476-509.**

44. The detailed attachments to the September 13, 2017 letter, clearly establish that APT/MII is not "synonymous" with or "substantially similar" to OIVIT. **Exhibit 9, 476-509.**

45. Plaintiffs' Montana counsel has provided the necessary information to BCBSMT to make clear that the OIVIT and CIIIT-type treatments are not "synonymous" with or "substantially similar" to APT/MII. **Exhibit 9, 471-509.**

THIRD CLAIM FOR RELIEF –

APT IS NOT EXCLUDED FROM COVERAGE

46. This claim for relief incorporates paragraphs 1 through 45 as if specifically set forth herein.

47. In BCBSMT's cease and desist letters and Mr. Herriges' letters, BCBSMT consistently asserts that APT is experimental under MED201.028, and, as a result, excluded from coverage.

48. Patients' BCBSMT Plans specifically state, under the heading "EXCLUSIONS AND LIMITATIONS," that "[a]ll Benefits provided under this Contract are subject to the exclusions and limitations in this section and as stated under the Benefit Section" and goes on to state that "**The Plan will not pay for**:

> "**15.** Any services, supplies, drugs and devices which are:
> **a.** Experimental/Investigational/Unproven services, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial." **Exhibit 1, at 80; Exhibit 2, at 183 and Exhibit 3, at 301**, respectively.

49. The policy defines "**EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN**" as follows:

> "A drug, device biological product or medical treatment or procedure is Experimental, Investigational and/or Unproven if **The Plan determines** that:
> - The drug, device, biological product or medical treatment or procedure cannot be lawfully marketed with approval of the appropriate governmental or regulatory agency and approval for marketing has not been given at the time the drug, device, biological product or medical treatment or procedure is furnished; or
> - The drug device, biological product or medical treatment or procedure is the subject of ongoing phase I, II or III clinical trials, or under study to

determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or

- The prevailing opinion among peer reviewed medical and scientific literature regarding the drug, device, biological product or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis." **Exhibit 1, at 96; Exhibit 2, at 200-201 and Exhibit 3, at 318-319**, respectively.

50. APT/MII utilizes a pump approved by the FDA and the APT/MII process is lawfully marketed under all laws applicable to such procedures; therefore, APT is not subject to an exclusion applicable to legal approval.

51. APT/MII is not subject to ongoing phase I, II or III clinical trials to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; therefore, it is not excluded as being part of such a clinical trial.

52. No peer reviewed medical or scientific literature regarding APT/MII has determined that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

53. Based upon the clear language of Patients' BCBSMT plan exclusions, APT/MII is not excluded from coverage under the clear language of Patients' BCBSMT Plan documents for being "experimental," "investigational" or "unproven."

FOURTH CLAIM FOR RELIEF –

MEDICAL POLICY MED201.028 DOES NOT PERTAIN TO

AND CANNOT BE USED TO EXCLUDE APT/MII

54. This claim for relief incorporates paragraphs 1 through 53 as if specifically set forth herein.

55. In BCBSMT's cease and desist letters and Mr. Herriges' letters, BCBSMT consistently asserts that MED201.028 is applicable to APT/MII, and it is MED201.028 that BCBSMT is relying upon to exclude APT/MII from coverage in Montana; MED201.028 states

that "The HCPCS code G9147 [for OIVIT] is specific to CIIIT." MED201.028 does not say that G9147 is specific to APT/MII or that APT/MII is "synonymous" with or "substantially similar" to CIIIT or OIVIT. **Exhibit 6, at 345, 357, 369 and 381.**

56. The disclaimer contained in MED201.028 also specifically states, under "**Coding**", that:

> "benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit, exclusions, and benefit limitations…" **Exhibit 6, at 404.** (emphasis added)

57. Nothing in MED201.028 makes any reference to APT/MII, and BCBSMT has not developed a medical policy that is specific to or that addresses BCBSMT coverage for APT/MII.

58. Despite several requests by Plaintiffs' Montana counsel for an objective medical analysis regarding the coverage under Patients' Plans specific to APT/MII, BCBSMT has not shown that it has conducted the required review of APT/MII under Patients' benefit contract or Summary Plan Description.

59. In the disclaimer in, under the "**Coding**", MED201.028 further states that:

> "[t]he presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**" **Exhibit 6, at 404.**

60. Based upon BCBSMT's own policies and procedures, the Plaintiffs' respectfully submit that, until BCBSMT adopts a medical policy specific to APT/MII, BCBSMT cannot deny coverage based upon individual service, supply, device or diagnosis codes which are covered under the Plaintiffs' Plans, such as the individually covered APT/MII codes.

61. Additionally, the "Rationale " upon which MED201.028 is based does not pertain to APT/MII, and, on July 28, 2017, Plaintiffs Montana counsel identified to BCBSMT studies

specifically showing that studies have "investigated the proposed mechanism of action of CIIIT in humans." **Exhibit 6, at 402; Exhibit 7, at 436-442.**

FIFTH CLAIM FOR RELIEF –

CODE G9147 IS NOT AN APPROPRIATE BILLING CODE FOR APT/MII

62. This claim for relief incorporates paragraphs 1 through 61 as if specifically set forth herein.

63. BCBSMT's cease and desist letters demanded that Trina bill for APT/MII under the code for Outpatient Intravenous Insulin Treatment (OIVIT), a treatment that is substantially different from APT/MII. **See Exhibit 4, 344-391.**

64. Since APT/MII is not OIVIT, G9147 is not an appropriate code for APT/MII.

65. In its cease and desist letters, BCBSMT violated its own policy when it attempted to use MED201.028 as the basis to demand that APT/MII be coded as G9147, and then stated that "[a]ccording to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures." **See Exhibit 6, at 345, 357, 369 and 381.**

66. At no time has BCBSMT asserted that G9147 is the specific medical code for APT/MII, and, in fact, in Mr. Herriges' letter of August 28, 2017, BCBSMT agreed that APT/MII does not have a specific code assigned to it. **Exhibit 8, 443-470.**

67. BCBSMT has not shown that G9147 is the specific code for APT/MII, and, since APT/MII is not OIVIT or CIIIT, Trina cannot comply with BCBSMT's demand to submit claims using the G9147 code, because G9147 is not the accurate code for APT/MII, and billing under an incorrect code for a procedure would violate applicable laws and regulations to Trina's operations and the Trina Covered Providers' licensing requirements.

68. Since, at this time, there is no specific code for APT/MII, Trina providers must

use the individual codes applicable to the outpatient coding, for the treatment.

69. Additional ambiguity now exists because BCBSMT, in Mr. Herriges' letter of October 6, 2017, stated, on one hand, that APT/MII was excluded under MED201.028 through the application of G9147 to APT/MII, and stated, on the other hand, that:

> "providers could nevertheless bill certain subsidiary services or supplies (e.g. 94681, 96365, 96366, etc.) rendered in conjunction with APT/MII, that may themselves otherwise be covered services/supplies, and which your clients were already billing prior to the April 2017 cease and desist letters. If your clients choose not to bill for what may otherwise be covered related services and supplies, it is at their discretion." **See Exhibit 10, at 513.** (emphasis added)

70. BCBSMT's coverage position on the treatment provided through APT/MII is now entirely ambiguous: (1) BCBSMT is either requiring Trina to bill the treatment for APT/MII exclusively under G9147, (2) BCBSMT is requiring Trina to bill the treatment for APT/MII individually in conjunction with G9147, or (3) BCBSMT is authorizing Trina to continue to submit Patients' treatments to BCBSMT for payment under the individual covered APT/MII codes, without the inclusion of G9147; based upon these options, Trina does not know what previously covered APT/MII codes BCBSMT's is now stating are excluded under Patients' Plans as communicated in BCBSMT's cease in desist letters and the later BCBSMT letters drafted by Mr. Herriges.

SIXTH CLAIM FOR RELIEF –

BCBSMT SHOULD BE PERMANENTLY ENJOINED FROM DENYING

COVERAGE TO PLAINTIFFS FOR APT/MII

71. This claim for relief incorporates paragraphs 1 through 70 as if specifically set forth herein.

72. BCBSMT's position as to Trina and APT/MII under the Patient's BCBSMT Plans has the effect of denying Patients coverage and treatment for APT/MII in Montana, and

BCBSMT's demand that Trina bill APT/MII as OIVIT under HCPCS G9147 puts Trina in a legally precarious place as to its billing and coding practices.

73. Under §27-19-102, MCA, a final injunction may be granted to the Plaintiffs to prevent BCBSMT from breaching its obligations to Plaintiffs under the Patient's Plans and applicable law, because (1) pecuniary compensation will not afford Plaintiffs adequate relief; (2) it would be extremely difficult to ascertain the amount of compensation which would accord adequate relief, and, in fact, no compensation would afford adequate relief to Plaintiffs; and (3) the restraint is necessary to prevent a multiplicity of judicial proceedings related the BCBSMT's current position.

74. BCBSMT should be permanently enjoined from excluding coverage for APT/MII under the clear language of the Patients' Plans.

75. BCBSMT should be permanently enjoined from demanding that APT/MII be billed as OIVIT under HCPC G9147.

SEVENTH CLAIM FOR RELIEF –

APPLICATION FOR PRELIMINARY INJUNCTION AND

TEMPORARY RESTRAINING ORDER

76. This claim for relief incorporates paragraphs 1 through 75 as if specifically set forth herein.

77. Plaintiffs request that a preliminary injunction and temporary restraining order be granted to preliminarily enjoin and temporarily restrain BCBSMT, until this Court enters judgment on the First through the Fifth claim, herein, as follows:

a. immediately enjoining and temporarily restraining BCBSMT from excluding coverage for APT/MII under Patients' Plan language, and

b. immediately enjoining and temporarily restraining BCBSMT from demanding that APT/MII be billed as OIVIT under HCPC G9147.

78. Plaintiffs' application for preliminary injunction and temporary restraining order may be granted, under §27-19-201 and §27-19-314, MCA, because:

(1) Plaintiffs First through Fifth claims state allegations that appear to show that Plaintiffs are entitled to the relief demanded and the relief in Plaintiffs' Sixth and Seventh claim consists in restraining BCBSMT from precluding coverage from the APT/MII as complained of by Plaintiffs, above, for both a limited period and into perpetuity,

(2) If BCBSMT is allowed to continue to exclude coverage under the Patients' Plans for APT/MII, as set forth in Plaintiffs' claims, BCBSMT doing so would produce a great and irreparable injury to both Patients and Trina; and

(3) If BCBSMT is allowed to continue to exclude coverage under the Patients' Plans for APT/MII, Patients will be denied their right to coverage under their Plans, and Trina will be unable to bill BCBSMT for APT/MII.

79. Plaintiffs request, under §27-19-314, MCA, that a temporary restraining order be issued, immediately, prior to BCBSMT answering this Complaint, until this Plaintiffs' claims for permanent injunctive relief and declaratory relief may be heard.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this court grant the following relief:

DECLARATORY RELIEF

1. Enter a judgment declaring that:

a. the covered APT/MII codes are covered by Patients' BCBSMT Plans;

b. APT/MII is substantially different from OIVIT and that it is not "synonymous" with or "substantially similar" to OIVIT or CIIIT or any other specifically named OIVIT treatment excluded by BCBSMT;

c. APT/MII is not excluded from coverage under Patients' Plans;

d. MED201.028, does not pertain to APT/MII and cannot be used by BCBSMT to exclude coverage for APT/MII under the Plaintiffs' contracts with BCBSMT; and

e. BCBSMT cannot require APT/MII to be coded as G9147 for purposes of obtaining reimbursement for treatment to BCBSMT insureds, because code G9147 is not an appropriate billing code for APT/MII, and Trina may submit for reimbursement to BCBSMT any covered individual billing codes it deems appropriate as to the APT/MII treatment process; and

f. the directives and conclusions by BCBSMT in the cease and desist letters and Mr. Herriges' letters on behalf of BCBSMT, of August 28th and October 6th, 2017, may not be applied to Trina, to Trina's employed providers or to APT/MII related billing, as a matter of law.

INJUNCTIVE RELIEF

1. Enter an order (1) temporarily restraining BCBSMT from denying coverage for APT/MII treatment provided to patients of Trina Health of Montana who are BCBSMT insureds, and (2) temporarily restraining BCBSMT from demanding that APT/MII be billed as OIVIT under HCPC G9147, and ordering BCBSMT continue to cover APT/MII claims submitted by Trina for BCBSMT covered patients in the same manner that it covered the treatment prior to determining that APT/MII was excluded from BCBSMT plans as detailed in the cease and desist letters.

2. Enter an order which permanently enjoins BCBSMT for excluding or denying coverage for APT/MII under the language of the Patients' Plans.

OTHER RELIEF

3. Enter an order:

   a. awarding Plaintiffs all costs and expenses in this action, including attorney fees, to the extent allowed in equity and by law; and

   b. awarding such additional relief to the Plaintiffs as the Court deems just and proper.

DATED this 23rd day of October, 2017.

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Laurie Zmrzel, CA SBN 131204 (*pro hac vice* pending)
5112 Bailey Loop
McClellan, CA 95652

ATTORNEYS FOR PLAINTIFFS

BLUE PREFERRED GOLD PPO 010

BRUNDAGE FUNERAL HOME

Effective January 1, 2017

BlueCross BlueShield of Montana

EXHIBIT
1
exhibitsticker.com

MEDICAL BENEFITS

FOR CUSTOMER SERVICE
Call 1-800-447-7828

DENTAL BENEFITS

FOR CUSTOMER SERVICE
Call 1-800-866-739-4090

FOR PREAUTHORIZATION
Call 1-855-313-8914 or Fax 1-866-589-8256 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

FOR INPATIENT ADMISSIONS
Call 1-855-313-8914 or Fax 1-866-589-8256 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

www.bcbsmt.com

- BCBSMT Provider Directory
- Wellness
- Other Online Services and Information

BLUECARD® NATIONWIDE/WORLD WIDE COVERAGE PROGRAM
1-800-810-BLUE (2583) – http://provider.bcbs.com

FOR MEDICAL APPEALS
Send via fax:
Non-Behavioral Health: 1-866-589-8256
Behavioral Health: 1-855-649-9681
or
Mail to:
Blue Cross and Blue Shield of Montana
PO Box 4309
Helena, MT 59604-4309

FOR DENTAL APPEALS
Send to:
Blue Cross and Blue Shield of Montana
PO Box 6227
Helena, MT 59604-6227

FOR PRESCRIPTION DRUG BENEFITS

Pharmacy Benefit Manager (PBM)

- Prime Therapeutics 1-800-423-1973
- For preauthorizations, fax: 1-877-828-3939

PBM Website www.myprime.com
Claim Forms 1-866-325-5230
Pharmacy Locator 1-866-325-5230
Specialty Care Pharmacy (BCBSMT Prime Specialty Network) 1-877-627-MEDS (6337)

- www.bcbsmt.com or www.myprime.com
- Prescriber Fax 1-877-828-3939

Mail Order Services

- **PrimeMail** 1-866-325-5230
  PO Box 27836
  Albuquerque, NM 87125-7836
- **Ridgeway Mail-Order Pharmacy** 1-800-630-3214
  2824 US Hwy 93 North
  Victor, MT 59875

Blue Cross and Blue Shield of Montana
3645 Alice Street
PO Box 4309
Helena, MT 59604-4309

FOR MEDICAL CLAIMS
Blue Cross and Blue Shield of Montana
PO Box 7982
Helena, MT 59604-7982

FOR DENTAL CLAIMS
Blue Cross and Blue Shield of Montana
PO Box 6227
Helena, MT 59604-6227

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Certain terms in this Member Guide are defined in the Definitions section of this Member Guide. Defined terms are capitalized.

NO COVERAGE UNTIL DUES PAID

This Member Guide is being provided to you because your employer has agreed to purchase health coverage from Blue Cross and Blue Shield of Montana. Your coverage will not be effective, and you will not be entitled to Benefits, until and unless your employer pays the required dues.

MEMBER GUIDE

This Member Guide is a summary of the Benefits available under the Group Plan. Nothing in this Member Guide will alter any of the terms, conditions, limitations, or Exclusions of the Group Plan. If questions should arise, the provisions of the Group Plan will prevail. Please refer to the Group Plan on file with your employer if you have any questions which aren't answered in the Member Guide or call your Blue Cross and Blue Shield of Montana representative.

PRIVACY OF INSURANCE AND HEALTH CARE INFORMATION

It is the policy of Blue Cross and Blue Shield of Montana to protect the privacy of Members through appropriate use and handling of private information. Further, appropriate handling and security of private information may be mandated by state and/or federal law.

The Group and Beneficiary Member may receive a copy of Blue Cross and Blue Shield of Montana's "Notice of Privacy Practices," or other information about privacy practices, by calling the telephone number or writing to the address shown on the inside cover of this Member Guide.

MEMBERS RIGHTS

When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

CONTINUITY OF CARE

If the Member's Participating Provider (professional) stops participating in the PPO network, the Member may request continued treatment from that provider for a period of time after the provider stops participating, except for pregnancy, the continuity of care period is 90 days or until the next policy renewal date, whichever is longer. For pregnancy, the continuity of care period is through the postpartum period. For the Member to qualify for continuity of care, the provider must: (1) agree that the Member is in an active course of treatment as defined by ARM 6.6.5908; (2) agree to accept the same allowed amount as the provider would have accepted if the provider had remained a Participating Provider; and (3) agree not to seek payment from the Member of any amount for which the Member would not have been responsible if the provider had remained a Participating Provider. Continuity of care protections are only for an active course of treatment and are not required for routine primary and preventive care.

IDENTITY THEFT SERVICES

Blue Cross and Blue Shield of Montana (BCBSMT) offers, at no additional cost to the Member, identity theft protection services, including credit monitoring, fraud detection, credit /identity repair and insurance to help protect the Member's information. These identity theft protection services are currently provided by BCBSMT's designated outside vendor and acceptance or declination of these services is optional to Member.

Members who wish to accept such identity theft protection services will need to individually enroll in the program online at www.bcbsmt.com or telephonically by calling the toll free telephone number on his/her identification card. Services may automatically end when the person is no longer an eligible Member. In addition, services may change or be discontinued at any time and BCBSMT does not guarantee that a particular vendor or service will be available at any given time. The services are provided as a convenience and are not considered covered benefits under this Member Guide.

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SCHEDULE OF BENEFITS

Blue Preferred Gold PPO 010

Group Name:	BRUNDAGE FUNERAL HOME
Group Number:	18B736
Effective Date:	January 1, 2017
Annual and Lifetime Plan Maximum:	None
Benefit Period:	Calendar Year

The Benefits are subject to the Benefit Period unless otherwise specified.

	In-Network	Out-of-Network
Deductible:		
Individual	$1,500	$3,000
Family	$3,000	$6,000
The In-Network and Out-of-Network Deductibles are separate amounts and one does not accumulate to the other. Any Copayments and Coinsurance do not accumulate to the Deductible.		
Coinsurance:	20%	40%
Copayments:		
Primary Care Provider (PCP)	$15	No Copayment; Deductible and Coinsurance Apply
Specialist	$30	No Copayment; Deductible and Coinsurance Apply
Urgent Care	$75	No Copayment; Deductible and Coinsurance Apply
Out of Pocket Amount:		
Individual	$4,000	$8,000
Family	$8,000	$16,000
The In-Network and Out-of-Network Out of Pocket Amounts are separate amounts and one does not accumulate to the other. Charges in excess of the Allowable Fee do not accumulate to help meet the Out of Pocket Amount.		

Some Benefits may have payment limitations. Refer to the specific Benefit in this Schedule of Benefits for additional information. In addition:

- For Pediatric Dental Services provided by an Out-of-Network Provider, Benefits will be provided as if such services were provided by an In-Network provider.
- For Emergency Services provided by an Out-of-Network Provider, Benefits will be provided as if such services were provided by an In-Network provider.
- Out-of-Network providers may bill the Member the difference between the Allowable Fee and the provider's charge, in addition to any applicable Deductible, Copayment or Coinsurance even if Preauthorization is obtained for the service, or if treatment is provided for Emergency Services or Pediatric Dental Services.

Term of Member Guide:	Monthly

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Accident		
Professional Provider Services	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services	20%	40%
Acupuncture	20%	40%
Maximum Per Benefit Period – 12 Visits		
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Ambulance	20%	20%
Autism Spectrum Disorders		
Services, except medications/prescription drugs and Applied Behavior Analysis (ABA) services that are described in the Benefit section entitled Autism Spectrum Disorders are covered under medical Benefits.		
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Medications/prescription drugs are covered under Prescription Drugs.		
ABA services are only covered for Members under 19 years of age	20%	40%
Birthing Centers	20%	40%
Chemical Dependency		
Professional Provider Services		
Outpatient	20%	40%
Inpatient	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services		
Outpatient	20%	40%
Inpatient	20%	40%
Chiropractic Services	20%	40%
Maximum Benefit Per Benefit Period for Chiropractic Manipulations – 10 Visits		
Convalescent Home Services	20%	40%
Maximum Per Benefit Period – 60 Days		
Diabetic Education Benefit		
The Deductible, Coinsurance and/or Copayment do not apply to the payment of the first $250. After the payment of $250, Deductible, Coinsurance and/or Copayment will apply.		
First $250	Deductible, Copayment and Coinsurance Do Not Apply	
After the first $250 in payment	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Diagnostic Services		
Diagnostic Imaging Services		
Computerized Tomography (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan)		
Professional Provider Services	20%	40%
Facility Services	20%	40%
All Other Covered Diagnostic Services		
Professional Provider Services	20%	40%
Facility Services	20%	40%
Durable Medical Equipment		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Durable Medical Equipment	20%	40%
Education Services		
Professional Provider Services	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services	20%	40%
Emergency Room Care	20%	20%
Home Health Care	20%	40%
Maximum Per Benefit Period – 180 Visits		
Hospice Care		
Professional Provider Services	Deductible, Copayment and Coinsurance Do Not Apply	
Facility Services	Deductible, Copayment and Coinsurance Do Not Apply	
Hospital		
Professional Services (when the Professional Provider is employed by the Hospital)		
Outpatient	20%	40%
Inpatient	20%	40%
Facility Services		
Outpatient	20%	40%
Inpatient	20%	40%
Mammograms		
Routine	Deductible, Copayment and Coinsurance Do Not Apply	40%*
Medical	Deductible, Copayment and Coinsurance Do Not Apply	40%
*Deductible and Coinsurance Do Not Apply to the payment of the first $70 for Routine mammograms provided by an Out-of-Network provider.		
Maternity Services		
Professional Provider Services	20%	40%
(Refer to the section of the Schedule of Benefits entitled Office Visits. However, the Office Visit Copayment only applies to the initial visit. Subsequent visits are included in the charges for labor and delivery.)		
Facility Services	20%	40%

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION **Deductible applies to all services unless noted otherwise.**	**IN-NETWORK COINSURANCE/ COPAYMENT**	**OUT-OF-NETWORK COINSURANCE/ COPAYMENT**
Medical Supplies	20%	40%
Mental Health		
Professional Provider Services		
Outpatient	20%	40%
Inpatient	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services		
Outpatient	20%	40%
Inpatient	20%	40%
Newborn Initial Care		
Professional Provider Services	20%	40%
Facility Services	20%	40%
The Deductible applies after the first 5 days of initial care.		
Office Visit		
Primary Care Provider (PCP)	$15*, No Deductible	40%
The Copayment applies to the In-Network office visit and covered services provided during the office visit, except surgery, Physical Therapy Speech Therapy, Occupational Therapy, Chiropractic Manipulation, Diagnostic Imaging, Laboratory Services and X-rays.		
Specialist	$30*, No Deductible	40%
The Copayment applies to the In-Network office visit and covered services provided during the office visit, except surgery, Physical Therapy Speech Therapy, Occupational Therapy, Chiropractic Manipulation, Diagnostic Imaging, Laboratory Services and X-rays.		
*Copayment does not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.		
Orthopedic Devices/Orthotic Devices	20%	40%
Other Facility Services – Inpatient and Outpatient	20%	40%
Pediatric Dental Care (For Members under 19 years of age)	30%	30%
Deductible and Coinsurance do not apply to fluoride treatments which are a Benefit for Members under age 19.		
Pediatric Orthodontic Services	30%	30%
Coverage limited to children under age 19 with an orthodontic condition meeting Medical Necessity criteria (e.g., severe, dysfunctional malocclusion) established by The Plan.		
Pediatric Vision Care (For Members under 19 years of age)		
Routine Exam	Deductible, Copayment and Coinsurance Do Not Apply	
Maximum Per Benefit Period – 1 Exam		
Frames and Lenses	20%	40%
Maximum Per Benefit Period – 1 Pair of Glasses or 2 Boxes of Contact Lenses		
Physician Medical Services (Other than the Office Visit)	20%	40%

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Prescription Drugs Refer to the last page of this Schedule of Benefits.		
Preventive Health Care		
Routine Services	Deductible, Copayment and Coinsurance Do Not Apply	40%
Prostheses Benefit		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Prosthetics	20%	40%
Rehabilitation Therapy		
Professional Services		
Outpatient	20%	40%
Inpatient	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services		
Outpatient	20%	40%
Inpatient	20%	40%
Surgery Center Services - Outpatient		
Professional Provider Services	20%	40%
Facility Services	20%	40%
Therapies – Outpatient		
Physical Therapy, Occupational Therapy, Speech Therapy, Cardiac Therapy		
Professional Provider Services	20%	40%
Facility Services	20%	40%
Transplants		
Professional Services		
Outpatient	20%	40%
Inpatient	20%	40%
Refer to the section of the Schedule of Benefits entitled Office Visits.		
Facility Services		
Outpatient	20%	40%
Inpatient	20%	40%
Urgent Care *Copayment does not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.	$75*, No Deductible	40%
Well-Child Care Services	Deductible, Copayment and Coinsurance Do Not Apply	40%, No Deductible

SCHEDULE OF BENEFITS, continued

PRESCRIPTION DRUG INFORMATION	DEDUCTIBLE	COPAYMENT/ COINSURANCE
Prescription Drugs (The Prescription Drugs Benefit utilizes a Drug List.) Any Copayments do not apply to certain contraceptive products. Refer to the Preventive Health Care Benefit. Any Copayments also do not apply to smoking cessation products and over-the-counter aids/medications, for two 90-day treatment regimens.		
Deductible	Does Not Apply	
Retail Value Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
Preferred Generic:		No Copayment
Non-Preferred Generic:		$10
Preferred Brand-Name:		$35
Non-Preferred Brand-Name:		$75
Retail Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
Preferred Generic:		$5
Non-Preferred Generic:		$15
Preferred Brand-Name:		$45
Non-Preferred Brand-Name:		$85
Retail Non-Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
Preferred Generic:		$5
Non-Preferred Generic:		$15
Preferred Brand-Name:		$45
Non-Preferred Brand-Name:		$85
Payment for Prescription Drug Products purchased at a Non-Participating Pharmacy will be reduced by 50%, in addition to any Copayment.		
Mail Service Maintenance Prescriptions Copayments for a **90-day supply** are:		
Preferred Generic:		No Copayment
Non-Preferred Generic:		$30
Preferred Brand-Name:		$105
Non-Preferred Brand-Name:		$225
Retail Value Participating Pharmacy Prescriptions Copayments for a **90-day supply** are is:		
Preferred Generic:		No Copayment
Non-Preferred Generic:		$30
Preferred Brand-Name:		$105
Non-Preferred Brand-Name:		$225
Specialty Medications purchased at participating Specialty Pharmacies in the Blue Cross and Blue Shield of Montana Prime Specialty Network (30-day supply only)		$150*

***An Out-of-Network 50% Coinsurance applies to Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy.**

The Member must pay the difference between a Brand-Name drug and the Generic equivalent in addition to the Copayment and/or Coinsurance if the Member chooses a Brand-Name drug when a Generic drug is available.

Any Copayment and/or Coinsurance amounts paid for prescription drugs do not apply to the Deductible. The 50% benefit reduction for prescription drugs purchased at a Non-Participating Pharmacy does not apply to the Out-of-Pocket maximum. The 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy does not apply to any Out of Pocket Amount.

PROVIDERS OF CARE FOR MEMBERS

The participation or nonparticipation of providers from whom a Member receives services, supplies, and medication impacts the amount The Plan will pay and the Member's responsibility for payment. Professional providers and facility providers are either In-Network or Out-of-Network providers. In-Network providers include Participating Providers and Preferred Provider Organization (PPO) providers. Out-of-Network providers are nonparticipating and non-PPO providers.

In-Network and Out-of-Network Professional Providers and Facility Providers

Professional providers include, but are not limited to, Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, Advanced Practice Registered Nurses, physician assistants, naturopathic physicians, acupuncturists and physical therapists.

For purposes of the In Network Office Visit Copayment benefit, Primary Care Providers (PCPs) include general practitioners, family practitioners, internists, pediatricians, obstetricians and gynecologists, naturopaths, physicians' assistants, registered nurse practitioners, psychiatrists, psychologists, licensed addiction counselors, licensed clinical professional counselors and licensed clinical social workers.

A specialist is a Physician, not included in the list of PCPs, who provides medical services in any generally accepted medical specialty or sub-specialty.

PCPs and specialists do not include chiropractors, acupuncturists, speech therapists, physical therapists, or occupational therapists. However, if a Member receives services from one of these providers and an office visit is billed, the specialist Copayment will be applied.

Facility providers include, but are not limited to, Hospitals, Rehabilitation Facilities, Home Health Agencies, Convalescent Homes, skilled nursing facilities, freestanding facilities for the treatment of Chemical Dependency or Mental Illness, and freestanding surgical facilities (surgery center).

The Member may obtain a list of Participating Providers from Blue Cross and Blue Shield of Montana free of charge by contacting The Plan at the number listed on the inside cover of this Member Guide.

PPO Providers

Blue Cross and Blue Shield of Montana has a PPO Network of Hospitals and surgery centers in Montana that is utilized under this Benefit Plan. Outside of the state of Montana, there are also Blue Cross and/or Blue Shield PPO Hospitals and surgery centers nationwide. The Member receives the In-Network Benefit when utilizing the PPO network or the nationwide Blue Cross and/or Blue Shield PPO Hospitals and surgery centers. If the Member obtains services or supplies from a non-PPO Network provider, the Out-of-Network Deductible, Coinsurance and Out-of-Pocket will apply as indicated on the Schedule of Benefits.

The exceptions to the Benefit reduction are:

- Emergency Services;
- Services that are unavailable within the PPO Network.

If a Member receives services from an out of state provider, then services must be provided by:

- Blue Cross and/or Blue Shield PPO facility providers; and/or
- Blue Cross and/or Blue Shield participating professional providers* or PPO professional providers.

*Some Blue Cross and/or Blue Shield Plans require services to be provided by a PPO professional provider for the Member to receive the highest level of Benefit. Contact The Plan for additional information on out of state services.

Emergency Services and services that are unavailable within the PPO Network will be covered as In Network. **However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if Preauthorization was obtained for such services.** The Member will be responsible for the balance of the nonparticipating provider's or non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment by the Member of any Deductible, Coinsurance and/or Copayment.

Out of PPO Network Referrals

There may be circumstances under which the most appropriate treatment for the Member's condition is not available through the PPO Network. When this occurs, it is recommended the Member's attending Physician contact The Plan for an out of PPO Network referral. If the referral is not approved, and the Member chooses to obtain services from a non-PPO Network provider, the Member will be responsible for the Out-of-Network Deductible and Coinsurance, in addition to any difference between the Blue Cross and Blue Shield of Montana Allowable Fee and the provider's billed charges.

If The Plan approves the referral, those services will process with the In-Network Deductible and Coinsurance. However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if The Plan approves the referral.

How Providers are Paid by The Plan and Member Responsibility

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield of Montana for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

How Providers are Paid by The Plan and Member Responsibility Outside of Montana

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network in the state where serves are provided.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

Pretreatment Estimate of Dental Benefits and Treatment Plan

If the Member's Dentist recommends a Course of Treatment that will cost more than $300, the Dentist should prepare a claim form describing the planned treatment (called a "treatment plan"), copies of necessary x-rays, photographs and models and an estimate of the charges prior to beginning the Course of Treatment. The Plan will review the report and materials, taking into consideration any alternative adequate Course of Treatment, and will notify the Member and the Dentist of the estimated Benefits which will be provided under this Member Guide. This is not a guarantee of payment, but an estimate of the Benefits available for the proposed services to be rendered. The

Plan's Pretreatment Estimates of Benefits are valid for 180 days, provided all eligibility and Member Guide requirements are met. If the approved procedure is not done within that time period, or if the patient's condition changes, the Member is responsible for asking the Dentist to submit another request and treatment plan, along with the required current documentation. A new Pretreatment Estimate of Benefits must then be issued by The Plan.

For Prescription Drug Products, the Member will be responsible for paying the specific Copayment/Coinsurance as described in the Prescription Drugs section.

The Plan will not pay for any services, supplies or medications which are not a Covered Medical Expense, or for which a Benefit maximum has been met, regardless of whether provided by a Participating Provider or a nonparticipating provider. The Member will be responsible for all charges for such services, supplies, or medications.

MEMBERS RIGHTS AND RESPONSIBILITIES

A Member has the right to:

1. Receive information about The Plan, the quality assurance program, the Member's health Benefit Plan, the names of participating health care providers, and the Member's rights and responsibilities.
2. Be treated with respect and recognition of the Member's dignity and right to privacy.
3. Have a candid discussion of appropriate or Medically Necessary treatment options for the Member's condition, regardless of cost or Benefit coverage.
4. Participate with health care providers in decision-making regarding the Member's health care.
5. Voice complaints or appeals about the managed care organization, health care providers or the care provided.
6. Talk to the Member's health care provider and expect that the Member's records and conversations are kept confidential.
7. When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

A Member has the responsibility to:

1. Provide, to the extent possible, information that The Plan and health care providers need in order to care for the Member.
2. Follow the treatment plans and instruction for care the Member has agreed upon with the Member's health care providers.

OUT-OF-AREA SERVICES – THE BLUECARD PROGRAM

Out-of-Area Services

Blue Cross and Blue Shield of Montana has a variety of relationships with other Blue Cross and/or Blue Shield Licensees. Generally, these relationships are called "Inter-Plan Arrangements." These Inter-Plan Arrangements work based on rules and procedures issued by the Blue Cross Blue Shield Association. Whenever a Member receives healthcare services outside of the Blue Cross and Blue Shield of Montana service area, the claims for those services may be processed through one of these Inter-Plan Arrangements. The Inter-Plan Arrangements are described below.

When a Member receives care outside of the Blue Cross and Blue Shield of Montana service area, the Member will receive care from one of two kinds of providers. Most providers ("participating providers") contract with the local Blue Cross and/or Blue Shield Licensee in that geographic area ("Host Blue"). Some providers ("nonparticipating providers") don't contract with the Host Blue. Blue Cross and Blue Shield of Montana explain below how we pay both kinds of providers.

1. BlueCard® Program

Under the BlueCard® Program, when a Member receives Covered Medical Expenses within the geographic area served by a Host Blue, Blue Cross and Blue Shield of Montana will remain responsible for what we agreed to in the contract. However, the Host Blue is responsible for contracting with and generally handling all interactions with its participating healthcare providers.

When the Member receives Covered Medical Expenses outside the Blue Cross and Blue Shield of Montana service area and the claim is processed through the BlueCard Program, the amount the Member pays for Covered Medical Expenses is calculated based on the lower of:

- The billed covered charges for the Member's Covered Medical Expenses; or
- The negotiated price that the Host Blue makes available to Blue Cross and Blue Shield of Montana.

Often, this "negotiated price" will be a simple discount that reflects an actual price that the Host Blue pays to the Member's healthcare provider. Sometimes, it is an estimated price that takes into account special arrangements with the Member's healthcare provider or provider group that may include types of settlements, incentive payments, and/or other credits or charges. Occasionally, it may be an average price, based on a discount that results in expected average savings for similar types of healthcare providers after taking into account the same types of transactions as with an estimated price.

Estimated pricing and average pricing, going forward, also take into account adjustments to correct for over- or underestimation of past pricing of claims, as noted above. However, such adjustments will not affect the price Blue Cross and Blue Shield of Montana uses for the Member's claim because they will not be applied after a claim has already been paid.

In some cases, Blue Cross and Blue Shield of Montana may, but is not required to, negotiate a payment with a non-participating healthcare provider on an exception basis.

Inter-Plan Programs: Federal/State Taxes/Surcharges/Fees

Federal or state laws or regulations may require a surcharge, tax or other fee. If applicable, Blue Cross and Blue Shield of Montana will include any such surcharge, tax or other fee as part of the claim charge passed on to the Member.

2. Non-Participating Healthcare Providers Outside of the Blue Cross and Blue Shield of Montana Service Area

a. Member Liability Calculation

When the Member incurs Covered Medical Expenses outside of the Blue Cross and Blue Shield of Montana service area for services provided by non-participating healthcare providers, the amount the Member pays for such services will generally be based on either the Host Blue's non-participating healthcare provider local payment or the pricing arrangements required by applicable state law. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph. Federal or state law, as applicable, will govern payments for out-of-network emergency services.

b. Exceptions.

In certain situations, Blue Cross and Blue Shield of Montana may use other payment bases, such as Covered Medical Expenses, the payment Blue Cross and Blue Shield of Montana would make if the healthcare services had been obtained within the Blue Cross and Blue Shield of Montana service area, or a special negotiated payment to determine the amount Blue Cross and Blue Shield of Montana will pay for services provided by non-participating healthcare providers. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph.

3. BlueCard Worldwide® Program

If the Member is outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member may be able to take advantage of the BlueCard Worldwide® Program when accessing Covered Medical

Expenses. The BlueCard Worldwide Program is unlike the BlueCard Program available in the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands in certain ways. For instance, although the BlueCard Worldwide Program assists the Member with accessing a network of inpatient, outpatient and professional providers, the network is not served by a Host Blue. As such, when the Member receive care from providers outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member will typically have to pay the providers and submit the claims himself/herself to obtain reimbursement for these services.

If the Member needs medical assistance services (including locating a doctor or hospital) outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands (hereinafter "BlueCard service area"), the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week. An assistance coordinator, working with a medical professional, will arrange a physician appointment or hospitalization, if necessary.

Benefits will not be provided for any services or supplies except for those provided for an Emergency Medical Condition and received through the Inter-Plan Arrangements, which includes the BlueCard program.

- **Inpatient Services**

  In most cases, if the Member contacts the BlueCard Worldwide Service Center for assistance, hospitals will not require the Member to pay for covered inpatient services, except for the cost-share amounts/deductibles, coinsurance, etc.. In such cases, the hospital will submit the Member's claims to the BlueCard Worldwide Service Center to begin claims processing. However, if the Member paid in full at the time of service, the Member must submit a claim to receive reimbursement for Covered Medical Expenses.

  The Member must contact Blue Cross and Blue Shield of Montana to obtain preauthorization to verify that Inpatient Services are for the treatment of an Emergency Medical Condition.

- **Outpatient Services**

  Outpatient Services are available for the treatment of an Emergency Medical Condition. Physicians, urgent care centers and other outpatient providers located outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands will typically require the Member to pay in full at the time of service. The Member must submit a claim to obtain reimbursement for Covered Medical Expenses.

- **Submitting a BlueCard Worldwide Claim**

  When the Member pays for Covered Medical Services outside the BlueCard service area, the Member must submit a claim to obtain reimbursement. For institutional and professional claims, the Member should complete a BlueCard Worldwide International claim form and send the claim form the provider's itemized bill(s) to the BlueCard Worldwide Service Center (the address is on the form) to initiate claims processing. Following the instructions on the claim form will help ensure timely processing of the Member's claim. The claim form is available from Blue Cross and Blue Shield of Montana, the BlueCard Worldwide Service Center or online at www.bluecardworldwide.com. If the Member needs assistance with the Member claim submission, the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week.

COMPLAINTS AND GRIEVANCES

Complaints and Grievances

The Plan has established a complaint and grievance process. A complaint involves a communication from the Member expressing dissatisfaction about The Plan's services or lack of action or disagreement with The Plan's response. A grievance will typically involve a complaint about a provider or a provider's office, and may include complaints about a provider's lack of availability or quality of care or services received from a provider's staff.

Most problems can be handled by calling Customer Service at the number appearing on the inside cover of this Member Guide. The Member may also file a written complaint or grievance with The Plan. The fax number, email address, and mailing address of The Plan appears on the inside cover of this Member Guide. Written complaints or

grievances will be acknowledged within 10 days of receipt. The Member will be notified of The Plan's response within 60 days from receipt of the Member's written complaint or grievance.

APPEALS

Claims Procedures

Types of Claims

Claims are classified by type of claim and the timeline in which a decision must be decided and a notice provided depends on the type of claim involved. The initial benefit claim determination notice will be included in the Member's explanation of benefits (EOB) or in a letter from The Plan, whether adverse or not. There are five types of claims:

1. **Pre-Service Claims**

   A pre-service claim is any claim for a Benefit that, under the terms of this Member Guide, requires authorization or approval from The Plan or The Plan's subcontracted administrator prior to receiving the Benefit.

2. **Urgent Care Claims**

   An urgent care claim is any pre-service claim where a delay in the review and adjudication of the claim could seriously jeopardize the Member's life or health or ability to regain maximum function or subject the Member to severe pain that could not be adequately managed without the care or treatment that is the subject of the claim.

3. **Post-Service Claims**

   A post-service claim is any claim for payment filed after a Benefit has been received and any other claim that is not a pre-service claim.

4. **Rescission Claims**

   A rescission of coverage is considered a special type of claim. A rescission is defined as any cancellation or discontinuation of coverage that has a retroactive effect based upon the Member's fraud or an intentional misrepresentation of a material fact. A cancellation or discontinuance of coverage that has a retroactive effect is not a rescission if and to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage or to routine changes, such as eligibility updates. A cancellation or discontinuance with a prospective effect only is not a rescission.

5. **Concurrent Care Claim**

   A concurrent care decision represents a decision of The Plan approving an ongoing course of medical treatment for the Member to be provided over a period of time or for a specific number of treatments. A concurrent care claim is any claim that relates to the ongoing course of medical or emergency treatment (and the basis of the approved concurrent care decision), such as a request by the Member for an extension of the number of treatments or the termination by The Plan of the previously approved time period for medical treatment.

Initial Claim Determination by Type of Claim

1. **Pre-Service Claim Determination and Notice**

   a. Notice of Determination

      Upon receipt of a pre-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial determination, but no later than 15 days after receiving the claim.

   b. Notice of Extension

      1. For reasons beyond the control of The Plan

         The Plan may extend the 15-day time period for an additional 15 days for reasons beyond The Plan's

control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision.

2. For receipt of information from the Member to decide the claim

If the extension is necessary due to the Member's failure to submit information necessary to decide the claim, the extension notice will specifically describe the information needed, and the Member will be given 45 days from receipt of the notice within which to provide the specified information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

c. Notice of Improperly Submitted Claim

If a pre-service claim request was not properly submitted, The Plan will notify the Member about the improper submission as soon as practicable, but no later than 5 days after The Plan's receipt of the claim, and will advise the Member of the proper procedures to be followed for filing a pre-service claim.

2. Urgent Care Claim Determination and Notice

a. Designation of Claim

Upon receipt of a pre-service claim, The Plan will make a determination if the claim involves urgent care. If a physician with knowledge of the Member's medical condition determines the claim involves urgent care, The Plan will treat the claim as an urgent care claim.

b. Notice of Determination

If the claim is treated as an urgent care claim, The Plan will provide the Member with notice of the determination, either verbally or in writing, as soon as possible consistent with the Member's medical exigencies but no later than 72 hours from The Plan's receipt of the claim. If verbal notice is provided, The Plan will provide a written notice within 3 days after the date The Plan notified the Member.

c. Notice of Incomplete or Improperly Submitted Claim

If an urgent care claim is incomplete or was not properly submitted, The Plan will notify the Member about the incomplete or improper submission no later than 24 hours from The Plan's receipt of the claim. The Member will have at least 48 hours to provide the necessary information. The Plan will notify the Member of the initial claim determination no later than 48 hours after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

3. Post-Service Claim Determination and Notice

a. Notice of Determination

In response to a post-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial **determination, but no later than 30 days after receiving the claim.**

b. Notice of Extension

1. For reasons beyond the control of The Plan

The Plan may extend the 30-day timeframe for an additional 15-day period for reasons beyond The Plan's control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision in such case.

2. For receipt of information from the Member to decide the claim

If the extension is necessary due to the Member's failure to submit information necessary to decide the claim, the extension notice will specifically describe the information needed. The Member will be given 45 days from receipt of the notice to provide the information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested, or the due date for the information.

4. Concurrent Care Determination and Time Frame for Decision and Notice

a. Request for Extension of Previously Approved Time Period or Number of Treatments

1. In response to the Member's claim for an extension of a previously approved time period for treatments or number of treatments, and if the Member's claim involves urgent care, The Plan will review the claim and notify the Member of its determination no later than 24 hours from the date The Plan received the Member's claim, provided the Member's claim was filed at least 24 hours prior to the end of the approved time period or number of treatments.

2. If the Member's claim was not filed at least 24 hours prior to the end of the approved time period or number of treatments, the Member's claim will be treated as and decided within the timeframes for an urgent care claim as described in the section entitled, "Initial Claim Determination by Type of Claim."

3. If the Member's claim did not involve urgent care, the time periods for deciding pre-service claims and post-service claims, as applicable, will govern.

b. Reduction or Termination of Ongoing Course of Treatment

Other than through a Plan amendment or termination, The Plan may not subsequently reduce or terminate an ongoing course of treatment for which the Member has received prior approval unless The Plan provides the Member with written notice of the reduction or termination and the scheduled date of its occurrence sufficiently in advance to allow the Member to appeal the determination and obtain a decision before the reduction or termination occurs.

5. Rescission of Coverage Determination and Notice of Intent to Rescind

If The Plan makes a decision to rescind the Member's coverage due to a fraud or an intentional misrepresentation of a material fact, The Plan will provide the Member with a Notice of Intent to Rescind at least thirty (30) days prior to rescinding coverage. The Notice of Intent to Rescind will include the following information:

a. The specific reason(s) for the rescission that show the fraud or intentional misrepresentation of a material fact;

b. The date when the notice period ends and the date to which coverage is to be retroactively rescinded;

c. A statement that the Member will have the right to appeal any final decision of The Plan to rescind coverage prior to or after the thirty (30) day period, and a description of The Plan's appeal procedures;

d. A reference to The Plan provision(s) on which the rescission is based;

e. A statement that the Member is entitled to receive upon request and free of charge reasonable access to, and copies of all documents and records and other information relevant to the rescission.

Notice of an Adverse Benefit Determination

An "adverse benefit determination" is defined as a rescission or a denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a Benefit. If The Plan's determination constitutes an adverse benefit determination, the notice to the Member will include:

1. Information sufficient to identify the benefit or claim involved, including, if applicable, the date of service, the health care provider, and the claim amount;

2. The reason(s) for the adverse benefit determination. If the adverse benefit determination is a rescission, the notice will include the basis for the fraud and/or intentional misrepresentation of a material fact;

3. A reference to the applicable Member Guide provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the adverse benefit determination is based;

4. A description of The Plan's internal appeal and external review procedures (and for urgent care claims only, a description of the expedited review process applicable to such claims), a description of and contact information for a consumer appeal assistance program, and if applicable, a statement of the Member's right to file a civil action under Section 502(a) of ERISA;

5. If applicable, a description of any additional information necessary to complete the claim and why the information is necessary;

6. If applicable, a statement that any internal Medical Policy or guideline or other medical information relied upon in making the adverse benefit determination, and an explanation for the same, will be provided, upon request and free of charge;
7. If applicable, a statement that an explanation for any adverse benefit determination that is based on an experimental treatment or similar exclusion or limitation or a medical necessity standard will be provided, upon request and free of charge;
8. If applicable, a statement that diagnosis and treatment codes will be provided, and their corresponding meanings, upon request and free of charge; and
9. A statement that reasonable access to and copies of all documents and records and other information relevant to the adverse benefit determination will be provided, upon request and free of charge.

How to File an Internal Appeal of an Adverse Benefit Determination

1. Time for Filing an Internal Appeal of an Adverse Benefit Determination

If the Member disagrees with an adverse benefit determination (including a rescission), the Member may appeal the determination within 180 days from receipt of the adverse benefit determination. With the exception of urgent care claims, The Member's appeal may be made verbally or in writing, should list the reasons why the Member does not agree with the adverse benefit determination, and must be sent to the address or fax number listed for appeals on the inside cover of this Member Guide. If the Member is appealing an urgent care claim, the Member may appeal the claim verbally by calling the telephone number listed for urgent care appeals on the inside cover of this Member Guide.

For additional assistance with an appeal, a Member may also contact the Commissioner of Securities and Insurance at: Montana Commissioner of Securities and Insurance, 804 Helena Ave., Helena, MT 59601 or call 1-800-332-6148 or 406-444-2040.

2. Access to Plan Documents

The Member may at any time during the filing period, receive reasonable access to and copies of all documents, records and other information relevant to the adverse benefit determination upon request and free of charge. Documents may be viewed at The Plan's office, at 3645 Alice Street, Helena, Montana, between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays. The Member may also request that Blue Cross and Blue Shield of Montana mail copies of all documentation to the Member free of charge.

3. Submission of Information and Documents

The Member may present written evidence and testimony, including any new or additional records, documents or other information that are relevant to the claim for consideration by The Plan until a final determination of the Member's appeal has been made.

4. Consideration of Comments

The review of the claim on appeal will take into account all evidence, testimony, new and additional records, documents, or other information the Member submitted relating to the claim, without regard to whether such information was submitted or considered in making the initial adverse benefit determination.

If The Plan considers, relies on or generates new or additional evidence in connection with its review of the Member's claim, The Plan will provide the Member with the new or additional evidence free of charge as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan. If The Plan relies on a new or additional rationale in denying the Member's claim on review, The Plan will provide the Member with the new or additional rationale as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan.

5. Scope of Review

The person who reviews and decides the Member's appeal will be a different individual than the person who decided the initial adverse benefit determination and will not be a subordinate of the person who made the initial adverse benefit determination. The review on appeal will not give deference to the initial adverse benefit determination and will be made anew. The Plan will not make any decision regarding hiring, compensation, termination, promotion or other similar matters with respect to the individual selected to conduct the review on appeal based upon how the individual will decide the appeal.

6. Consultation with Medical Professionals

If the claim is, in whole or in part, based on medical judgment, The Plan will consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment. The health care professional will not have been involved in the initial adverse benefit determination (nor have been a subordinate of any person previously consulted). The Member may request information regarding the identity of any health care professional whose advice was obtained during the review of the Member's claim.

Time Period for Notifying Member of Final Internal Adverse Benefit Determination

The time period for deciding an appeal of an adverse benefit determination and notifying the Member of the final internal adverse benefit determination depends upon the type of claim. The chart below provides the time period in which The Plan will notify the Member of its final internal adverse benefit determination for each type of claim.

Type of Claim on Appeal	Time Period for Notification of Final Internal Adverse Benefit Determination
Urgent Care Claim	No later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency.
Pre-Service Claim	No later than 30 days from the date The Plan received the Member's appeal.
Post-Service Claim	No later than 60 days from the date The Plan received the Member's appeal.
Concurrent Care Claim	• If the Member's claim involved urgent care, no later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency. • If the Member's claim did not involve urgent care, the time period for deciding a pre-service (non-urgent care) claim or a post-service claim, as applicable, will govern.
Rescission Claim	No later than 60 days from the date The Plan received the Member's appeal.

Content of Notice of Final Internal Adverse Benefit Determination

If the decision on appeal upholds, in whole or in part, the initial adverse benefit determination, the final internal adverse benefit determination notice will include the following information:

1. Information sufficient to identify the claim involved in the appeal, including, as applicable, the date of service, the health care provider, and the claim amount;
2. The title and qualifying credentials of each health care professional participating in the appeal;
3. A statement from each health care professional participating in the appeal of his/her/their understanding of the basis for the Member's appeal;
4. The specific reason(s) for the final internal adverse benefit determination, including a discussion of the decision. If the final internal adverse benefit determination upholds a rescission, the notice will include the basis for the fraud or intentional misrepresentation of a material fact;
5. A reference to the applicable Member Guide provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the final internal adverse benefit determination is based;
6. If applicable, a statement describing the Member's right to request an external review and the time limits for requesting an external review;
7. If applicable, a statement that any internal Medical Policy or guideline or medical information relied on in making the final internal adverse benefit determination will be provided, upon request and free of charge;
8. If applicable, an explanation of the scientific or clinical judgment for any final internal adverse benefit determination that is based on a medical necessity or an experimental treatment or similar exclusion or limitation as applied to the Member's medical circumstances;
9. If applicable, a statement that diagnosis and treatment codes will be provided, with their corresponding meanings, upon request and free of charge;

10. A description of and contact information for a consumer appeal assistance program and a statement of the Member's right to file a civil action under Section 502(a) of ERISA; and
11. A statement that reasonable access to and copies of all documents and records and other information relevant to the final internal adverse benefit determination will be provided, upon request and free of charge.

External Review Procedures – In General

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member may submit a request for external review. In addition, external review is limited to only those adverse benefit determinations that involve:

1. Rescissions of coverage; and
2. Medical judgment, including those adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit or adverse benefit determinations that certain treatments are experimental or investigational.

External review is not available for:

1. Adverse benefit determinations that are based on contractual or legal interpretations without any use of medical judgment; and
2. Adverse benefit determinations that are based on a failure to meet requirements for eligibility under a group health plan.

Standard External Review Procedures

There are two types of external review: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entitles the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

External reviews (standard or expedited) of adverse benefit determinations or final internal adverse benefit determinations based upon a determination that certain treatments are experimental or investigational are discussed in separate sections, following the section entitled Expedited External Review Procedures, below.

1. Request for a Standard External Review

The Member must submit a written request to The Plan for a standard external review within 4 months from the date the Member receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

The Plan must complete a preliminary review within 5 business days from receipt of the Member's request for a standard external review to determine whether:

- **a.** The Member is or was covered under The Plan when the health care item or service was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care item or service was provided;
- **b.** The adverse benefit determination or final internal adverse benefit determination relates to the Member's failure to meet The Plan's eligibility requirements;
- **c.** The Member has exhausted (or is not required to exhaust) The Plan's internal appeals process;
- **d.** The Member has provided all the information and forms required to process the external review.

Within 1 day after completing its review, The Plan will notify the Member in writing if the request is eligible for external review. If further information or materials are necessary to complete the review, the written notice will describe the information or materials and the Member will be given the remainder of the 4 month period or 48 hours after receipt of the written notice, whichever is later, to provide the necessary information or materials. If the request is not eligible for external review, The Plan will outline the reasons for ineligibility in the notice, include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance and provide the Member with contact information for the U.S. Employee Benefits Security Administration (toll free number 866.444.EBSA (3272) and contact information for the Commissioner's office.

3. Assignment of an IRO

If the Member's request is eligible for external review, The Plan will within 1 business day assign the request for external review on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Montana Commissioner of Securities and Insurance to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will also take into account other circumstances, including conflict of interest concerns.

4. Initiation of External Review and Opportunity to Submit Additional Documents

Within 1 business day of assigning the IRO, The Plan will notify the Member, in writing, or the Member's authorized representative, that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

5. Plan Submission of Documents to the IRO

Within 5 business days after the date the IRO is assigned, The Plan must submit the documents and any information considered in making the benefits denial to the IRO. The Plan's failure to timely provide such documents and information will not constitute cause for delaying the external review. If The Plan fails to timely provide the documents and information, the IRO may terminate the external review and reverse the adverse benefit determination or final internal adverse benefit determination. If the IRO does so, it must notify the Member and The Plan within 1 business day after making the decision.

6. Reconsideration by Plan

On receiving any information submitted by the Member, the IRO must forward the information to The Plan within 1 business day. The Plan may then reconsider its adverse benefit determination or final internal adverse benefit determination. If The Plan decides to reverse its adverse benefit determination or final internal adverse benefit determination, The Plan must provide written notice to the Member and IRO within 1 business day after making the decision. On receiving The Plan's notice, the IRO must terminate its external review.

7. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the following in reaching a decision:

a. The Member's medical records;
b. The Member's treating provider(s)'s recommendations;
c. Reports from appropriate health care professionals and other documents, opinions, and recommendations submitted by The Plan and the Member;
d. The terms and conditions of The Plan, including specific coverage provisions, to ensure that the IRO's decision is not contrary to the terms and conditions of The Plan, unless the terms and conditions do not comply with applicable law;
e. Appropriate practice guidelines, which must include applicable Evidence-Based Standards;
f. Any applicable clinical review criteria developed and used by The Plan unless the criteria are inconsistent with the terms and conditions of The Plan or do not comply with applicable law;
g. The applicable Medical Policies of The Plan;
h. The opinion of the IRO's clinical reviewer or reviewers after considering information described in this notice to the extent the information or documents are available and the clinical reviewer or reviewers consider them appropriate.

8. Written Notice of the IRO's Final External Review Decision

The IRO will send written notification of its decision to the Member and to The Plan within 45 days after the IRO's receipt of the request for external review. The notice will include:

a. A general description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;
b. The date the IRO received the assignment to conduct the external review and the date of the IRO's decision;
c. References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;
d. A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and any Evidence-Based Standards relied on in making the decision;
e. A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;
f. A statement that judicial review may be available to the Member and The Plan; and
g. Contact information for a consumer appeal assistance program at the Commissioner of Securities and Insurance.

9. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan will immediately provide coverage or issue payment according to the written terms and benefits of the Member Guide.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that the timeframe for decisions and notifications is shorter.

1. Request for Expedited External Review

Under the following circumstances, the Member may request an expedited external review:

a. If the Member received an adverse benefit determination that denied the Member's claim and: (1) the Member filed a request for an internal urgent care appeal; and (2) the delay in completing the internal appeal process would seriously jeopardize the life or health of the Member or the Member's ability to regain maximum function; or
b. Upon receipt of a final internal adverse benefit determination which involves: (1) a medical condition of the Member for which a delay in completing the standard external review would seriously jeopardize the Member's life or health or the Member's ability to regain maximum function; or (2) an admission, availability of care, a continued stay, or a health care item or service for which the Member received emergency services, but has not been discharged from a facility.

2. Preliminary Review

Upon receiving the Member's request for expedited external review, The Plan will immediately determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section. After the preliminary review is complete, The Plan will immediately notify the Member or the Member's authorized representative in writing of its eligibility determination. If the Plan determines the Member's request is ineligible for review, the notice must include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance. The notice must also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If a request is eligible for expedited external review, The Plan will assign an IRO pursuant to and in compliance with the independence and other selection requirements set forth in the Assignment of an IRO paragraph, Standard External Review Procedures section. The Plan will transmit all documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO in as expeditious of a manner as possible (including by phone, facsimile, or electronically).

4. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the same documents and information set forth in the Standard of Review paragraph, Standard External Review Procedures section.

5. Notice of Final External Review Decision

The IRO will provide the Member and The Plan with notice of its final external review decision as expeditiously as the Member's medical condition or circumstances require, but not more than 72 hours after the IRO receives the expedited external review request. If the notice is not in writing, the IRO must provide written confirmation of its decision to the Member and to The Plan within 48 hours after the date the IRO verbally conveyed the decision. The written notice will include:

a. A description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;
b. The date the IRO received the assignment to conduct the external review and the date of the IRO's decision;
c. References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;
d. A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and any Evidence-Based Standards relied on in making the decision;
e. A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;
f. A statement that judicial review may be available to the Member or The Plan; and
g. Contact information for the appropriate consumer appeal assistance program at the Commissioner of Securities and Insurance.

6. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan will immediately approve coverage that was the subject of the adverse benefit determination or final internal adverse benefit determination according to the written terms and benefits of the Member Guide.

7. Inapplicability of Expedited External Review

An expedited external review may not be provided for retrospective adverse benefit determinations or retrospective final internal adverse benefit determinations.

External Review Procedures – Experimental or Investigational

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member or the Member's authorized representative may submit a request for external review. In addition, external review as outlined in the next two sections is limited to only those adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational.

Standard External Review Procedures

There are two types of external review of adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entitles the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

1. Request for a Standard External Review

The Member or the Member's authorized representative must submit a written request to The Plan for a standard external review within 4 months from the date the Member or the Member's authorized representative receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

Upon receipt of a request for standard external review, The Plan must complete a preliminary review within 5 business days to determine whether:

a. The Member is or was covered under The Plan when the health care service or treatment was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care service or treatment was provided;

b. The requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination: (i) is a covered benefit under the Member's health plan except for The Plan's determination that the health care service or treatment is experimental or investigational for a particular medical condition; and (ii) is not explicitly listed as an excluded benefit under the Member's health plan;

c. The Member's treating health care provider has certified that one of the following situations is applicable: (i) standard health care services or treatments have not been effective in improving the condition of the Member; (ii) standard health care services or treatments are not medically appropriate for the Member; or (iii) there is no available standard health care service or treatment covered by The Plan that is more beneficial than the requested health care service or treatment;

d. (i) the Member's treating health care provider has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the Member, in the physician's opinion, than any available standard health care services or treatments; or (ii) a physician who is licensed, board-certified, or eligible to take the examination to become board-certified and is qualified to practice in the area of medicine appropriate to treat the Member's condition has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested by the Member who is subject to the adverse benefit determination or final internal adverse benefit determination is likely to be more beneficial to the Member than any available standard health care services or treatments; and

e. The Member has exhausted The Plan's internal appeals process or the Member is exempt from exhausting The Plan's internal appeals process.

Within 1 business day after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will within 1 business day assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day of assigning the IRO, The Plan will notify the Member or the Member's authorized representative in writing that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice, for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

4. Plan Submission of Documents to the IRO

Within 5 business days after assigning an IRO, The Plan will provide to the assigned IRO any documents and information considered in making the adverse benefit determination or the final internal adverse benefit

determination. Failure by the Plan to timely provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information within 5 business days, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan of its decision.

5. Reconsideration by The Plan

The IRO will forward any information submitted by Member or the Member's authorized representative to the Plan, within 1 business day of its receipt. The Plan may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by The Plan may not delay or terminate the IRO's external review. The external review may be terminated only if The Plan decides, on completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage for the requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will notify the Member or the Member's authorized representative and the IRO immediately in writing of its decision. The IRO will terminate the external review on receipt of the notice from The Plan.

6. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. In selecting Clinical Peers to conduct the external review, the assigned IRO will select physicians or other health care providers who meet minimum statutorily prescribed qualifications and who, through clinical experience in the past 3 years, are experts in the treatment of the Member's condition and knowledgeable about the recommended or requested health care service or treatment. The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Within 20 days after selection, each Clinical Peer will provide an opinion to the assigned IRO on whether the requested health care service or treatment should be covered. In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached during The Plan's internal appeals process.

Each Clinical Peer's opinion will be in writing and include the following information:

a. a description of the Member's medical condition;

b. a description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the requested health care service or treatment is more likely than not to be more beneficial to the Member than any available standard health care services or treatments and that the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments;

c. a description and analysis of any Medical or Scientific Evidence considered in reaching the opinion;

d. a description and analysis of any Evidence-Based Standard; and

e. information on whether the clinical peer's rationale for the opinion is based on the Member's medical records and/or the attending provider's or health care professional's recommendation.

7. Written Notice of the IRO's Final External Review Decision

Within 20 days after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision and provide written notice of the decision to the Member or the Member's authorized representative and to The Plan.

If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should be covered, the IRO shall make a decision to reverse The Plan's adverse benefit determination or final internal adverse benefit determination. If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should not be covered, the IRO shall make a decision to uphold The Plan's adverse benefit determination or final internal adverse benefit determination. If the Clinical Peers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the IRO shall obtain the opinion of an additional Clinical Peer. The additional Clinical Peer shall use the same

information to reach an opinion as used by the Clinical Peers who have already submitted their opinions. The selection of the additional Clinical may not extend the time within which the assigned IRO is required to make a decision based on the opinions of the Clinical Peers.

The IRO will include in its written notice:

a. a general description of the reason for the request for external review;
b. the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;
c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

8. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that requests for external review may be made differently and the timeframe for decisions and notifications is shorter.

1. Request for an Expedited External Review

The Member or the Member's authorized representative may make an oral or written request for an expedited external review of an adverse benefit determination or a final internal adverse benefit determination if the Member's treating health care provider certifies, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

2. Preliminary Review

Upon receipt of a request for an expedited external review, The Plan must immediately complete a preliminary review to determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section, above.

Immediately after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will immediately assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular expedited external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day after assignment of the IRO, The Plan will notify the Member or the Member's authorized representative, in writing, that The Plan has initiated an external review and that the Member or the Member's

authorized representative may submit additional information to the IRO for the IRO's consideration in its external review.

4. Plan Submission of Documents to the IRO

Upon assigning an IRO, The Plan will provide any documents and information considered in making the adverse benefit determination or the final internal adverse benefit determination to the assigned IRO electronically, by telephone, by facsimile, or by any other available expeditious method. Failure by the Plan to provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information upon IRO assignment, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan accordingly.

5. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. The assigned IRO will select physicians or other health care providers using the same criteria as set forth in the Standard of Review paragraph in the Standard External Review Procedures, above, The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Each Clinical Peer will provide an opinion to the assigned IRO as expeditiously and the Member's medical condition or circumstances require but no later than 5 calendar days after being selected as a Clinical Peer, on whether the requested health care service or treatment should be covered. If the Clinical Peer's opinion was initially made orally, the Clinical Peer shall provide the IRO written confirmation of the opinion within 48 hours after the opinion was initially made.

In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached by The Plan. Each Clinical Peer's opinion may be rendered orally or in writing and will include the same information as set forth in the Standard of Review paragraph in the Standard External Review Procedures section, above.

6. Written Notice of the IRO's Final External Review Decision

Within 48 hours after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision based upon the recommendations of a majority of the Clinical Peers conducting the review, and will provide oral or written notice of the decision to the Member or the Member's authorized representative and to the Plan. If the IRO's notice is provided orally, the IRO will provide written confirmation of the decision within 48 hours of the initial oral notice.

The IRO will include in its written notice:

a. a general description of the reason for the request for external review;
b. the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;
c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

7. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Deemed Exhaustion of Internal Appeal Process

1. The Member will be deemed to have exhausted the internal appeal process and may request external review or pursue any available remedies under state law or if applicable, a civil action under 502(a) of ERISA, if The Plan fails to comply with its claims and appeals procedures, except that claims and appeals procedures will not be deemed exhausted based on violations that are:
   a. De minimis;
   b. Non-prejudicial to the Member;
   c. Attributable to good cause or matters beyond The Plan's control;
   d. In the context of an ongoing, good faith exchange of information between the Member and The Plan; and
   e. Not reflective of a pattern or practice of violations by The Plan.
2. Upon request of the Member, The Plan will provide an explanation of a violation within 10 days. The explanation will include a description of the basis for The Plan's assertion that the violation does not result in the deemed exhaustion of The Plan's internal claims and appeals procedures.
3. If the Member seeks external or judicial review based on deemed exhaustion of The Plan's internal claims and appeals procedures, and the external reviewer or court rejects the Member's request, The Plan will notify the Member within a reasonable period of time, not to exceed 10 days, of the Member's right to resubmit the Member's internal appeal. The timeframe for appealing the adverse benefit determination begins to run when the Member receives the notice of the right to resubmit the Member's internal appeal.

PREAUTHORIZATION

The Plan has designated certain covered services which require Preauthorization in order for the Member to receive the maximum Benefits possible under this Member Guide.

The Member is responsible for satisfying the requirements for Preauthorization. This means that the Member must request Preauthorization or assure that the Member's Physician, provider of services, the Member's authorized representative, or a Family Member complies with the requirements below. If the Member utilizes a Network Provider for covered services, that provider may request Preauthorization for the services. However, it is the Member's responsibility to assure that the services are preauthorized before receiving care.

To request Preauthorization, the Member or his/her Physician must call the Preauthorization number shown on the Member's Identification Card **before** receiving treatment. The Plan will assist in coordination of the Member's care so that his/her treatment is received in the most appropriate setting for his/her condition and that the Member receives the highest level of Benefits under this Member Guide.

Preauthorization does not guarantee that the care and services a Member receives are eligible for Benefits under the Member Guide. In addition, a nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield of Montana and provider charges plus Deductible, Coinsurance and/or Copayment even if the service is an Emergency Service or the if the service has been Preauthorized.

Preauthorization Process for Inpatient Services

For an Inpatient facility stay, the Member must request Preauthorization from The Plan **before** the Member's scheduled admission. The Plan will consult with the Member's Physician, Hospital, or other facility to determine if Inpatient level of care is required for the Member's illness or injury. The Plan may decide that the treatment the Member needs could be provided just as effectively in a different setting (such as the Outpatient department of the Hospital, an Ambulatory Surgical Facility, or the Physician's office).

If The Plan determines that the Member's treatment does not require Inpatient level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Member Guide, the Member may be responsible for the full cost of the services.

Unscheduled Inpatient admissions, such as admissions for Emergency Medical Conditions and maternity care should be preauthorized within two days after the admission.

Preauthorization Process for Mental Illness, Severe Mental Illness and Chemical Dependency Services

All Inpatient and partial hospitalization services related to treatment of Mental Illness, Severe Mental Illness and Chemical Dependency must be Preauthorized by The Plan. Preauthorization is also required for the following Outpatient Services and must be submitted no later than 15 business days before the service is provided:

- Electroconvulsive therapy;
- Intensive Outpatient Treatment;
- Neuropsychological testing;
- Psychological testing;
- Repetitive Transcranial Magnetic Stimulation;
- Applied Behavior Analysis (ABA).

Preauthorization is not required for therapy visits to a Physician or other professional Provider licensed to perform covered services under this Member Guide. However, all services are subject to the provisions in the section entitled Concurrent Review.

If The Plan determines that the Member's treatment does not require Inpatient or partial hospital level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay or partial hospital level of care, without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Member Guide, the Member may be responsible for the full cost of the services.

Preauthorization Process for Other Outpatient Services

In addition to the Preauthorization requirements outlined above, The Plan also requires Preauthorization, which must be submitted no later than 15 business days before the service is provided, for certain Outpatient services, including:

- Dialysis treatment - Out-of-Network;
- High-cost injections, including but not limited to IVIG, Avastin, Rituxan, and Remicade injections.
- Home Health Care;
- Home Hemodialysis;
- Home Infusion Therapy;
- Hospice Services;
- Molecular Genetic Testing;
- Outpatient elective surgery - Out-of-Network;
- Transplant Evaluations;
- Diagnostic sleep studies for Obstructive Sleep Apnea;
- Radiation Therapy

For additional information on Preauthorization, the Member or the Provider may call the Customer Service number on the Member's identification card.

It is NOT necessary to preauthorize standard x-ray and lab services or Routine office visits.

If The Plan does not approve the Outpatient Service, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with the services without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Member Guide, the Member may be responsible for the full cost of the services.

The Benefits section of this Member Guide details the services which are subject to Preauthorization.

Preauthorization Request Involving Non-Urgent Care

Except in the case of a Preauthorization Request Involving Urgent Care (see below), The Plan will provide a written response to the Member's Preauthorization request no later than 15 days following the date we receive the Member's request. This period may be extended one time for up to 15 additional days, if we determine that additional time is necessary due to matters beyond our control.

If The Plan determines that additional time is necessary, The Plan will notify the Member in writing, prior to the expiration of the original 15-day period, that the extension is necessary, along with an explanation of the circumstances requiring the extension of time and the date by which The Plan expects to make the determination.

If an extension of time is necessary due to the need for additional information, The Plan will notify the Member of the specific information needed, and the Member will have 45 days from receipt of the notice to provide the additional information.

The Plan will provide a written response to the Member's request for Preauthorization within 15 days following receipt of the additional information. The procedure for appealing an adverse Preauthorization determination is set forth in the section entitled Complaints and Grievances.

Preauthorization Request Involving Urgent Care

A Preauthorization Request Involving Urgent Care is any request for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the Member or the ability of the Member to regain maximum function; or in the opinion of a Physician with knowledge of the Member's medical condition, would subject the Member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the Preauthorization request.

In case of a Preauthorization Request Involving Urgent Care, The Plan will respond to the Member no later than 72 hours after receipt of the request, unless the Member fails to provide sufficient information, in which case, the Member will be notified of the missing information within 24 hours and will have no less than 48 hours to provide the information. A Benefit determination will be made as soon as possible (taking into account medical exigencies) but no later than 72 hours after the initial request, or within 48 hours after the missing information is received (if the initial request is incomplete).

NOTE: The Plan's response to the Member's Preauthorization Request Involving Urgent Care, including an adverse determination, if applicable, may be issued orally. A written notice will also be provided within three days following the oral notification.

Preauthorization Request Involving Emergency Care

If the Member is admitted to the Hospital for Emergency Care and there is not time to obtain Preauthorization, the Member's Provider must notify The Plan within two working days following the Member's emergency admission.

Preauthorization Required For Certain Prescription Drug Products and Other Medications

Prescription Drug Products, which are self-administered, process under the Prescription Drugs section of this Member Guide. There are other medications that are administered by a Covered Provider which process under the medical Benefits.

1. **Prescription Drugs – Covered Under the Prescription Drugs Benefit**

   Certain prescription drugs, which are self-administered, require Preauthorization. Please refer to the Prescription Drugs section for complete information about the Prescription Drug Products that are subject to Preauthorization, step therapy, and quantity limits, the process for requesting Preauthorization, and related information.

2. **Other Medications – Covered Under Medical Benefits**

   Medications that are administered by a Covered Provider will process under the medical Benefits of this Member Guide. Certain medications administered by a Covered Provider require Preauthorization. The medications that require Preauthorization are subject to change by The Plan.

   For any medication that is subject to Preauthorization, the Member or provider should fax the request for Preauthorization to the Blue Cross and Blue Shield of Montana Medical Review Preauthorization Department at 1-866-589-8256. The Member or provider may also submit a written request for Preauthorization. Preauthorization forms are located on The Plan website at www.bcbsmt.com, and may be printed directly from the website. The Plan will notify the Member and provider of the Preauthorization determination.

In making determinations of coverage, The Plan may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

To determine which medications are subject to Preauthorization, the Member or provider should refer to the list of medications which applies to the Member's Plan on The Plan website at www.bcbsmt.com or call the Customer Service toll-free number identified on the Member's identification card or The Plan website at www.bcbsmt.com.

General Provisions Applicable to All Required Preauthorizations

1. No Guarantee of Payment

Preauthorization does not guarantee payment of Benefits by The Plan. Even if the Benefit has been Preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date of service or the Member's Benefits may have changed as of the date the service.

2. Request for Additional Information

The Preauthorization process may require additional documentation from the Member's health care provider or pharmacist. In addition to the written request for Preauthorization, the health care provider or pharmacist may be required to include pertinent documentation explaining the proposed services, the functional aspects of the treatment, the projected outcome, treatment plan and any other supporting documentation, study models, prescription, itemized repair and replacement cost statements, photographs, x-rays, etc., as may be requested by The Plan to make a determination of coverage pursuant to the terms and conditions of this Member Guide.

3. Failure to Obtain Preauthorization

If the Member does not obtain Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Member Guide, the Member may be responsible for the full cost of the services.

Any treatment the Member receives which is not a covered service under this Member Guide, or is not determined to be Medically Necessary, or is not performed in the appropriate setting will be excluded from the Member's Benefits. This applies even if Preauthorization approval was requested or received.

Concurrent Review

Whenever it is determined by The Plan, that Inpatient care or an ongoing course of treatment may no longer meet medical necessity criteria or is considered Experimental/Investigational/Unproven (EIU), the Member, Member's Provider or the Member's authorized representative may submit a request to The Plan for continued services. If the Member, the Member's Provider or the Member's authorized representative requests to extend care beyond the approved time limit and it is a Request Involving Urgent Care, The Plan will make a determination on the request/appeal as soon as possible (taking into account medical exigencies) but no later than 72 hours after it receives the initial request, or within 48 hours after it receives the missing information (if the initial request is incomplete).

Care Management

The goal of Care Management is to help the Member receive the most appropriate care that is also cost effective. If the Member has an ongoing medical condition or a catastrophic illness, the Member should contact The Plan. If appropriate, a care manager will be assigned to work with the Member and the Member's providers to facilitate a treatment plan. Care Management includes Member education, referral coordination, utilization review and individual care planning. Involvement in Care Management does not guarantee payment by The Plan.

ELIGIBILITY AND ENROLLMENT

Who is Eligible

Employees

All employees of the Group are eligible if they are:

1. A member of the organization or employing unit, or a beneficiary of the trust to which this Member Guide is issued; and
2. Employed an average of 20-40 hours per week or more. The minimum number of work hours required to be eligible will be determined by the group. The requirement will not be less than 20 hours or more than 40 hours. This includes a sole proprietor, partner, and independent contractor if these are included as an employee under the health benefit plan of the Small Employer.

At the employer's discretion, seasonal employees may be eligible employees provided they are not designated as temporary and that they work the required number of hours per week. Officers of the employer group are subject to the same eligibility requirements as other employees, including working the required number of hours per week. Persons working on a part-time, temporary and/or substitute basis are not eligible employees. Temporary basis means a definite period of time, not to exceed twelve months, with no guarantee of employment on a permanent basis. A part-time basis means anything less than the hourly requirement of an eligible employee.

If an employee remains actively at work and the employee's hours have been reduced to less than that required by the group, the employee may apply for the employer's or trustees' consent to remain a member of the Group for up to one year from the date of the reduction in work hours.

Retirees

Retirees are eligible for coverage if the:

1. Group offers retiree coverage; and
2. Eligibility guidelines for retiree coverage, established by the Group, are met.

Contact your Group Leader to determine if retiree coverage is available.

Applying for Coverage

An Applicant may apply for coverage in for himself/herself and/or any eligible Dependents (see below) by submitting the application(s) for medical insurance form, along with any exhibits, appendices, addenda and/or other required information ("Application(s)") to Blue Cross and Blue Shield of Montana. The Application(s) for coverage may or may not be accepted.

No eligibility rules or variations in premium will be imposed based on health status, medical condition, claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability, disability, or any other health status related factor. Applicants will not be discriminated against for coverage under this Plan on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

Variation in the administration, processes or Benefits of this policy that are based on clinically indicated, reasonable medical management practices, or are part of permitted wellness incentives, disincentives and/or other programs do not constitute discrimination.

Enrollment

1. Initial Enrollment Period for Eligible Employees and Dependents

   Eligible employees and their Dependents must apply for membership within 30 days of the initial Effective Date of the Group if they are employed by the Group on that date. Eligible employees, who are not employed by the Group on the Group's initial Effective Date, and their Dependents, are eligible to apply for membership within 30 days following completion of the probationary waiting period shown on the Group Application.

Effective Date of Coverage

a. If the probationary waiting period is less than 90 days, the Effective Date of coverage (for those who apply within the periods of eligibility) will be at 12:01 a.m. on the 1st or the 15th of the month after completion of the probationary period, subject to the Group's anniversary date and meeting all eligibility and enrollment requirements; or

b. If the probationary waiting period is 90 days, the Effective Date of coverage (for those who apply within the periods of eligibility) will be at 12:01 a.m. on the 90th day of the probationary period, subject to the Group's anniversary date and meeting all eligibility and enrollment requirements.

2. Annual Enrollment Period for Eligible Employees and Dependents

Employees and Family Members who do not apply within the initial period of eligibility may apply only during the Group's annual open enrollment period. The annual open enrollment period will be determined by the Group and Blue Cross and Blue Shield of Montana. Appropriate notice of the annual enrollment period will be provided to the employees.

Effective Date of Coverage

The Effective Date of coverage (for those who apply within the periods of eligibility) will be at 12:01 a.m. on the 1st or the 15th of the month in which the person became eligible, subject to the Group's anniversary date and meeting all eligibility and enrollment requirements.

3. Special Enrollment for Loss of Coverage

Eligible Individuals

A special enrollment period may be available for the following eligible employees and/or Dependents:

a. Eligible employee.

An eligible employee who is not currently enrolled and when enrollment was previously offered to the employee and declined, the employee was covered under another group health plan or had other health insurance coverage.

b. Dependent of Beneficiary Member.

The Dependent of a Beneficiary Member who is not enrolled and when enrollment was previously offered and declined, the Dependent was covered under another group health plan or had other health insurance coverage.

c. Eligible employee and Dependent.

An eligible employee and Dependent who are not enrolled and when enrollment was previously offered to the employee or Dependent and declined, the employee or Dependent was covered under another group health plan or had other health insurance coverage.

Conditions for Special Enrollment

a. When the employee declined enrollment for the employee or the Dependent, the employee stated in writing that coverage under another group health plan or other health insurance coverage was the reason for declining enrollment; and

1. The employee or Dependent had COBRA continuation coverage and the COBRA continuation coverage has expired; or

2. The employee or Dependent had other coverage that was not under a COBRA continuation provision and the other coverage has been terminated because of:

a. A loss of eligibility for the coverage. Loss of eligibility for coverage includes a loss coverage as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment, and any loss of eligibility after a period that is measured by reference to any of the forgoing. However, loss of eligibility does not include a loss of coverage due to failure of the individual or the Beneficiary Member to pay premiums on a timely basis or termination of coverage for cause; or

b. Employer contributions towards the other coverage have been terminated; or

c. A situation in which the employee or Dependent incurs a claim that would meet or exceed a lifetime limit on non-essential benefits; or

d. A situation in which The Plan no longer offers any benefits to the class of similarly situated individuals that includes the individual.

3. The employee or Dependent loses eligibility under either the Children's Health Insurance Program or the Medicaid Program, or the employee or Dependent becomes eligible for financial assistance for group health coverage, under either the Children's Health Insurance Program or the Medicaid Program.

b. The employee must request enrollment (for the employee or the employee's Dependents) not later than 31 days after the exhaustion of the COBRA continuation coverage or termination of the other coverage because of loss of eligibility or termination of employer contributions.

c. The employee must request enrollment for the employee and or Dependent not later than 60 days after the date of termination of coverage under either the Children's Health Insurance Program or the Medicaid Program.

d. The employee must request enrollment for the employee or Dependent not later than 60 days after the date the employee or Dependent is determined to be eligible for financial assistance under the Children's Health insurance Program or the Medicaid Program.

e. Enrollment during a special enrollment period is subject to all other applicable enrollment requirements of The Plan and the provisions of this Member Guide.

Effective Date of Enrollment

Enrollment due to loss of coverage will be effective not later than the first day of the first calendar month beginning after the date the completed request for enrollment is received.

Special Enrollment for Marriage, Birth, Adoption or Placement for Adoption

Application must be made for coverage within 30 days from the date of a special enrollment event or limited enrollment event. The Member must provide acceptable proof of a qualifying event with the application. Special enrollment qualifying events are discussed in detail below. The Plan will review this proof to verify the Member's eligibility for a special enrollment. Failure to provide acceptable proof of a qualifying event with the application will delay or prevent the processing of the application and enrollment in coverage. Please call the Customer Service number on the inside cover of this Member Guide for examples of acceptable proof for the following qualifying events.

Eligible Individuals

A special enrollment period may be available for the following individuals:

a. Eligible employee.

An eligible employee who is not enrolled because of an election to not enroll during a previous enrollment period, and a person becomes a Dependent of the eligible employee through marriage, birth, or adoption or placement for adoption.

b. Spouse of a Beneficiary Member.

An individual who becomes a Spouse of the Beneficiary Member or a Spouse of the Beneficiary Member and a child becomes a Dependent of the Beneficiary Member through birth, adoption or placement for adoption.

In the case of marriage, only the Spouse or the Spouse's children can be added at that time, not any additional children in the family who were not enrolled when previously eligible.

c. Dependents.

An individual who is a Dependent of a Beneficiary Member through marriage, adoption or placement for adoption, or an individual who is a Dependent of a Member through birth. A child placed for adoption will be eligible for coverage as of the date of adoption or placement for adoption and a child born to a Member will be eligible for coverage from the moment of birth subject to all the provisions of the section entitled Effective Date of Coverage.

In the case of birth or adoption of a child, only the newborn or newly adopted child can be added to the coverage at that time, not a Spouse or any other children who were not enrolled when previously eligible.

Enrollment Period

The special enrollment period for Dependents under this section is for a period of 30 days and begins on the date of the marriage, birth, or adoption or placement for adoption. Enrollment during a special enrollment period is subject to all other applicable enrollment requirements of The Plan and provisions of this Member Guide.

Effective Date of Coverage

Enrollment will be effective as follows:

a. In the case of marriage, the date of marriage if the completed request for enrollment (application) is received by The Plan within 30 days after the date of marriage. If the application is received after 31 days of the date of marriage, the enrollee will be considered a Late Enrollee.

b. For a newborn born to a Member, the date of birth. Coverage will continue for 31 days. Coverage for the newborn will be provided only if the Beneficiary Member remains covered on the health plan during the 31 day period. If the Beneficiary Member does not remain covered for 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.

Coverage will continue for the child after the 31 day period if within the first 30 days of coverage, the Beneficiary Member:

1. Notifies The Plan to continue the coverage for the child; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if the Plan is not notified to continue coverage.

c. In the case of a Dependent's adoption or placement for adoption, the date of such adoption or placement for adoption. Children will be covered for a period of 31 days upon adoption or placement for adoption, including the date of placement, provided the Beneficiary Member remains covered under the Member Guide for those 31 days. If the Beneficiary Member does not remain covered for 31 days, the adopted child or the child placed for adoption will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.

Coverage will continue for the child after the 31 day period if within the first 30 days of coverage, the Beneficiary Member:

1. Notifies The Plan to continue the coverage for the child; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if the Plan is not notified to continue coverage. In the event the placement is disrupted prior to legal adoption and the child is removed from placement, coverage shall cease upon the date the placement is disrupted.

When Benefits Begin

The Member is entitled to the Benefits of this Member Guide beginning on the Member's Effective Date.

QUALIFIED MEDICAL CHILD SUPPORT ORDER (QMSCO)

Beneficiary Members and Family Members can obtain, without charge, a copy of the procedures governing Qualified Medical Child Support Order (QMCSO) determinations from Blue Cross and Blue Shield of Montana.

FAMILY AND MEDICAL LEAVE ACT (FMLA)

1. The Family and Medical Leave Act of 1993 (FMLA) requires employers, who employ at least 50 workers within a 75 mile radius of the workplace, to provide eligible employees with up to 12 weeks of leave during any 12-Month period for any of the following reasons:
   - **a.** To care for a newborn child;
   - **b.** Because a child has been placed with the employee for adoption or foster care;
   - **c.** To care for a Spouse, child, or parent of the employee;
   - **d.** The employee's own serious health condition makes the employee unable to perform his or her job.
2. Eligible employees are those who have been employed by the employer for at least 12 Months and who have worked at least 1,250 hours for that employer during the previous 12-Month period.
3. The health Benefits of an employee and Dependents, if any, will be maintained during FMLA leave on the same terms and conditions as if the employee had not taken leave.
4. The health Benefits of an employee and Dependents, if any, may lapse at the employer's discretion during FMLA leave because the employee does not pay his or her share of the premiums in a timely manner or the employee does not elect health Benefits during the FMLA leave. Upon return from leave, the employee and dependents, if any, will be reenrolled in the health benefit plan as if the coverage had not lapsed.
5. The employee's reenrollment in the health plan will be effective upon the date on which the employee returns to work.
6. An employee who takes FMLA leave and fails to pay any required premium contribution or fails to return from leave will be entitled to COBRA coverage for the maximum COBRA coverage period beginning when the FMLA coverage terminated.

TERMINATION OF COVERAGE

Termination When Employment Ceases or Family Member Status Changes

1. When Employment Ceases

   If the Effective Date of the Group Plan is the first day of the month, membership, including that of any Family Members will terminate at the end of the Month in which the Group notifies us that the Member is no longer employed by the Group.

   If the Effective Date of the Group Plan is the fifteenth day of the Month, membership, including that of any Family Member, will terminate on the earlier of:

   - **a.** The fifteenth day of the Month in which the Group Notifies The Plan that the Member is no longer employed by the Group; or
   - **b.** The fifteenth day of the following Month.

2. Change of status for Medical Benefits

   Coverage for a Family Member will **terminate automatically** at midnight, Mountain Standard Time, on the last day of the Month in which a child reaches age 26 years. Coverage for a Spouse will terminate at midnight, Mountain Standard Time, on the last day of the Month in which the Spouse's marriage to the Beneficiary Member is terminated.

3. Change of status for Pediatric Dental Benefits

   Coverage for a Family Member will **terminate automatically** at midnight, Mountain Standard Time, on the last day of the Month in which a child reaches age 19 years of age.

Termination of Benefits

When the membership of a Beneficiary Member and/or Family Members is terminated for any reason listed in this section or any other section, Benefits will no longer be provided and The Plan will not make payment for services provided to them after the date on which cancellation becomes effective.

However, if the Member is receiving Inpatient Care on the date coverage terminates, the Member will continue to receive the Benefits payable under this Member Guide:

1. For 30 days; or
2. Until the Member is discharged from the Inpatient Care facility, whichever occurs first.

Certificate of Creditable Coverage

Even though this health plan does not have a preexisting condition exclusion period, The Plan will issue a Certificate of Creditable Coverage to the Member, upon request, following termination of coverage.

CONTINUATION OF COVERAGE

COBRA

Certain employers maintaining group health coverage plans (whether insured or self-insured) must provide COBRA continuation coverage for qualified beneficiaries when group health coverage is lost. The right to COBRA continuation coverage was created by a federal law, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). To lose coverage means to cease to be covered under the same terms and conditions as in effect immediately before a qualifying event. A loss of coverage need not occur immediately after a qualifying event so long as the loss of coverage occurs before the end of the maximum COBRA coverage period. A qualified beneficiary is entitled to the coverage made available to similarly situated employees.

COBRA requires qualified beneficiaries or a representative acting on behalf of a qualified beneficiary to provide certain notices to the plan administrator (generally the employer), and requires the plan administrator to provide certain notices to qualified beneficiaries. The plan administrator is also the COBRA Administrator unless the plan administrator has designated another individual or entity to administer COBRA.

1. Small Employer Exception

   Small employer plans are generally exempt from the COBRA regulations. A small employer plan, for the purposes of COBRA, is defined as an employer plan that normally employed fewer than 20 employees, including part-time employees, during the preceding calendar year. A group health plan that is a multi-employer plan (as defined in Internal Revenue Code (IRC)) is a small-employer plan if each of the employers contributing to the plan for a calendar year normally employed fewer than 20 employees during the preceding calendar year. Whether the plan is a multi-employer plan or not, the term employer includes all members of a controlled group.

   A small employer employs fewer than 20 employees during a calendar year if it had fewer than 20 employees on at least 50 percent of its typical business days during that year. Only common-law employees are counted for purposes of the small employer exception; self-employed individuals, independent contractors (and their employees and independent contractors), and corporate directors are not counted.

2. Qualified Beneficiaries

   Continuation of coverage is available to qualified beneficiaries. A qualified beneficiary is:

   a. Any individual who, on the day before a qualifying event, is covered under a group health plan either as a covered employee, the Spouse of a covered employee, or the Dependent child of a covered employee; or
   b. Any child born to or placed for adoption with a covered employee during a period of COBRA continuation.

   Individuals added to a qualified beneficiary's COBRA coverage (e.g., a new Spouse or person added as the result of a Special Enrollment event, etc.) do not become qualified beneficiaries in their own right, with the exception of 2(b) above.

Nonresidents - An individual is not a qualified beneficiary if the individual's status as a covered employee is attributable to a period in which the individual was a nonresident alien who received from the individual's employer no earned income (within the meaning of IRC section 911(d)(2)) that constituted income from sources within the United States (within the meaning of IRC section 861(a)(3)). If, pursuant to the preceding sentence, an individual is not a qualified beneficiary, then a Spouse or Dependent child of the individual is not considered a qualified beneficiary by virtue of the relationship to the individual.

3. Qualifying Events

A qualifying event is any of a set of specified events that occur while a group health plan is subject to COBRA and which causes a qualified beneficiary to lose coverage under the plan.

a. Employee

An employee will become a qualified beneficiary if the employee loses coverage under the plan because either one of the following qualifying events happen:

1. Employee's hours of employment are reduced; or
2. Employment ends for any reason other than gross misconduct.

b. Spouse

The Spouse of an employee will become a qualified beneficiary if the Spouse loses coverage under the plan because any of the following qualifying events happen:

1. The employee dies;
2. The employee's hours of employment are reduced;
3. The employee's employment ends for any reason other than gross misconduct;
4. The employee becomes entitled to Medicare benefits (under Part A, Part B, or both); or
5. Divorce or legal separation from the employee.

c. Dependent Children

Dependent children will become qualified beneficiaries if they lose coverage under the plan because any of the following qualifying events happen:

1. The employee dies;
2. The employee's hours of employment are reduced;
3. The employee's employment ends for any reason other than gross misconduct;
4. The employee becomes entitled to Medicare benefits (Part A, Part B, or both);
5. The employee becomes divorced or legally separated; or
6. The child stops being eligible for coverage under the plan as a "Dependent child."

d. Retirees

If the plan provides retiree health coverage, a proceeding in bankruptcy under Title 11 of the United States Code can sometimes be a qualifying event. If a proceeding in bankruptcy is filed with respect to the employer, and that bankruptcy results in the loss of coverage for any retired employee covered under the plan, the covered retiree will become a qualified beneficiary with respect to the bankruptcy. The covered retiree's covered Spouse or surviving Spouse, and Dependent children will also become qualified beneficiaries if bankruptcy results in the loss of their coverage under the plan.

4. Period of Coverage

a. A qualified beneficiary may continue coverage for up to 18 months when the employee loses coverage under the plan due to one of the following qualifying events:

1. A reduction in work hours; or
2. Voluntary or involuntary termination of employment for reasons other than gross misconduct.

b. A qualified beneficiary may continue coverage for up to 36 months when the qualified beneficiary loses coverage under the plan due to one of the following qualifying events:

1. The employee's death;
2. Divorce or legal separation from the employee;
3. The covered employee becoming entitled to Medicare benefits under Title XVIII of the Social Security Act; or
4. A covered Dependent child ceases to be a Dependent child of the covered employee under the terms of the group health plan.

c. Bankruptcy

If the employer files Chapter 11 bankruptcy which results in loss of coverage (or substantial elimination of coverage within one year before or after bankruptcy is filed), a qualified beneficiary may continue coverage up to the following applicable periods:

1. Covered retiree: The maximum duration of the COBRA coverage is the lifetime of the retired covered employee.
2. Covered Spouse, surviving Spouse, or Dependent child of covered retiree: The maximum duration of the COBRA coverage ends the earlier of:

a. the date of death (of the Spouse, surviving Spouse or Dependent child); or
b. 36 months after the death of the covered retiree.

5. Providing Notice of Qualifying Events

a. Responsibilities of Qualified Beneficiaries

1. General Notice Requirements

The qualified beneficiary or a representative of the qualified beneficiary must notify the administrator of the qualifying events listed below within 60 days after the latest of (1) the qualifying event; (2) the loss of coverage, or (3) the date that the qualified beneficiary receives information concerning COBRA coverage in a General Notice.

a. Divorce or legal separation;
b. Covered Dependent child ceases to be a Dependent child of a covered employee under terms of the plan; or
c. A second qualifying event. (See 5(a)(2)).

Notification of a qualifying event must be timely mailed to the plan administrator (generally your employer), or to the entity identified as the COBRA Administrator in the General COBRA Notice provided to you upon enrollment or when your coverage is terminated. **Important Information: If notices are not received within the timeframes specified below, the qualified beneficiary will not be provided COBRA coverage.**

A single notice sent by or on behalf of the covered employee or any one of the qualified beneficiaries affected by the qualifying event satisfies the notice requirement for all qualified beneficiaries.

The following information should be included:

a. Name of covered employee;
b. Subscriber identification number;
c. Employee and qualified beneficiary names, address and telephone number (also note any different addresses for other qualified beneficiaries);
d. Employer/former employer;
e. Whether the event is a qualifying event; disability, or second qualifying event; and
f. Date of qualifying event.

Certain COBRA qualifying events have additional notice requirements which are explained in more detail below.

2. Second Qualifying Event

The qualified beneficiary or a representative of the qualified beneficiary must notify the administrator within 60 days of a second qualifying event. **Important Information: If notice is not received within the timeframes specified below, an extension of COBRA coverage will not be provided to the qualified beneficiary.**

The initial 18-month COBRA coverage period may be extended for an additional 18 months (for a total of 36 months) for Spouses and Dependents who initially elected COBRA coverage if:

a. The first qualifying event is the employee's termination of employment or reduction in hours;
b. The second qualifying event occurs during the initial 18-month COBRA coverage period;
c. The second qualifying event has a 36-month maximum coverage period (see Period of Coverage (4)(b)); and
d. The second qualifying event is one that would have caused loss of coverage in the absence of the first qualifying event.

If COBRA coverage was previously extended from 18 months to 29 months due to a Medicare disability determination, the maximum COBRA coverage period under a second qualifying event will be 36 months.

If a qualifying event that is a termination of employment or reduction of hours occurs within 18 months after the covered employee becomes entitled to Medicare, then the maximum coverage period for the Spouse and Dependent children will end 36 months from the date the employee became entitled to Medicare as a result of turning 65 (but the covered employee's maximum coverage period will be 18 months).

3. Disability Extension

A qualified beneficiary may be entitled to a disability extension of up to 11 additional months. If a qualified beneficiary is entitled to the extension, which shall not extend the total period of continuation coverage beyond 29 months, the extension applies to each qualified beneficiary who is not disabled, as well as to the disabled beneficiary, and it applies independently with respect to each of the qualified beneficiaries.

To qualify for a disability extension, the following requirements must be met:

a. The qualifying event must be a termination or reduction of hours of a covered employee's employment; and
b. The qualified beneficiary must have been determined under Title II or XVI of the Social Security Act (SSA) to be disabled at any time during the first 60 days of the COBRA continuation coverage.

Individuals who have been determined by SSA to be disabled prior to the occurrence of a qualifying event and the disability continues to exist at the time of the qualifying event, qualified beneficiaries are considered to meet the statutory requirements of being disabled within the first 60 days of COBRA coverage.

In the case of a qualified beneficiary who is a child born to or placed for adoption with a covered employee during a period of COBRA continuation coverage, the period of the first 60 days of COBRA continuation coverage is measured from the date of birth or placement for adoption.

The qualified beneficiary must provide a disability notice before the end of the first 18 months of coverage.

The qualified beneficiary or a representative of the qualified beneficiary must also provide notice to the administrator within 30 days after the date of any final determination under the SSA that the qualified beneficiary is no longer disabled. Coverage will be terminated the later of (1) the first day of the month that is more than 30 days after a final determination by SSA that the individual is no longer disabled; or (2) the end of the COBRA period that applies without regard to the disability extension.

b. Responsibilities of Plan Administrator

The plan administrator must notify the party responsible for administering COBRA within 30 days of the following events.

1. The employee's death;
2. The employee's termination (other than for gross misconduct);
3. Reduction in work hours of employment;
4. A proceeding in bankruptcy with respect to an employer from whose employment a covered employee retires; and
5. The covered employee becomes entitled to Medicare.

c. Responsibilities of the COBRA Administrator

The COBRA administrator must notify qualified beneficiaries of their right to COBRA coverage within 14 days after receiving notice of a qualifying event by providing qualified beneficiaries with a COBRA Election form.

If the plan administrator is the COBRA administrator, the plan administrator must notify qualified beneficiaries of their right to COBRA coverage within 44 days after receiving notice of a qualifying event.

6. Election of COBRA Coverage - Notice Requirements

After a qualified beneficiary or COBRA administrator has provided notice of a qualifying event, the qualified beneficiary will receive a COBRA Election form.

Each qualified beneficiary has an independent right to elect COBRA coverage. The qualified beneficiary or a representative of the qualified beneficiary must return the COBRA Election form to the administrator within 60 days from the date on the COBRA Election form. **Important Information: If the COBRA Election form is not returned within the 60-day timeframe, COBRA coverage will not be provided to any qualified beneficiaries.**

7. Trade Adjustment Assistance Eligible Employees

Employees who lost coverage as the result of a termination or a reduction of hours and who qualify for "trade adjustment assistance" ("TAA") under the Trade Act of 1974, as amended, are entitled to a second opportunity to elect COBRA coverage, if such coverage was not elected within the first 60 days after coverage is lost.

The second COBRA election period provisions are effective for individuals with respect to whom petitions for certification for trade adjustment assistance are filed on or after November 4, 2002. The second election period begins on the first day the employee began receiving TAA (or would have become eligible to begin receiving TAA but for exhaustion of unemployment compensation), but only if made within six months after group health coverage is lost. Notice must be provided in accordance with "Responsibility of Qualified Beneficiary" above.

This coverage may continue for 18 months from the date COBRA coverage begins. When the employee elects coverage, the election can include coverage for previously covered Dependents. Dependents are not qualified beneficiaries in their own right under this provision and therefore do not have an independent election.

8. Payment of Premium

The first premium payment must be made within 45 days of the date of the election of COBRA continuation coverage and must include payments retroactive to the date coverage would normally have terminated under this plan.

Subsequent payments must be made within 30 days after the first day of each coverage period. Payment is considered to be made on the date payment is sent to the employer or COBRA administrator. If the premium is not paid by the first day of the coverage period, a grace period of 30 days will be allowed for payment. The Member may instead request to be billed for continuation coverage for the following coverage periods: quarterly, semi-annually or annually.

9. Termination of Continued Coverage

a. Coverage terminates the last day of the maximum required period under COBRA;

b. Any of the following events will result in termination of coverage prior to expiration of the 18-Month, 29-Month, or 36-Month period:

1. The first day on which timely payment is not made with respect to the qualified beneficiary;
2. The date upon which the employer or employee organization ceases to provide any group health plan (including successor plans) to any employee;
3. The date, after the date of the COBRA election, upon which the qualified beneficiary first becomes covered under any other group health plan; or
4. The date, after the date of the COBRA election, upon which the qualified beneficiary first becomes entitled to Medicare benefits.

10. Conversion Notice

During the 180 days preceding expiration of COBRA coverage, the qualified beneficiary will be notified of the options to enroll under a conversion health plan, if such an option exists.

11. Questions Concerning COBRA Coverage

For any questions concerning COBRA coverage, contact Blue Cross and Blue Shield of Montana (BCBSMT) at 1-800-447-7828.

12. Provide Notice of Address Changes

In order to protect all COBRA rights, Members must notify the administrator and Blue Cross and Blue Shield of Montana of any changes to the Member's or Family Member's addresses. A Member should also keep a copy of any notices for personal records.

Conversion Coverage

Montana law entitles certain persons to conversion coverage without evidence of insurability upon termination of their eligibility for group coverage or COBRA coverage. This coverage is at the option of the insured on any of the forms then customarily issued by Blue Cross and Blue Shield of Montana to individual policy holders, with the exception of those whose eligibility is determined by their affiliation other than by employment with a common entity.

1. Transfer upon change in employment status

Conversion coverage is available if the Member has been covered under this Group Plan for at least three months and is:

- **a.** A Beneficiary Member or Family Member whose coverage ceased because of termination of membership in a group eligible for coverage under the Group Plan;
- **b.** A Beneficiary Member or Family Member whose coverage ceased because of termination of employment of the Beneficiary Member;
- **c.** A Beneficiary Member or Family Member whose coverage ceased because of discontinuance of the Beneficiary Member's employer's business; or
- **d.** A Beneficiary Member or Family Member whose coverage terminated because of discontinuance of the coverage by the Beneficiary Member's employer where the employer does not provide for any other group disability insurance or plan.

2. Transfer upon change in Family Member status

Conversion coverage is available following the termination of any continuation of coverage provisions of this Member Guide, for the following persons:

- **a.** A Family Member of a Beneficiary Member who has died.
- **b.** The Beneficiary Member's Spouse who enrolled as a Family Member and whose marriage ended because of divorce, annulment, or legal separation and the Beneficiary Member is still covered under the Group policy.
- **c.** The Beneficiary Member's child who has been enrolled as a Family Member and coverage is terminated because the child reaches the age of 26 years.

3. Enrollment in conversion coverage

The Member will be enrolled under the Blue Cross and Blue Shield of Montana conversion coverage program if the Member:

a. Meets the qualifications outlined in the conversion provision.

b. Applies to Blue Cross and Blue Shield of Montana and pay dues within 31 days after termination of group coverage.

c. Is not covered under another major medical disability policy or plan.

4. Benefits to Members Hospitalized on Date of Transfer to Conversion Coverage

If the Member is in the Hospital on the date of transfer of membership to a Blue Cross and Blue Shield of Montana conversion coverage plan, the Member will continue to receive the Benefits payable under this Member Guide for 30 days from the date of transfer or until the Member is discharged from the Hospital, whichever occurs first.

If the Member is in the Hospital on the date of transfer of membership from conversion coverage to another group health plan, Benefits will be subject to the limitations of the new health plan.

BENEFITS

The Plan will pay for the following Benefits provided by a Covered Provider based on the Allowable Fee and subject to any Deductible, Copayment, Coinsurance and other provisions, as applicable.

Benefits outlined in this section are subject to the Plan's Medical Policy, any specific exclusions identified for that specific Benefit and to the exclusions and limitations outlined in the Exclusions and Limitations section.

Accident

Services which are provided for bodily injuries resulting from an Accident.

Acupuncture

Services provided by a licensed acupuncturist to treat Illness or Injury.

The Schedule of Benefits describes payment limitations for these services.

Advanced Practice Registered Nurses and Physician Assistants - Certified

Services provided by an Advanced Practice Registered Nurse or a physician assistant-certified who is licensed to practice medicine in the state where the services are provided and when payment would otherwise be made if the same services were provided by a Physician.

Ambulance

Licensed ground and air ambulance transport required for a Medically Necessary condition to the nearest appropriate site.

Anesthesia Services

Anesthesia services provided by a Physician (other than the attending Physician) or nurse anesthetist including the administration of spinal anesthesia and the injection or inhalation of a drug or other anesthetic agent. The Plan will not pay for.

1. Hypnosis;

2. Local anesthesia or intravenous (IV) sedation that is considered to be an Inclusive Service/Procedure;

3. Anesthesia consultations before surgery that are considered to be Inclusive Services/Procedures because the Allowable Fee for the anesthesia performed during the surgery includes this anesthesia consultation; or

4. Anesthesia for dental services or extraction of teeth, except anesthesia provided at a Hospital in conjunction with dental treatment will be covered only when a nondental physical Illness or Injury exists which makes Hospital care Medically Necessary to safeguard the Member's health. Dental services and treatment are not a Benefit of this Member Guide, except as specifically included in the Dental Accident and Pediatric Dental Benefit.

Approved Clinical Trials

Routine Patient Costs provided in connection with an Approved Clinical Trial.

Autism Spectrum Disorders

Diagnosis and treatment of autistic disorder, Asperger's Disorder or Pervasive Developmental Disorder.

Covered services include:

1. Habilitative Care or Rehabilitative Care, including, but not limited to, professional, counseling and guidance services and treatment programs; Applied Behavior Analysis (ABA), also known as Lovaas Therapy; discrete trial training, pivotal response training, intensive intervention programs, and early intensive behavioral intervention;
2. Medications;
3. Psychiatric or psychological care; and
4. Therapeutic care provided by a speech-language pathologist, audiologist, occupational therapist or physical therapist.

Note: Applied Behavior Analysis (ABA), also known as Lovaas Therapy, is only available for Members under age 19.

Birthing Centers

Services for the delivery of a newborn provided at a birthing center.

Blood Transfusions

Blood transfusions, including the cost of blood, blood plasma, blood plasma expanders and packed cells. Storage charges for blood are paid when a Member has blood drawn and stored for the Member's own use for a planned surgery.

Chemical Dependency

Benefits for Chemical Dependency will be paid as any other Illness.

Outpatient Services

Care and treatment for Chemical Dependency when the Member is not an Inpatient Member and provided by:

1. a Hospital;
2. a Mental Health Treatment Center;
3. a Chemical Dependency Treatment Center;
4. a Physician or prescribed by a Physician;
5. a psychologist;
6. a licensed social worker;
7. a licensed professional counselor;
8. an addiction counselor licensed by the state; or
9. a licensed psychiatrist.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Chemical Dependency; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by the Chemical Dependency.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Care Services

Care and treatment of Chemical Dependency, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;

2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity services provided at a Residential Treatment Center are Benefits of this Group Plan.

Preauthorization is required for Inpatient Care services and Residential Treatment Center services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Chemical Dependency, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization services. Please refer to the section entitled Preauthorization.

Chemotherapy

The use of drugs approved for use in humans by the U.S. Food and Drug Administration and ordered by the physician for the treatment of disease.

Chiropractic Services

Services of a licensed chiropractor.

The Schedule of Benefits describes payment limitations for these services.

Contraceptives

Services and supplies related to contraception, including but not limited to, oral contraceptives, contraceptive devices and injections, subject to the terms and limitations of the Member Guide. Oral contraceptives are paid as described in the Preventive Health Care section or under the Prescription Drugs section.

Deductible and Coinsurance do not apply to contraceptives covered under the Preventive Health Care Benefit, whether provided during an office visit or through the Prescription Drugs Benefit. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy.

Convalescent Home Services

Services of a Convalescent Home as an alternative to Hospital Inpatient Care. The Plan will not pay for custodial care.

NOTE: The Plan will not pay for the services of a Convalescent Home if the Member remains inpatient at the Convalescent Home when a skilled level of care is not Medically Necessary.

Preauthorization is required for Convalescent Home services. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Dental Accident Services

Dental services provided by physicians, dentists, oral surgeons and/or any other provider are not covered under this Member Guide except that, Medically Necessary services for the initial repair or replacement of sound natural teeth which are damaged as a result of an Accident, are covered, except that orthodontics, dentofacial orthopedics, or related appliances are not covered, even if related to the Accident.

The Plan will not pay for services for the repair of teeth which are damaged as the result of biting and chewing.

Diabetic Education

Outpatient self-management training and education services for the treatment of diabetes provided by a Covered Provider with expertise in diabetes.

The Schedule of Benefits describes payment limitations for these services.

Diabetes Treatment (Office Visit)

Services and supplies for the treatment of diabetes provided during an office visit. For additional Benefits related to the treatment of diabetes, e.g., surgical services and medical supplies, refer to that specific Benefit.

Diagnostic Services

1. Diagnostic Imaging Procedures

Diagnostic Imaging which includes Computerized Tomography Scan (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan).

2. All Other Covered Diagnostic Services

a. X-rays and Other Radiology. Some examples of other radiology include:

- Nuclear medicine
- Ultrasound

b. Laboratory Tests. Some examples of laboratory tests include:

- Urinalysis
- Blood tests
- Throat cultures

c. Diagnostic Testing. Tests to diagnose an Illness or Injury. Some examples of diagnostic testing include:

- Electroencephalograms (EEG)
- Electrocardiograms (EKG or ECG)

This Benefit does not include diagnostic services such as biopsies which are covered under the surgery Benefit.

Durable Medical Equipment

The appropriate type of equipment used for therapeutic purposes **where the Member resides**. Durable medical equipment, which requires a written prescription, must also be:

1. able to withstand repeated use (consumables are not covered);
2. primarily used to serve a medical purpose rather than for comfort or convenience; and
3. generally not useful to a person who is not ill or injured.

The Plan will not pay for the following items:

1. exercise equipment;
2. car lifts or stair lifts;
3. biofeedback equipment;
4. self-help devices which are not medical in nature, regardless of the relief they may provide for a medical condition;
5. air conditioners and air purifiers;
6. whirlpool baths, hot tubs, or saunas;
7. waterbeds;
8. other equipment which is not always used for healing or curing;
9. Deluxe equipment. The Plan has the right to decide when deluxe equipment is required. However, upon such decision, payment for deluxe equipment will be based on the Allowable Fee for standard equipment.
10. computer-assisted communication devices;

11. durable medical equipment required primarily for use in athletic activities;
12. replacement of lost or stolen durable medical equipment;
13. repair to rental equipment; and
14. duplicate equipment purchased primarily for Member convenience when the need for duplicate equipment is not medical in nature.

Education Services

Education services, other than diabetic education, that are related to a medical condition.

Emergency Room Care

1. Emergency room care for an accidental Injury.
2. Emergency room care for Emergency Services.

Home Health Care

The following services, when prescribed and supervised by the Member's attending Physician provided in the Member's home by a licensed Home Health Agency and which are part of the Member's treatment plan:

1. Nursing services.
2. Home Health Aide services.
3. Hospice services.
4. Physical Therapy.
5. Occupational Therapy.
6. Speech Therapy.
7. Medical social worker.
8. Medical supplies and equipment suitable for use in the home.
9. Medically Necessary personal hygiene, grooming and dietary assistance.

The Plan will not pay for:

1. Maintenance or custodial care visits.
2. Domestic or housekeeping services.
3. "Meals-on-Wheels" or similar food arrangements.
4. Visits, services, medical equipment, or supplies not approved or included as part of the Member's treatment plan.
5. Services for the treatment of Mental Illness.
6. Services provided in a nursing home or skilled nursing facility.

Preauthorization is required for home health care. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Home Infusion Therapy Services

The preparation, administration, or furnishing of parenteral medications, or parenteral or enteral nutritional services to a Member by a Home Infusion Therapy Agency, including:

1. Education for the Member, the Member's caregiver, or a Family Member.
2. Pharmacy.
3. Supplies.
4. Equipment.
5. Skilled nursing services when billed by a Home Infusion Therapy Agency.

NOTE: Skilled nursing services billed by a Licensed Home Health Agency will be covered under the home health care Benefit.

Home infusion therapy services must be ordered by a Physician and provided by a licensed Home Infusion Therapy Agency. A licensed Hospital, which provides home infusion therapy services, must have a Home Infusion Therapy Agency license or an endorsement to its Hospital facility license for home infusion therapy services.

Preauthorization is required for home infusion therapy services. Please refer to the section entitled Preauthorization.

Hospice Care

A coordinated program of home care and Inpatient Care that provides or coordinates palliative and supportive care to meet the needs of a terminally ill Member and the Member's Immediate Family. Benefits include:

1. Inpatient and Outpatient care;
2. Home care;
3. Nursing services - skilled and non-skilled;
4. Counseling and other support services provided to meet the physical, psychological, spiritual and social needs of the terminally ill Member; and
5. Instructions for care of the Member, counseling and other support services for the Member's Immediate Family.

Preauthorization is required for hospice care. Please refer to the section entitled Preauthorization.

Hospital Services - Facility and Professional

Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations
    a. Room and board, which includes special diets and nursing services.
    b. Intensive care and cardiac care units which include special equipment and concentrated nursing services provided by nurses who are Hospital employees.
2. Miscellaneous Hospital Services
    a. Laboratory procedures.
    b. Operating room, delivery room, recovery room.
    c. Anesthetic supplies.
    d. Surgical supplies.
    e. Oxygen and use of equipment for its administration.
    f. X-ray.
    g. Intravenous injections and setups for intravenous solutions.
    h. Special diets when Medically Necessary.
    i. Respiratory therapy, chemotherapy, radiation therapy, dialysis therapy.
    j. Physical Therapy, Speech Therapy and Occupational Therapy.
    k. Drugs and medicines which:
        1. Are approved for use in humans by the U.S. Food and Drug Administration; and
        2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
        3. Require a Physician's written prescription.

        Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.

Preauthorization is required for Inpatient Care. Please refer to the section entitled Preauthorization.

Inpatient Care services are subject to the following conditions:

1. Days of care
    a. The number of days of Inpatient Care provided is 365 days.
    b. In computing the number of Inpatient Care days available, days will be counted according to the standard midnight census procedure used in most Hospitals. The day a Member is admitted to a Hospital is counted,

but the day a Member is discharged is not. If a Member is discharged on the day of admission, one day is counted.

c. The day a Member enters a Hospital is the day of admission. The day a Member leaves a Hospital is the day of discharge.

2. The Member will be responsible to the Hospital for payment of its charges if the Member remains as an Inpatient Member when Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member. No Benefits will be paid for Inpatient Care provided primarily for diagnostic or therapy services.

3. Preauthorization is required for Inpatient Care. Please refer to the section entitled Preauthorization.

Inpatient Care Medical Services Billed by a Professional Provider

Nonsurgical services by a Covered Provider, Concurrent Care and Consultation Services.

Medical services do not include surgical or maternity services. Inpatient Care medical services are covered only if the Member is eligible for Benefits under the Hospital Services, Inpatient Care Services section for the admission.

Medical care visits are limited to one visit per day per Covered Provider unless a Member's condition requires a Physician's constant attendance and treatment for a prolonged period of time.

Observation Beds/Rooms

Payment will be made for observation beds when Medically Necessary.

Outpatient Hospital Services

Use of the Hospital's facilities and equipment for surgery, respiratory therapy, chemotherapy, radiation therapy and dialysis therapy.

Inborn Errors of Metabolism

Treatment under the supervision of a Physician of inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism and for which medically standard methods of diagnosis, treatment and monitoring exist. Benefits include expenses of diagnosing, monitoring, and controlling the disorders by nutritional and medical assessment, including but not limited to clinical services, biochemical analysis, medical supplies, prescription drugs, corrective lenses for conditions related to the inborn error of metabolism, nutritional management, and Medical Foods used in treatment to compensate for the metabolic abnormality and to maintain adequate nutritional status.

Infertility - Diagnosis and Treatment

The Plan will pay for:

The diagnosis and treatment of infertility, including:

- Medically Necessary evaluation to determine cause of infertility
- Artificial insemination (AI) or intrauterine insemination (IUI)
- Medically Necessary Reproductive procedures not related to in vitro fertilization.

The Plan will not pay for:

1. Prescription drugs used to treat infertility.
2. Services, supplies, drugs and devices related to in vitro fertilization.

Mammograms (Routine and Medical)

Mammography examinations.

The minimum mammography examination recommendations are:

1. One baseline mammogram for women ages 35 through 39.
2. One mammogram every two years for women ages 40 through 49, or more frequently as recommended by a Physician.
3. One mammogram every year for women age 50 or older.

Maternity Services - Professional and Facility Covered Providers

1. Prenatal and postpartum care.
2. Delivery of one or more newborns.
3. Hospital Inpatient Care for conditions related directly to pregnancy. Inpatient Care following delivery will be covered for whatever length of time is necessary and will be at least 48 hours following a vaginal delivery and at least 96 hours following a delivery by cesarean section. The decision to shorten the length of stay of Inpatient Care to less than that stated in the preceding sentence must be made by the attending health care provider and the mother.

   Under Federal law, Benefits may not be restricted for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, under Federal law, Covered Providers may not be required to obtain Preauthorization from The Plan for prescribing a length of stay not in excess of 48 hours (or 96 hours).

4. Payment for any maternity services by the professional provider is limited to the Allowable Fee for total maternity care, which includes delivery, prenatal and postpartum care.

Please refer also to the Newborn Initial Care section.

Medical Supplies

The following supplies for use outside of a Hospital:

1. Supplies for insulin pumps, syringes and related supplies for conditions such as diabetes.
2. Injection aids, visual reading and urine test strips, glucagon emergency kits for treatment of diabetes. One insulin pump for each warranty period is covered under the Durable Medical Equipment Benefit.
3. Sterile dressings for conditions such as cancer or burns.
4. Catheters.
5. Splints.
6. Colostomy bags and related supplies.
7. Supplies for renal dialysis equipment or machines.

Medical supplies are covered only when:

1. Medically Necessary to treat a condition for which Benefits are payable.
2. Prescribed by a Covered Provider.

Mental Health

Benefits provided for mental health are for the treatment of Mental Illness and Severe Mental Illness as defined in the section entitled "Definitions."

Benefits include but are not limited to, Inpatient Care services, Outpatient services, rehabilitation services and medication for the treatment of Mental Illness or Severe Mental Illness.

Payment for mental health Benefits will be made as for any other illness.

Outpatient Services

Care and treatment of Mental Illness or Severe Mental Illness if the Member is not an Inpatient Member and is provided by:

1. a Hospital;
2. a Physician or prescribed by a Physician;
3. a Mental Health Treatment Center;
4. a Chemical Dependency Treatment Center;
5. a psychologist;

6. a licensed social worker;
7. a licensed professional counselor;
8. a licensed addiction counselor; or
9. a licensed psychiatrist.
10. a licensed Advanced Practice Registered Nurse with a specialty in mental health.
11. a licensed Advanced Practice Registered Nurse with prescriptive authority and specializing in mental health.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Mental Illness or Severe Mental Illness; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by Mental Illness or Severe Mental Illness.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Services

Care and treatment of Mental Illness or Severe Mental Illness, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity residential services provided at a Residential Treatment Center are Benefits of this Member Guide.

Preauthorization is required for Inpatient Care services and Residential Treatment Center services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Mental Illness or Severe Mental Illness, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization. Please refer to the section entitled Preauthorization.

Naturopathy

Services provided by a licensed naturopathic provider are covered if such services are a Benefit of this Group Plan.

Newborn Initial Care

1. The initial care of a newborn at birth provided by a Physician.
2. Nursery Care - Hospital nursery care of newborn infants.

Office Visits

Covered services provided in a Covered Provider's office during a Professional Call and covered services provided in the home by a Covered Provider. Visits are limited to one visit per day per provider.

Oral Surgery

Benefits will be provided for the following:

- Excision or biopsy of tumors or cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth
- Excision of exostoses of the jaws and hard palate (provided that this procedure is not done in preparation for dentures or other prostheses)

- Treatment of fractures of facial bone
- External incision and drainage of cellulitis (not including treatment of dental abscesses)
- Incision of accessory sinuses, salivary glands or ducts
- Surgical removal of complete bony impacted teeth
- Reduction of dislocation of, or excision of, the temporomandibular joints.

Orthopedic Devices/Orthotic Devices

A supportive device for the body or a part of the body, head, neck or extremities, including but not limited to, leg, back, arm and neck braces. In addition, when Medically Necessary, Benefits will be provided for adjustments, repairs or replacement of the device because of a change in the Member's physical condition.

The Plan will not pay for foot orthotics defined as any in-shoe device designed to support the structural components of the foot during weight-bearing activities

Pediatric Dental Care

Dental Benefits include coverage for the following Dental Services as long as these services are rendered by a Dentist or a Physician. When the term "Dentist" is used in this Member Guide, it will mean Dentist or Physician.

Diagnostic Evaluations

Diagnostic evaluations aid the Dentist in determining the nature or cause of a dental disease and include:

D0120 Periodic oral evaluation - Limited to 1 every 6 months
D0140 Limited oral evaluation - problem focused
D0150 Comprehensive oral evaluation - Limited to 1 every 6 months
D0160 Detailed and extensive oral evaluation - problem focused, by report
D0180 Comprehensive periodontal evaluation
D9310 Consultation (diagnostic service provided by dentist or physician other than practitioner providing treatment)

Benefits will not be provided for tests and oral pathology procedures, or for re-evaluations.

Preventive Services

Preventive services are performed to prevent dental disease. Dental Services include:

D1120 Prophylaxis - Child - Limited to 1 every 6 months
D1206 Topical fluoride varnish - Less than age 19 - 2 in 12 months
D1208 Topical application of fluoride (excluding prophylaxis) - Less than age 19 - 2 in 12 months

Diagnostic Radiographs

Diagnostic radiographs are x-rays taken to diagnose a dental disease, including their interpretations, and include:

D0210 Intraoral - complete series (including bitewings) 1 every 60 (sixty) months
D0220 Intraoral - periapical first film
D0230 Intraoral - periapical - each additional film
D0240 Intraoral - occlusal film
D0270 Bitewing - single film Adult - 1 set every calendar year / Children - 1 set every 6 months
D0272 Bitewings - two films - Adult - 1 set every calendar year / Children - 1 set every 6 months
D0274 Bitewings - four films Adult - 1 set every calendar year / Children - 1 set every 6 months
D0277 Vertical bitewings - 7 to 8 films - Adult - 1 set every calendar year / Children - 1 set every 6 months
D0330 Panoramic film - 1 film every 60 (sixty) months
D0340 Cephalometric x-ray
D0350 Oral / Facial Photographic Images
D0391 Interpretation of Diagnostic Image

Benefits will not be provided for any radiographs taken in conjunction with Temporomandibular Joint (TMJ) Dysfunction.

Miscellaneous Preventive Services

Miscellaneous preventive services are other services performed to prevent dental disease and include:

D1351 Sealant - per tooth - unrestored permanent molars - Less than age 19. 1 sealant per tooth every 36 months
D1352 Preventative resin restorations in a moderate to high caries risk patient - permanent tooth - 1 sealant per tooth every 36 months.
D1510 Space maintainer - fixed - unilateral - Limited to children under age 19
D1515 Space maintainer - fixed - bilateral - Limited to children under age 19
D1520 Space maintainer - removable - unilateral - Limited to children under age 19
D1525 Space maintainer - removable - bilateral - Limited to children under age 19
D1550 Re-cementation of space maintainer - Limited to children under age 19

Benefits are not available for nutritional, tobacco and oral hygiene counseling.

Basic Restorative Services

Basic restorative services are restorations necessary to repair basic dental decay, including tooth preparation, all adhesives, bases, liners and polishing. Dental Services include:

D2140 Amalgam - one surface, primary or permanent
D2150 Amalgam - two surfaces, primary or permanent
D2160 Amalgam - three surfaces, primary or permanent
D2161 Amalgam - four or more surfaces, primary or permanent
D2330 Resin-based composite - one surface, anterior
D2331 Resin-based composite - two surfaces, anterior
D2332 Resin-based composite - three surfaces, anterior
D2335 Resin-based composite - four or more surfaces or involving incisal angle (anterior)

Benefits will not be provided for restorations placed within 12 months of the initial placement by the same Dentist.

Non-Surgical Extractions

Non-surgical extractions are non-surgical removal of tooth and tooth structures and include:

D7140 Extraction, erupted tooth or exposed root (elevation and/or forceps removal)

Non-Surgical Periodontal Services

Non-surgical periodontal service is the non-surgical treatment of a dental disease in the supporting and surrounding tissues of the teeth (gums) and includes:

D4341 Periodontal scaling and root planning-four or more teeth per quadrant - Limited to 1 every 24 months
D4342 Periodontal scaling and root planning-one to three teeth, per quadrant - Limited to 1 every 24 months
D4355 Full mouth debridement to enable comprehensive evaluation and diagnosis - Limited to 1 per lifetime
D4910 Periodontal maintenance - 4 in 12 months combined with adult prophylaxis after the completion of active periodontal therapy
D7921 Collect - Apply Autologous Product - Limited to 1 in 36 months

Benefits will not be provided for chemical treatments, localized delivery of chemotherapeutic agents without history of active periodontal therapy, or when performed on the same date (or in close proximity) as active periodontal therapy.

Adjunctive Services

Adjunctive general services include:

D9110 Palliative treatment of dental pain - minor procedure
D9220 Deep sedation/general anesthesia - first 30 minutes
D9221 Deep sedation/general anesthesia - each additional 15 minutes
D9241 Intravenous conscious sedation/analgesia - first 30 minutes
D9242 Intravenous conscious sedation/analgesia - each additional 15 minutes
D9610 Therapeutic drug injection, by report

Benefits will not be provided for local anesthesia, nitrous oxide analgesia, therapeutic parenteral drugs, or other drugs or medicaments and/or their application.

Endodontic Services

Endodontics is the treatment of dental disease of the tooth pulp and includes:

D3220 Therapeutic pulpotomy (excluding final restoration) - If a root canal is within 45 days of the pulpotomy, the pulpotomy is not a covered service since it is considered a part of the root canal procedure and benefits are not payable separately.
D3222 Partial pulpotomy for apexogenesis - permanent tooth with incomplete root development If a root canal is within 45 days of the pulpotomy, the pulpotomy is not a covered service since it is considered a part of the root canal procedure and benefits are not payable separately.
D3230 Pulpal therapy (resorbable filling) - anterior, primary tooth (excluding final restoration) - Limited to primary incisor teeth for members up to age 6 and for primary molars and cuspids up to age 11 and is limited to once per tooth per lifetime.
D3240 Pulpal therapy (resorbable filling) - posterior, primary tooth excluding final restoration). Incomplete endodontic treatment when you discontinue treatment. - Limited to primary incisor teeth for members up to age 6 and for primary molars and cuspids up to age 11 and is limited to once per tooth per lifetime.
D3310 Anterior root canal (excluding final restoration)
D3320 Bicuspid root canal (excluding final restoration)
D3330 Molar root canal (excluding final restoration)
D3346 Retreatment of previous root canal therapy-anterior
D3347 Retreatment of previous root canal therapy-bicuspid
D3348 Retreatment of previous root canal therapy-molar
D3351 Apexification/recalcification - initial visit (apical closure/calcific repair of perforations, root resorption, etc.)
D3352 Apexification/recalcification - interim medication replacement (apical closure/calcific repair of perforations, root resorption, etc.)
D3353 Apexification/recalcification - final visit (includes completed root canal therapy, apical closure/calcific repair of perforations, root resorption, etc.)
D3354 Pulpal regeneration (completion of regenerative treatment in an immature permanent tooth with a necrotic pulp) does not include final restoration
D3410 Apicoectomy/periradicular surgery - anterior
D3421 Apicoectomy/periradicular surgery - bicuspid (first root)
D3425 Apicoectomy/periradicular surgery - molar (first root)
D3426 Apicoectomy/periradicular surgery (each additional root)
D3450 Root amputation - per root
D3920 Hemisection (including any root removal) - not including root canal therapy

Pulpal debridement is considered part of endodontic therapy when performed by the same Dental Provider and not associated with a definitive emergency visit.

Benefits will not be provided for the following "Endodontic Services":

- Endodontic retreatments provided within 12 months of the initial endodontic therapy by the same Dentist.
- Pulp vitality tests, endodontic endosseous implants, intentional reimplantations, canal preparation, fitting of preformed dowel and post, or post removal.
- Endodontic therapy if the Member discontinues endodontic treatment.

Oral Surgery Services

Oral surgery means the procedures for surgical extractions and other dental surgery under local anesthetics and includes:

D7210 Surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone and/or section of tooth
D7220 Removal of impacted tooth - soft tissue
D7230 Removal of impacted tooth - partially bony
D7240 Removal of impacted tooth - completely bony
D7241 Removal of impacted tooth - completely bony with unusual surgical complications
D7250 Surgical removal of residual tooth roots (cutting procedure)
D7251 Coronectomy - intentional partial tooth removal
D7270 Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth

D7280 Surgical access of an unerupted tooth
D7310 Alveoloplasty in conjunction with extractions - per quadrant
D7311 Alveoloplasty in conjunction with extractions - one to three teeth or tooth spaces, per quadrant
D7320 Alveoloplasty not in conjunction with extractions - per quadrant
D7321 Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant
D7471 Removal of exostosis
D7510 Incision and drainage of abscess - intraoral soft tissue
D7910 Suture of recent small wounds up to 5 cm
D7953 Bone replacement graft for ridge preservation - per site
D7971 Excision of pericoronal gingiva
D9930 Treatment of complications (post-surgical) unusual circumstances, by report

Benefits will not be provided for the following Oral Surgery procedures:

- Surgical services related to a congenital malformation.
- Prophylactic removal of third molars or impacted teeth (asymptomatic, nonpathological), or for complete bony impactions covered by another benefit plan.
- Excision of tumors or cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth.
- Excision of exostoses of the jaws and hard palate (provided that this procedure is not done in preparation for dentures or other prostheses); treatment of fractures of facial bones; external incision and drainage of cellulitis; incision of accessory sinuses, salivary glands or ducts; reduction of dislocation, or excision of the temporomandibular joints.

Surgical Periodontal Services

Surgical periodontal service is the surgical treatment of a dental disease in the supporting and surrounding tissues of the teeth (gums) and includes:

D4210 Gingivectomy or gingivoplasty - four or more teeth - Limited to 1 every 36 months
D4211 Gingivectomy or gingivoplasty - one to three teeth
D4212 Gingivectomy or gingivoplasty - with restorative procedures, per tooth – Limited to 1 every 36 months
D4240 Gingival flap procedure, four or more teeth - Limited to 1 every 36 months
D4241 Gingival flap procedure, including root planing, one to three contiguous teeth or tooth bounded spaces per quadrant - Limited to 1 every 36 months
D4249 Clinical crown lengthening-hard tissue
D4260 Osseous surgery (including flap entry and closure), four or more contiguous teeth or bounded teeth spaces per quadrant - Limited to 1 every 36 months
D4261 Osseous surgery (including flap entry and closure), one to three contiguous teeth or bounded teeth spaces per quadrant - Limited to 1 every 36 months
D4263 Cone replacement graft - first site in quadrant - Limited to 1 every 36 months
D4270 Pedicle soft tissue graft procedure
D4271 Free soft tissue graft procedure (including donor site surgery)
D4273 Subepithelial connective tissue graft procedures (including donor site surgery)
D4275 Soft tissue allograft - Limited to 1 every 36 months
D4277 Free soft tissue graft 1st tooth
D4278 Free soft tissue graft - additional teeth
D4355 Full mouth debridement to enable comprehensive evaluation and diagnosis - Limited to 1 per lifetime

Benefits will not be provided for guided tissue regeneration, or for biologic materials to aid in tissue regeneration.

Major Restorative Services

Restorative services restore tooth structures lost as a result of dental decay or fracture and include:

D2510 Inlay - metallic - one surface - An alternate benefit will be provided
D2520 Inlay - metallic - two surfaces - An alternate benefit will be provided
D2530 Inlay - metallic - three surfaces - An alternate benefit will be provided
D2542 Onlay - metallic - two surfaces - Limited to 1 per tooth every 60 months
D2543 Onlay - metallic - three surfaces - Limited to 1 per tooth every 60 months
D2544 Onlay - metallic - four or more surfaces - Limited to 1 per tooth every 60 months

D2740 Crown - porcelain/ceramic substrate - Limited to 1 per tooth every 60 months
D2750 Crown - porcelain fused to high noble metal - Limited to 1 per tooth every 60 months
D2751 Crown - porcelain fused to predominately base metal - Limited to 1 per tooth every 60 months
D2752 Crown - porcelain fused to noble metal - Limited to 1 per tooth every 60 months
D2780 Crown - 3/4 cast high noble metal - Limited to 1 per tooth every 60 months
D2781 Crown - 3/4 cast predominately base metal - Limited to 1 per tooth every 60 months
D2783 Crown - 3/4 porcelain/ceramic - Limited to 1 per tooth every 60 months
D2790 Crown - full cast high noble metal - Limited to 1 per tooth every 60 months
D2791 Crown - full cast predominately base metal - Limited to 1 per tooth every 60 months
D2792 Crown - full cast noble metal - Limited to 1 per tooth every 60 months
D2794 Crown - titanium - Limited to 1 per tooth every 60 months
D2940 Protective Restoration
D2981 Inlay Repair
D2982 Onlay Repair
D2983 Veneer Repair
D2990 Resin infiltration/smooth surface - Limited to 1 every 36 months.

Benefits will be provided for the replacement of a lost or defective crown. However, Benefits will not be provided for the restoration of occlusion or incisal edges due to bruxism or harmful habits.

Benefits for major restorations are limited to one per tooth every 60 months whether placement was provided under this Member Guide or under any prior dental coverage, even if the original crown was stainless steel. Crowns placed over implants will be covered.

Prosthodontic Services

Prosthodontics involve procedures necessary for providing artificial replacements for missing natural teeth and includes:

D5110 Complete denture - maxillary - Limited to 1 every 60 months
D5120 Complete denture - mandibular - Limited to 1 every 60 months
D5130 Immediate denture - maxillary - Limited to 1 every 60 months
D5140 Immediate denture - mandibular - Limited to 1 every 60 months
D5211 Maxillary partial denture - resin base (including any conventional clasps, rests and teeth) - Limited to 1 every 60 months
D5212 Mandibular partial denture - resin base (including any conventional clasps, rests and teeth) - Limited to 1 every 60 months
D5213 Maxillary partial denture - cast metal framework with resin denture base (including any conventional clasps, rests and teeth) - Limited to 1 every 60 months
D5214 Mandibular partial denture - cast metal framework with resin denture base (including any conventional clasps, rests and teeth) - Limited to 1 every 60 months
D5281 Removable unilateral partial denture-one piece cast metal (including clasps and teeth) - Limited to 1 every 60 months
D5410 Adjust complete denture - maxillary
D5411 Adjust complete denture - mandibular
D5421 Adjust partial denture - maxillary
D5422 Adjust partial denture - mandibular
D5510 Repair broken complete denture base
D5520 Replace missing or broken teeth - complete denture (each tooth)
D5610 Repair resin denture base
D5620 Repair cast framework
D5630 Repair or replace broken clasp
D5640 Replace broken teeth - per tooth
D5650 Add tooth to existing partial denture
D5660 Add clasp to existing partial denture
D5710 Rebase complete maxillary denture - Limited to 1 in a 36-month period 6 months after the initial installation
D5720 Rebase maxillary partial denture - Limited to 1 in a 36-month period 6 months after the initial installation
D5721 Rebase mandibular partial denture - Limited to 1 in a 36-month period 6 months after the initial installation

D5730 Reline complete maxillary denture - Limited to 1 in a 36-month period 6 months after the initial installation

D5731 Reline complete mandibular denture - Limited to 1 in a 36-month period 6 months after the initial installation

D5740 Reline maxillary partial denture - Limited to 1 in a 36-month period 6 months after the initial installation

D5741 Reline mandibular partial denture - Limited to 1 in a 36-month period 6 months after the initial installation

D5750 Reline complete maxillary denture (laboratory) - Limited to 1 in a 36-month period 6 months after the initial installation

D5751 Reline complete mandibular denture (laboratory) - Limited to 1 in a 36-month period 6 months after the initial installation

D5760 Reline maxillary partial denture (laboratory) - Limited to 1 in a 36-month period 6 months after the initial installation

D5761 Reline mandibular partial denture (laboratory) Rebase/Reline - Limited to 1 in a 36-month period 6 months after the initial installation.

D5850 Tissue conditioning (maxillary)

D5851 Tissue conditioning (mandibular)

Note: An implant is a covered procedure only if determined to be a Dental Necessity. Claim review is conducted by The Plan who reviews the clinical documentation submitted by the treating Dentist. If The Plan determines an arch can be restored with a standard prosthesis or restoration, no Benefits will be allowed for the individual implant or implant procedures. Only the second phase of treatment (the prosthodontic phase-placing of the implant crown, bridge denture or partial denture) may be subject to the alternate Benefit provision of The Plan.

D6010 Endosteal Implant - 1 every 60 months

D6012 Surgical Placement of Interim Implant Body - 1 every 60 months

D6040 Eposteal Implant - 1 every 60 months

D6050 Transosteal Implant, Including Hardware - 1 every 60 months

D6053 Implant supported complete denture

D6054 Implant supported partial denture

D6055 Connecting Bar - implant or abutment supported - 1 every 60 months

D6056 Prefabricated Abutment - 1 every 60 months

D6057 Custom Abutment - 1 every 60 months

D6058 Abutment supported porcelain ceramic crown - 1 every 60 months

D6059 Abutment supported porcelain fused to high noble metal - 1 every 60 months

D6060 Abutment supported porcelain fused to predominately base metal crown - 1 every 60 months

D6061 Abutment supported porcelain fused to noble metal crown - 1 every 60 months

D6062 Abutment supported cast high noble metal crown - 1 every 60 months

D6063 Abutment supported cast predominately base metal crown - 1 every 60 months

D6064 Abutment supported cast noble metal crown - 1 every 60 months

D6065 Implant supported porcelain/ceramic crown - 1 every 60 months

D6066 Implant supported porcelain fused to high metal crown - 1 every 60 months

D6067 Implant supported metal crown - 1 every 60 months

D6068 Abutment supported retainer for porcelain/ceramic fixed partial denture - 1 every 60 months

D6069 Abutment supported retainer for porcelain fused to high noble metal fixed partial denture - 1 every 60 months

D6070 Abutment supported retainer for porcelain fused to predominately base metal fixed partial denture - 1 every 60 months

D6071 Abutment supported retainer for porcelain fused to noble metal fixed partial denture - 1 every 60 months

D6072 Abutment supported retainer for cast high noble metal fixed partial denture 1 every 60 months

D6073 Abutment supported retainer for predominately base metal fixed partial denture - 1 every 60 months

D6074 Abutment supported retainer for cast noble metal fixed partial denture - 1 every 60 months

D6075 Implant supported retainer for ceramic fixed partial denture - 1 every 60 months

D6076 Implant supported retainer for porcelain fused to high noble metal fixed partial denture - 1 every 60 months

D6077 Implant supported retainer for cast metal fixed partial denture - 1 every 60 months

D6078 Implant/abutment supported fixed partial denture for completely edentulous arch - 1 every 60 months

D6079 Implant/abutment supported fixed partial denture for partially edentulous arch - 1 every 60 months

D6080 Implant Maintenance Procedures -1 every 60 months

D6090 Repair Implant Prosthesis - 1 every 60 months

D6091 Replacement of Semi-Precision or Precision Attachment - 1 every 60 months

D6095 Repair Implant Abutment - 1 every 60 months

BENEFIT
D6100 Implant Removal - 1 every 60 months
D6101 Debridement periimplant defect, covered if implants are covered - Limited to 1 every 60 months
D6102 Debridement and osseous periimplant defect, covered if implants are covered - Limited to 1 every 60 months
D6103 Bone graft implant periimplant defect, covered if implants are covered
D6014 Bone graft implant periimplant defect, covered if implants are covered
D6190 Implant Index - 1 every 60 months
D6210 Pontic - cast high noble metal - Limited to 1 every 60 months
D6211 Pontic - cast predominately base metal - Limited to 1 every 60 months
D6212 Pontic - cast noble metal - Limited to 1 every 60 months
D6214 Pontic - titanium - Limited to 1 every 60 months
D6240 Pontic - porcelain fused to high noble metal - Limited to 1 every 60 months
D6241 Pontic - porcelain fused to predominately base metal - Limited to 1 every 60 months
D6242 Pontic - porcelain fused to noble metal - Limited to 1 every 60 months
D6245 Pontic - porcelain/ceramic - Limited to 1 every 60 months
D6519 Inlay/onlay - porcelain/ceramic - Limited to 1 every 60 months
D6520 Inlay - metallic - two surfaces - Limited to 1 every 60 months
D6530 Inlay - metallic - three or more surfaces - Limited to 1 every 60 months
D6543 Onlay - metallic - three surfaces - 1 every 60 months
D6544 Onlay - metallic - four or more surfaces - 1 every 60 months
D6545 Retainer - cast metal for resin bonded fixed prosthesis - 1 every 60 months
D6548 Retainer - porcelain/ceramic for resin bonded fixed prosthesis - 1 every 60 months
D6740 Crown - porcelain/ceramic - 1 every 60 months
D6750 Crown - porcelain fused to high noble metal - 1 every 60 months
D6751 Crown - porcelain fused to predominately base metal - 1 every 60 months
D6752 Crown - porcelain fused to noble metal - 1 every 60 months
D6780 Crown - 3/4 cast high noble metal - 1 every 60 months
D6781 Crown - 3/4 cast predominately base metal - 1 every 60 months
D6782 Crown - 3/4 cast noble metal - 1 every 60 months
D6783 Crown - 3/4 porcelain/ceramic - 1 every 60 months
D6790 Crown - full cast high noble metal - 1 every 60 months
D6791 Crown - full cast predominately base metal - 1 every 60 months
D6792 Crown - full cast noble metal - 1 every 60 months
D6973 Core buildup for retainer, including any pins - 1 every 60 months
D9940 Occlusal guard, by report - 1 in 12 months for patients 13 and older

Prosthetics placed over implants will be covered.

Tissue conditioning is part of a denture or a reline/rebase, when performed on the same day as the delivery.

Benefits will not be provided for the following Prosthodontic Services:

- Treatment to replace teeth which were missing prior to the Effective Date, except those teeth missing due to congenital malformation.
- Splinting of teeth, including double retainers for removable partial dentures and fixed bridgework.

Miscellaneous Restorative and Prosthodontic Services

Other restorative and prosthodontics services include:

D0470 Diagnostic Models
D2910 Re-cement inlay
D2920 Re-cement crown
D2929 Prefabricated porcelain crown - primary - Limited to 1 every 60 months
D2930 Prefabricated stainless steel crown - primary tooth - Under age 15 - Limited to 1 per tooth in 60 months
D2931 Prefabricated stainless steel crown - permanent tooth - Under age 15 - Limited to 1 per tooth in 60 months
D2950 Core buildup, including any pins- Limited to 1 per tooth every 60 months
D2951 Pin retention - per tooth, in addition to restoration
D2954 Prefabricated post and core, in addition to crown- Limited to 1 per tooth every 60 months

D2980 Crown repair, by report
D6930 Recement fixed partial denture
D6980 Fixed partial denture repair, by report

Orthodontic Services

Orthodontic procedures and treatment include examination records, tooth guidance and repositioning (straightening) of the teeth for Members. Coverage for orthodontic services is shown on the Schedule of Benefits. Covered services include:

D8010 Limited orthodontic treatment of the primary dentition
D8020 Limited orthodontic treatment of the transitional dentition
D8030 Limited orthodontic treatment of the adolescent dentition
D8050 Interceptive orthodontic treatment of the primary dentition
D8060 Interceptive orthodontic treatment of the transitional dentition
D8070 Comprehensive orthodontic treatment of the transitional dentition
D8080 Comprehensive orthodontic treatment of the adolescent dentition
D8210 Removable appliance therapy
D8220 Fixed appliance therapy
D8660 Pre-orthodontic treatment visit
D8670 Periodic orthodontic treatment visit (as part of contract)
D8680 Orthodontic retention (removal of appliances, construction and placement of retainer(s)

Note: Benefits for codes D0330, D0340, D0350, and D0470 will be applied to the lifetime orthodontia maximum when performed as part of orthodontia treatment.

Special Provisions Regarding Orthodontic Services:

- Pediatric Orthodontic Services – Coverage is limited to children under age 19 with an orthodontic condition meeting Medical Necessity criteria established by The Plan (e.g., severe, dysfunctional malocclusion.
- Orthodontic services are paid over the Course of Treatment, up to the maximum Benefit Period orthodontic Benefit. Benefits cease when the Member is no longer covered, whether or not the entire Benefit has been paid out.
- Orthodontic treatment is started on the date the bands or appliances are inserted.
- Payment for diagnostic services performed in conjunction with orthodontics is applied to the orthodontic Benefit and subject to the Benefit Period maximum for orthodontic services.
- If orthodontic treatment is terminated for any reason before completion, Benefits will cease on the date of termination.
- If the Member's coverage is terminated prior to the completion of the orthodontic treatment plan, the Member is responsible for the remaining balance of treatment costs.
- Recementation of an orthodontic appliance by the same Provider who placed the appliance and/or who is responsible for the ongoing care of the Member is not covered.
- Benefits are not available for replacement or repair of an orthodontic appliance.
- For services in progress on the Effective Date, Benefits will be reduced based on the benefits paid prior to this coverage beginning.

Important Information About the Member's Dental Benefits

1. Dental Procedures Which Are Not Dentally Necessary

Please note that in order to provide dental care Benefits at a reasonable cost, this Member Guide provides Benefits only for those covered Dental Services and eligible dental treatment that are determined by The Plan to be Dentally Necessary.

No Benefits will be provided for procedures which are not Dentally Necessary. Dentally Necessary generally means that a specific procedure provided to the Member is required for the treatment or management of a dental symptom or condition and that the procedure performed is the most efficient and economical procedure which can safely be provided to the Member, as determined by The Plan.

The fact that a Physician or Dentist may prescribe, order, recommend or approve a procedure does not of itself make such a procedure or supply Dentally Necessary.

2. Care By More Than One Dentist

   If the Member changes Dentists in the middle of a particular Course of Treatment, Benefits will be provided as if the Member had stayed with the same Dentist until treatment was completed. There will be no duplication of Benefits.

3. Non-Compliance with Prescribed Care

   Any additional treatment and resulting liability which is caused by the lack of a Member's cooperation with the Dentist or from non-compliance with prescribed dental care will be the responsibility of the Member.

The Plan will not pay for:

1. Services or supplies not specifically listed as a Dental Service, or when they are related to a non-covered service.
2. Amounts which are in excess of the Allowable Fee, as determined by The Plan.
3. Dental Services for treatment of congenital or developmental malformation, except as included in the pediatric orthodontic Benefit.
4. Services performed for cosmetic purposes, including but not limited to bleaching teeth and grafts to improve aesthetics.
5. Dental Services or appliances for the diagnosis and/or treatment of temporomandibular joint dysfunction and related disorders or to increase vertical dimension.
6. Dental Services which are performed due to an accidental injury. Injury caused by chewing or biting an object or substance placed in the mouth is not considered an accidental injury.
7. Services or supplies that do not meet accepted standards of dental practice.
8. Hospital and ancillary charges.
9. Services or supplies for which "discounts" or waiver of Deductible or Coinsurance amounts are offered.
10. Services or supplies received from someone other than a Dentist or Denturist, except for those services received from a licensed dental hygienist under the supervision and guidance of a Dentist, where applicable.
11. Services or supplies received for behavior management or consultation purposes.
12. Charges for nutritional, tobacco or oral hygiene counseling.
13. Charges for local, state or territorial taxes on Dental Services or procedures.
14. Charges for the administration of infection control procedures as required by local, state or federal mandates.
15. Charges for duplicate, temporary or provisional prosthetic device or other duplicate, temporary or provisional appliances.
16. Orthodontic services, except Pediatric Orthodontic Services are covered when Medically Necessary.
17. Charges for telephone consultations, email or other electronic consultations, missed appointments, completion of a claim form or forwarding requested records or x-rays.
18. Charges for prescription or non-prescription mouthwashes, rinses, topical solutions, preparations or medicament carriers.
19. Charges for personalized complete or partial dentures and overdentures, related services and supplies, or other specialized techniques.
20. Charges for athletic mouth guards, isolation of tooth with rubber dam, metal copings, mobilization of erupted/malpositioned tooth, precision attachments for partials and/or dentures and stress breakers.
21. Charges for a partial or full denture or fixed bridge which includes replacement of a tooth which was missing prior to the Member's Effective Date under this Member Guide; except this exclusion will not apply if such partial or full denture or fixed bridge also includes replacement of a missing tooth which was extracted after the Member's Effective Date.
22. Any services, treatments or supplies included as Dental Services under other hospital, medical and/or surgical coverage.
23. Case presentations or detailed and extensive treatment planning when billed for separately.

Pediatric Vision Care

The following services only may be provided by a licensed ophthalmologist or optometrist operating within the scope of his or her license, or a dispensing optician to Members under 19 years of age:

1. One Routine vision exam per Benefit Period.
2. One pair of glasses (frames and lenses) or two boxes of contacts per Benefit Period.

The Plan will not pay for any vision service, treatment or materials not specifically listed above.

Postmastectomy Care and Reconstructive Breast Surgery

Postmastectomy Care

Inpatient Care for the period of time determined by The Plan in consultation with the Attending Physician, and the Member, to be Medically Necessary following a mastectomy.

Reconstructive Breast Surgery

1. All stages of Reconstructive Breast Surgery after a mastectomy including, but not limited to:
   a. All stages of reconstruction of the breast on which a mastectomy has been performed.
   b. Surgery and reconstruction of the other breast to establish a symmetrical appearance.
   c. Chemotherapy.
   d. Prostheses and physical complications of all stages of a mastectomy and breast reconstruction, including lymphedemas.

   Coverage described in 1(a) through 1(d) will be provided in a manner determined in consultation with the Attending Physician and the patient.
2. Breast prostheses as the result of a mastectomy.

For specific Benefits related to postmastectomy care, refer to that specific Benefit, e.g., surgical services and Hospital services.

Prescription Drugs

Refer to the Prescription Drugs section in the Schedule of Benefits for specific information on the application of any Deductible, Copayment and/or Coinsurance.

The Prescription Drugs Benefit is for Prescription Drug Products which are self-administered. This Benefit does not include medications which are administered by a Covered Provider. If a medication is administered by a Covered Provider, the claim will process under the Member's medical Benefits. **Please refer to the Preauthorization section for complete information about the medications that are subject to the Member's medical Benefits, the process for requesting Preauthorization for medications subject to the Member's medical Benefits, and related information.**

Subject to the terms, conditions, and limitations of this Member Guide, The Plan will pay for Prescription Drug Products, which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Require a Physician's written prescription; and
3. Are dispensed under federal or state law pursuant to a prescription order or refill.

Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.

Drug Lists

Covered drugs are selected by The Plan based upon the recommendations of a committee, which is made up of current and previously practicing physicians and pharmacists from across the country, some of which are employed by or affiliated with Blue Cross and Blue Shield of Montana. The committee considers drugs regulated by the FDA for inclusion on the Drug List. Some of the factors committee members evaluate include each drug's safety, effectiveness, cost, and how it compares with drugs currently on the Drug List. The committee considers drugs that are newly approved by the FDA, as well as those that have been on the market for some time. Entire drug classes are also regularly reviewed. Changes to the Drug List can be made from time to time.

The Plan may offer multiple Drug Lists. By accessing www.bcbsmt.com or www.myprime.com or calling the Customer Service toll-free number on the Member's identification card, the Member or provider can determine the Drug List that applies to the Member's Plan and whether a particular drug is on the Drug List.

The Member, or the Member's prescribing health care provider, can ask for a Drug List exception if the Member's drug is not on the Drug List (also known as a formulary). To request this exception, the Member or the Member's prescriber, can call the number on the back of the Member's ID card to ask for a review. If the Member has a health condition that may jeopardize his/her life, health or keep the Member from regaining function, or the Member's current drug therapy uses a non-covered drug, the Member or the Member's prescriber, may be able to ask for an expedited review process. Blue Cross and Blue Shield of Montana will notify the Member or the Member's prescriber, of the coverage decision within 24 hours after they receive the request for an expedited review. If the coverage request is denied, Blue Cross and Blue Shield of Montana will let the Member and the Member's prescriber, know why it was denied and offer the Member a covered alternative drug (if applicable). If the Member's exception is denied, the Member may appeal the decision according to the appeals process the Member will receive with the denial determination. The Member should call the number on the back of the ID card if the Member has any questions.

Covered Prescription Drug Products

The following Prescription Drugs Products, obtained from a Participating Pharmacy, either retail or mail order, or a retail nonparticipating pharmacy, are covered:

1. Legend drugs - drugs requiring written prescriptions and dispensed by a licensed pharmacist for treatment of an Illness or Injury.
2. One prescription oral agent for controlling blood sugar levels for each class of drug approved by the United States food and drug administration.
3. Insulin on prescription.
4. Disposable insulin needles/syringes.
5. Test strips.
6. Lancets.
7. Oral contraceptives, contraceptive devices, implantables or injections prescribed by a Physician.
8. Smoking cessation products and over-the-counter smoking cessation aids/medications with a written prescription, as required by the Affordable Care Act. Tobacco counseling is available under the Preventive Health Care Benefit.

The Schedule of Benefits lists any Deductible, Copayment and/or Coinsurance that the member is responsible for and payment limitations for these Prescription Drug Products.

Non-Covered Prescription Drug Products

The Plan will not pay for:

1. Nonlegend drugs other than insulin.
2. Compounded medications.
3. Anabolic Steroids.
4. Any drug used for the purpose of weight loss.
5. Fluoride supplements, except as required by the Affordable Care Act for children under age 6.
6. Drugs which are not approved by the FDA for a particular use or purpose or when used for a purpose other than the purpose for which the FDA approval is given, except as required by law or regulation. Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.
7. Over-the-counter drugs that do not require a prescription, except over-the-counter smoking cessation aids with a written prescription.
8. Prescription Drug Products for which there is an exact over-the-counter equivalent.
9. Prescription Drug Products for cosmetic purposes, including the treatment of alopecia (hair loss) (e.g., Minoxidil, Rogaine).
10. Therapeutic devices or appliances, including needles, syringes, support garments and other non-medicinal substances, regardless of intended use, except those otherwise covered under this section.
11. Prescription Drug Products used for erectile dysfunction.

12. Prescription Drug Products used for the treatment of infertility.
13. Insulin pumps and glucose meters. Insulin pumps and glucose meters are covered under the Durable Medical Equipment Benefit. Insulin pump supplies are covered under the Medical Supplies Benefit.
14. Drugs or items labeled "Caution - limited by federal law to investigational use," or experimental drugs, even though the Member is charged for the item.
15. Biological sera, blood, or blood plasma.
16. Prescription Drug Products which are to be taken by or administered to the Member, in whole or in part, while the Member is a patient in a licensed Hospital, rest home, sanitarium, extended care facility, convalescent hospital, nursing home, or similar institution which operates or allows to be operated on its premises, a facility for dispensing pharmaceuticals. Medication in these situations is part of the facility's charge.
17. Any Prescription Drug Product refilled in excess of the number specified by the Physician, or any refill dispensed after one year from the Physician's original order.
18. Replacement prescription drugs or Prescription Drug Products due to loss, theft or spoilage .
19. Prescription Drug Products obtained from a pharmacy located outside the United States for consumption within the United States.
20. Prescription Drug Products provided by a mail-order pharmacy that is not approved by The Plan.
21. Repackaged medications.
22. Non-sedating antihistamines.
23. Brand-Name Proton Pump Inhibitors (PPIs).
24. Prescription Drug Products determined by The Plan to have inferior efficacy or significant safety issues.

Controlled Substances Limitation

If The Plan determines that a Member may be receiving quantities of controlled substance medications not supported by FDA approved dosages or recognized treatment guidelines, any Benefits for additional drugs may be subject to a review for Medical Necessity, appropriateness and other restrictions.

Purchase and Payment of Prescription Drug Products

Prescription Drug Products may be obtained using an outpatient retail pharmacy or a mail-order pharmacy approved by The Plan. To use a mail-order pharmacy, the Member must send an order form with the prescription to the address listed on the mail-order service form and pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The address of each mail order pharmacy approved by The Plan is listed on the inside cover of this Member Guide.

If drugs or Prescription Drug Products are purchased at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the Member presents the Member's ID card at the time of purchase, the Member must pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The Member will only be required to pay the appropriate Deductible, Copayment and/or Coinsurance and the difference between the cost of the Brand-Name drug and the Generic equivalent if the amount can be determined by the pharmacy at the time of purchase.

Exceptions to this provision may be allowed for certain preventive medications (including prescription contraceptive medications) if the Member's health care Provider submits a request to The Plan indicating that the Generic drug would be medically inappropriate, along with supporting documentation. If The Plan grants the exception request, any difference between the cost of the Brand-Name drug and the Generic equivalent will be waived.

If the Member uses a Participating Pharmacy to fill a prescription, but elects to submit the claim directly to the Plan's Pharmacy Benefit Manager, instead of having the Participating Pharmacy submit the claim, the Member will be reimbursed for the prescription drug based on the amount that would have been paid to the Participating Pharmacy, less the any Deductible, Copayment and/or Coinsurance.

If drugs or Prescription Drug Products are purchased at a nonparticipating outpatient pharmacy, the Member must pay for the prescription at the time of dispensing and then file a prescription drug claim form with The Plan's Pharmacy Benefit Manager for reimbursement. The Member will be reimbursed for the prescription drug at 50% of

the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance and any additional charge for the difference between the cost of the Brand-Name drug and the Generic equivalent.

Prescription Drug Products Subject to Preauthorization, Step Therapy or Quantity Limits

1. Prescription Drug Products subject to Preauthorization require prior approval from The Plan's Pharmacy Benefit Manager before they can qualify for coverage under The Plan. If the Member does not obtain Preauthorization before a Prescription Drug Product is dispensed, the Member may pay for the prescription and then pursue authorization of the drug from The Plan's Pharmacy Benefit Manager. If the authorization is approved by The Plan's Pharmacy Benefit Manager, the Member should then submit a claim for the prescription drug on a prescription claim form to The Plan's Pharmacy Benefit Manager for reimbursement.
2. Preauthorization does not guarantee payment of the Prescription Drug Product by The Plan. Even if the prescription drug has been preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date the drug is dispensed or the Member's Benefits may have changed as of the date the drug is dispensed.
3. A step therapy program is designed to help the Member use the lowest cost product(s) within a drug class. Drugs subject to step therapy are widely considered equivalent to other products within the class by both physicians and pharmacists. In order to obtain a medication within a step therapy program, the member must fail a first line drug. In general, first line products are usually generic medications. In some cases, a pharmacy policy will allow the step therapy to be waived. The pharmacy policies are located on The Plan website at www.bcbsmt.com.
4. A quantity limit is a limitation on the number or amount of a Prescription Drug Product covered within a certain time period. Quantity limits are established to ensure that prescribed quantities are consistent with clinical dosing guidelines, to control for billing errors by pharmacies, to encourage dose consolidation, appropriate utilization, and to avoid misuse/abuse of the medication. A prescription written for a quantity in excess of the established limit will require a Preauthorization before Benefits are available.

Certain Prescription Drug Products, such as those used to treat rheumatoid arthritis, growth hormone deficiency, hepatitis C, or more serious forms of anemia, hypertension, and epilepsy, are subject to Preauthorization, step therapy, or quantity limits. The Prescription Drug Products included in the prescription drug program are subject to change, and medications for other conditions may be added to the program.

If the Member's provider is prescribing a Prescription Drug Product subject to Preauthorization, step therapy, or quantity limits, the provider should fax the request for Preauthorization to The Plan's Pharmacy Benefit Administrator at the fax number listed on the inside cover of this Member Guide. The Member and provider will be notified of The Plan's Pharmacy Benefit Administrator's determination.

In making determinations of coverage, The Plan's Pharmacy Benefit Administrator may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, Pharmacy Benefit Manager evaluations, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

To find out more about Preauthorization/step therapy/quantity limits or to determine which Prescription Drug Products are subject to Preauthorization, step therapy or quantity limits, the Member or provider should refer to the Drug List which applies to the Member's Plan at www.bcbsmt.com or www.myprime.com or call the Customer Service toll-free number identified on the Member's identification card.

Specialty Medications

1. Specialty Medications are generally prescribed for individuals with complex or ongoing medical conditions such as multiple sclerosis, hemophilia, hepatitis C and rheumatoid arthritis. These high cost medications also have one or more of the following characteristics:
   - **a.** Injected or infused, but some may be taken by mouth
   - **b.** Unique storage or shipment requirements
   - **c.** Additional education and support required from a health care professional
   - **d.** Usually not stocked at retail pharmacies

2. For the highest level of Benefits, Specialty Medications must be acquired through The Plan's contracted Specialty Pharmacy listed on the inside cover of this Member Guide. A list of covered Specialty Medications may be found on The Plan website at www.bcbsmt.com. Registration and other applicable forms are also located on the website.

Preventive Health Care

Covered preventive services include, but are not limited to:

1. Services that have an "A" or "B" rating in the United States Preventive Services Task Force's current recommendations (additional information is provided by accessing http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm); and
2. Immunizations recommended by the Advisory Committee of Immunizations Practices of the Centers for Disease Control and Prevention; and
3. Health Resources and Services Administration (HRSA) Guidelines for Preventive Care & Screenings for Infants, Children, Adolescents and Women;

   In addition to the screening services recommended under the HRSA Guidelines, the following services are included:

   a. Lactation Services

      Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period. In addition, Benefits are provided for the purchase of manual or electric breast pumps or the rental of Hospital-grade pumps. The purchase of electric breast pumps is limited to two electric breast pumps per Benefit Period. Payment will be made according to the Preventive Health Care Benefit on the Schedule of Benefits.

   b. Contraceptives

      Food and Drug Administration approved contraceptive methods, including certain contraceptive products, sterilization procedures for women, and patient education and counseling for all women with reproductive capacity. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy; and

4. Current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention issued prior to or after November 2009.

Examples of Preventive Health Care services include, but are not limited to, physical examinations, colonoscopies, immunizations and vaccinations.

For more detailed information on all covered services, contact Customer Service or access www.bcbsmt.com.

Prostheses

The appropriate devices used to replace a body part missing because of an Accident, Injury, or Illness.

When placement of a prosthesis is part of a surgical procedure, it will be paid under Surgical Services.

Payment for deluxe prosthetics will be based on the Allowable Fee for a standard prosthesis.

The Plan will not pay for the following items:

1. computer-assisted communication devices;
2. replacement of lost or stolen prosthesis.

Note: The prosthesis will not be considered a replacement if the prosthesis no longer meets the medical needs of the Member due to physical changes or a deteriorating medical condition.

Radiation Therapy

The use of x-ray, radium, or radioactive isotopes ordered by the attending Physician and performed by a Covered Provider for the treatment of disease.

Rehabilitation – Facility and Professional

Rehabilitation Therapy and other covered services, as outlined in this Rehabilitation section, billed by a Rehabilitation Facility provider or a Professional Provider for services provided to a Member.

The Plan will not pay when the primary reason for Rehabilitation is any one of the following:

1. Custodial Care;
2. Diagnostic admissions;
3. Maintenance, nonmedical self-help, or vocational educational therapy;
4. Social or cultural rehabilitation;
5. Learning and developmental disabilities; and
6. Visual, speech, or auditory disorders because of learning and developmental disabilities or psychoneurotic and psychotic conditions.

Benefits will not be provided under this Rehabilitation section for treatment of Chemical Dependency or Mental Illness as defined in the Chemical Dependency and Mental Illness sections.

Benefits will be provided for services, supplies and other items that are within the scope of the Rehabilitation benefit described in this Rehabilitation section only as provided in and subject to the terms, conditions and limitations applicable to this Rehabilitation benefit section and other applicable terms, conditions and limitations of this Member Guide. Other Benefit sections of this Member Guide, such as but not limited to Hospital Services, do not include Benefits for any services, supplies or items that are within the scope of the Rehabilitation benefit as outlined in this section.

Rehabilitation Facility Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations
   a. Room and Board, which includes but is not limited to dietary and general, medical and rehabilitation nursing services.
2. Miscellaneous Rehabilitation Facility Services (whether or not such services are Rehabilitation Therapy or are general, medical or other services provided by the Rehabilitation Facility during the Member's admission), including but not limited to:
   a. Rehabilitation Therapy services and supplies, including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy.
   b. Laboratory procedures.
   c. Diagnostic testing.
   d. Pulmonary services and supplies, including but not limited to oxygen and use of equipment for its administration.
   e. X-rays and other radiology.
   f. Intravenous injections and setups for intravenous solutions.
   g. Special diets when Medically Necessary.
   h. Operating room, recovery room.
   i. Anesthetic and surgical supplies.
   j. Drugs and medicines which:
      1. Are approved for use in humans by the U.S. Food and Drug Administration; and
      2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
      3. Require a Physician's written prescription.

      Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.
3. Rehabilitation Facility Inpatient Care Services do not include services, supplies or items for any period during which the Member is absent from the Rehabilitation Facility for purposes not related to rehabilitation, including but not limited to intervening inpatient admissions to an acute care Hospital.

Preauthorization is required for Rehabilitation Facility Inpatient Care. Please refer to the section entitled Preauthorization.

Rehabilitation Facility Inpatient Care is subject to the following conditions:

1. The Member will be responsible to the Rehabilitation Facility for payment of the Facility's charges if the Member remains as an Inpatient Member when Rehabilitation Facility Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member.
2. The term "Rehabilitation Facility" does not include:
   - **a.** A Hospital when a Member is admitted to a general medical, surgical or specialty floor or unit (other than a rehabilitation unit) for acute Hospital care, even though rehabilitation services are or may be provided as a part of acute care.
   - **b.** A nursing home;
   - **c.** A rest home;
   - **d.** Hospice;
   - **e.** A skilled nursing facility;
   - **f.** A Convalescent Home;
   - **g.** A place for care and treatment of Chemical Dependency;
   - **h.** A place for treatment of Mental Illness;
   - **i.** A long-term, chronic-care institution or facility providing the type of care listed above.

Rehabilitation Facility Inpatient Care Services Billed by a Professional Provider

All Professional services provided by a Covered Provider who is a physiatrist or other Physician directing the Member's Rehabilitation Therapy. Such professional services include care planning and review, patient visits and examinations, consultation with other physicians, nurses or staff, and all other professional services provided with respect to the Member. Professional services provided by other Covered Providers (i.e., who are not the Physician directing the Member's Rehabilitation Therapy) are not included in the rehabilitation Benefit, but are included to the extent provided in and subject to the terms, conditions and limitations of other contract benefits (e.g., Physician Medical Services).

Outpatient Rehabilitation

Rehabilitation Therapy provided on an outpatient basis by a facility or professional provider.

Surgical Services

Surgical Services Billed by a Professional Provider

Services by a professional provider for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery. The charge for a surgical suite outside of the Hospital is included in the Allowable Fee for the surgery.

Surgical Services Billed by an Outpatient Surgical Facility or Freestanding Surgery Centers

Services of a surgical facility or a freestanding surgery center licensed, or certified for Medicare, by the state in which it is located and have an effective peer review program to assure quality and appropriate patient care. The surgical procedure performed in a surgical facility or a freestanding surgery center is recognized as a procedure which can be safely and effectively performed in an Outpatient setting.

The Plan will pay for a Recovery Care Bed when Medically Necessary and provided for less than 24 hours. Payment will not exceed the semiprivate room rate that would be billed for an inpatient stay.

Surgical Services Billed by a Hospital (Inpatient and Outpatient)

Services of a Hospital for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery.

Telemedicine

Benefits for services provided by Telemedicine when such services are Medically Necessary Covered Medical Expenses provided by a Covered Provider.

Therapies for Down Syndrome

Benefits will be provided for the diagnosis and treatment of Down syndrome for a covered child under 19 years of age. Covered services include:

- Medically Necessary Habilitative Care or Rehabilitative Care that is prescribed, provided, or ordered by a licensed Physician, including but not limited to professional, counseling, and guidance services and treatment programs. Habilitative Care and Rehabilitative Care includes Medically Necessary interactive therapies derived from evidence-based research, including intensive intervention programs and early intensive behavioral intervention.
- Medically Necessary therapeutic care that is provided by a licensed speech-language pathologist a physical therapist or an occupational therapist;

When treatment is expected to require extended services, Blue Cross and Blue Shield of Montana may request that the treating Physician provide a treatment plan based on evidence-based screening criteria. The treatment plan will consist of the diagnosis, proposed treatment by type and frequency, the anticipated duration of treatment, the anticipated outcomes stated as goals, and the reasons the treatment is Medically Necessary. Blue Cross and Blue Shield of Montana may request that the treatment plan be updated every 6 months.

Therapies - Outpatient

Services provided for Physical Therapy, Speech Therapy, cardiac therapy and Occupational Therapy, not including Rehabilitation Therapy.

Transplants

For certain transplants, Blue Cross and Blue Shield of Montana contracts with a number of Centers of Excellence that provide transplant services. Blue Cross and Blue Shield of Montana highly recommends use of the Centers of Excellence because of the quality of the outcomes at these facilities. Members being considered for a transplant procedure are encouraged to contact Blue Cross and Blue Shield of Montana Customer Service to discuss the possible benefits of utilizing the Centers of Excellence.

Transplant services include:

1. Organ procurement including transportation of the surgical/harvesting team, surgical removal of the donor organ, evaluation of the donor organ and transportation of the donor or donor organ to the location of the transplant operation.
2. Donor services including the pre-operative services, transplant related diagnostic lab and x-ray services, and the transplant surgery hospitalization. Transplant related services are covered for up to six months after the transplant.
3. Hospital Inpatient Care services.
4. Surgical services.
5. Anesthesia.
6. Professional provider and diagnostic Outpatient services.
7. Licensed ambulance travel or commercial air travel for the Member receiving the treatment to the nearest Hospital with appropriate facilities.

Payment by The Plan is subject to the following conditions:

1. When both the transplant recipient and donor are members, both will receive Benefits.
2. When the transplant recipient is a Member and the donor is not, both will receive Benefits to the extent that benefits for the donor are not provided under other hospitalization coverage.
3. When the transplant recipient is not a Member and the donor is, the donor will receive Benefits to the extent that benefits are not provided to the donor by hospitalization coverage of the recipient.

The Plan will not pay for:

1. Experimental/Investigational/Unproven procedures.
2. Transplants of a nonhuman organ or artificial organ implant.
3. Donor searches.

Preauthorization is required for Transplants. Please refer to the section entitled Preauthorization.

Well-Child Care

Well-child care provided by a Physician or a health care professional supervised by a Physician.

Benefits shall include coverage for:

1. Histories;
2. Physical examinations;
3. Developmental assessments;
4. Anticipatory guidance;
5. Laboratory tests;
6. Routine immunizations.

COORDINATION OF BENEFITS WITH OTHER INSURANCE

The Coordination of Benefits (COB) provision applies when a Member has health care coverage under more than one plan. "Plan" is defined below.

The order in which each plan will make payment for Covered Medical Expenses is governed by the order of benefit determination rules. The plan that pays first is called the primary plan. The primary plan must pay Covered Medical Expenses in accordance with its Member Guide terms without regard to the possibility that another plan may cover some expenses. The plan that pays after the primary plan is the secondary plan. The secondary plan may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Definitions

For the purpose of this section only, the following definitions apply:

Plan

Any of the following that provide benefits, or services, for medical or dental care or treatment include:

1. group and nongroup health insurance contracts;
2. health maintenance organization (HMO) contracts;
3. Closed Panel Plans or other forms of group or group type coverage (whether insured or uninsured);
4. medical care components of long-term care contracts, such as skilled nursing care; and
5. Medicare or any other federal governmental plan, as permitted by law.

The term plan does not include:

1. excepted benefits pursuant to 33-22-140(8)(a), (b), (c), (d), (e), (f), (g), (h), (j), and (k), MCA;
2. school accident type coverage;
3. benefits for non-medical components of long-term care policies; or
4. a governmental plan, which, by law, provides benefits that are in excess of those of any private insurance plan or other nongovernmental plan.

Each contract for coverage is a separate plan. If a plan has two parts and COB rules apply only to one of the two, each of the parts is treated as a separate plan.

This Plan

In a COB provision, "this plan" means that part of the Member Guide providing the health care benefits to which the COB provision applies and which may be reduced because of the benefits of other plans. Any other part of the Member Guide providing health care benefits is separate from this plan. A contract may apply one COB provision to certain benefits, such as dental benefits, coordinating only with similar benefits, and may apply another COB provision to coordinate other benefits.

Order of Benefit Determination Rules

The rules that determine whether this plan is a primary plan, or secondary plan, when the person has health care coverage under more than one plan.

1. When this plan is primary, it determines payment for Covered Medical Expenses first before those of any other plan without considering any other plan's benefits.
2. When this plan is secondary, it determines its benefits after those of another plan and may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Allowable Expense

A Covered Medical Expense, including deductibles, coinsurance and copayments, that is covered at least in part by any plan covering the Member. When a plan provides benefits in the form of services, the reasonable cash value of each service will be considered an allowable expense and a benefit paid. An expense that is not covered by any plan covering the Member is not an allowable expense. In addition, any expense that a provider by law or in accordance with a contractual agreement is prohibited from charging a Member is not an allowable expense.

The following are examples of expenses that are not allowable expenses:

1. The difference between the cost of a semi-private hospital room and a private hospital room is not an allowable expense, unless one of the plans provides coverage for private hospital room expenses.
2. If a Member is covered by two or more plans that compute their benefit payments on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology, any amount in excess of the highest reimbursement amount for a specific benefit is not an allowable expense.
3. If a Member is covered by two or more plans that provide benefits or services on the basis of negotiated fees, an amount in excess of the highest of the negotiated fees is not an allowable expense.
4. If a Member is covered by one plan that calculates its benefits or services on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology and another plan that provides its benefits or services on the basis of negotiated fees, the primary plan's payment arrangement shall be the allowable expense for all plans. However, if the provider has contracted with the secondary plan to provide the benefit or service for a specific negotiated fee or payment amount that is different than the primary plan's payment arrangement and if the provider's contract permits, the negotiated fee or payment shall be the allowable expense used by the Secondary plan to determine its benefits.
5. The amount of any benefit reduction by the primary plan because a Member has failed to comply with the plan provisions is not an allowable expense. Examples of these types of plan provisions include second surgical opinions, precertification of admissions, and preferred provider arrangements.

Closed Panel Plan

A plan that provides health care benefits to covered persons primarily in the form of services through a panel of providers that have contracted with or are employed by the plan, and that excludes coverage for services provided by other providers, except in cases of emergency or referral by a panel member.

Custodial Parent

The parent awarded custody by a court decree or, in the absence of a court decree, is the parent with whom the child resides more than one half of the calendar year excluding any temporary visitation.

Order of Benefit Determination Rules

When a Member is covered by two or more plans, the rules for determining the order of benefit payments are as follows:

1. The primary plan pays or provides its benefits according to its terms of coverage and without regard to the benefits of under any other Plan; and
2. Except as provided below, a plan that does not contain a COB provision that is consistent with this regulation is always primary unless the provisions of both plans state that the complying plan is primary.

   Coverage that is obtained by virtue of membership in a group that is designed to supplement a part of a basic package of benefits, and provides that this supplementary coverage, shall be excess to any other parts of the plan provided by the Group. Examples of these types of situations are major medical coverages that are superimposed over base plan hospital and surgical benefits, and insurance type coverages that are written in connection with a closed panel plan to provide out-of-network benefits.

3. A plan may consider the benefits paid or provided by another plan in calculating payment of its benefits only when it is secondary to that other plan.

4. Each plan determines its order of benefits using the first of the following rules that apply:

   Non-Dependent or Dependent.

   The plan that covers the person as an employee or retiree is the primary plan and the plan that covers the employee or retiree as a dependent is the secondary plan. However, if the person is a Medicare beneficiary and, as a result of federal law, Medicare is secondary to the plan covering the person as a dependent; and primary to the plan covering the person as other than a dependent (e.g., a retired employee); then the order of benefits between the two plans is reversed so that the plan covering the person as an employee or retiree is the secondary plan and the other plan is the primary plan.

   Dependent Child Covered Under More Than One Plan.

   Unless there is a court decree stating otherwise, when a dependent child is covered by more than one plan, the order of benefits is determined as follows:

   1. **Dependent Child - Parents are married or are living together**

      a. The plan of the parent whose birthday falls earlier in the calendar year is the primary plan; or
      b. If both parents have the same birthday, the plan that has covered the parent the longest is the primary plan.

   2. **Dependent Child - Parents are divorced or separated or not living together**

      a. If a court decree states that one of the parents is responsible for the dependent child's health care expenses or health care coverage and the plan of that parent has actual knowledge of those terms, that plan is primary. This rule applies to plan years commencing after the plan is given notice of the court decree;
      b. If a court decree states that both parents are responsible for the dependent child's health care expenses or health care coverage, the provisions of (a) above shall determine the order of benefits;
      c. If a court decree states that the parents have joint custody without specifying that one parent has responsibility for the health care expenses or health care coverage of the dependent child, the provisions of (a) above shall determine the order of benefits; or
      d. If there is no court decree allocating responsibility for the dependent child's health care expenses or health care coverage, the order of benefits for the child are as follows:

         - The plan covering the custodial parent;
         - The plan covering the Spouse of the custodial parent;
         - The plan covering the non-custodial parent; and then;
         - The plan covering the Spouse of the non-custodial parent.

3. **Dependent Child Covered Under More than One Plan of Individuals Who Are Not the Parents of the Child**

   The provisions of (1) or (2) above shall determine the order of benefits as if those individuals were the parents of the child.

4. **Active Employee or Retired or Laid-off Employee**

   The plan that covers a person as an active employee, that is, an employee who is neither laid off nor retired, (or is a dependent of such employee) is the primary plan. The plan covering that same person as a retired or laid-off employee (and the dependent of such employee) is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

5. **COBRA or State Continuation Coverage**

   If a person whose coverage is provided pursuant to COBRA or under a right of continuation provided by state or other federal law is covered under another plan, the plan covering the person as an employee or retiree or covering the person as a dependent of an employee or retiree is the primary plan and the COBRA or state or other federal continuation coverage is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

6. **Longer or Shorter Length of Coverage**

   The plan that covered the person as an employee or retiree longer is the primary plan and the plan that covered the person the shorter period of time is the secondary plan.

If the preceding rules do not determine the order of benefits, the allowable expenses shall be shared equally between the plans meeting the definition of plan. In addition, this plan will not pay more than it would have paid had it been the primary plan.

Effect on the Benefits of This Plan

When this plan is secondary, it may reduce its benefits so that the total benefits paid or provided by all plans during a plan year are not more than the total allowable expenses. In determining the amount to be paid for any claim, the secondary plan will calculate the benefits it would have paid in the absence of other health care coverage and apply that calculated amount to any allowable expense under its plan that is unpaid by the primary plan. The secondary plan may then reduce its payment by the amount so that, when combined with the amount paid by the primary plan, the total benefits paid or provided by all plans for the claim do not exceed the total allowable expense for that claim. In addition, the secondary plan shall credit to its plan deductible any amounts it would have credited to its deductible in the absence of other health care coverage.

If a covered person is enrolled in two or more closed panel plans and if, for any reason, including the provision of service by a non-panel provider, benefits are not payable by one closed panel plan, COB shall not apply between that plan and other closed panel plans.

Right to Receive and Release Needed Information

Certain facts about health care coverage and services are needed to apply these COB rules and to determine benefits payable under this plan and other plans. Blue Cross and Blue Shield of Montana may get the facts it needs from or give them to other organizations or persons for the purpose of applying these rules and determining benefits payable under this plan and other plans covering the Member claiming benefits. Blue Cross and Blue Shield of Montana need not inform, or get the consent of, any person to do this. Each Member claiming benefits under this plan must give Blue Cross and Blue Shield of Montana any facts it needs to apply those rules and determine benefits payable.

Facility of Payment

A payment made under another plan may include an amount that should have been paid under this plan. If it does, Blue Cross and Blue Shield of Montana may pay that amount to the organization that made that payment. That amount will then be treated as though it were a benefit paid under this plan. Blue Cross and Blue Shield of Montana

will not have to pay that amount again. The term "payment made" includes providing benefits in the form of services, in which case "payment made" means the reasonable cash value of the benefits provided in the form of services.

Right of Recovery

If the amount of the payments made by Blue Cross and Blue Shield of Montana is more than it should have paid under this COB provision, it may recover the excess from one or more of the Members it has paid or for whom it has paid; or any other person or organization that may be responsible for the benefits or services provided for the Member. The "amount of the payments made" includes the reasonable cash value of any benefits provided in the form of services.

Coordination With Medicare

The Plan will coordinate benefits with Medicare according to the federal Medicare secondary payor laws and regulations ("MSP rules"). This means that The Plan and/or Medicare may adjust payment so that the combined payments by The Plan and Medicare will be no more than the charge for the Benefits received by the Member. The Plan will never pay more than it would pay if the Member was not covered by Medicare.

1. For Working Aged

Medicare pays secondary to The Plan for Benefits for Beneficiary Members and their Spouses who are Members, covered by employers with 20 or more employees, who qualify for age-based Medicare as a result of attaining age 65 and older and who are covered by virtue of the Beneficiary Member's current employment status.

Medicare will be the primary for a Member that refuses coverage under this Group Plan.

Medicare will pay primary to The Plan for the working aged Members covered by employers with fewer than 20 employees, including a multi-employer association if the Member is covered by an employer within the multi-employer association with fewer than 20 employees.

2. For Disabled Members under Age 65

Medicare pays secondary to The Plan for Benefits for Members under age 65, covered by employers with 100 or more employees, who qualify for disability-based Medicare and are covered by virtue of a Beneficiary Member's current employment status.

Medicare pays primary to The Plan for disabled Members under age 65 covered by employers with fewer than 100 employees.

3. For End-Stage Renal Disease

Medicare pays secondary to The Plan for Benefits for Members who qualify for Medicare as a result of end-stage renal disease ("ESRD"), regardless of employer size, and are entitled to Benefits payable under this Group Plan, for the first 30 months that a particular Member qualifies for Medicare as a result of ESRD. After the 30 month period, Medicare will pay primary to The Plan.

Special Coordination of Benefits rules apply if a Member is entitled to Medicare based on ESRD and Medicare based on either age or disability.

a. If The Plan is required to pay before Medicare under 1 or 2 above for a Member before the Member qualifies for Medicare based on ESRD, The Plan will continue to pay primary to Medicare after the Member becomes covered under Medicare based on ESRD but only for the 30 month period above, after which Medicare will pay primary to The Plan.

b. If The Plan is required to pay primary to Medicare based on ESRD and the Member that qualifies for Medicare based on ESRD above later becomes entitled to age-based or disability-based Medicare during the 30 month period, Medicare will pay second to The Plan for the duration of the 30 month period, after which Medicare will pay primary to The Plan. If the Member qualifies for age-based or disability-based Medicare after the 30 month period, Medicare will pay primary to The Plan.

c. Medicare continues to be primary to The Plan after an aged or disabled Member becomes eligible for Medicare based on ESRD if:

1. The Member is already entitled to Medicare on the basis of age or disability when the Member becomes eligible for Medicare based on ESRD; and
2. The Group has fewer than 20 employees in the case of age-based Medicare or fewer than 100 employees in the case of disability-based Medicare.

4. For Retired Persons

Medicare is primary to The Plan for Beneficiary Members age 65 if the Beneficiary Member is a qualified individual age 65 and over and retired.

Medicare is primary to The Plan for Beneficiary Member's Spouse who is also a Member and who is a qualified individual if both the Beneficiary Member and the Member Spouse are age 65 and over and retired.

5. Current Employment Status

Under the MSP rules, a Member has current employment status if the Member is:

a. Actively working as an employee; or
b. Not actively working but is receiving disability benefits from an employer but only for a period of up to 6 months; or
c. Not actively working but retains employment rights in the industry (including but not limited to a Member who is temporarily laid off or on sick leave, teachers and other seasonal workers), has not been terminated by an employer, is not receiving disability benefits from an employer for more than 6 months, is not receiving Social Security disability benefits and has group health coverage under this Group Plan that is not COBRA coverage.

Other Insurance

If a property or casualty insurer pays for services provided to the Member and coordination of benefits is not applicable, The Plan will credit the Member's Deductible, Copayment or Coinsurance, as applicable, if the Member notifies The Plan of the payment, within 12 months of the date of service.

EXCLUSIONS AND LIMITATIONS

All Benefits provided under this Member Guide are subject to the Exclusions and limitations in this section and as stated under the Benefit section. **The Plan will not pay for:**

1. All services, supplies, drugs and devices which are provided to treat any Illness or Injury arising out of employment when the Member's employer has elected or is required by law to obtain coverage for Illness or Injury under state or federal Workers' Compensation laws, occupational disease laws, or similar legislation, including employees' compensation or liability laws of the United States. This Exclusion applies to all services and supplies provided to treat such Illness or Injury even though:

   a. Coverage under the government legislation provides benefits for only a portion of the services incurred.
   b. The employer has failed to obtain such coverage required by law.
   c. The Member waives his or her rights to such coverage or benefits.
   d. The Member fails to file a claim within the filing period allowed by law for such benefits.
   e. The Member fails to comply with any other provision of the law to obtain such coverage or benefits.
   f. The Member was permitted to elect not to be covered by the Workers' Compensation Act but failed to properly make such election effective.

   This Exclusion will not apply if the Member is permitted by statute not to be covered and the Member elects not to be covered by the Workers' Compensation Act, occupational disease laws, or liability laws.

   This Exclusion will not apply if the Member's employer was not required and did not elect to be covered under any Workers' Compensation, occupational disease laws or employer's liability acts of any state, country, or the United States.

2. Services, supplies, drugs and devices which the Member is entitled to receive or does receive from TRICARE, the Veteran's Administration (VA), and Indian Health Services but not Medicaid. This Exclusion is not intended to exclude Covered Medical Expenses from coverage if a Member is a resident of a Montana State institution when Benefits are provided.

   Note: Under some circumstances, the law allows certain governmental agencies to recover for services rendered to the Member. When such a circumstance occurs, the Member will receive an explanation of benefits.

3. Services, supplies, drugs and devices to treat any Injury or Illness resulting from war, declared or undeclared, insurrection, rebellion, or armed invasion.

4. Any loss for which a contributing cause was commission by the Member of a felony, or attempt to commit a felony. This exclusion does not apply if the loss is related to being a victim of domestic violence or if the commission of the felony is related to a preexisting medical condition.

5. Services for which a Member is not legally required to pay or charges that are made only because Benefits are available under this Member Guide.

6. Services, supplies, drugs and devices provided to the Member before the Member's Effective Date or after the Member's coverage terminates.

7. Nonsurgical treatment for malocclusion of the jaw, including services for temporomandibular joint dysfunction, anterior or internal dislocations, derangements and myofascial pain syndrome, orthodontics (dentofacial orthopedics), or related appliances.

8. Orthodontics.

9. All dental services, including but not limited to ridge augmentation and vestibuloplasty, whether performed by Physicians, dentists, oral surgeons and/or any other provider, except for services provided as the result of a Dental Accident.

10. Vision services, including but not limited to prescription, fitting or provision of eyeglasses or contact lenses and Lasik Surgery, except for services covered under the Pediatric Vision Care Benefit. In addition, vision services may be covered for specific conditions in Medical Policy.

11. Hearing aids, except that Medically Necessary cochlear implants may be covered per Medical Policy.

12. Cosmetic services except when provided to correct a condition resulting from an Accident, a condition resulting from an Injury or to treat a congenital anomaly, as applicable in Medical Policy.

13. For travel by a Member or provider.

14. Any service or procedure which is determined by The Plan to be an Inclusive Service/Procedure.

15. Any services, supplies, drugs and devices which are:

    a. Experimental/Investigational/Unproven services, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.
    b. Not accepted standard medical practice. The Plan may consult with physicians or national medical specialty organizations for advice in determining whether the service or supply is accepted medical practice.
    c. Not a Covered Medical Expense.
    d. Not Medically Necessary.
    e. Not covered under applicable Medical Policy.

16. Any services, supplies, drugs and devices considered to be Experimental/Investigational/Unproven and which are provided during a Phase I or II clinical trial, or the experimental or research arm of a Phase III clinical trial, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial. This includes services, supplies, drugs and devices under study to determine the maximum tolerated dosage(s), toxicity, safety, efficacy or efficacy as compared with standard treatment, or for the diagnosis of the condition in question.

17. Transplants of a nonhuman organ or artificial organ implant.

18. Private duty nursing.

19. Abortions, except in the case of rape or incest, or for a pregnancy which, as certified by a physician, places the woman in danger of death unless an abortion is performed.

20. Reversal of an elective sterilization.

21. Services, supplies, drugs and devices related to in vitro fertilization.

22. Chiropractic services and supplies.

23. Routine foot care for Members without co-morbidities, except Routine foot care is covered if a Member has co-morbidities such as diabetes.

24. Treatment of flat foot conditions and the prescription of supportive devices for such conditions and the treatment of subluxations of the foot.

25. Foot orthotics.

26. Services, supplies, drugs and devices related to treatment for psychological or psychogenic sexual dysfunctions.

27. Services, supplies, drugs and devices relating to any of the following treatments or related procedures:

- **a.** Homeopathy.
- **b.** Hypnotherapy.
- **c.** Rolfing.
- **d.** Holistic medicine.
- **e.** Religious counseling.
- **f.** Self-help programs.

28. Services provided by a massage therapist.

29. Sanitarium care, custodial care, rest cures, or convalescent care to help the Member with daily living tasks. Examples include but are not limited to, help in:

- **a.** Walking.
- **b.** Getting in and out of bed.
- **c.** Bathing.
- **d.** Dressing.
- **e.** Feeding.
- **f.** Using the toilet.
- **g.** Preparing special diets.
- **h.** Supervision of medication which is usually self-administered and does not require the continuous attention of medical personnel.

No payment will be made for admissions or parts of admissions to a Hospital, skilled nursing facility, or extended care facility for the types of care outlined in this exclusion.

30. Over-the-counter food supplements, formulas, and/or Medical Foods, regardless of how administered except when used for Inborn Errors of Metabolism.

31. Services, supplies, drugs and devices for the surgical treatment of any degree of obesity, whether provided for weight control or any medical condition.

32. Services, supplies, drugs and devices for weight reduction or weight control. This Exclusion does not include intensive behavioral dietary counseling when services are provided by a Physician, Physician Assistant or Nurse Practitioner.

33. Charges associated with health clubs, weight loss clubs or clinics.

34. Services, supplies, drugs and devices for the treatment of Illness, Injury and/or complications resulting from services that are not Covered Medical Expenses, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.

35. Tutoring services.

36. Any services, supplies, drugs and devices not provided in or by a Covered Provider.

37. Services, supplies, drugs and devices primarily for personal comfort, hygiene, or convenience which are not primarily medical in nature.

38. Deluxe medical equipment including, but not limited to, durable medical equipment, prosthetics and communication devices except as included in the Durable Medical Equipment Benefit and the Prosthetic Benefit in the section entitled "Benefits."

39. All services, supplies, drugs and devices provided to treat any Illness or Injury arising out of employment as an athlete by or on a team or sports club engaged in any contact sport that includes significant physical contact between the athletes involved, including but not limited to football, hockey, roller derby, rugby, lacrosse, wrestling and boxing, where the Member's employer is not required by law to obtain coverage for Illness or Injury under state or federal workers' compensation, occupational disease or similar laws.

40. Applied Behavior Analysis (ABA) services, except as specifically included in this Member Guide under Autism Spectrum Disorders.

41. Services, supplies, drugs and devices provided outside of the United States, except if such services are provided as the result of an Emergency Medical Condition.

42. Services, supplies, drugs and devices which are not listed as a Benefit as described in this Member Guide.

CLAIMS

How to Obtain Payment for Covered Expenses for Benefits

1. If a Member obtains benefits from a Participating Provider, the Participating Provider will submit claims to The Plan for the Member. If a Member obtains benefits from a nonparticipating provider, the Member may be required to submit all claims to The Plan. All claims for services must be submitted on or before December 31 of the calendar year following the year in which services were received. All claims must provide enough information about the services for The Plan to determine whether or not they are a Covered Medical Expense. Submission of such information is required before payment will be made. In certain instances, Blue Cross and Blue Shield of Montana may require that additional documents or information including, but not limited to, accident reports, medical records, and information about other insurance coverage, claims, payments and settlements, be submitted within the timeframe requested for the additional documentation before payment will be made.

However, claims for prescription drugs purchased from a nonparticipating pharmacy must be submitted within one year from the date of purchase.

2. If a Member purchases drugs or Prescription Drug Products at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the ID card is presented at the time of purchase, the Member must pay for the Prescription Drug Product and the Participating Pharmacy will submit a claim for the cost of the covered prescription drug or Prescription Drug Product to The Plan's Pharmacy Benefit Manager. The cost of the covered drug or Prescription Drug Product will then accumulate to the Member's Deductible and Out-of-Pocket Amount. Once the Deductible is met, the Member will only be required to pay the appropriate Coinsurance if the amount can be determined by the pharmacy at the time of purchase.

If a Member purchases drugs or Prescription Drug Products at a nonparticipating pharmacy, the Member must pay for the prescription at the time of dispensing and then within one year of the date of purchase submit a claim for the prescription drug on a form to The Plan's Pharmacy Benefit Manager for reimbursement. The Member will be reimbursed for the prescription drug at 50% of the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance.

3. Claims must be submitted to the address listed on the inside cover of this Member Guide.

Prescription Drug Claims - Filling Prescriptions at a Retail Pharmacy

Outpatient prescription drugs are available through the Prime Therapeutics Prescription Drugs Benefit. Prime Therapeutics is the Pharmacy Benefit Manager.

1. Go to a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy that accepts Member ID cards. To find out if a pharmacy takes part in the program, ask the pharmacist. To find a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy nearest the Member, check the list on the website www.bcbsmt.com or call the pharmacy locator at the telephone number on the inside cover of this document.
2. Present the prescription and the Member's ID card to the pharmacist.
3. Make sure that the pharmacist has complete and correct information about the Member for whom the prescription is written, including sex and date of birth.
4. When the Member receives a prescription, he or she should sign the pharmacy log and pay his or her share of the cost.
5. If a Member purchases prescription drugs from a participating outpatient pharmacy or mail-service pharmacy approved by The Plan, the Member must pay for the Prescription Drug Product and the pharmacy will submit the prescription drug claims to Prime Therapeutics.
6. The Member must pay the difference between a Brand-Name drug and the Generic equivalent if the Member purchases a Brand-Name prescription drug when a Generic drug substitute is available.
7. The Plan makes use of a Drug List, which is a list of covered prescription drugs for dispensing to Members as appropriate.
8. For prescriptions filled at a pharmacy that is not part of the network, the Member will need to pay the pharmacist the entire cost of the prescription at the time the prescription is filled and dispensed and submit a paper claim to Prime Therapeutics for reimbursement. If a Member does not present his or her ID card at a Participating Pharmacy, a paper claim must be submitted by the Member to Prime Therapeutics for reimbursement. The Member will be reimbursed at 50% of the contracted rate minus Deductible, Copayment and/or Coinsurance, if applicable, in both situations. The Member will not receive the preferred pricing.
9. Prescriptions filled at Hospital pharmacies are not eligible for reimbursement unless they are listed as a network pharmacy.

Prime Therapeutics claim forms are available by calling The Plan at the telephone number on the inside cover of this document.

Mail-Service Pharmacy

A convenient way to get maintenance prescriptions is through the mail. Maintenance prescriptions are those that the Member expects to continue using for an extended period of time and for which a prescription can be written for up to a 90-day supply. Coverage for costly prescriptions should be verified prior to ordering. Specific Benefits are outlined in the Prescription Drugs section in this document.

Ordering prescriptions through the mail service pharmacy is very easy. To obtain a mail service claim form, call The Plan at the telephone number on the inside cover of this document.

To order a prescription:

1. Complete all sections and sign the Mail-Service order form.
2. Enclose the following:
   a. the original prescription written for a 90-day supply;
   b. the Member's current pharmacy telephone number, prescription numbers to be transferred; and
   c. the Member's telephone number.
3. Mail the form to the mail service pharmacy at the address listed on the form.

PREMIUM (DUES) REBATES

Distribution and Accounting of Premium (Dues) Rebates

In the event federal or state law requires Blue Cross and Blue Shield of Montana to rebate a portion of an annual premium (dues) payment, Blue Cross and Blue Shield of Montana will pay the Group the total rebate applicable to the Member Guide, and the Group will distribute from the rebate a pro-rata share of the rebate to each Employee and former Employee based upon the respective contribution to the premium (dues) rebated.

The Group shall assure appropriate notification to federal and state tax agencies and that each payment to Employees and former Employees will be accompanied by appropriate federal and state documentation.

The Group shall develop and retain records and documentation evidencing accurate distribution of any rebate and shall provide such records to Blue Cross and Blue Shield of Montana as follows:

1. Prior to March 15, the following information will be required for the prior year:
   - **a.** The percent of the premium (dues) paid by each Employee;
   - **b.** The percent of the premium (dues) paid by the Group;
   - **c.** The percent of the rebate to be provided to each Employee; and
   - **d.** The percent of the rebate to be retained by the Group.
2. Following actual distribution of the rebate, the following information will be required:
   - **a.** Amount of rebate paid to each Employee;
   - **b.** Amount of rebate retained by the Group; and
   - **c.** Amount of any unclaimed rebate and how it will be reported to the State.

The Group will assure that any unclaimed rebate amounts will be reported in accordance with the unclaimed property laws of the applicable Employee's state of domicile.

COBRA

If Blue Cross and Blue Shield of Montana does not administer the Group's COBRA requirements, then the rebate payment will include COBRA premiums that the Group must return to each COBRA recipient.

GENERAL PROVISIONS

Modification of Group Plan

The Plan may make administrative changes or changes in dues, terms or Benefits in the Group Plan by giving written notice to the Group at least 60 days in advance of the effective date of the changes. Dues may not be increased more than once during a 12-month period, except as allowed by Montana law.

No change in the Group Plan will be valid unless in writing and signed by the President of Blue Cross and Blue Shield of Montana. No other agent or representative or employee of The Plan may change any part of this Member Guide.

Clerical Errors

No clerical error on the part of The Plan shall operate to defeat any of the rights, privileges, or Benefits of any Member covered under the Group Plan. Upon discovery of errors or delays, an equitable adjustment of charges and Benefits will be made. Clerical errors shall not prevent administration of the Group Plan in strict accordance with its terms.

Notices Under Contract

Any notice required by the Group Contract may be given by United States mail, postage paid. Notice to the Beneficiary Member will be mailed to the address appearing on the records of The Plan. Notice to The Plan must be sent to Blue Cross and Blue Shield of Montana at the address listed on the inside cover of this Member Guide. Any time periods included in a notice shall be measured from the date the notice was mailed.

A Beneficiary Member or Family Member may reasonably request, in writing, that any communication of the Member's health information be sent to an alternate address or by alternative means should disclosure of any of the Member's health information endanger the Member.

Contract Not Transferable by the Member

No person, other than the Beneficiary Member or a Family Member listed on the subscriber application for membership and accepted by The Plan, is entitled to Benefits under the Group Contract. The Contract is not transferable to any other person.

Rescission of Member Guide

This Member Guide is subject to rescission if the Member commits an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of a material fact, concerning a Member's health, claims history, or current receipt of health care services.

Validity of Contract

If any part, term, or provision of the Group Contract is held by the courts to be illegal or in conflict with or not in compliance with any applicable law of the state of Montana or the United States, the Group Contract shall not be rendered invalid but shall be construed and applied in accordance with such provisions as would have applied had the Contract been in conformance with applicable law and the validity of the remaining portions or provisions shall not be affected. The rights and obligations of the parties shall be construed and enforced as if the Contract did not contain the particular part, term, or provision held to be invalid.

Waiver

The waiver by The Plan of any breach of any provision of the Group Plan will not be construed as a waiver of any subsequent breach of the same or any other provision. The failure of The Plan to exercise any right hereunder will not operate as a waiver of such right. All rights and remedies provided herein are cumulative.

Payment by the Plan

Payment under the Group Contract is not assignable by the Member to any third party. Payment made by The Plan shall satisfy any further obligation of The Plan.

Conformity With State Statutes

The provisions of this Member Guide conform to the minimum requirements of Montana law and have control over any conflicting statutes of any state in which the insured resides on or after the Effective Date of the Group Plan.

Forms for Proof of Loss

The Plan shall furnish, upon written request of a Member claiming to have a loss under the Group Plan, forms of proof of loss for completion by the Member. The Plan shall not, by reason of the requirement to furnish such forms, have any responsibility for or with reference to the completion of such form or the manner of any such completion or attempted completion.

Members Rights

Members have only those rights as specifically provided in the Group Plan. In addition, when requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary

of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

Alternate Care

The Plan may, at its sole discretion, make payment for services which are not listed as a Benefit of the Group Plan in order to provide quality care at a lesser cost. Such payments will be made only upon mutual agreement by the Member and The Plan.

Alternate Dental Benefits

In all cases in which there is more than one Course of Treatment possible, the Benefit will be based upon the most efficient Course of Treatment, as determined by The Plan.

If the Member and Dentist or Physician decide on personalized restorations, or personalized complete or partial dentures and overdentures, or to employ specialized techniques for dental services rather than standard procedures, the Benefits provided will be limited to the Benefit for the standard procedures for Dental Services, as determined by The Plan.

Benefit Maximums

Once The Plan pays the maximum amount for a specific Benefit, no further payment will be made for that specific condition under any other provisions of the Group Plan.

Pilot Programs

The Plan reserves the right to develop and enter into pilot programs under which health care services not normally covered under the Group Plan will be paid. The existence of a pilot program does not guarantee any Member the right to participate in the pilot program or that the pilot program will be permanent.

Fees

The Plan reserves the right to charge the Member a reasonable fee for providing information or documents to the Member which were previously provided in writing to the Member. Fees may be charged for the costs of copying labor, supplies and postage. Fees will not be charged for searching for and retrieving the requested information.

Subrogation

1. To the extent that Benefits have been provided or paid under the Group Plan, The Plan may be entitled to subrogation against a judgment or recovery received by a Member from a third party found liable for a wrongful act or omission that caused the Injury requiring payment for Benefits.
2. The Member will take no action through settlement or otherwise which prejudices the rights and interest of The Plan under the Group Plan.
3. If the Member intends to institute an action for damages against a third party, the Member will give The Plan reasonable notice of intention to institute the action. Reasonable notice will include information reasonably calculated to inform The Plan of facts giving rise to the third party action and of the prospects for recovery.
4. The Member may request that The Plan pay a proportional share of the reasonable costs of the third-party action, including attorney fees. If The Plan elects not to participate in the cost of the action, The Plan waives 50 percent of its subrogation interest.
5. The right of subrogation may not be enforced until the Member has been completely compensated for the injuries.

Statements are Representations

All statements and descriptions in any application shall be considered representations and not warranties. Misrepresentations, omissions, concealment of facts and incorrect statements shall not prevent a recovery under the Member Guide unless:

1. Fraudulent;

2. Material either to the acceptance of the risk or to the hazard assumed by The Plan; or
3. The Plan in good faith would not have issued the Member Guide, would not have issued the Member Guide in as large an amount or at the same premium or rate or would not have provided coverage with respect to the hazard resulting in the loss if the true facts had been made known to The Plan as required either by the application for the Member Guide or otherwise. No statement made for the purpose of effecting coverage shall avoid such coverage or reduce Benefits unless contained in a written instrument signed by the Member, a copy of which has been furnished to such Member.

When the Member Moves Out of State

If the Member moves to an area served by another Blue Cross or Blue Shield plan, the Member's coverage will be transferred to the plan serving the new address. The new plan must offer coverage that is in compliance with the conversion laws of that state. This coverage is that which is normally provided to Members who leave a group and apply for new coverage as individuals. Although subject to the conversion laws of that state, such coverage is usually provided without a medical examination or health statement. If the Member accepts the conversion coverage, the new plan will credit the Member for the length of time of enrollment with Blue Cross and Blue Shield of Montana toward any of its own waiting periods. Any physical or mental conditions covered by The Plan will be covered by the new plan without a new waiting period if the new plan offers this feature to others carrying the same type of coverage. The premium rate and benefits available from the new plan may vary significantly from those offered by The Plan.

The new plan may also offer other types of coverage that are outside of the transfer program. This coverage may require a medical examination or health statement to exclude coverage for preexisting conditions and may not apply time enrolled in Blue Cross and Blue Shield of Montana to waiting periods.

Right to Audit

The Plan reserves the right to audit a Group's employment records to determine whether all employees of the Group are eligible. The Plan further reserves the right to correspond directly with employees to obtain affidavits certifying such eligibility.

Independent Relationship

Participating Providers furnishing care to a Member do so as independent contractors with The Plan; however, the choice of a provider is solely the Member's. Under the laws of Montana, The Plan cannot be licensed to practice medicine or surgery and The Plan does not assume to do so. The relationship between a provider and a patient is personal, private, and confidential. The Plan is not responsible for the negligence, wrongful acts, or omissions of any providers, or provider's employees providing services, or Member receiving services. The Plan is not liable for services or facilities which are not available to a Member for any reason.

Blue Cross and Blue Shield of Montana as an Independent Plan

The Group, on behalf of itself and its employees, hereby expressly acknowledges its understanding that the Group Contract constitutes a contract solely between the Group and The Plan, that The Plan is an independent corporation operating under a license with the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans (the "Association") permitting The Plan to use the Blue Cross and Blue Shield Service Mark in the state of Montana, and that The Plan is not contracting as the agent of the Association. The Group further acknowledges and agrees that it has not entered into the Group Contract based upon representations by any person other than The Plan and that no person, entity, or organization other than The Plan shall be held accountable or liable to the Group for any of The Plan's obligations to the Group created under the Group Contract. This paragraph shall not create any additional obligations whatsoever on the part of The Plan other than those obligations created under other provisions of the Group Contract.

STATEMENT OF ERISA RIGHTS

Statement of ERISA Rights

Note: Any reference in this section to the plan means the Member's group medical benefits plan. The plan administrator is the Member's employer. Plan and plan administrator do not refer to Blue Cross and Blue Shield of Montana in the statement of ERISA rights.

1. As a participant in a group medical benefits plan, the Member is entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974. ERISA provides that all plan participants shall be entitled to:
   - **a.** Examine without charge, at the plan administrator's office and at other specified locations such as work sites, all plan documents, including insurance contracts and copies of all documents filed by the plan with the U.S. Department of Labor, such as annual reports and plan descriptions.
   - **b.** Obtain copies of all plan documents and other plan information upon written request to the plan administrator. The administrator may make a reasonable charge for the copies.
   - **c.** Receive a summary of the plan's annual financial report. The plan administrator is required by law to furnish each participant with a copy of this summary financial report.
2. In addition to creating rights for plan participants, ERISA imposes obligations upon the persons who are responsible for the operation of the plan. These persons, called fiduciaries, have a duty to do so prudently and in the interest of the Member and other Plan participants and beneficiaries.
3. No one, including the Member's employer or any other person, may fire the Member or otherwise discriminate against the Member to prevent the Member from obtaining a welfare benefit or exercising the Member's rights under ERISA.
4. If the Member's claim for a welfare Benefit is denied in whole or part, the Member must receive a written explanation of the reason for the denial. The Member has the right to have the plan administration review and reconsider the Member's claim.
5. Under ERISA there are steps the Member can take to enforce the above rights. For instance, if the Member requests materials from the plan and does not receive them within 30 days, the Member may file suit in a federal court. In such a case, the court may require the plan administrator to provide the materials and pay the Member up to $110 per day until the Member receives the materials unless the materials were not sent because of reasons beyond the control of the administrator.
6. If the Member has a claim for Benefits which is denied or ignored, in whole or in part, the Member may file suit in a state or federal court. If it should happen that plan fiduciaries misuse the plan's money, or if the Member is discriminated against for asserting the Member rights, the Member may seek assistance from the U.S. Department of Labor, or the Member may file suit in a federal court.

   The court will decide who should pay court costs and legal fees. If the Member is successful, the court may order the person the Member has sued to pay these costs and fees. If the Member loses, the court may order the Member to pay these costs and fees; for example, if it finds the Member's claim is frivolous.
7. If the Member has any questions about this statement or the Member's rights under ERISA, the Member should contact the plan administrator or the nearest office of the Employee Benefits Security Administration of the U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210.

DEFINITIONS

This section defines certain words used throughout this Member Guide. These words are capitalized whenever they are used as defined.

ACCIDENT

An unexpected traumatic incident or unusual strain which is:

1. Identified by time and place of occurrence;
2. Identifiable by part of the body affected; and
3. Caused by a specific event on a single day.

Some examples include:

1. Fracture or dislocation.
2. Sprain or strain.
3. Abrasion, laceration.
4. Contusion.
5. Embedded foreign body.
6. Burns.
7. Concussion.

ADVANCED PRACTICE REGISTERED NURSE

Nurses who have additional professional education beyond the basic nursing degree required of a registered nurse and are considered Advanced Practice Registered Nurses by applicable state law. Advanced Practice Registered Nurses include nurse practitioners, nurse-midwives, nurse-anesthetists and clinical nurse specialists.

AFFILIATE/AFFILIATED

Any entity or person who directly or indirectly through one or more intermediaries controls, is controlled by, or under common control with a specified entity or person.

ALLOWABLE FEE

The Allowable Fee is based on, but not limited to, the following:

1. Medicare RBRVS based is a system established by Medicare to pay physicians for a "work unit." The RBRVS value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the Medicare RBRVS system can be considerably less than the nonparticipating providers' billed charge; or
2. Diagnosis-related group (DRG) methodology is a system used to classify hospital cases into one of approximately 500 to 900 groups that are expected to have similar hospital resource use. Payment for each DRG is based on diagnoses, procedures, age, sex, expected discharge date, discharge status, and the presence of complications. The amount of payment for each DRG is generally within a fixed range because each patient is expected to use the same level of hospital resources for the given DRG regardless of the actual hospital resources used. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the DRG system can be considerably less than the nonparticipating providers' billed charge; or
3. Billed charge is the amount billed by the provider; or
4. Case rate methodology is an all inclusive rate for an episode of care for a specific clinical condition paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the Case Rate system can be considerably less than the nonparticipating providers' billed charge; or
5. Per diem methodology is an all inclusive daily rate paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the Per Diem system can be considerably less than the nonparticipating providers' billed charge; or
6. Flat fee per category of service is a fixed payment amount for a category of service. For instance, a category of service could be a delivery, an imaging service, a lab service or an office visit. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the Flat fee per category of service system can be considerably less than the nonparticipating providers' billed charge; or
7. Flat fee per unit of service fixed payment amount for a unit of service, For instance, a unit of service could be the amount of "work units" customarily required for a delivery, or an office visit, or a surgery. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to

nonparticipating providers under the Flat fee per unit system can be considerably less than the nonparticipating providers' billed charge; or

8. Percent off of billed charge is a payment amount where a percentage is deducted from the billed charges; or
9. A percentage of Medicare allowance is a payment amount where a percentage is deducted to the amount that Medicare would allow as payment for the service; or
10. The amount negotiated with the pharmacy benefit manager or manufacturer or the actual price for prescription or drugs; or
11. The American Society of Anesthesiologists' Relative Value Guide is a system established by the American Society of Anesthesiologists to pay anesthesiologists for a "work unit." The payment value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the system can be considerably less than the nonparticipating providers' billed charge.
12. For nonparticipating providers in Montana, the Allowable Fee is developed from base Medicare reimbursements, excluding any Medicare adjustments using information on the claim, and adjusted by a predetermined factor established by the Plan. Such factor will not be less than 100% of the base Medicare reimbursement rate. For services for which a Medicare reimbursement rate is not available, the Allowable Fee for nonparticipating providers will represent an average contract rate for Participating Providers adjusted by a predetermined factor established by the Plan and updated on a periodic basis. Such factor shall not be less than 80% of the average contract rates and will be updated not less than every 2 years. Blue Cross and Blue Shield of Montana will utilize the same claim processing rules and/or edits that it utilizes in processing Participating Provider claims for processing claims submitted by nonparticipating providers which may also alter the Allowable Fee for a particular service. In the event the Plan does not have any claim edits or rules, the Plan may utilize the Medicare claim rules or edits that are used by Medicare in processing the claims. The Allowable Fee will not include any additional payments that may be permitted under the Medicare laws or regulations which are not directly attributable to a specific claim, including but not limited to, disproportionate share and graduate medical education payments.

Any change to the Medicare reimbursement amount will be implemented by the Plan within 90 days after the effective date that such change is implemented by the Centers for Medicaid and Medicare Services, or its successor.

In the event the nonparticipating Allowable Fee does not equate to the nonparticipating provider's billed charges, the Member will be responsible for the difference, along with any applicable Copayment, Coinsurance and Deductible amount. This difference may be considerable. To find out an estimate of the Plan's nonparticipating Allowable Fee for a particular service, Members may call the customer service number shown on the back of their Identification Card.

Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

ALLOWABLE FEE (Dental Services)

The amount determined by the Plan as the maximum amount eligible for payment of Benefits. A participating Dentist agrees to accept payment of the Allowable Fee from the Plan for covered Dental Services, together with any Deductible, Coinsurance and/or Copayment for the Member, as payment in full. Nonparticipating Dentists do not have to accept the Plan's payment as payment in full and can bill the Member for the difference between payment by the Plan and provide charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating Dentist's charges after payment by the Plan and payment of any Deductible, Coinsurance and/or Copayment.

APPLIED BEHAVIOR ANALYSIS (ABA) - (ALSO KNOWN AS LOVAAS THERAPY)

Medically Necessary interactive therapies or treatment derived from evidence-based research. The goal of ABA is to improve socially significant behaviors to a meaningful degree, including:

- increase desired behaviors or social interaction skills;
- teach new functional life, communication, or social, skills;
- maintain desired behaviors, such as teaching self control and self-monitoring procedures;
- appropriate transfer of behavior from one situation or response to another;

- restrict or narrow conditions under which interfering behaviors occur;
- reduce interfering behaviors such as self injury.

ABA therapy and treatment includes Pivotal Response Training, Intensive Intervention Programs, and Early Intensive Behavioral Intervention, and the terms are often used interchangeably. The ABA benefit also includes Discrete Trial Training, a single cycle of behaviorally based instruction routine that is a companion treatment with ABA.

Services must be provided by an appropriately certified provider.

APPROVED CLINICAL TRIAL

Approved clinical trial means a phase I, phase II, phase III, or phase IV, clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other Life-Threatening Condition. The trial must be:

1. Conducted under an investigational new drug application reviewed by the United States Food and Drug Administration;
2. Exempt from an investigational new drug application; or
3. Approved or funded by:
   - The National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, or a cooperative group or center of any of the foregoing entities;
   - A cooperative group or center of the United States Department of Defense or the United States Department of Veterans Affairs;
   - A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes for Health for center support groups; or
   - The United States Departments of Veterans Affairs, Defense, or Energy if the study or investigation has been reviewed and approved through a system of peer review determined by the United States Secretary of Health and Human Services to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and provide unbiased scientific review by individuals who have no interest in the outcome of the review.

BASIC HEALTH BENEFIT PLAN

A health benefit plan, (except a Uniform Health Benefit Plan), developed by a Small Employer carrier that has a lower benefit value than the Small Employer carrier's standard benefit plan and that provides the benefits required under the Small Employer Health Insurance Availability Act.

BENEFICIARY MEMBER

A person in the employee Group who has applied for, been accepted as a Member, and maintains membership in The Plan under the terms of this Member Guide.

BENEFIT

Services, supplies and medications that are provided to a Member and covered under this Member Guide as a Covered Medical Expense or Dental Service.

BENEFIT PERIOD

For the Member Guide - Is the period of time shown in the Schedule of Benefits.

For the Member - Is the same as for the Member Guide except if the Member's Effective Date is after the Effective Date of the Member Guide, the Benefit Period begins on the Member's Effective Date and ends on the same date the Member Guide Benefit Period ends. Thus, the Member's Benefit Period may be less than 12 months.

BEST EVIDENCE

Means evidence based on

1. Randomized Clinical Trials;
2. A Cohort Study or Case-Control Study, if randomized clinical trials are not available;
3. A Case Series, if Randomized Clinical Trials, Cohort Studies or Case-Control Studies are unavailable;
4. An Expert Opinion, if Randomized Clinical Trials, Cohort Studies, Case-Control Studies or Case Series are unavailable.

BLUE CROSS AND BLUE SHIELD OF MONTANA PRIME SPECIALTY NETWORK
Specialty Pharmacy providers who have entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

BRAND-NAME
A drug or product manufactured by a single manufacturer as defined by a nationally recognized provider of drug product database information. There may be some cases where two manufacturers will produce the same product under one license, known as a co-licensed product, which would also be considered as a Brand-Name drug. There may also be situations where a drug's classification changes from Generic to Preferred or Non-preferred Brand-Name due to a change in the market resulting in the Generic drug being a single source, or the drug product database information changing, which would also result in a corresponding change to your payment obligations from Generic to Preferred or Non-preferred Brand-Name.

CARE MANAGEMENT
A process that assesses and evaluates options and services required to meet the Member's health care needs. Care Management may involve a team of health care professionals, including Covered Providers, The Plan and other resources to work with the Member to promote quality, cost-effective care.

CASE-CONTROL STUDY
A retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

CASE SERIES
An evaluation of a series of patients with a particular outcome, without the use of a control group.

CHEMICAL DEPENDENCY
The uncontrollable or excessive use of addictive substances including but not limited to alcohol, morphine, cocaine, heroin, opium, cannabis, barbiturates, amphetamines, tranquilizers and/or hallucinogens, and the resultant physiological and/or psychological dependency which develops with continued use of such addictive substances requiring medical care as determined by a licensed addiction counselor or other appropriate medical practitioner.

CHEMICAL DEPENDENCY TREATMENT CENTER
A treatment facility that provides a program for the treatment of Chemical Dependency pursuant to a written treatment plan approved and monitored by a Physician or addiction counselor licensed by the state. The facility must also be licensed or approved as a Chemical Dependency Treatment Center by the department of health and human services or must be licensed or approved by the state where the facility is located.

CLINICAL PEER
A physician or other health care provider who:

1. holds a nonrestricted license in a state of the United States, and
2. is trained or works in the same or a similar specialty to the specialty that typically manages the medical condition, procedure, or treatment under review.

COHORT STUDY
A prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

COINSURANCE
The percentage of the Allowable Fee payable by the Member for Covered Medical Expenses or Dental Services. The applicable Coinsurance for In-Network Covered Medical Expenses or Dental Services and Out-of-Network Covered Medical Expenses or Dental Services is stated in the Schedule of Benefits.

CONCURRENT CARE
Medical care rendered concurrently with surgery during one Hospital admission by a Physician other than the operating surgeon for treatment of a medical condition different from the condition for which surgery was performed; or

Medical care by two or more Physicians rendered concurrently during one Hospital admission when the nature or severity of the Member's condition requires the skills of separate Physicians.

CONSULTATION SERVICES
Services of a consulting Physician requested by the attending Physician. These services include discussion with the attending Physician and a written report by the consultant based on an examination of the Member.

CONTRACT
This Group Contract, the Group application and any amendments, endorsements, riders, or modifications to the Contract made to it by The Plan. The Group Contract is issued to the employer.

CONVALESCENT HOME
An institution, or distinct part thereof, other than a Hospital, which is licensed pursuant to state or local law. A Convalescent Home is:

1. a skilled nursing facility;
2. an extended care facility;
3. an extended care unit; or
4. a transitional care unit.

A Convalescent Home is primarily engaged in providing continuous nursing care by or under the direction and supervision of a registered nurse for sick or injured persons during the convalescent stage of their Illness or injuries and is not, other than incidentally, a rest home or home for Custodial Care, or for the aged.

NOTE: A Convalescent Home shall not include an institution or any part of an institution otherwise meeting this definition, which is primarily engaged in the care and treatment of Mental Illness or Chemical Dependency.

COPAYMENT
The specific dollar amount payable by the Member for Covered Medical Expenses. The applicable Copayments are stated in the Schedule of Benefits.

COURSE OF TREATMENT
Any number of dental procedures or treatments performed by a Dentist or Physician in a planned series resulting from a dental examination in which the need for such procedures or treatments was determined.

COVERED MEDICAL EXPENSE
Expenses incurred for Medically Necessary services, supplies and medications that are based on the Allowable Fee and:

1. Covered under the Group Plan;
2. In accordance with Medical Policy; and
3. Provided to the Member by and/or ordered by a covered provider for the diagnosis or treatment of an active Illness or Injury or in providing maternity care.

In order to be considered a Covered Medical Expense, the Member must be charged for such services, supplies and medications.

COVERED PROVIDER
A participating or nonparticipating provider which has been recognized by Blue Cross and Blue Shield of Montana as a provider of services for Benefits described in this Member Guide. A provider may, because of the limited scope of practice, be covered only for certain services provided. To determine if a provider is covered, The Plan looks to the nature of the services rendered, the extent of licensure and The Plan's recognition of the provider.

Covered Providers include professional providers and facility providers including Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, nurse specialists, naturopathic physicians, Advanced Practice Registered Nurses, physician assistants, Hospitals and Freestanding Surgical Facilities.

CREDITABLE COVERAGE
Coverage that the Member had for medical benefits under any of the following plans, programs and coverages:

1. a group health plan
2. health insurance coverage
3. Title XVIII, part A or B, of the Social Security Act, 42 U.S.C. 1935c through 1395i-4 or 42 U.S.C. 1395j through 1395w-4 (Medicare)

4. Title XIX of the Social Security Act, 42 U.S.C. 1396a through 1396u, other than coverage consisting solely of a benefit under section 1928, 42 U.S.C. 1396s (Medicaid)
5. Title 10, chapter 55, United States Code (TRICARE)
6. a medical care program of the Indian Health Service or of a tribal organization
7. the Montana Comprehensive Health Association provided for in 33-22-1503 (MCHA)
8. a health plan offered under Title 5, chapter 89, of the United States Code (Federal Employee Health Benefits Program)
9. a public health plan
10. a health benefit plan under Section 5(e) of the Peace Corps Act, 22 U.S.C. 2504(e)
11. a high risk pool in any state

Creditable Coverage does not include coverage consisting solely of coverage of excepted Benefits.

CUSTODIAL CARE

Any service, primarily for personal comfort or convenience, that provides general maintenance, preventive, and/or protective care without any clinical likelihood of improvement of the Member's condition. Custodial Care Services also means those services which do not require the technical skills, professional training and clinical assessment ability of medical and/or nursing personnel in order to be safely and effectively performed. These services can be safely provided by trained or capable non-professional personnel, are to assist with routine medical needs (e.g. simple care and dressings, administration of routine medications, etc.) and are to assist with activities of daily living (e.g. bathing, eating, dressing, etc.).

DEDUCTIBLE

The dollar amount each Member must pay for In-Network Covered Medical Expenses or Dental Services and Out-of-Network Covered Medical Expenses or Dental Services incurred during the Benefit Period before The Plan will make payment for any Covered Medical Expense or Dental Services to which the Deductible applies. The In-Network and Out-of-Network Deductibles are separate and one does not accumulate to the other.

Only the Allowable Fee for Covered Medical Expenses or Dental Services is applied to the Deductible. Thus, Coinsurance, Copayment, noncovered services, and amounts billed by nonparticipating providers do not apply to the Deductible and are the Member's responsibility.

If two or more Members covered under the same Family Membership satisfy the family Deductible as shown on the Schedule of Benefits in a single Benefit Period, the Deductible does not apply for the remainder of that Benefit Period for any Member of the Family Membership.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, only one In-Network or Out-of-Network Deductible will be applied to that Hospital stay (facility charges only). If the Member satisfied the Member's Deductible prior to that Hospital stay, no Deductible will be applied to that stay.

DENTAL PROVIDER

A Dental Provider may be participating or nonparticipating. A participating Dental Provider is a provider who has a contract with Blue Cross and Blue Shield of Montana. These providers agree to accept payment directly from Blue Cross and Blue Shield of Montana for covered dental benefits. This payment, together with the Member's Deductible and Coinsurance described in the Schedule of Benefits, is accepted as payment in full. The Member may obtain a list of participating Dental Providers from Blue Cross and Blue Shield of Montana upon request.

If a Member receives services from a nonparticipating Dental Provider, the Member is responsible for the balance of the nonparticipating provider's bill after payment by Blue Cross and Blue Shield of Montana.

DENTAL SERVICES

Dental services for which allowances are provided in this Contract.

DENTALLY NECESSARY/DENTAL NECESSITY

Those services, supplies, or appliances covered under The Plan which are:

1. Essential to, consistent with, and provided for the diagnosis or the direct care and treatment of the dental condition or injury; and
2. Provided in accordance with and are consistent with generally accepted standards of dental practice in the United States; and

3. Not primarily for the convenience of the Member or his Dentist; and
4. The most economical supplies, appliances, or levels of dental service that are appropriate for the safe and effective treatment of the Member.

DENTIST
A person licensed to practice dentistry in the state where the service is provided.

DENTURIST
A person licensed as a Denturist in the state where the service is provided.

DEPENDENT
1. the Beneficiary Member's Spouse;
2. the Beneficiary Member's Domestic Partner;
3. the Beneficiary Member's unmarried or married child up to age 26, including an eligible foster child;
4. children for whom the Beneficiary Member becomes legally responsible by reason of placement for adoption, as defined in Montana law; or
5. an unmarried child of the Beneficiary Member who is 26 years of age or older and disabled.

For purposes of this Member Guide the unmarried child will be considered disabled if the child:

1. was covered under this Member Guide before age 26;
2. cannot support himself/herself because of intellectual disability or physical disability; and
3. is legally dependent on the Beneficiary Member for support.

Proof of those qualifications must be supplied to The Plan within 31 days following the child's 26th birthday. Although there is no limiting age for disabled children, The Plan reserves the right to require periodic certification from the Beneficiary Member of such incapacity and dependency. Certification will not be requested more frequently than annually after the two-year period following the child's 26th birthday.

DOMESTIC PARTNER
A person that meets the following definition:

1. Neither partner is currently "married" to another;
2. The partners are at least 18 years of age;
3. The partners are not related by blood to a degree that would bar marriage in the State of Montana;
4. The partners are each other's sole Domestic Partner and intend to remain so indefinitely; and
5. The partners are responsible for each other's common welfare and have a financial interdependent relationship evidenced by any of the following:
   a. Mutually granted financial or health care powers of attorney;
   b. Designation of each other as primary beneficiary in wills, life insurance policies or retirement plans;
   c. Executed a joint lease, mortgage or deed; or
   d. Have joint ownership of a banking account

DRUG LIST
A list that identifies those Prescription Drug Products that are covered by The Plan for dispensing to Members when appropriate. This list is reviewed quarterly and subject to modification. Details can be found on the pharmacy page at www.bcbsmt.com or by visiting www.myprime.com.

EFFECTIVE DATE
For a Member - the Effective Date of a Member's coverage means the date the Member:

1. has met the requirements of The Plan stated in this Member Guide; and
2. is shown on the records of The Plan to be eligible to receive Benefits.

For the Member Guide - the Effective Date of the Member Guide is the date shown on the face of this Member Guide

For any endorsement, rider, or amendment - the Effective Date is the date shown on the Member Guide unless otherwise shown on the endorsement, rider and amendment.

EMERGENCY MEDICAL CONDITION

A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition that places the health of the individual in serious jeopardy, would result in serious impairment to bodily functions, or serious dysfunction of any bodily organ or part; or with respect to a pregnant woman having contractions, that there is inadequate time to safely transfer the woman to another hospital for delivery or that a transfer may pose a threat to the health or safety of the woman or the unborn fetus.

EMERGENCY SERVICES

Services, medicines or supplies furnished or required to evaluate and treat an Emergency Medical Condition.

ERISA

The Employee Retirement Income Security Act of 1974, as amended and all regulations applicable thereto.

EVIDENCE-BASED STANDARD

The conscientious, explicit, and judicious use of the current Best Evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

EXCLUSION

A provision which states that The Plan has no obligation under this Member Guide to make payment.

EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN

A drug, device, biological product or medical treatment or procedure is Experimental, Investigational and/or Unproven if **The Plan determines** that:

- The drug, device, biological product or medical treatment or procedure cannot be lawfully marketed without approval of the appropriate governmental or regulatory agency and approval for marketing has not been given at the time the drug, device, biological product or medical treatment or procedure is furnished; or
- The drug, device, biological product or medical treatment or procedure is the subject of ongoing phase I, II or III clinical trials, or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or
- The prevailing opinion among peer reviewed medical and scientific literature regarding the drug, device, biological product or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

EXPERT OPINION

A belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

FAMILY MEMBER

A Dependent who has been accepted as a Member of the plan and enrolled by a Beneficiary Member.

FAMILY MEMBERSHIP

The family unit including the Beneficiary Member and all Family Members who have been accepted as Members of The Plan.

FREESTANDING INPATIENT FACILITY

For treatment of Chemical Dependency, it means a facility which provides treatment for Chemical Dependency in a community-based residential setting for persons requiring 24-hour supervision and which is a Chemical Dependency Treatment Center. Services include medical evaluation and health supervision; Chemical Dependency education; organized individual, group and family counseling; discharge referral to Medically Necessary supportive services; and a client follow-up program after discharge.

For treatment of Mental Illness, it means a facility licensed by the state and specializing in the treatment of Mental Illness.

GENERIC
A drug that has the same active ingredient as a Brand-Name drug and is allowed to be produced after the Brand-Name drug's patent has expired. In determining the brand or generic classification for covered drugs, Blue Cross and Blue Shield of Montana uses the generic/brand status assigned by a nationally recognized provider of drug product database information. A list of Preferred Generic drugs is available on the Blue Cross and Blue Shield of Montana website at www.bcbsmt.com. The Member may also contact Customer Service for more information.

GROUP
The organization, employer, or trust to which the Contract has been issued and includes the Beneficiary Members and their Family Members.

GROUP PLAN
The Contract between Blue Cross and Blue Shield of Montana and the Group.

HABILITATIVE CARE
Coverage will be provided for Habilitative Care services when the Member requires help to keep, learn or improve skills and functioning for daily living. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. other services for people with disabilities. These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

HOME HEALTH AGENCY
An agency licensed by the state which provides home health care to Members in the Member's home.

HOME HEALTH AIDE
A nonprofessional worker who has been trained for home care of the sick and is employed by a Home Health Agency.

HOME INFUSION THERAPY AGENCY
A health care provider that provides home infusion therapy services.

HOSPITAL
A facility providing, by or under the supervision of licensed Physicians, services for medical diagnosis, treatment, rehabilitation and care of injured, disabled, or sick individuals. A Hospital has an organized medical staff that is on call and available within 20 minutes, 24 hours a day, 7 days a week and provides 24-hour nursing care by licensed registered nurses.

ILLNESS
An alteration in the body or any of its organs or parts which interrupts or disturbs the performance of a vital function, thereby causing or threatening pain or weakness.

IN-NETWORK
Providers who are:

1. Participating Blue Cross and Blue Shield of Montana Professional Providers;
2. Participating Blue Cross and Blue Shield of Montana Facility Providers, except for Hospitals and surgery centers;
3. PPO Hospitals and surgery centers; or
4. Blue Cross and/or Blue Shield PPO providers outside of Montana.

INCLUSIVE SERVICES/PROCEDURES
A portion of a service or procedure which is necessary for completion of the service or procedure or a service or procedure which is already described or considered to be part of another service or procedure.

INJURY
Physical damage to an individual's body, caused directly and independent of all other causes. An Injury is not caused by an Illness, disease or bodily infirmity.

INPATIENT CARE

Care provided to a Member who has been admitted to a facility as a registered bed patient and who is receiving services, supplies and medications under the direction of a Covered Provider with staff privileges at that facility. Examples of facilities to which a Member might be admitted include:

1. Hospitals;
2. Transitional care units;
3. Skilled nursing facilities;
4. Convalescent homes;
5. Freestanding inpatient facilities.

INPATIENT MEMBER

A Member who has been admitted to a facility as a registered bed patient for Inpatient Care.

LIFE-THREATENING CONDITION

Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

MEDICAL FOODS

Nutritional substances in any form that are:

1. formulated to be consumed or administered enterally under supervision of a Physician;
2. specifically processed or formulated to be distinct in one or more nutrients present in natural food;
3. intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or certain nutrients contained in ordinary foodstuffs or who have other specific nutrient requirements as established by medical evaluation; and
4. essential to optimize growth, health, and metabolic homeostasis.

MEDICAL OR SCIENTIFIC EVIDENCE

Evidence found in the following sources:

1. peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
2. peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's library of medicine for indexing in Index Medicus and Excerpta Medica, published by the Reed Elsevier group;
3. medical journals recognized by the Secretary of Health and Human Services under 42 U.S.C. 1395x(t)(2)(B) of the federal Social Security Act;
4. the following standard reference compendia:
   a. the American Hospital Formulary Service Drug Information;
   b. Drug Facts and Comparisons;
   c. the American Dental Association Guide to Dental Therapeutics; and
   d. the United States Pharmacopeia;
5. findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
   a. the federal Agency for Healthcare Research and Quality;
   b. the national Institutes of Health;
   c. the National Cancer Institute;
   d. the National Academy of Sciences;
   e. the Centers for Medicare and Medicaid Services;
   f. the Food and Drug Administration; and
   g. any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or
6. any other medical or scientific evidence that is comparable to the sources listed in subsection 4 or 5.

MEDICAL POLICY

The policy of The Plan which is used to determine if health care services including medical and surgical procedures, medication, medical equipment and supplies, processes and technology meet the following nationally accepted criteria:

1. final approval from the appropriate governmental regulatory agencies;
2. scientific studies showing conclusive evidence of improved net health outcome; and
3. in accordance with any established standards of good medical practice.

MEDICALLY NECESSARY (FOR AUTISM, ASPERGER'S DISORDER AND PERVASIVE DEVELOPMENTAL DISORDER)

Any care, treatment, intervention, service, or item that is prescribed, provided or ordered by a Physician or psychologist and that will or is reasonably expected to:

1. Prevent the onset of an Illness, condition, Injury, or disability;
2. Reduce or improve the physical, mental, or developmental effects of an Illness, condition, or Injury, or disability; or
3. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (FOR DOWN SYNDROME)

Any care, treatment, intervention, service, or item that is prescribed, provided, or ordered by a Physician licensed in this state and that will or is reasonably expected to:

1. Reduce or improve the physical, mental, or developmental effects of Down syndrome; or
2. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (OR MEDICAL NECESSITY)

Health care services that a Physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an Illness, Injury, disease or its symptoms, and that are:

1. in accordance with generally accepted standards of medical practice;
2. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's Illness, Injury or disease; and
3. not primarily for the convenience of the patient, Physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the view of Physicians practicing in relevant clinical areas and any other relevant factors.

The fact that services were recommended or performed by a Covered Provider does not automatically make the services Medically Necessary. The decision as to whether the services were Medically Necessary can be made only after the Member receives the services, supplies, or medications and a claim is submitted to The Plan. The Plan may consult with Physicians or national medical specialty organizations for advice in determining whether services were Medically Necessary.

MEMBER

Both the Beneficiary Member and Family Members.

MEMBER GUIDE

The summary of Benefits issued to a Member that describes the Benefits available under the Group Plan.

MEMBER'S IMMEDIATE FAMILY

The Member's Spouse and children or parents and siblings who are caring for the hospice patient in that family.

MENTAL HEALTH TREATMENT CENTER

A treatment facility organized to provide care and treatment for Mental Illness through multiple modalities or techniques pursuant to a written treatment plan approved and monitored by an interdisciplinary team, including a licensed Physician, psychiatric social worker and psychologist. The facility must be:

1. licensed as a mental health treatment center by the state;
2. funded or eligible for funding under federal or state law; or
3. affiliated with a Hospital under a contractual agreement with an established system for patient referral.

MENTAL ILLNESS

A clinically significant behavioral or psychological syndrome or pattern that occurs in a person and that is associated with:

1. present distress or a painful symptom;
2. a disability or impairment in one or more areas of functioning; or
3. a significantly increased risk of suffering death, pain, disability, or an important loss of freedom.

Mental Illness must be considered as a manifestation of a behavioral, psychological, or biological dysfunction in a person.

Mental Illness does not include:

1. developmental disorders;
2. speech disorders;
3. psychoactive substance use disorders;
4. eating disorders (except for bulimia and anorexia nervosa);
5. impulse control disorders (except for intermittent explosive disorder and trichotillomania); or
6. Severe Mental Illness.

MONTH

For the purposes of this Member Guide, a Month has 30 days even if the actual calendar Month is longer or shorter.

MULTIDISCIPLINARY TEAM

A group of health service providers who are either licensed, certified, or otherwise approved to practice their respective professions in the state where the services are provided. Members of the Multidisciplinary Team may include, but are not limited to, a licensed psychologist, licensed speech therapist, registered physical therapist, or licensed occupational therapist.

OCCUPATIONAL THERAPY

Therapy involving the treatment of neuromusculoskeletal and psychological dysfunction through the use of speech tasks or goal-directed activities designed to improve the functional performance of an individual.

ORTHOPEDIC DEVICES

Rigid or semirigid supportive devices which restrict or eliminate motion of a weak or diseased body part. Orthopedic Devices are limited to braces, corsets and trusses.

OUT-OF-NETWORK

Providers who are:

1. Non-participating professional providers;
2. Non-participating facility providers;
3. Non-PPO Network Hospitals and surgery centers; or
4. Blue Cross and Blue Shield of Montana Participating Hospitals and surgery centers that are not in the PPO Network.

OUT OF POCKET AMOUNT

For the Member:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance each Member must pay for Covered Medical Expenses and Dental Services incurred during the Benefit Period. Once the Member has satisfied the applicable Out of Pocket Amount, the Member will not be

required to pay the Member's Deductible, Coinsurance and Copayment for Covered Medical Expenses and Dental Services for the remainder of that Benefit Period. The Out of Pocket Amount for the Member is listed in the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, the Deductible and Coinsurance for the entire Hospital stay (facility charges only) will only apply to the Out of Pocket Amount of the Benefit Period in which the inpatient stay began. If the Member satisfied the Out of Pocket Amount prior to that Hospital stay, no Deductible or Coinsurance will be applied to that stay.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

For the Family:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance for Covered Medical Expenses and Dental Services a Family Membership must pay for services incurred during that Benefit Period. Once the Deductible, Coinsurance and Copayment paid by the Member during the Benefit Period for two or more Family Members covered under the same Family Membership total the applicable Out of Pocket Amount for the family, the Members covered under the same Family Membership will not be required to pay the Deductible, Coinsurance and Copayment for Covered Medical Expenses and Dental Services the remainder of that Benefit Period. The Out of Pocket Amount for the family is listed on the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other. For family coverage when only two Members are enrolled, the two Members each must meet their Individual Out of Pocket Amounts only.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

OUTPATIENT

Services or supplies provided to the Member by a Covered Provider while the Member is not an Inpatient Member.

PARTIAL HOSPITALIZATION

A time-limited ambulatory (Outpatient) program offering active treatment which is therapeutically intensive, encompassing structured clinical services within a stable, therapeutic program. The program can involve day, evening and weekend treatment. The underlying aim of this treatment is stabilization of clinical instability resulting from severe impairment and/or dysfunction in major life areas.

A Partial Hospitalization program should offer four to eight hours of therapy five days a week. The hours of therapy per day and the frequency of visits per week will vary depending on the clinical symptoms and progress being made with each individual.

PARTICIPATING BLUE CROSS AND BLUE SHIELD OF MONTANA FACILITY PROVIDER

A facility which has a contract with Blue Cross and Blue Shield of Montana and may include, but are not limited to, Hospitals, home health agencies, Convalescent Homes, skilled nursing facilities, Freestanding Inpatient Facilities and freestanding surgical facilities. Please read the section entitled Providers of Care for Members.

PARTICIPATING BLUE CROSS AND BLUE SHIELD OF MONTANA PROFESSIONAL PROVIDER

A provider who has a contract with Blue Cross and Blue Shield of Montana and may include, but are not limited to, Physicians, physician assistants, nurse specialists, dentists, podiatrists, speech therapists, physical therapists and occupational therapists. Please read the section entitled Providers of Care for Members.

PARTICIPATING PHARMACY

A pharmacy which has entered into an agreement with the pharmacy benefit manager to provide Prescription Drug Products to Members and has agreed to accept specified reimbursement rates. Participating Pharmacies may be Value Participating Pharmacies or Participating Pharmacies.

PARTICIPATING PROVIDER
A Participating Blue Cross and Blue Shield of Montana Professional Provider or a Participating Blue Cross and Blue Shield of Montana Facility Provider.

PHYSICAL THERAPY
Treatment of disease or injury by the use of therapeutic exercise and other interventions that focus on improving posture, locomotion, strength, endurance, balance, coordination, joint mobility, flexibility, functional activities of daily living and pain relief.

PHYSICIAN
A person licensed to practice medicine in the state where the service is provided.

PLAN - THE PLAN
Blue Cross and Blue Shield of Montana, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company.

PPO-A PREFERRED PROVIDER ORGANIZATION
A provider or group of providers which have contracted with The Plan to provide services to Members covered under PPO Benefit Contracts.

PPO NETWORK
A provider or group of providers which have a PPO contract with Blue Cross Blue Shield of Montana. The Member may obtain a list of PPO providers from Blue Cross Blue Shield of Montana upon request. Payment to a non-PPO Network provider is subject to the non-PPO Network provider reduction shown in the Schedule of Benefits and the Special Provisions section of this document.

PREAUTHORIZATION
The process that determines in advance the Medical Necessity or Experimental, Investigational and/or Unproven nature of certain care and services under the Member Guide. Preauthorization is used to inform the Member whether or not a proposed service, medication, supply, or on-going treatment is Medically Necessary and is a Covered Medical Expense of the Member Guide.

Preauthorization does not guarantee that the care and services a Member receives are eligible for Benefits under the Member Guide. At the time the Member's claims are submitted, they will be reviewed in accordance with the terms of the Member Guide.

PREFERRED BRAND-NAME
A covered non-specialty Brand-Name drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Brand Name drug tier payment level.

PREFERRED GENERIC
A covered Generic drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Generic drug tier payment level.

PRESCRIPTION DRUG PRODUCT
A medication, product or device approved by the Food and Drug Administration.

PROFESSIONAL CALL
An interview between the Member and the professional provider in attendance. The professional provider must examine the Member and provide or prescribe medical treatment. "Professional Call" does not include telephone calls or any other communication where the Member is not examined by the professional provider, except as included in the Benefit section entitled Telemedicine.

PROOF OF LOSS
The documentation accepted by Blue Cross and Blue Shield of Montana upon which payment of Benefits is made.

QUALIFIED INDIVIDUAL (For an Approved Clinical Trial)

An individual with group health coverage or group or individual health insurance coverage who is eligible to participate in an Approved Clinical Trial according to the trial protocol for the treatment of cancer or other Life-Threatening Condition because:

1. The referring health care professional is participating in the clinical trial and has concluded that the individual's participation in the trial would be appropriate; or
2. The individual provides medical and scientific information establishing that the individual's participation in the clinical trial is appropriate because the individual meets the conditions described in the trial protocol.

RANDOMIZED CLINICAL TRIAL

A controlled, prospective study of patients who have been assigned at random to an experimental group or a control group at the beginning of the study with only the experimental group of patients receiving a specific intervention. The term includes a study of the groups for variables and anticipated outcomes over time.

RECONSTRUCTIVE BREAST SURGERY

Surgery performed as a result of a mastectomy to reestablish symmetry between the breasts. The term includes augmentation mammoplasty, reduction mammoplasty, and mastopexy.

RECOVERY CARE BED

A bed occupied in an Outpatient surgical center for less than 24 hours by a patient recovering from surgery or other treatment.

REHABILITATION FACILITY

A facility, or a designated unit of a facility, licensed, certified or accredited to provide Rehabilitation Therapy including:

1. A facility that primarily provides Rehabilitation Therapy, regardless of whether the facility is also licensed as a Hospital or other facility type;
2. A freestanding facility or a facility associated or co-located with a Hospital or other facility;
3. A designated rehabilitation unit of a Hospital;
4. For purposes of the Rehabilitation Therapy Benefit, any facility providing Rehabilitation Therapy to a Member, regardless of the category of facility licensure.

REHABILITATION THERAPY

A specialized, intense and comprehensive program of therapies and treatment services (including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy) provided by a Multidisciplinary Team for treatment of an Injury or physical deficit. A Rehabilitation Therapy program is:

1. provided by a Rehabilitation Facility in an Inpatient Care or outpatient setting;
2. provided under the direction of a qualified Physician and according to a formal written treatment plan with specific goals;
3. designed to restore the patient's maximum function and independence; and
4. Medically Necessary to improve or restore bodily function and the Member must continue to show measurable progress.

REHABILITATIVE CARE

Coverage will be provided for Rehabilitative Care services when the Member requires help to keep, get back or improve skills and functioning for daily living that have been lost or impaired because the Member was sick, hurt or disabled. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. psychiatric rehabilitation.

These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

RESIDENTIAL TREATMENT CENTER

A facility setting offering a defined course of therapeutic intervention and special programming in a controlled environment which also offers a degree of security, supervision, structure and is licensed by the appropriate state and local authority to provide such service. It does not include half-way houses, wilderness programs, supervised

living, group homes, boarding houses or other facilities that provide primarily a supportive environment and address long-term social needs, even if counseling is provided in such facilities. Patients are medically monitored with 24 hour medical availability and 24 hour onsite nursing service for patients with Mental Illness and/or Chemical Dependency. Requirements: Blue Cross and Blue Shield of Montana requires that any Mental Illness and/or Substance Use Disorder Residential Treatment Center must be licensed in the state where it is located, or accredited by a national organization that is recognized by Blue Cross and Blue Shield of Montana as set forth in its current credentialing policy, and otherwise meets all other credentialing requirements set forth in such policy.

ROUTINE

Examinations or services provided when there is no objective indication of impairment of normal bodily function. Routine does not include the diagnosis or treatment of any Injury or Illness.

ROUTINE PATIENT COSTS

All items and services covered by a group health plan or a plan of individual or group health insurance coverage when the items or services are typically covered for a Qualified Individual who is not enrolled in an Approved Clinical Trial. The term does not include:

1. An investigational item, device, or service that is part of the trial;
2. An item or service provided solely to satisfy data collection and analysis needs for the trial if the item or service is not used in the direct clinical management of the patient; or
3. A service that is clearly inconsistent with widely accepted and established standards of care for the individual's diagnosis.

SEVERE MENTAL ILLNESS

The following disorders as defined by the American psychiatric association:

1. schizophrenia;
2. schizoaffective disorder;
3. bipolar disorder;
4. major depression;
5. panic disorder;
6. obsessive-compulsive disorder; and
7. autism.

Coverage for a child with autism who is 18 years of age or younger is provided under the Autism Spectrum Disorders Benefit if the child is diagnosed with:

1. Autistic Disorder;
2. Asperger's Disorder; or
3. Pervasive Developmental Disorder not otherwise specified.

SMALL EMPLOYER

A person, firm, corporation, partnership, or bona fide association that:

1. Is actively engaged in business; and
2. With respect to a calendar year and a plan year, employed at least 1 but not more than 50 Eligible Employees during the preceding calendar year and employed at least two employees on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small or large employer must be based on the average number of employees reasonably expected to be employed by the employer in the current calendar year.

In determining the number of eligible employees, companies are considered one employer if they are:

1. Affiliated companies;
2. Eligible to file a combined tax return for purposes of state taxation; or
3. Members of a bona fide association.

SPECIALTY MEDICATIONS

High cost, hard to manage injectables, select orals, and/or infused therapies that are administered by the patient or Physician for the treatment of chronic Illness.

SPECIALTY PHARMACY

A pharmacy which has entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

SPEECH THERAPY

The treatment of communication impairment and swallowing disorders.

SPOUSE

The opposite sex or the same sex person to whom the Beneficiary Member is legally married, based upon the law in effect at the time of and in the state or other appropriate jurisdiction in which the marriage was performed, recognized, or declared.

TELEMEDICINE

Telemedicine means the use of interactive audio, video, or other telecommunications technology that is:

1. Used by a health care provider or health care facility to deliver health care services at a site other than the site where the patient is located; and
2. Delivered over a secure connection that complies with the requirements of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.

The term includes the use of electronic media for consultation relating to the health care diagnosis or treatment of a patient in real time or through the use of store-and-forward technology. The term does not include the use of audio-only telephone, e-mail, or facsimile transmissions.

Notice That Lifetime Limit No Longer Applies and Enrollment Opportunity

The lifetime limit on the dollar value of benefits under this group health plan coverage no longer applies. Individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to reenroll in the plan. Individuals have 30 days beginning with the start of the plan year to request enrollment.

Enrollment will be effective retroactively to the first day of the plan year beginning on or after September 23, 2010.

Notice of Opportunity to Enroll in connection with Extension of Dependent Coverage to Age 26

Children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage for children ended before attainment of age 26 are eligible to enroll in this group health coverage, regardless of student status, financial dependency or marital status. Individuals may request enrollment for such children for 30 days beginning with the start of the plan year.

Enrollment will be effective retroactively to the first day of the plan year beginning on or after September 23, 2010.

For additional information regarding these notices, contact:

Blue Cross and Blue Shield of Montana
3645 Alice Street
Helena, MT 59601
1-800-447-7828

BlueCross BlueShield of Montana

Blue Cross and Blue Shield of Montana
3645 Alice Street
P.O. Box 4309
Helena, MT 59604-4309

PET EXHIBIT 1-107

EXHIBIT
2
exhibitsticker.com

PET EXHIBIT 2-108

Blue Cross Blue Shield of Montana

P.O. Box 3238
Naperville, IL 60566-7238
Address Service Requested

May 10, 2017

BARRY BRIGGS
PO BOX 82
DILLON, MT 59725

Subject:
Your kit is enclosed

Member ID:
928040327

To contact us: 1-855-258-8471

Dear BARRY BRIGGS,

Enclosed is the copy of the policy fulfillment kit you requested. The kit includes all the latest updated material.

Our goal is to serve your health insurance needs through all of life's changes. If you have any questions, feel free to call us at the number above.

Sincerely,

Your Customer Advocates
Blue Cross and Blue Shield of Montana

Enclosure

We're happy to provide our letters, at no cost, in Spanish, Tagalog, Chinese, Navajo, or Braille.

- **Español:** Para asistencia en Español, por favor llame al numero ubicado en la parte posterior de su tarjeta de identificación.
- **Tagalog:** Upang humingi ng tulong sa Tagalog, paki tawagan ang numero na nakasulat sa inyong kard.
- **中文:** 如果需要中文幫助，請撥打您卡上的電話號碼。
- **Dine:** Dinék'ehji áka'a'doowoo.ł biniiyé, t'áá shǫǫdi koji' hodíilnih béésh bee hane'í bi nanbo bee néé ho'dólzinígíí biniiyé nanitinígíí bine'dęę' bikáá'

BlueCross BlueShield of Montana

Frequently Asked Questions

How do I make changes to my policy, plan or personal information?

If you bought your plan directly from us, you can call us at the Customer Service number listed on your member ID card. We can help you make the changes you need.

If you have a Marketplace plan, any changes will have to be made through the Marketplace. You can log into your account online at healthcare.gov or call the Marketplace toll free at 800-318-2596.

Some changes, such as adding or dropping a dependent, could change your monthly premium.

How do I sign up for Blue Access for Members℠?

Blue Access for Members gives you easy access to your account information.

1. Click on "Log In" at the top of our website at www.bcbsmt.com.
2. Click.on "Register Now."
3. You'll need your member ID card, your ZIP code and your email address to sign up.

How do I make my monthly premium payment?

You can pay your premium by bank draft, with check or money order, using a debit card, or with cash. You can also set up automatic monthly payments using electronic funds transfer by calling Customer Service at the number listed on your member ID card. Find out how at www.bcbsmt.com/member/payment-options.

What is the "Standard Authorization Form to Use or Disclose Protected Health Information (PHI)"?

This form allows BCBSMT to disclose certain health information to the organization(s) or person(s) you name. For example, you may want to allow BCBSMT to provide your claims information to another person, such as a family member. You can sign the form for yourself or on behalf of a minor dependent child.

The form is included with your package for your convenience only. If you decide to use the form, please review it with care.

Am I covered when I travel?

Some BCBSMT plans offer coverage while traveling through BlueCard®, our unique program that gives members access to contracting doctors and hospitals outside a plan's service area, across the nation and around the world.

BlueCard coverage will differ based on your plan and on whether you choose a doctor or hospital in a BCBS network. Be sure to call Customer Service at the number on the back of your member ID card before your trip to find out what you can do if you need care while away from home. Log in to Blue Access for Members for details.

BlueCross BlueShield of Montana

At a Glance

Summary of your Blue Cross and Blue Shield of Montana health insurance coverage

Medical Plan Name: Blue Preferred Gold PPO
Network: Blue Preferred
Identification Number: 928040327
Coverage Date: 01/01/2017
Termination Date: 12/31/2017
Method of Payment: Monthly

Covered Members:
BARRY J BRIGGS
MARY ANNE ANNE BRIGGS

Translation and TTY services available for our members

To assist our members with special communication needs, and if your first language is not English, you can obtain assistance for the following:

- Members may ask to speak to a bilingual staff member (English or Spanish) by calling the Customer Service number on the back of your member ID card.
- Members may ask for access to a telephone-based translation service to assist with other languages.
- Some written forms and member materials are available in Spanish through our Customer Service
- BCBS provides TDD/TTY services and language assistance for incoming callers for deaf, hard-of-hearing and speech-disabled members:
    - Members can call 1-406-444-4212
    - Members can utilize their Teletypewriter (TTY) or Telecommunication Device (TDD) to access a teletype operator.

Deaf, hard-of-hearing and speech-disabled members:

- Members can utilize their Telecommunication Device (TDD) to access a teletype operator.

Thank you for choosing Blue Cross and Blue Shield of Montana.

BlueCross BlueShield of Montana

If you, or someone you are helping, have questions, you have the right to get help and information in your language at no cost. To talk to an interpreter, call 855-258-8471.

العربية Arabic	إن كان لديك أو لدى شخص تساعده أسئلة، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم فوري، اتصل على الرقم 855-258-8471.
繁體中文 Chinese	如果您, 或您正在協助的對象, 對此有疑問, 您有權利免費以您的母語獲得幫助和訊息 洽詢一位翻譯員, 請撥電話 號碼 855-258-8471。
Français French	Si vous, ou quelqu'un que vous êtes en train d'aider, avez des questions, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 855-258-8471.
Deutsch German	Falls Sie oder jemand, dem Sie helfen, Fragen haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 855-258-8471 an.
Italiano Italian	Se tu o qualcuno che stai aiutando avete domande, hai il diritto di ottenere aiuto e informazioni nella tua lingua gratuitamente. Per parlare con un interprete, puoi chiamare il numero 855-258-8471.
日本語 Japanese	ご本人様、またはお客様の身の回りの方でも、ご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、855-258-8471までお電話ください。
한국어 Korean	만약 귀하 또는 귀하가 돕는 사람이 질문이 있다면 귀하는 무료로 그러한 도움과 정보를 귀하의 언어로 받을 수 있는 권리가 있습니다. 통역사가 필요하시면 855-258-8471로 전화하십시오.
Diné Navajo	T'áá ni, éí doodago ła'da bíká anánílwo'ígíí, na'ídíłkidgo, ts'ídá bee ná ahóóti'i' t'áá níík'e níká a'doolwoł dóó bína'ídíłkidígíí bee nił hodoonih. Ata'dahalne'ígíí bich'į' hodíílnih kwe'é 855-258-8471.
Norsk Norwegian	Hvis du, eller noen du hjelper, har spørsmål, har du rett til å få hjelp og informasjon på ditt språk uten kostnad. For å snakke med en tolk, ring 855-258-8471.
Pennsilfaanisch Deitsch Pennsylvanian-Dutch	Wann du, odder ebber as du an helfe bischt, Questions hoscht, hoscht du's Recht fer Hilf un Information griege in dei eegni Schprooch as nix koschte zellt. Wann du mit en Interpreter schwetze wettscht, kannscht du 855-258-8471 uffrufe.
Русский Russian	Если у вас или человека, которому вы помогаете, возникли вопросы, у вас есть право на бесплатную помощь и информацию, предоставленную на вашем языке. Чтобы связаться с переводчиком, позвоните по телефону 855-258-8471.
Español Spanish	Si usted o alguien a quien usted está ayudando tiene preguntas, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 855-258-8471.
Tagalog Tagalog	Kung ikaw, o ang isang taong iyong tinutulungan ay may mga tanong, may karapatan kang makakuha ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang tagasalin-wika, tumawag sa 855-258-8471.
ไทย Thai	หากคุณ หรือคนที่คุณกำลังช่วยเหลือมีข้อสงสัยใด ๆ คุณมีสิทธิ์ที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่มีค่าใช้จ่าย พูดคุยกับล่ามโดยติดต่อที่หมายเลข 855-258-8471.
Українська Ukrainian	Якщо у Вас чи у когось, хто отримує Вашу допомогу, виникають питання, у Вас є право отримати безкоштовну допомогу та інформацію Вашою рідною мовою. Щоб зв'язатись з перекладачем, зателефонуйте за номером 855-258-8471.
Tiếng Việt Vietnamese	Nếu quý vị, hoặc người mà quý vị đang giúp đỡ, có câu hỏi, thì quý vị có quyền được giúp và nhận thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 855-258-8471.

Health care coverage is important for everyone.

We provide free communication aids and services for anyone with a disability or who needs language assistance.
We do not discriminate on the basis of race, color, national origin, sex, gender identity, age or disability.

To receive language or communication assistance free of charge, please call us at 855-710-6984.

If you believe we have failed to provide a service, or think we have discriminated in another way, contact us to file a grievance.

Office of Civil Rights Coordinator
300 E. Randolph St.
35th Floor
Chicago, Illinois 60601

Phone: 855-664-7270 (voicemail)
TTY/TDD: 855-661-6965
Fax: 855-661-6960
Email: CivilRightsCoordinator@hcsc.net

You may file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, at:

U.S. Dept. of Health & Human Services
200 Independence Avenue SW
Room 509F, HHH Building 1019
Washington, DC 20201

Phone: 800-368-1019
TTY/TDD: 800-537-7697
Complaint Portal: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf
Complaint Forms: http://www.hhs.gov/ocr/office/file/index.html

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Blue Cross Blue Shield of Montana

EZ Blue Payment Option

Automatic Premium Payment Authorization Agreement

Take these simple steps for hassle-free monthly premium payments:

- Verify with your financial institution that it can accept automated electronic withdrawals.
- Complete this request online by going to bcbsmt.com and logging in to Blue Access for Members℠.
- If submitting by fax, please fax this form to **888-697-0686.**
- If submitting this form by mail, please use this address:

Blue Cross and Blue Shield of Montana
P.O. Box 3236
Naperville, IL 60566-9708

If you have any questions about this program, please call our Member Service Department toll-free at **855-258-8471.**

AGREEMENT

I request and authorize Blue Cross and Blue Shield of Montana (BCBSMT) and/or its designee to obtain payment of amounts becoming due by initiating charges to my account in the form of checks, share drafts, or electronic debit entries, and I request and authorize the Financial Institution named below to accept and honor the same to my account. As the account holder, by signing below, I also certify, in the event that this draft is being drawn from a company checking account, that I am authorized to approve this transaction, that the company is not paying any portion of the premium for this subscriber, either directly, or through reimbursement, and that the employer/company is not deducting any part of the premium from gross income under section 106 or section 162 of the Internal Revenue Code. I understand that both the financial institution and BCBSMT reserve the right to terminate this payment program and/or my participation therein. I also understand that I may discontinue this payment program at any time with at least 10 days advance notice to Blue Cross and Blue Shield of Montana by telephone prior to a scheduled withdrawal date.

Please complete the following:

☐ **Yes** ☐ **No** Deduct ongoing monthly premium payments only from my checking or savings account. Drafts will be drawn on the last day of each month, for the following month of coverage. If the draft date falls on a non-business day or a holiday, the premium payment will be deducted from my account on the next business day. Please ensure adequate funds are available at the time of application. Blue Cross and Blue Shield of Montana is not responsible for fees incurred due to insufficient funds. Select one of the following draft options.

☐ 1 MONTH BANK DRAFT PREMIUM AMOUNT EACH TIME
(12 PAYMENTS PER YEAR)

BCBSMT member ID/applicant's Social Security number: _____

Name of member/applicant: _____

Name of depositor(s) if other than the member/applicant: _____

Phone number of member/applicant/depositor: _____

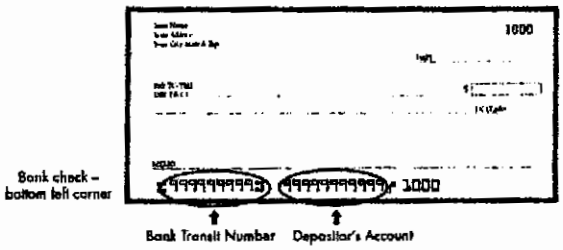
Name of bank, city and state where account is authorized: _____

_____

Please check one: ❑ Checking Account ❑ Savings Account

Bank Transit Number: _____

Depositor's Account Number: _____



I have read and accept the above agreement.

Please continue to pay your premiums by check or money order until you receive a confirmation letter from us stating the date automatic payments will begin.

Depositor's Signature: _____ Date: _____

A Division of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

350040.0916

BlueCross BlueShield of Montana

Standard Authorization Form To Use or Disclose Protected Health Information (PHI)

I. Individual (Name and information of person whose protected health information is being disclosed):

Name		Date of Birth
Group #	Identification/Subscriber #	Social Security Number
Address	City	State ZIP
Area Code & Telephone Number		

II. Authorization and Purpose:

I request and authorize Blue Cross and Blue Shield of Montana to disclose my protected health information as described below. **I understand that if the person/organization authorized to receive and use the information is not a health plan or health care provider, the disclosed information may no longer be protected by federal privacy regulations.**

Persons/Organizations authorized to receive your information	Relationship	Purpose
Address	City	State ZIP

III. Specific Description of Information to be Used or Disclosed *(Please Complete **Parts A and B** in this Section)*

This Authorization CANNOT be used to disclose Psychotherapy Notes.

A. Release of Sensitive Protected Health Information Under State Law

You must check "yes" or "no" if you authorize the release of medical information, test results, records or communications specific to ***(note: "yes" means this information is included in the categories you designate in Part B below)*** :

- Human Immunodeficiency Virus (HIV) or HIV/Acquired Immune Deficiency Syndrome
- Sexually transmitted or "communicable" diseases (includes hepatitis, as well as venereal diseases);
- Drug, alcohol or substance abuse;
- Mental health or developmental disabilities (including mental retardation or similar disabilities, for example, those attributable to cerebral palsy, autism or neurological dysfunctions); and
- Genetic testing.

Yes ☐ No ☐

B. Release of Protected Health Information *(check one or more)*

			Dates of Services From:	To:
☐	Health Plan Benefit Information:	Includes information contained in your benefit booklet (i.e., copayments, coinsurance, eligibility and other benefit information).		
☐	Claims	Includes information related to payment of your claims for service you received, including pertinent information located on a claim form (i.e., billed amount, general procedure descriptions claim payment or denial reasons, etc.).		
☐	Service Determination Information:	Includes any information related to pre-service, concurrent and post-service decisions.		

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☐ Premium Information: Includes information related to billing cycles, bank draft changes, etc.

☐ Services from (provider or supplier): Provider name: _____
(Includes information related to services rendered by a specific provider or supplier.)

☐ Other: _____
(Specify other information that is not listed in one of the categories

IV. Expiration and Revocation:

Expiration: This authorization will expire on (must choose one):

☐ 24 months from the date it is signed

☐ Other (insert date or event, not to exceed 24 months from the date it is signed): _____

Right to Revoke: I understand that I may revoke this authorization at any time by giving written notice to the address listed at the bottom of this form. **I understand that revocation of this authorization will not affect any action the above named entity took in reliance on this authorization before the above named entity received my written notice of revocation.**

V. Signature (this document must be signed by the individual, parent of minor child or the individual's personal representative):

I understand that this authorization is voluntary and that the health plan cannot condition my eligibility for benefits, treatment, enrollment or payment of claims on the signing of this authorization. I understand that if I am signing on behalf of a minor child, this authorization will expire upon the child reaching the age of 18, unless there is proof of legal guardianship.

_____ _____
Signature **Date: month/day/year**

If you are signing as a Power of Attorney, Legal Guardian, Executor or Administrator complete the following and attach a copy of the Legal documents. You do NOT have to attach copies of these documents if they are already on file with Blue Cross and Blue Shield of Montana:

_____ _____
Personal Representative's Name **Relationship to Individual**

_____ _____ _____ _____
Personal Representative's Address **City** **State** **ZIP**

_____
Personal Representative's Area Code & Telephone Number

BEFORE RETURNING THIS FORM YOU SHOULD KEEP A COPY FOR YOUR RECORDS BY EITHER:

(1) MAKING A PHOTOCOPY OF THIS SIGNED AUTHORIZATION; OR
(2) COMPLETING THE DUPLICATE AUTHORIZATION FORM YOU RECEIVED OR PRINTED

Mail your completed signed authorization to:
Blue Cross and Blue Shield of Montana
P.O. Box 805107
Chicago, IL 60680-4112

If you need assistance completing the form, please refer to the instructions above or contact the Customer Service number listed on the back of your Member Identification Card.

Any changes to the format, content or branding of this form are strictly prohibited without review and approval ofthe HCSC Privacy Office. Please forward requests for changes to the Privacy_Office@bcbsil.com.

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BlueCross BlueShield of Montana

Make the Most of Your Blue Cross and Blue Shield of Montana (BCBSMT) Plan.

Now that you have your 2017 BCBSMT plan, here are some tips to help you make the most of your benefits this year.

Knowledge is key.

- **Know What's Covered**
  - Keep this book handy
  - Check your plan when you schedule visits, tests or procedures
- **Know Where to Go**
  - Remember, you may save time and money by visiting retail clinics and urgent care centers for nonemergencies
  - Go to the nearest ER for life-or-death illness or injury
- **Know the Costs**
  - Deductibles
  - Copays and/or coinsurance
  - Out-of-pocket maximum

Visit **www.bcbsmt.com/insurance-basics** for more details.

Blue Access for Members℠ (BAM)

The gateway to help manage your personal health information.

Log in and look.

- Access your health history
- Check your claims
- Find doctors and hospitals
- View your benefits
- Use our online tools

Registering for your BAM account is easy:*

1. Visit **www.bcbsmt.com/member**
2. Click on "Log In" in the upper right-hand side of the page
3. Click on "Register Now"
4. Use the information on your member ID card, your ZIP Code and your email address to complete the registration process

* Note: BCBSMT makes no representation or warranty with respect to the accuracy or completeness of information on BAM. The information on BAM is based upon information provided by you and claims received by BCBSMT, which information has not been independently verified.

Download the BCBSMT App

Carry your health plan with you wherever you go:

- Look up your ID
- Find providers in your network
- Check your benefits
- Track your claims

To download the app, go to Google Play or the App Store or text** BCBSMT to 33633.

** Message and data rates may apply. Terms and conditions and privacy policy at www.bcbsmt.com/mobile/text-messaging.

Where You Go for Care Matters

It's important to think where to go when you need medical care.

Thinking where to go when you have a health issue may make a difference in costs and time.

You have options.

	Average Costs	Average Wait Times	Examples of Health Issues
24/7 Nurseline Around the clock help 24 hours a day, 7 days a week	¢	17 seconds*	Registered nurses are on call to answer your health questions 24 hours a day, 7 days a week
Your Doctor Your first choice for nonemergency care	$	24 minutes*	• Cuts and scrapes • Fever, colds and flu • Minor burns • Ear or sinus pain • Shots • Eye swelling, pain • Sore throat • Stomach ache • Physicals • Minor allergic reactions
Retail Clinics For care when you can't see your doctor	$	15 minutes	• Infections • Minor injuries or pain • Flu shots • Skin problems • Bronchitis • Cold and flu • Sore and strep throat • Allergies
Urgent Care When it's not a true emergency, but you need help now	$ $ $ $	11-20 minutes**	• Migraines or headaches • Urinary tract infection • Back pain • Cuts that need stitches • Sprains or strains • Animal bites
Emergency Room When life is in danger from illness or injury	$ $ $ $ $ $	4 hours, 7 minutes†	• Chest pain, stroke • Head or neck injuries • Heart attack • Fainting, dizziness, weakness • Problems breathing • Seizures • Sudden or severe pain • Severe vomiting, diarrhea • Uncontrolled bleeding • Broken bones

Key points to remember:

- **24/7 Nurseline.** You may call our 24/7 Nurseline at **877-213-2565.** Registered nurses can answer your general health questions and help you decide if you need care and where you could go. Have your member ID card ready before you call.
- **Use the ER for emergencies only.** When your injury or illness is serious, call 911 or go to the nearest emergency room. You don't need a referral. If it's not an emergency, you may be able to save money by seeing your regular doctor for colds, minor sprains and other less serious conditions.

* Medical Practice Pulse Report 2009, Press Ganey Associates. *http://helpandtraining.pressganey.com/Documents_secure/Pulse%20Reports/2009_ED_Pulse_Report.*

** Urgent Care Benchmarking Study Results. Journal of Urgent Care Medicine. January 2012.

† Emergency Department Pulse Report 2010 Patient Perspectives on American Health Care. Press Ganey Associates. *http://helpandtraining.pressganey.com/researchResources/hospitals/emergencyDepartment/emergencyPulsereport.aspx*

Provider Finder®

Easily search for physicians, specialists and hospitals in your plan's network.

Seeing providers in network helps you get the most from your benefits. Your out-of-pocket costs may be lower when you see in-network providers. Going to in-network hospitals may make a big difference in your costs also.

Check before any visit.

- Compare doctors and hospitals
- Get information on providers
- Get directions to provider locations
- Find out some wait times
- See awards and recognitions
- Read and write reviews
- See what languages the doctor speaks

1. Visit **www.bcbsmt.com**
2. Log in to BAM, go to the "Doctors and Hospitals" tab and click "Find a Doctor"
3. Search by network, doctor, hospital or area to find the most up-to-date listing of health care providers for your plan's network

Get ready before you see your doctor.

Notes can help you make the best use of your time with your doctor. Bring a pen and write as you talk.

Here is what your visit notes could include:

A list of symptoms:

- When did your health concern start?
- Where does it hurt?
- How badly does it hurt?
- Does it get better or worse with activity?
- Does rest help?
- Does what you eat matter?

Your health history:

- Past illnesses, injuries, diseases, allergies
- Your family's health history

Your list of questions:

- Some questions you know ahead of time.
- Some questions pop up as you talk with your doctor.

Current medication:

- A list of drugs OR
- Prescription and over-the-counter containers

Records:

- Records from previous tests or procedures, including X-rays
- Written test results and surgery reports

Learn more about taking care of your health

facebook.com/BCBSMT

youtube.com/bcbsmt

twitter.com/bcbsmt

connect.bcbsmt.com

Your Prescription Drug Coverage

Your prescription drug coverage has a network of pharmacies, online tools, and more.

The Drug List

The drug list is a list of covered medications available to BCBSMT members. If your drug is not on the list, check with your doctor for a covered alternative to consider.

Always check the list.

Once you have your prescription, you may save money by:

- Checking to see if your prescription is on the drug list at **www.bcbsmt.com/member/prescription-drug-plan-information/drug-lists.**
- Checking for a generic or lower-cost preferred brand drug. (Ask your doctor if these alternatives may be right for you.)
- Filling your prescriptions at a Value Pharmacy Network pharmacy. If you fill your prescription for a covered prescription drug at a non-Value Pharmacy Network pharmacy, you may pay more out of pocket.

Log in to your Blue Access for Members (BAM) account at **www.bcbsmt.com/member** to learn more about specific drug coverage on your prescription drug benefit.

Examples of Generic Drug Options for Common Drugs

Drug Class	Generic Options
Heartburn/Acid Reduction	lansoprazole, omeprazole, pantoprazole, rabeprazole, esomeprazole
Attention Deficit Hyperactivity Disorder	amphetamine/dextroamphetamine (ER), dexmethylphenidate, methylphenidate (ER)
Bipolar/Psychosis	olanzapine, quetiapine, risperidone, ziprasidone
Cholesterol Lowering	atorvastatin, fenofibric acid, fluvastatin, lovastatin, niacin, omega-3 fatty acids, pravastatin, simvastatin
Depression	bupropion (SR), citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine (ER), sertarline, venlafaxine (ER)
High Blood Pressure	atenolol, benazepril, benazepril (HCTZ), betaxolol, bisoprolol, candesartan, candesartan (HCTZ), enalapril, enalapril (HCTZ), irbesartan, irbesartan (HCTZ), lisinopril, lisinopril (HCTZ), losartan, losartan (HCTZ), metoprolol, metoprolol (ER), propranolol, ramipril, valsartan (HCTZ)
Osteoporosis	alendronate, ibandronate, raloxifen, zoledronic acid, risedronate
Sleep Aids	eszopiclone, zaleplon, zolpidem (ER)
Thyroid Replacement	levothyroxine, Levothroid, Levoxyl, Unithroid

This list is for example only and is not all-inclusive.

Value Pharmacy Network

Your prescription drug benefit may include a Value Pharmacy Network.

Check if your plan has a Value Pharmacy Network.

- **30-Day Supply:** If you fill a prescription for up to a 30-day supply of a covered prescription drug from a Value Pharmacy Network pharmacy, you may pay the lowest copay/coinsurance amount.
- **90-Day Supply:** You can also fill a prescription for up to a 90-day supply of a covered prescription drug at a participating Value Pharmacy Network pharmacy. You may pay the lowest copay/coinsurance amount for that quantity.
- Filling a prescription at a non-Value Pharmacy Network pharmacy may cost you more.

Visit Prime Therapeutics* at **myprime.com** to search for a Value Pharmacy Network pharmacy near you.

90-Day Supply Options

If you are taking medication on a routine basis, you may be able to get a 90-day supply.

Where can you get a 90-day supply?

- Through the mail order program
- At a participating retail pharmacy in the Value Pharmacy Network

You can find more information by logging in to your Blue Access for Members (BAM) account at **www.bcbsmt.com/member.**

Specialty Pharmacy Program

Your prescription drug benefit may include a specialty pharmacy program through Prime Therapeutics Specialty Pharmacy.

What are specialty medications?

Specialty medications are those used to treat serious or chronic conditions. Examples include:

- Hepatitis C
- Hemophilia
- Multiple sclerosis
- Rheumatoid arthritis

These drugs are typically given by injection, but may be topical or taken by mouth. They often require careful adherence to treatment plans, have special handling or storage requirements, and may not be stocked by retail pharmacies.

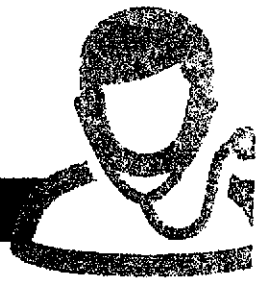
For more information, call Prime Therapeutics at **877-627-6337.**

Medical or Pharmacy Benefit?

- Specialty medications that require professional services for administration are usually covered under your medical benefit plan.
- Coverage for self-administered specialty medications is provided through your pharmacy benefit plan.

* Prime Therapeutics LLC is a separate pharmacy benefit management company, which also operates PrimeMail, a home delivery pharmacy service. Blue Cross and Blue Shield of Montana contracts with Prime Therapeutics to provide pharmacy benefit management and home delivery pharmacy services. Blue Cross and Blue Shield of Montana, as well as several other independent Blue Cross and Blue Shield Plans, has an ownership interest in Prime Therapeutics LLC.

Doctor's Orders: Some medicines on the drug list have special requirements.



What do I have to do to get my prescription?

Prior Authorization

Sometimes prior approval is needed before a drug may be covered.

- Your doctor will need to submit a prior authorization request to Prime Therapeutics.

Step Therapy

Some drugs may not be covered unless you try another preferred drug first.

- Ask your doctor if the preferred drug is right for you or have your doctor submit a prior authorization request for your other drug to Prime Therapeutics.

Quantity Limits

There may be dispensing limits on certain medicines. For example, a medication taken twice daily may be limited to 60 tablets for 30 days.

- If your doctor thinks you need more than the dispensing limit, he or she will need to ask for an override authorization from Prime Therapeutics.

Your doctor can call **888-723-7443** with questions or to ask for any forms.

Well onTarget®

Motivation and guidance for your health and wellness journey.

Whether you want to make a game plan, track your progress or get started on your journey, Well onTarget* provides tools and resources to help guide you toward your health and wellness goals.

Make a plan and track your progress.

Take your health assessment today! It shows you where you stand with issues like:

- Activity level
- Stress management
- Nutrition
- Tobacco use
- Weight, blood pressure, cholesterol metrics

Resources include:

- Online courses on topics related to any wellness goals identified by your health assessment
- Health trackers to track your progress toward any wellness goals identified by your health assessment
- A Blue Points℠ reward program**
  - The more you use the program, the more you earn
  - Redeem points for discounts on a wide range of products

Learn more at **wellontarget.com**.

* Well onTarget is an informational resource provided to members and is not a substitute for the independent medical judgment of a health care provider. Member instructed to consult with their health care provider before beginning their journey toward wellness.

** Blue Points Program Rules are subject to change without prior notice. See the Program Rules on the Well onTarget Member Wellness Portal at wellontarget.con further information.

PET EXHIBIT 2-122

Blue365®

Save with the member discount program.

Blue365 is just one more advantage of being a BCBSMT member. Save money on health and wellness products and services that are often not covered by your benefit plan. There are no claims to file and no referrals or pre-certifications.

Shop and save.

Jenny Craig® | Seattle Sutton's® | Nutrisystem®

Save on:

- Healthy meals
- Membership fees (if applicable)
- Nutritional products and services

Reebok | SKECHERS®

- 20% off and free shipping
- Select Reebok athletic equipment for adults and kids
- Select SKECHERS Performance, Sport, Work and Corporate Casual styles

Snap Fitness™

- 50% discount off the best current enrollment offer (no processing fees)
- 5% discount off monthly dues
- Up to five personal training sessions for 10% off
- Free online workout tools
- One month online nutrition and meal planning
- Free fitness tests twice a year
- 30-day trial for $8.95

Dental Solutions℠ Discount Program

- $9.95 sign-up and $6 monthly fee
- Dental discount card
- Up to 50% discount at more than 61,000 dentists and 185,000 locations across the country

Retrofit℠

- 15% off private Expert 10 and Expert 15 weight loss coaching programs
- Private coaching
- Food and activity logging
- Seamless integration with Fitbit® activity trackers and wireless scales

TruHearing® | Beltone™

Save on:

- Hearing tests
- Hearing aids

Log in to BAM and click on "Member Discount Program" under "Quick Links," or visit **Blue365Deals.com/BCBSMT**. Once you sign up, weekly "Featured Deals" will be emailed to you. These deals offer special savings for a short period of time.

Value-added products and services may be discontinued or changed at any time and may be subject to geographical availability.

The relationship between these vendors and Blue Cross and Blue Shield of Montana (BCBSMT) is that of independent contractors.

Blue365 is a discount program only for BCBSMT members. This is NOT insurance. Some of the services offered through this program may be covered under your health plan. Please check your benefit booklet or call the Customer Service number on the back of your ID card for specific benefit facts. Use of Blue365 does not change your monthly payment, nor do costs of the services or products count toward any maximums and/or plan deductibles. Discounts are only given through vendors who take part in this program. BCBSMT does not guarantee or make any claims or recommendations about the program's services or products. You may want to talk to your doctor before using these services and products. BCBSMT reserves the right to stop or change this program at any time without notice.

ers are

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BLUE PREFERRED GOLD PPO-104

INDIVIDUAL PLAN

THIS CONTRACT IS NOT A MEDICARE POLICY. If you are eligible for Medicare, review the Medicare Supplement Buyers Guide from Blue Cross and Blue Shield of Montana.

BlueCross BlueShield of Montana

BLUEPREFERREDGOLDINDEXC2017

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FOR BCBSMT CUSTOMER SERVICE AND PREAUTHORIZATION

FOR CUSTOMER SERVICE
Call 1-855-258-8471

FOR PREAUTHORIZATION
Call 1-855-462-1782 or Fax 1-866-589-8253 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

FOR INPATIENT ADMISSIONS
Call 1-855-462-1782 or Fax 1-866-589-8253 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

www.bcbsmt.com
- BCBSMT Provider Directory
- Wellness
- Customer Service
- Other Online Services and Information

BLUECARD® NATIONWIDE/WORLD WIDE COVERAGE PROGRAM
1-800-810-BLUE (2583) – http://provider.bcbs.com

FOR APPEALS
Send via fax to 1-866-589-8256
or mail to Blue Cross Blue Shield at:
PO Box 4309
Helena, MT 59604-4309

FOR URGENT CARE APPEALS
Call 1-855-258-8471

FOR PRESCRIPTION DRUG BENEFITS

Pharmacy Benefit Manager (PBM)

• Prime Therapeutics	1-800-423-1973
• For preauthorizations, fax:	1-877-243-6930
PBM Website	www.myprime.com
Claim Forms	1-866-325-5230
Pharmacy Locator	1-866-325-5230
Specialty Care Pharmacy (BCBSMT Prime Specialty Network)	1-877-627-MEDS (6337)
• www.bcbsmt.com or www.myprime.com	1-877-828-3939
• Prescriber Fax	

Mail Order Services

• **PrimeMail** PO Box 27836 Albuquerque, NM 87125-7836	1-866-325-5230
• **Ridgeway Mail-Order Pharmacy** 2824 US Hwy 93 North Victor, MT 59875	1-800-630-3214

Blue Cross and Blue Shield of Montana
3645 Alice Street
PO Box 4309
Helena, MT 59604-4309

FOR CLAIMS
Blue Cross and Blue Shield of Montana
PO Box 7982
Helena, MT 59604-7982

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Certain terms in this Contract are defined in the Definitions section of this Contract. Defined terms are capitalized.

THIS CONTRACT

1. If the Member is not satisfied with this Contract for any reason, the Contract may be returned within 10 days of its delivery. The Plan will refund the amount of dues paid, thus voiding the Contract from the beginning.
2. The Plan agrees to pay for the Covered Medical Expenses as outlined in this Contract subject to the following conditions:
   a. All statements made in any application for membership or any statement of health must be correct.
   b. The Plan must receive the Monthly Dues on or before the time listed on the Member's bill. **Payment of monthly dues is a condition precedent to coverage under this Contract.**
3. Payment by The Plan will be subject to the terms, conditions and limitations of this Contract and any endorsements, amendments and/or riders.
4. Payment will only be made for services which are provided to Members after the Effective Date of this Contract and before the date on which this Contract terminates.

MEMBERS RIGHTS

When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

CONTINUITY OF CARE

If the Member's Participating Provider (professional) stops participating in the PPO network, the Member may request continued treatment from that provider for a period of time after the provider stops participating, except for pregnancy, the continuity of care period is 90 days or until the next policy renewal date, whichever is longer. For pregnancy, the continuity of care period is through the postpartum period. For the Member to qualify for continuity of care, the provider must: (1) agree that the Member is in an active course of treatment as defined by ARM 6.6.5908; (2) agree to accept the same allowed amount as the provider would have accepted if the provider had remained a Participating Provider; and (3) agree not to seek payment from the Member of any amount for which the Member would not have been responsible if the provider had remained a Participating Provider. Continuity of care protections are only for an active course of treatment and are not required for routine primary and preventive care.

PRIVACY OF INSURANCE AND HEALTH CARE INFORMATION

It is the policy of Blue Cross and Blue Shield of Montana to protect the privacy of Members through appropriate use and handling of private information. Further, appropriate handling and security of private information may be mandated by state and/or federal law.

The Beneficiary Member may receive a copy of Blue Cross and Blue Shield of Montana's "Notice of Privacy Practices," or other information about privacy practices, by calling the telephone number or writing to the address shown on the inside cover of this Contract.

PAYMENT OF DUES

Payment of Initial Dues

The first Month's dues must be paid to and accepted by The Plan before this Contract is in effect.

Payment of Monthly Dues

Dues are payable by each Beneficiary Member in advance, in the amounts and at the times shown on the Member's bill.

Payment Provisions

Blue Cross and Blue Shield of Montana only accepts premium (dues) and cost-sharing payments from:

1. The Member;
2. The Member's family;
3. Required Entities (the entities the law requires Blue Cross and Blue Shield of Montana to accept premium and cost-sharing payments from, which currently are Ryan White HIV/AIDS programs, under title XXVI of the Public Health Service Act, Indian tribes, tribal organizations and urban Indian organizations; and State and Federal government programs, as described in 45 C.F.R. § 156.1250); and
4. Private non-profit foundations that make premium or cost-sharing assistance available to the Member:
   a. for the entire coverage period of the Member's Contract;
   b. based solely on financial criteria;
   c. regardless of the Member's health status, and
   d. regardless of which issuer and/or benefit plan the Member chooses.

Blue Cross and Blue Shield of Montana does not accept premium and cost-sharing payments from any other third party. A violation of this policy may result in premium and cost-sharing payments paid by a third party not being credited to the Member's account or coverage or refunded to Member, which may result in the retroactive termination or cancellation of coverage.

Grace Period

Unless, not less than 30 days prior to the dues' due date, Blue Cross and Blue Shield of Montana has delivered to the Beneficiary Member or has mailed to the Member's last address as shown on the records of Blue Cross and Blue Shield of Montana, written notice of its intention not to renew this Contract beyond the period for which the dues have been accepted, a grace period of ten days will be granted for the payment of each Monthly Dues amount falling due after the first dues payment, during which grace period the Contract will continue in force.

IDENTITY THEFT SERVICES

Blue Cross and Blue Shield of Montana (BCBSMT) offers, at no additional cost to the Member, identity theft protection services, including credit monitoring, fraud detection, credit /identity repair and insurance to help protect the Member's information. These identity theft protection services are currently provided by BCBSMT's designated outside vendor and acceptance or declination of these services is optional to Member.

Members who wish to accept such identity theft protection services will need to individually enroll in the program online at www.bcbsmt.com or telephonically by calling the toll free telephone number on his/her identification card. Services may automatically end when the person is no longer an eligible Member. In addition, services may change or be discontinued at any time and BCBSMT does not guarantee that a particular vendor or service will be available at any given time. The services are provided as a convenience and are not considered covered benefits under this Contract.

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Annual and Lifetime Plan Maximum:	None
Benefit Period:	Calendar Year

The Benefits are subject to the Benefit Period unless otherwise specified.

	In-Network	Out-of-Network
Deductible:		
Individual	$1,400	$5,600
Family	$2,800	$11,200
The In-Network and Out-of-Network Deductibles are separate amounts and one does not accumulate to the other.		
Any Copayments and Coinsurance do not accumulate to the Deductible.		
Deductible per Visit or Occurrence:		
Emergency Room Care	$750*	$750*
Inpatient Admission	$300*	$1,500*
Outpatient Surgery	$200*	$1,500*
*These Per Occurrence Deductibles are in addition to Deductible and any Coinsurance.		
Coinsurance:	20%	50%
Copayments:		
Urgent Care	$20	No Copayment; Deductible and Coinsurance Apply
Out of Pocket Amount:		
Individual	$3,350	$13,400
Family	$6,700	$26,800
The In-Network and Out-of-Network Out of Pocket Amounts are separate amounts and one does not accumulate to the other. Charges in excess of the Allowable Fee do not accumulate to help meet the Out of Pocket Amount.		

Some Benefits may have payment limitations. Refer to the specific Benefit in this Schedule of Benefits for additional information. In addition:

- For Emergency Services provided by an Out-of-Network Provider, Benefits will be provided as if such services were provided by an In-Network provider.
- Out-of-Network providers may bill the Member the difference between the Allowable Fee and the provider's charge, in addition to any applicable Deductible, Copayment or Coinsurance even if Preauthorization is obtained for the service or treatment is provided for Emergency Services.

Term of Contract:	Monthly

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION **Deductible applies to all services unless noted otherwise.**	**IN-NETWORK COINSURANCE/ COPAYMENT**	**OUT-OF-NETWORK COINSURANCE/ COPAYMENT**
Accident		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Acupuncture	20%	50%
Maximum Per Benefit Period – 12 Visits		
Ambulance	20%	20%
Autism Spectrum Disorders		
Services, except medications/prescription drugs and Applied Behavior Analysis (ABA) services that are described in the Benefit section entitled Autism Spectrum Disorders are covered under medical Benefits.		
Medications/prescription drugs are covered under Prescription Drugs.		
ABA services are only covered for Members under 19 years of age	20%	50%
Birthing Centers	20%	50%
Chemical Dependency		
Professional Provider Services		
Outpatient	20%*	50%
Inpatient	20%	50%
*Deductible and Coinsurance do not apply to Primary Care Provider (PCP) home and office visits for Chemical Dependency.		
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Chiropractic Services	20%	50%
Maximum Benefit Per Benefit Period for Chiropractic Manipulations – 10 Visits		
Convalescent Home Services	20%	50%
Maximum Per Benefit Period – 60 Days		
Refer to Page 1 for the Inpatient Admissions Deductible.		
Diabetic Education Benefit		
The Deductible and Coinsurance do not apply to the Payment of the first $250. After the payment of $250, Deductible and Coinsurance will apply.		
First $250	Deductible and Coinsurance Do Not Apply	
After the first $250 in payment	20%	50%

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BENEFIT INFORMATION **Deductible applies to all services unless noted otherwise.**	**IN-NETWORK COINSURANCE/ COPAYMENT**	**OUT-OF-NETWORK COINSURANCE/ COPAYMENT**
Diagnostic Services		
Diagnostic Imaging Services		
Computerized Tomography (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan)		
Professional Provider Services	20%	50%
Facility Services	20%	50%
All Other Covered Diagnostic Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Durable Medical Equipment		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Durable Medical Equipment	20%	50%
Education Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Emergency Room Care	20%	20%
Refer to Page 1 for the Emergency Room Deductible.		
Home Health Care	20%	50%
Maximum Per Benefit Period – 180 Visits		
Hospice Care		
Professional Provider Services	Deductible and Coinsurance Do Not Apply	50%
Facility Services	Deductible and Coinsurance Do Not Apply	50%
Hospital		
Professional Services (when the Professional Provider is employed by the Hospital)		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Mammograms		
Routine	Deductible and Coinsurance Do Not Apply	50%*
Medical	Deductible and Coinsurance Do Not Apply	50%
*Deductible and Coinsurance do not apply to the payment of the first $70 for Routine mammograms provided by an Out-of-Network provider.		

PET EXHIBIT 2-133

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWO COINSURANCE COPAYMENT
Maternity Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Medical Supplies	20%	50%
Mental Health		
Professional Provider Services		
Outpatient	20%*	50%
Inpatient	20%	50%
*Deductible and Coinsurance do not apply to Primary Care Provider (PCP) home and office visits for Mental Illness.		
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Partial Hospitalization is covered under the Inpatient Treatment Benefit.		
Newborn Initial Care		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
The applicable Inpatient Admission Deductible and plan Deductible apply after the first 5 days of initial care.		
Office Visit		
Primary Care Provider (PCP)	20%*	50%
Deductible and Coinsurance do not apply to the first 3 In-Network PCP visits.		
However, Deductible and Coinsurance apply to the following covered services provided during those first 3 office visits: surgery, Physical Therapy, Speech Therapy, Occupational Therapy, Chiropractic Manipulation, Diagnostic Imaging, Laboratory Services and X-rays.		
Specialist	20%*	50%
*Deductible and Coinsurance do not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.		
Orthopedic Devices/Orthotic Devices	20%	50%
Other Facility Services – Inpatient and Outpatient	20%	50%
Pediatric Vision Care (For Members under 19 years of age)		
Routine Exam	Deductible and Coinsurance Do Not Apply	
Maximum Per Benefit Period – 1 Exam		
Frames and Lenses	20%	50%
Maximum Per Benefit Period – 1 Pair of Glasses or 2 boxes of Contact Lenses		
Physician Medical Services (Other than the Office Visit)	20%	50%

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Prescription Drugs Refer to the last page of this Schedule of Benefits.		
Preventive Health Care		
Routine Services	Deductible and Coinsurance Do Not Apply	50%
Prostheses Benefit		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Prosthetics	20%	50%
Rehabilitation Therapy		
Professional Services		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Surgery Center Services - Outpatient		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Outpatient Surgery Deductible.		
Therapies – Outpatient		
Physical Therapy, Occupational Therapy, Speech Therapy, Cardiac Therapy		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Transplants		
Professional Services		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Urgent Care *Copayment does not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.	$20*, No Deductible	50%
Well-Child Care Services	Deductible and Coinsurance Do Not Apply	50%, No Deductible

PRESCRIPTION DRUG INFORMATION	DEDUCTIBLE	COPAYMEN COINSURAN

Prescription Drugs
(The Prescription Drugs Benefit utilizes a Drug List.) Any Deductible, Copayment and/or Coinsurance do not apply to certain contraceptive products. Refer to the Preventive Health Care Benefit. Any Deductible, Copayment and/or Coinsurance also do not apply to smoking cessation products and over-the-counter aids/medications, for two 90-day treatment regimens.

Deductible — Does Not Apply

Retail Value Participating Pharmacy Prescriptions
Copayments for a **30-day supply** are:

Preferred Generic:	No Copayment
Non-Preferred Generic:	$10
Preferred Brand-Name:	$50
Non-Preferred Brand-Name:	$100

Retail Participating Pharmacy Prescriptions
Copayments for a **30-day supply** are:

Preferred Generic:	$5
Non-Preferred Generic:	$15
Preferred Brand-Name:	$60
Non-Preferred Brand-Name:	$110

Retail Non-Participating Pharmacy Prescriptions
Copayments for a **30-day supply** are:

Preferred Generic:	$5
Non-Preferred Generic:	$15
Preferred Brand-Name:	$60
Non-Preferred Brand-Name:	$110

Payment for Prescription Drug Products purchased at a Non-Participating Pharmacy will be reduced by 50%, in addition to any Copayment.

Mail Service Maintenance Prescriptions
Copayments for a **90-day supply** are:

Preferred Generic:	No Copayment
Non-Preferred Generic:	$30
Preferred Brand-Name:	$150
Non-Preferred Brand-Name:	$300

Retail Value Participating Pharmacy Prescriptions
Copayments for a **90-day supply** are:

Preferred Generic:	No Copayment
Non-Preferred Generic:	$30
Preferred Brand-Name:	$150
Non-Preferred Brand-Name:	$300

Specialty Medications purchased at participating Specialty Pharmacies in the Blue Cross and Blue Shield of Montana Prime Specialty Network
(30-day supply only) — $250*

***An Out-of-Network 50% Coinsurance applies to Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy.**

The Member must pay the difference between a Brand-Name drug and the Generic equivalent in addition to the Copaym and/or Coinsurance if the Member chooses a Brand-Name drug when a Generic drug is available.

Any Copayment and/or Coinsurance amounts paid for prescription drugs do not apply to the Deductible. The 50% benefi reduction for prescription drugs purchased at a Non-Participating Pharmacy does not apply to the Out-of-Pocket maximu The 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharma does not apply to any Out of Pocket Amount.

PROVIDERS OF CARE FOR MEMBERS

The participation or nonparticipation of providers from whom a Member receives services, supplies, and medication impacts the amount The Plan will pay and the Member's responsibility for payment. Professional providers and facility providers are either In-Network or Out-of-Network providers. In-Network providers include Participating Providers and Preferred Provider Organization (PPO) providers. Out-of-Network providers are nonparticipating and non-PPO providers.

In-Network and Out-of-Network Professional Providers and Facility Providers

Professional providers include, but are not limited to, Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, Advanced Practice Registered Nurses, physician assistants, naturopathic physicians, acupuncturists and physical therapists.

Primary Care Providers (PCPs) include general practitioners, family practitioners, internists, pediatricians, obstetricians and gynecologists, psychiatrists, psychologists, naturopaths, physicians' assistants, registered nurse practitioners, psychiatrists, psychologists, licensed addiction counselors, licensed clinical professional counselors and licensed clinical social workers.

A specialist is a Physician, not included in the list of PCPs, who provides medical services in any generally accepted medical specialty or sub-specialty.

PCPs and specialists do not include chiropractors, acupuncturists, speech therapists, physical therapists, or occupational therapists.

Facility providers include, but are not limited to, Hospitals, Rehabilitation Facilities, Home Health Agencies, Convalescent Homes, skilled nursing facilities, freestanding facilities for the treatment of Chemical Dependency or Mental Illness, and freestanding surgical facilities (surgery center).

The Member may obtain a list of Participating Providers from Blue Cross and Blue Shield of Montana free of charge by contacting The Plan at the number listed on the inside cover of this Contract.

PPO Providers

Blue Cross and Blue Shield of Montana has a PPO Network of Hospitals and surgery centers in Montana that is utilized under this Benefit Plan. Outside of the state of Montana, there are also Blue Cross and/or Blue Shield PPO Hospitals and surgery centers nationwide. The Member receives the In-Network Benefit when utilizing the PPO network or the nationwide Blue Cross and/or Blue Shield PPO Hospitals and surgery centers. If the Member obtains services or supplies from a non-PPO Network provider, the Out-of-Network Deductible, Coinsurance and Out-of-Pocket will apply as indicated on the Schedule of Benefits.

The exceptions to the Benefit reduction are:

- Emergency Services;
- Services that are unavailable within the PPO Network.

If a Member receives services from an out of state provider, then services must be provided by:

- Blue Cross and/or Blue Shield PPO facility providers; and/or
- Blue Cross and/or Blue Shield participating professional providers* or PPO professional providers.

*Some Blue Cross and/or Blue Shield Plans require services to be provided by a PPO professional provider for the Member to receive the highest level of Benefit. Contact The Plan for additional information on out of state services.

Emergency Services and services that are unavailable within the PPO Network will be covered as In Network. **However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if Preauthorization was obtained for such services.** The Member will be responsible for the balance of the nonparticipating provider's or non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment by the Member of any Deductible, Coinsurance and/or Copayment.

Out of PPO Network Referrals

There may be circumstances under which the most appropriate treatment for the Member's condition is not available through the PPO Network. When this occurs, it is recommended the Member's attending Physician contact The Plan for an out of PPO Network referral. If the referral is not approved, and the Member chooses to obtain services from a non-PPO Network provider, the Member will be responsible for the Out-of-Network Deductible and Coinsurance, in addition to any difference between the Blue Cross and Blue Shield of Montana Allowable Fee and the provider's billed charges.

If The Plan approves the referral, those services will process with the In-Network Deductible and Coinsurance. However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if The Plan approves the referral.

How Providers are Paid by The Plan and Member Responsibility

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield of Montana for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

How Providers are Paid by The Plan and Member Responsibility Outside of Montana

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network in the state where serves are provided.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

For Prescription Drug Products, the Member will be responsible for paying the specific Copayment/Coinsurance as described in the Prescription Drugs section.

The Plan will not pay for any services, supplies or medications which are not a Covered Medical Expense, or for which a Benefit maximum has been met, regardless of whether provided by a Participating Provider or a nonparticipating provider. The Member will be responsible for all charges for such services, supplies, or medications.

MEMBERS RIGHTS AND RESPONSIBILITIES

A Member has the right to:

1. Receive information about The Plan, the quality assurance program, the Member's health Benefit Plan, the names of participating health care providers, and the Member's rights and responsibilities.
2. Be treated with respect and recognition of the Member's dignity and right to privacy.
3. Have a candid discussion of appropriate or Medically Necessary treatment options for the Member's condition, regardless of cost or Benefit coverage.
4. Participate with health care providers in decision-making regarding the Member's health care.
5. Voice complaints or appeals about the managed care organization, health care providers or the care provided.
6. Talk to the Member's health care provider and expect that the Member's records and conversations are kept confidential.
7. When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

A Member has the responsibility to:

1. Provide, to the extent possible, information that The Plan and health care providers need in order to care for the Member. .
2. Follow the treatment plans and instruction for care the Member has agreed upon with the Member's health care providers.

OUT-OF-AREA SERVICES – THE BLUECARD PROGRAM

Out-of-Area Services

Blue Cross and Blue Shield of Montana has a variety of relationships with other Blue Cross and/or Blue Shield Licensees. Generally, these relationships are called "Inter-Plan Arrangements." These Inter-Plan Arrangements work based on rules and procedures issued by the Blue Cross Blue Shield Association. Whenever a Member receives healthcare services outside of the Blue Cross and Blue Shield of Montana service area, the claims for those services may be processed through one of these Inter-Plan Arrangements. The Inter-Plan Arrangements are described below.

When a Member receives care outside of the Blue Cross and Blue Shield of Montana service area, the Member will receive care from one of two kinds of providers. Most providers ("participating providers") contract with the local Blue Cross and/or Blue Shield Licensee in that geographic area ("Host Blue"). Some providers ("nonparticipating providers") don't contract with the Host Blue. Blue Cross and Blue Shield of Montana explain below how we pay both kinds of providers.

1. BlueCard® Program

Under the BlueCard® Program, when a Member receives Covered Medical Expenses within the geographic area served by a Host Blue, Blue Cross and Blue Shield of Montana will remain responsible for what we agreed to in the contract. However, the Host Blue is responsible for contracting with and generally handling all interactions with its participating healthcare providers.

When the Member receives Covered Medical Expenses outside the Blue Cross and Blue Shield of Montana service area and the claim is processed through the BlueCard Program, the amount the Member pays for Covered Medical Expenses is calculated based on the lower of:

- The billed covered charges for the Member's Covered Medical Expenses; or
- The negotiated price that the Host Blue makes available to Blue Cross and Blue Shield of Montana.

Often, this "negotiated price" will be a simple discount that reflects an actual price that the Host Blue pays to the Member's healthcare provider. Sometimes, it is an estimated price that takes into account special arrangements with the Member's healthcare provider or provider group that may include types of settlements, incentive payments, and/or other credits or charges. Occasionally, it may be an average price, based on a discount that results in expected average savings for similar types of healthcare providers after taking into account the same types of transactions as with an estimated price.

Estimated pricing and average pricing, going forward, also take into account adjustments to correct for over- or underestimation of past pricing of claims, as noted above. However, such adjustments will not affect the price Blue Cross and Blue Shield of Montana uses for the Member's claim because they will not be applied after a claim has already been paid.

In some cases, Blue Cross and Blue Shield of Montana may, but is not required to, negotiate a payment with a non-participating healthcare provider on an exception basis.

Inter-Plan Programs: Federal/State Taxes/Surcharges/Fees

Federal or state laws or regulations may require a surcharge, tax or other fee. If applicable, Blue Cross and Blue Shield of Montana will include any such surcharge, tax or other fee as part of the claim charge passed on to the Member.

2. Non-Participating Healthcare Providers Outside of the Blue Cross and Blue Shield of Montana Service Area

a. Member Liability Calculation

When the Member incurs Covered Medical Expenses outside of the Blue Cross and Blue Shield of Montana service area for services provided by non-participating healthcare providers, the amount the Member pays for such services will generally be based on either the Host Blue's non-participating healthcare provider local payment or the pricing arrangements required by applicable state law. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph. Federal or state law, as applicable, will govern payments for out-of-network emergency services.

b. Exceptions.

In certain situations, Blue Cross and Blue Shield of Montana may use other payment bases, such as Covered Medical Expenses, the payment Blue Cross and Blue Shield of Montana would make if the healthcare services had been obtained within the Blue Cross and Blue Shield of Montana service area, or a special negotiated payment to determine the amount Blue Cross and Blue Shield of Montana will pay for services provided by non-participating healthcare providers. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph.

3. BlueCard Worldwide® Program

If the Member is outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member may be able to take advantage of the BlueCard Worldwide® Program when accessing Covered Medical Expenses. The BlueCard Worldwide Program is unlike the BlueCard Program available in the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands in certain ways. For instance, although the BlueCard Worldwide Program assists the Member with accessing a network of inpatient, outpatient and professional providers, the network is not served by a Host Blue. As such, when the Member receive care from providers outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member will typically have to pay the providers and submit the claims himself/herself to obtain reimbursement for these services.

If the Member needs medical assistance services (including locating a doctor or hospital) outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands (hereinafter "BlueCard service area"), the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week. An assistance coordinator, working with a medical professional, will arrange a physician appointment or hospitalization, if necessary.

Benefits will not be provided for any services or supplies except for those provided for an Emergency Medical Condition and received through the Inter-Plan Arrangements, which includes the BlueCard program.

- **Inpatient Services**

  In most cases, if the Member contacts the BlueCard Worldwide Service Center for assistance, hospitals will not require the Member to pay for covered inpatient services, except for the cost-share amounts/deductibles, coinsurance, etc.. In such cases, the hospital will submit the Member's claims to the BlueCard Worldwide Service Center to begin claims processing. However, if the Member paid in full at the time of service, the Member must submit a claim to receive reimbursement for Covered Medical Expenses.

  The Member must contact Blue Cross and Blue Shield of Montana to obtain preauthorization to verify that Inpatient Services are for the treatment of an Emergency Medical Condition.

- **Outpatient Services**

  Outpatient Services are available for the treatment of an Emergency Medical Condition. Physicians, urgent care centers and other outpatient providers located outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands will typically require the Member to pay in full at the time of service. The Member must submit a claim to obtain reimbursement for Covered Medical Expenses.

- **Submitting a BlueCard Worldwide Claim**

  When the Member pays for Covered Medical Services outside the BlueCard service area, the Member must submit a claim to obtain reimbursement. For institutional and professional claims, the Member should complete a BlueCard Worldwide International claim form and send the claim form the provider's itemized bill(s) to the BlueCard Worldwide Service Center (the address is on the form) to initiate claims processing. Following the instructions on the claim form will help ensure timely processing of the Member's claim. The claim form is available from Blue Cross and Blue Shield of Montana, the BlueCard Worldwide Service Center or online at www.bluecardworldwide.com. If the Member needs assistance with the Member claim submission, the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week.

COMPLAINTS AND GRIEVANCES

Complaints and Grievances

The Plan has established a complaint and grievance process. A complaint involves a communication from the Member expressing dissatisfaction about The Plan's services or lack of action or disagreement with The Plan's response. A grievance will typically involve a complaint about a provider or a provider's office, and may include complaints about a provider's lack of availability or quality of care or services received from a provider's staff.

Most problems can be handled by calling Customer Service at the number appearing on the inside cover of this Contract. The Member may also file a written complaint or grievance with The Plan. The fax number, email address, and mailing address of The Plan appears on the inside cover of this Contract. Written complaints or grievances will be acknowledged within 10 days of receipt. The Member will be notified of The Plan's response within 60 days from receipt of the Member's written complaint or grievance.

APPEALS

Claims Procedures

Types of Claims

Claims are classified by type of claim and the timeline in which a decision must be decided and a notice provided depends on the type of claim involved. The initial benefit claim determination notice will be included in the Member's explanation of benefits (EOB) or in a letter from The Plan, whether adverse or not. There are five types of claims:

1. **Pre-Service Claims**

   A pre-service claim is any claim for a Benefit that, under the terms of this Contract, requires authorization or approval from The Plan or The Plan's subcontracted administrator prior to receiving the Benefit.

2. **Urgent Care Claims**

   An urgent care claim is any pre-service claim where a delay in the review and adjudication of the claim could seriously jeopardize the Member's life or health or ability to regain maximum function or subject the Member to severe pain that could not be adequately managed without the care or treatment that is the subject of the claim.

3. **Post-Service Claims**

   A post-service claim is any claim for payment filed after a Benefit has been received and any other claim that is not a pre-service claim.

4. **Rescission Claims**

   A rescission of coverage is considered a special type of claim. A rescission is defined as any cancellation or discontinuation of coverage that has a retroactive effect based upon the Member's fraud or an intentional misrepresentation of a material fact. A cancellation or discontinuance of coverage that has a retroactive effect is not a rescission if and to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage or to routine changed, such as eligibility updates. A cancellation or discontinuance with a prospective effect only is not a rescission.

5. **Concurrent Care Claim**

   A concurrent care decision represents a decision of The Plan approving an ongoing course of medical treatment for the Member to be provided over a period of time or for a specific number of treatments. A concurrent care claim is any claim that relates to the ongoing course of medical or emergency treatment (and the basis of the approved concurrent care decision), such as a request by the Member for an extension of the number of treatments or the termination by The Plan of the previously approved time period for medical treatment.

Initial Claim Determination by Type of Claim

1. **Pre-Service Claim Determination and Notice**

   a. Notice of Determination

      Upon receipt of a pre-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial determination, but no later than 15 days after receiving the claim.

   b. Notice of Extension

      1. For reasons beyond the control of The Plan

         The Plan may extend the 15-day time period for an additional 15 days for reasons beyond The Plan's control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision.

      2. For receipt of information from the Member to decide the claim

         If the extension is necessary due to the Member's failure to submit information necessary to decide the

claim, the extension notice will specifically describe the information needed, and the Member will be given 45 days from receipt of the notice within which to provide the specified information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

c. Notice of Improperly Submitted Claim

If a pre-service claim request was not properly submitted, The Plan will notify the Member about the improper submission as soon as practicable, but no later than 5 days after The Plan's receipt of the claim, and will advise the Member of the proper procedures to be followed for filing a pre-service claim.

2. Urgent Care Claim Determination and Notice

a. Designation of Claim

Upon receipt of a pre-service claim, The Plan will make a determination if the claim involves urgent care. If a physician with knowledge of the Member's medical condition determines the claim involves urgent care, The Plan will treat the claim as an urgent care claim.

b. Notice of Determination

If the claim is treated as an urgent care claim, The Plan will provide the Member with notice of the determination, either verbally or in writing, as soon as possible consistent with the Member's medical exigencies but no later than 72 hours from The Plan's receipt of the claim. If verbal notice is provided, The Plan will provide a written notice within 3 days after the date The Plan notified the Member.

c. Notice of Incomplete or Improperly Submitted Claim

If an urgent care claim is incomplete or was not properly submitted, The Plan will notify the Member about the incomplete or improper submission no later than 24 hours from The Plan's receipt of the claim. The Member will have at least 48 hours to provide the necessary information. The Plan will notify the Member of the initial claim determination no later than 48 hours after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

3. Post-Service Claim Determination and Notice

a. Notice of Determination

In response to a post-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial **determination, but no later than 30 days after receiving the claim.**

b. Notice of Extension

1. For reasons beyond the control of The Plan

The Plan may extend the 30-day timeframe for an additional 15-day period for reasons beyond The Plan's control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision in such case.

2. For receipt of information from the Member to decide the claim

If the extension is necessary due to the Member's failure to submit information necessary to decide the claim, the extension notice will specifically describe the information needed. The Member will be given 45 days from receipt of the notice to provide the information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested, or the due date for the information.

4. Concurrent Care Determination and Time Frame for Decision and Notice

a. Request for Extension of Previously Approved Time Period or Number of Treatments

1. In response to the Member's claim for an extension of a previously approved time period for treatments or number of treatments, and if the Member's claim involves urgent care, The Plan will review the claim and notify the Member of its determination no later than 24 hours from the date The Plan received the

Member's claim, provided the Member's claim was filed at least 24 hours prior to the end of the approved time period or number of treatments.

2. If the Member's claim was not filed at least 24 hours prior to the end of the approved time period or number of treatments, the Member's claim will be treated as and decided within the timeframes for an urgent care claim as described in the section entitled, "Initial Claim Determination by Type of Claim."
3. If the Member's claim did not involve urgent care, the time periods for deciding pre-service claims and post-service claims, as applicable, will govern.

b. Reduction or Termination of Ongoing Course of Treatment

Other than through a Plan amendment or termination, The Plan may not subsequently reduce or terminate an ongoing course of treatment for which the Member has received prior approval unless The Plan provides the Member with written notice of the reduction or termination and the scheduled date of its occurrence sufficiently in advance to allow the Member to appeal the determination and obtain a decision before the reduction or termination occurs.

5. Rescission of Coverage Determination and Notice of Intent to Rescind

If The Plan makes a decision to rescind the Member's coverage due to a fraud or an intentional misrepresentation of a material fact, The Plan will provide the Member with a Notice of Intent to Rescind at least thirty (30) days prior to rescinding coverage. The Notice of Intent to Rescind will include the following information:

a. The specific reason(s) for the rescission that show the fraud or intentional misrepresentation of a material fact;
b. The date when the notice period ends and the date to which coverage is to be retroactively rescinded;
c. A statement that the Member will have the right to appeal any final decision of The Plan to rescind coverage prior to or after the thirty (30) day period, and a description of The Plan's appeal procedures;
d. A reference to The Plan provision(s) on which the rescission is based;
e. A statement that the Member is entitled to receive upon request and free of charge reasonable access to, and copies of all documents and records and other information relevant to the rescission.

Notice of an Adverse Benefit Determination

An "adverse benefit determination" is defined as a rescission or a denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a Benefit. If The Plan's determination constitutes an adverse benefit determination, the notice to the Member will include:

1. Information sufficient to identify the benefit or claim involved, including, if applicable, the date of service, the health care provider, and the claim amount;
2. The reason(s) for the adverse benefit determination. If the adverse benefit determination is a rescission, the notice will include the basis for the fraud and/or intentional misrepresentation of a material fact;
3. A reference to the applicable Contract provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the adverse benefit determination is based;
4. A description of The Plan's internal appeal and external review procedures (and for urgent care claims only, a description of the expedited review process applicable to such claims), a description of and contact information for a consumer appeal assistance program, and if applicable, a statement of the Member's right to file a civil action under Section 502(a) of ERISA;
5. If applicable, a description of any additional information necessary to complete the claim and why the information is necessary;
6. If applicable, a statement that any internal Medical Policy or guideline or other medical information relied upon in making the adverse benefit determination, and an explanation for the same, will be provided, upon request and free of charge;
7. If applicable, a statement that an explanation for any adverse benefit determination that is based on an experimental treatment or similar exclusion or limitation or a medical necessity standard will be provided, upon request and free of charge;
8. If applicable, a statement that diagnosis and treatment codes will be provided, and their corresponding meanings, upon request and free of charge; and

9. A statement that reasonable access to and copies of all documents and records and other information relevant to the adverse benefit determination will be provided, upon request and free of charge.

How to File an Internal Appeal of an Adverse Benefit Determination

1. Time for Filing an Internal Appeal of an Adverse Benefit Determination

If the Member disagrees with an adverse benefit determination (including a rescission), the Member may appeal the determination within 180 days from receipt of the adverse benefit determination. With the exception of urgent care claims, The Member's appeal may be made verbally or in writing, should list the reasons why the Member does not agree with the adverse benefit determination, and must be sent to the address or fax number listed for appeals on the inside cover of this Contract. If the Member is appealing an urgent care claim, the Member may appeal the claim verbally by calling the telephone number listed for urgent care appeals on the inside cover of this Contract.

For additional assistance with an appeal, a Member may also contact the Commissioner of Securities and Insurance at: Montana Commissioner of Securities and Insurance, 804 Helena Ave., Helena, MT 59601 or call 1-800-332-6148 or 406-444-2040.

2. Access to Plan Documents

The Member may at any time during the filing period, receive reasonable access to and copies of all documents, records and other information relevant to the adverse benefit determination upon request and free of charge. Documents may be viewed at The Plan's office, at 3645 Alice Street, Helena, Montana, between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays. The Member may also request that Blue Cross and Blue Shield of Montana mail copies of all documentation to the Member free of charge.

3. Submission of Information and Documents

The Member may present written evidence and testimony, including any new or additional records, documents or other information that are relevant to the claim for consideration by The Plan until a final determination of the Member's appeal has been made.

4. Consideration of Comments

The review of the claim on appeal will take into account all evidence, testimony, new and additional records, documents, or other information the Member submitted relating to the claim, without regard to whether such information was submitted or considered in making the initial adverse benefit determination.

If The Plan considers, relies on or generates new or additional evidence in connection with its review of the Member's claim, The Plan will provide the Member with the new or additional evidence free of charge as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan. If The Plan relies on a new or additional rationale in denying the Member's claim on review, The Plan will provide the Member with the new or additional rationale as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan.

5. Scope of Review

The person who reviews and decides the Member's appeal will be a different individual than the person who decided the initial adverse benefit determination and will not be a subordinate of the person who made the initial adverse benefit determination. The review on appeal will not give deference to the initial adverse benefit determination and will be made anew. The Plan will not make any decision regarding hiring, compensation, termination, promotion or other similar matters with respect to the individual selected to conduct the review on appeal based upon how the individual will decide the appeal.

6. Consultation with Medical Professionals

If the claim is, in whole or in part, based on medical judgment, The Plan will consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment. The health care professional will not have been involved in the initial adverse benefit determination (nor have been a subordinate of any person previously consulted). The Member may request information regarding the identity of any health care professional whose advice was obtained during the review of the Member's claim.

Time Period for Notifying Member of Final Internal Adverse Benefit Determination

The time period for deciding an appeal of an adverse benefit determination and notifying the Member of the final internal adverse benefit determination depends upon the type of claim. The chart below provides the time period in which The Plan will notify the Member of its final internal adverse benefit determination for each type of claim.

Type of Claim on Appeal	Time Period for Notification of Final Internal Adverse Benefit Determination
Urgent Care Claim	No later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency.
Pre-Service Claim	No later than 30 days from the date The Plan received the Member's appeal.
Post-Service Claim	No later than 60 days from the date The Plan received the Member's appeal.
Concurrent Care Claim	• If the Member's claim involved urgent care, no later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency. • If the Member's claim did not involve urgent care, the time period for deciding a pre-service (non-urgent care) claim or a post-service claim, as applicable, will govern.
Rescission Claim	No later than 60 days from the date The Plan received the Member's appeal.

Content of Notice of Final Internal Adverse Benefit Determination

If the decision on appeal upholds, in whole or in part, the initial adverse benefit determination, the final internal adverse benefit determination notice will include the following information:

1. Information sufficient to identify the claim involved in the appeal, including, as applicable, the date of service, the health care provider, and the claim amount;
2. The title and qualifying credentials of each health care professional participating in the appeal;
3. A statement from each health care professional participating in the appeal of his/her/their understanding of the basis for the Member's appeal;
4. The specific reason(s) for the final internal adverse benefit determination, including a discussion of the decision. If the final internal adverse benefit determination upholds a rescission, the notice will include the basis for the fraud or intentional misrepresentation of a material fact;
5. A reference to the applicable Contract provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the final internal adverse benefit determination is based;
6. If applicable, a statement describing the Member's right to request an external review and the time limits for requesting an external review;
7. If applicable, a statement that any internal Medical Policy or guideline or medical information relied on in making the final internal adverse benefit determination will be provided, upon request and free of charge;
8. If applicable, an explanation of the scientific or clinical judgment for any final internal adverse benefit determination that is based on a medical necessity or an experimental treatment or similar exclusion or limitation as applied to the Member's medical circumstances;
9. If applicable, a statement that diagnosis and treatment codes will be provided, with their corresponding meanings, upon request and free of charge;
10. A description of and contact information for a consumer appeal assistance program and a statement of the Member's right to file a civil action under Section 502(a) of ERISA; and
11. A statement that reasonable access to and copies of all documents and records and other information relevant to the final internal adverse benefit determination will be provided, upon request and free of charge.

External Review Procedures – In General

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member may submit a request for external review. In addition, external review is limited to only those adverse benefit determinations that involve:

1. Rescissions of coverage; and
2. Medical judgment, including those adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit or adverse benefit determinations that certain treatments are experimental or investigational.

External review is not available for:

1. Adverse benefit determinations that are based on contractual or legal interpretations without any use of medical judgment; and
2. Adverse benefit determinations that are based on a failure to meet requirements for eligibility under a group health plan.

Standard External Review Procedures

There are two types of external review: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entitles the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

External reviews (standard or expedited) of adverse benefit determinations or final internal adverse benefit determinations based upon a determination that certain treatments are experimental or investigational are discussed in separate sections, following the section entitled Expedited External Review Procedures, below.

1. Request for a Standard External Review

The Member must submit a written request to The Plan for a standard external review within 4 months from the date the Member receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

The Plan must complete a preliminary review within 5 business days from receipt of the Member's request for a standard external review to determine whether:

a. The Member is or was covered under The Plan when the health care item or service was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care item or service was provided;
b. The adverse benefit determination or final internal adverse benefit determination relates to the Member's failure to meet The Plan's eligibility requirements;
c. The Member has exhausted (or is not required to exhaust) The Plan's internal appeals process;
d. The Member has provided all the information and forms required to process the external review.

Within 1 day after completing its review, The Plan will notify the Member in writing if the request is eligible for external review. If further information or materials are necessary to complete the review, the written notice will describe the information or materials and the Member will be given the remainder of the 4 month period or 48 hours after receipt of the written notice, whichever is later, to provide the necessary information or materials. If the request is not eligible for external review, The Plan will outline the reasons for ineligibility in the notice, include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance and provide the Member with contact information for the U.S. Employee Benefits Security Administration (toll free number 866.444.EBSA (3272) and contact information for the Commissioner's office.

3. Assignment of an IRO

If the Member's request is eligible for external review, The Plan will within 1 business day assign the request for external review on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Montana Commissioner of Securities and Insurance to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will also take into account other circumstances, including conflict of interest concerns.

4. Initiation of External Review and Opportunity to Submit Additional Documents

Within 1 business day of assigning the IRO, The Plan will notify the Member, in writing, or the Member's authorized representative, that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

5. Plan Submission of Documents to the IRO

Within 5 business days after the date the IRO is assigned, The Plan must submit the documents and any information considered in making the benefits denial to the IRO. The Plan's failure to timely provide such documents and information will not constitute cause for delaying the external review. If The Plan fails to timely provide the documents and information, the IRO may terminate the external review and reverse the adverse benefit determination or final internal adverse benefit determination. If the IRO does so, it must notify the Member and The Plan within 1 business day after making the decision.

6. Reconsideration by Plan

On receiving any information submitted by the Member, the IRO must forward the information to The Plan within 1 business day. The Plan may then reconsider its adverse benefit determination or final internal adverse benefit determination. If The Plan decides to reverse its adverse benefit determination or final internal adverse benefit determination, The Plan must provide written notice to the Member and IRO within 1 business day after making the decision. On receiving The Plan's notice, the IRO must terminate its external review.

7. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the following in reaching a decision:

a. The Member's medical records;
b. The Member's treating provider(s)'s recommendations;
c. Reports from appropriate health care professionals and other documents, opinions, and recommendations submitted by The Plan and the Member;
d. The terms and conditions of The Plan, including specific coverage provisions, to ensure that the IRO's decision is not contrary to the terms and conditions of The Plan, unless the terms and conditions do not comply with applicable law;
e. Appropriate practice guidelines, which must include applicable Evidence-Based Standards;
f. Any applicable clinical review criteria developed and used by The Plan unless the criteria are inconsistent with the terms and conditions of The Plan or do not comply with applicable law;
g. The applicable Medical Policies of The Plan;
h. The opinion of the IRO's clinical reviewer or reviewers after considering information described in this notice to the extent the information or documents are available and the clinical reviewer or reviewers consider them appropriate.

8. Written Notice of the IRO's Final External Review Decision

The IRO will send written notification of its decision to the Member and to The Plan within 45 days after the IRO's receipt of the request for external review. The notice will include:

a. A general description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;
b. The date the IRO received the assignment to conduct the external review and the date of the IRO's decision;
c. References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;
d. A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and any Evidence-Based Standards relied on in making the decision;

e. A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;
f. A statement that judicial review may be available to the Member and The Plan; and
g. Contact information for a consumer appeal assistance program at the Commissioner of Securities and Insurance.

9. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan will immediately provide coverage or issue payment according to the written terms and benefits of the Contract.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that the timeframe for decisions and notifications is shorter.

1. Request for Expedited External Review

Under the following circumstances, the Member may request an expedited external review:

a. If the Member received an adverse benefit determination that denied the Member's claim and: (1) the Member filed a request for an internal urgent care appeal; and (2) the delay in completing the internal appeal process would seriously jeopardize the life or health of the Member or the Member's ability to regain maximum function; or
b. Upon receipt of a final internal adverse benefit determination which involves: (1) a medical condition of the Member for which a delay in completing the standard external review would seriously jeopardize the Member's life or health or the Member's ability to regain maximum function; or (2) an admission, availability of care, a continued stay, or a health care item or service for which the Member received emergency services, but has not been discharged from a facility.

2. Preliminary Review

Upon receiving the Member's request for expedited external review, The Plan will immediately determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section. After the preliminary review is complete, The Plan will immediately notify the Member or the Member's authorized representative in writing of its eligibility determination. If the Plan determines the Member's request is ineligible for review, the notice must include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance. The notice must also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If a request is eligible for expedited external review, The Plan will assign an IRO pursuant to and in compliance with the independence and other selection requirements set forth in the Assignment of an IRO paragraph, Standard External Review Procedures section. The Plan will transmit all documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO in as expeditious of a manner as possible (including by phone, facsimile, or electronically).

4. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the same documents and information set forth in the Standard of Review paragraph, Standard External Review Procedures section.

5. Notice of Final External Review Decision

The IRO will provide the Member and The Plan with notice of its final external review decision as expeditiously as the Member's medical condition or circumstances require, but not more than 72 hours after the IRO receives the expedited external review request. If the notice is not in writing, the IRO must provide written confirmation of its

decision to the Member and to The Plan within 48 hours after the date the IRO verbally conveyed the decision The written notice will include:

a. A description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;

b. The date the IRO received the assignment to conduct the external review and the date of the IRO's decisi

c. References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;

d. A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and ar Evidence-Based Standards relied on in making the decision;

e. A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;

f. A statement that judicial review may be available to the Member or The Plan; and

g. Contact information for the appropriate consumer appeal assistance program at the Commissioner of Securities and Insurance.

6. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, Th Plan will immediately approve coverage that was the subject of the adverse benefit determination or final intern adverse benefit determination according to the written terms and benefits of the Contract.

7. Inapplicability of Expedited External Review

An expedited external review may not be provided for retrospective adverse benefit determinations or retrospective final internal adverse benefit determinations.

External Review Procedures – Experimental or Investigational

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member or the Member's authorized representative may submit a reque for external review. In addition, external review as outlined in the next two sections is limited to only those adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational.

Standard External Review Procedures

There are two types of external review of adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entities the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

1. Request for a Standard External Review

The Member or the Member's authorized representative must submit a written request to The Plan for a standar external review within 4 months from the date the Member or the Member's authorized representative receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

Upon receipt of a request for standard external review, The Plan must complete a preliminary review within 5 business days to determine whether:

a. The Member is or was covered under The Plan when the health care service or treatment was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care service or treatment was provided;

b. The requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination: (i) is a covered benefit under the Member's health plan except for The Plan's determination that the health care service or treatment is experimental or investigational for a

particular medical condition; and (ii) is not explicitly listed as an excluded benefit under the Member's health plan;

c. The Member's treating health care provider has certified that one of the following situations is applicable: (i) standard health care services or treatments have not been effective in improving the condition of the Member; (ii) standard health care services or treatments are not medically appropriate for the Member; or (iii) there is no available standard health care service or treatment covered by The Plan that is more beneficial than the requested health care service or treatment;

d. (i) the Member's treating health care provider has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the Member, in the physician's opinion, than any available standard health care services or treatments; or (ii) a physician who is licensed, board-certified, or eligible to take the examination to become board-certified and is qualified to practice in the area of medicine appropriate to treat the Member's condition has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested by the Member who is subject to the adverse benefit determination or final internal adverse benefit determination is likely to be more beneficial to the Member than any available standard health care services or treatments; and

e. The Member has exhausted The Plan's internal appeals process or the Member is exempt from exhausting The Plan's internal appeals process.

Within 1 business day after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will within 1 business day assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day of assigning the IRO, The Plan will notify the Member or the Member's authorized representative in writing that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice, for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

4. Plan Submission of Documents to the IRO

Within 5 business days after assigning an IRO, The Plan will provide to the assigned IRO any documents and information considered in making the adverse benefit determination or the final internal adverse benefit determination. Failure by the Plan to timely provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information within 5 business days, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan of its decision.

5. Reconsideration by The Plan

The IRO will forward any information submitted by Member or the Member's authorized representative to the Plan, within 1 business day of its receipt. The Plan may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by The Plan

may not delay or terminate the IRO's external review. The external review may be terminated only if The Plan decides, on completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage for the requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will notify the Member or the Member's authorized representative and the IRO immediately in writing of its decision. The IRO will terminate the external review on receipt of the notice from The Plan.

6. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. In selecting Clinical Peers to conduct the external review, the assigned IRO will select physicians or other health care providers who meet minimum statutorily prescribed qualifications and who, through clinical experience in the past 3 years, are experts in the treatment of the Member's condition and knowledgeable about the recommended or requested health care service or treatment. The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Within 20 days after selection, each Clinical Peer will provide an opinion to the assigned IRO on whether the requested health care service or treatment should be covered. In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached during The Plan's internal appeals process.

Each Clinical Peer's opinion will be in writing and include the following information:

a. a description of the Member's medical condition;
b. a description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the requested health care service or treatment is more likely than not to be more beneficial to the Member than any available standard health care services or treatments and that the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments;
c. a description and analysis of any Medical or Scientific Evidence considered in reaching the opinion;
d. a description and analysis of any Evidence-Based Standard; and
e. information on whether the clinical peer's rationale for the opinion is based on the Member's medical records and/or the attending provider's or health care professional's recommendation.

7. Written Notice of the IRO's Final External Review Decision

Within 20 days after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision and provide written notice of the decision to the Member or the Member's authorized representative and to The Plan.

If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should be covered, the IRO shall make a decision to reverse The Plan's adverse benefit determination or final internal adverse benefit determination. If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should not be covered, the IRO shall make a decision to uphold The Plan's adverse benefit determination or final internal adverse benefit determination. If the Clinical Peers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the IRO shall obtain the opinion of an additional Clinical Peer. The additional Clinical Peer shall use the same information to reach an opinion as used by the Clinical Peers who have already submitted their opinions. The selection of the additional Clinical may not extend the time within which the assigned IRO is required to make a decision based on the opinions of the Clinical Peers.

The IRO will include in its written notice:

a. a general description of the reason for the request for external review;
b. the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;

c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

8. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that requests for external review may be made differently and the timeframe for decisions and notifications is shorter.

1. Request for an Expedited External Review

The Member or the Member's authorized representative may make an oral or written request for an expedited external review of an adverse benefit determination or a final internal adverse benefit determination if the Member's treating health care provider certifies, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

2. Preliminary Review

Upon receipt of a request for an expedited external review, The Plan must immediately complete a preliminary review to determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section, above.

Immediately after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will immediately assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular expedited external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day after assignment of the IRO, The Plan will notify the Member or the Member's authorized representative, in writing, that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO for the IRO's consideration in its external review.

4. Plan Submission of Documents to the IRO

Upon assigning an IRO, The Plan will provide any documents and information considered in making the adverse benefit determination or the final internal adverse benefit determination to the assigned IRO electronically, by telephone, by facsimile, or by any other available expeditious method. Failure by the Plan to provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information upon IRO assignment, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately

upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan accordingly.

5. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. The assigned IRO will select physicians or other health care providers using the same criteria as set forth in the Standard of Review paragraph in the Standard External Review Procedures, above, The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Each Clinical Peer will provide an opinion to the assigned IRO as expeditiously and the Member's medical condition or circumstances require but no later than 5 calendar days after being selected as a Clinical Peer, on whether the requested health care service or treatment should be covered. If the Clinical Peer's opinion was initially made orally, the Clinical Peer shall provide the IRO written confirmation of the opinion within 48 hours after the opinion was initially made.

In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached by The Plan. Each Clinical Peer's opinion may be rendered orally or in writing and will include the same information as set forth in the Standard of Review paragraph in the Standard External Review Procedures section, above.

6. Written Notice of the IRO's Final External Review Decision

Within 48 hours after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision based upon the recommendations of a majority of the Clinical Peers conducting the review, and will provide oral or written notice of the decision to the Member or the Member's authorized representative and to the Plan. If the IRO's notice is provided orally, the IRO will provide written confirmation of the decision within 48 hours of the initial oral notice.

The IRO will include in its written notice:

a. a general description of the reason for the request for external review;
b. the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;
c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

7. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Deemed Exhaustion of Internal Appeal Process

1. The Member will be deemed to have exhausted the internal appeal process and may request external review or pursue any available remedies under state law or if applicable, a civil action under 502(a) of ERISA, if The Plan fails to comply with its claims and appeals procedures, except that claims and appeals procedures will not be deemed exhausted based on violations that are:

a. De minimis;
b. Non-prejudicial to the Member;
c. Attributable to good cause or matters beyond The Plan's control;
d. In the context of an ongoing, good faith exchange of information between the Member and The Plan; and
e. Not reflective of a pattern or practice of violations by The Plan.

2. Upon request of the Member, The Plan will provide an explanation of a violation within 10 days. The explanation will include a description of the basis for The Plan's assertion that the violation does not result in the deemed exhaustion of The Plan's internal claims and appeals procedures.
3. If the Member seeks external or judicial review based on deemed exhaustion of The Plan's internal claims and appeals procedures, and the external reviewer or court rejects the Member's request, The Plan will notify the Member within a reasonable period of time, not to exceed 10 days, of the Member's right to resubmit the Member's internal appeal. The timeframe for appealing the adverse benefit determination begins to run when the Member receives the notice of the right to resubmit the Member's internal appeal.

PREAUTHORIZATION

The Plan has designated certain covered services which require Preauthorization in order for the Member to receive the maximum Benefits possible under this Contract.

The Member is responsible for satisfying the requirements for Preauthorization. This means that the Member must request Preauthorization or assure that the Member's Physician, provider of services, the Member's authorized representative, or a Family Member complies with the requirements below. If the Member utilizes a Network Provider for covered services, that provider may request Preauthorization for the services. However, it is the Member's responsibility to assure that the services are preauthorized before receiving care.

To request Preauthorization, the Member or his/her Physician must call the Preauthorization number shown on the Member's Identification Card **before** receiving treatment. The Plan will assist in coordination of the Member's care so that his/her treatment is received in the most appropriate setting for his/her condition and that the Member receives the highest level of Benefits under this Contract.

Preauthorization does not guarantee that the care and services a Member receives are eligible for Benefits under the Contract. In addition, a nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield of Montana and provider charges plus Deductible, Coinsurance and/or Copayment even if the service is an Emergency Service or the if the service has been Preauthorized.

Preauthorization Process for Inpatient Services

For an Inpatient facility stay, the Member must request Preauthorization from The Plan **before** the Member's scheduled admission. The Plan will consult with the Member's Physician, Hospital, or other facility to determine if Inpatient level of care is required for the Member's illness or injury. The Plan may decide that the treatment the Member needs could be provided just as effectively in a different setting (such as the Outpatient department of the Hospital, an Ambulatory Surgical Facility, or the Physician's office).

If The Plan determines that the Member's treatment does not require Inpatient level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Unscheduled Inpatient admissions, such as admissions for Emergency Medical Conditions and maternity care should be preauthorized within two days after the admission.

Preauthorization Process for Mental Illness, Severe Mental Illness and Chemical Dependency Services

All Inpatient and partial hospitalization services related to treatment of Mental Illness, Severe Mental Illness and Chemical Dependency must be Preauthorized by The Plan. Preauthorization is also required for the following Outpatient Services and must be submitted no later than 15 business days before the service is provided:

- Electroconvulsive therapy;
- Intensive Outpatient Treatment;
- Neuropsychological testing;

- Psychological testing;
- Repetitive Transcranial Magnetic Stimulation.
- Applied Behavioral Analysis (ABA)

Preauthorization is not required for therapy visits to a Physician or other professional Provider licensed to perform covered services under this Contract. However, all services are subject to the provisions in the section entitled Concurrent Review.

If The Plan determines that the Member's treatment does not require Inpatient or partial hospital level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay or partial hospital level of care, without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Preauthorization Process for Other Outpatient Services

In addition to the Preauthorization requirements outlined above, The Plan also requires Preauthorization, which must be submitted no later than 15 business days before the service is provided, for certain Outpatient services, including:

- Dialysis treatment - Out-of-Network;
- High-cost injections, including but not limited to IVIG, Avastin, Rituxan, and Remicade injections.
- Home Health Care;
- Home Hemodialysis;
- Home Infusion Therapy;
- Hospice Services;
- Molecular Genetic Testing;
- Outpatient elective surgery - Out-of-Network;
- Transplant Evaluations;
- Diagnostic sleep studies for Obstructive Sleep Apnea;
- Radiation Therapy

For additional information on Preauthorization, the Member or the Provider may call the Customer Service number on the Member's identification card.

It is NOT necessary to preauthorize standard x-ray and lab services or Routine office visits.

If The Plan does not approve the Outpatient Service, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with the services without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

The Benefits section of this Contract details the services which are subject to Preauthorization.

Preauthorization Request Involving Non-Urgent Care

Except in the case of a Preauthorization Request Involving Urgent Care (see below), The Plan will provide a written response to the Member's Preauthorization request no later than 15 days following the date we receive the Member's request. This period may be extended one time for up to 15 additional days, if we determine that additional time is necessary due to matters beyond our control.

If The Plan determines that additional time is necessary, The Plan will notify the Member in writing, prior to the expiration of the original 15-day period, that the extension is necessary, along with an explanation of the circumstances requiring the extension of time and the date by which The Plan expects to make the determination.

If an extension of time is necessary due to the need for additional information, The Plan will notify the Member of the specific information needed, and the Member will have 45 days from receipt of the notice to provide the additional information.

The Plan will provide a written response to the Member's request for Preauthorization within 15 days following receipt of the additional information. The procedure for appealing an adverse Preauthorization determination is set forth in the section entitled Complaints and Grievances.

Preauthorization Request Involving Urgent Care

A Preauthorization Request Involving Urgent Care is any request for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the Member or the ability of the Member to regain maximum function; or in the opinion of a Physician with knowledge of the Member's medical condition, would subject the Member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the Preauthorization request.

In case of a Preauthorization Request Involving Urgent Care, The Plan will respond to the Member no later than 72 hours after receipt of the request, unless the Member fails to provide sufficient information, in which case, the Member will be notified of the missing information within 24 hours and will have no less than 48 hours to provide the information. A Benefit determination will be made as soon as possible (taking into account medical exigencies) but no later than 72 hours after the initial request, or within 48 hours after the missing information is received (if the initial request is incomplete).

NOTE: The Plan's response to the Member's Preauthorization Request Involving Urgent Care, including an adverse determination, if applicable, may be issued orally. A written notice will also be provided within three days following the oral notification.

Preauthorization Request Involving Emergency Care

If the Member is admitted to the Hospital for Emergency Care and there is not time to obtain Preauthorization, the Member's Provider must notify The Plan within two working days following the Member's emergency admission.

Preauthorization Required For Certain Prescription Drug Products and Other Medications

Prescription Drug Products, which are self-administered, process under the Prescription Drugs section of this Contract. There are other medications that are administered by a Covered Provider which process under the medical Benefits.

1. **Prescription Drugs – Covered Under the Prescription Drugs Benefit**

   Certain prescription drugs, which are self-administered, require Preauthorization. Please refer to the Prescription Drugs section for complete information about the Prescription Drug Products that are subject to Preauthorization, step therapy, and quantity limits, the process for requesting Preauthorization, and related information.

2. **Other Medications – Covered Under Medical Benefits**

   Medications that are administered by a Covered Provider will process under the medical Benefits of this Contract. Certain medications administered by a Covered Provider require Preauthorization. The medications that require Preauthorization are subject to change by The Plan.

   For any medication that is subject to Preauthorization, the Member or provider should fax the request for Preauthorization to the Blue Cross and Blue Shield of Montana Medical Review Preauthorization Department at 1-855-313-8908. The Member or provider may also submit a written request for Preauthorization. Preauthorization forms are located on The Plan website at www.bcbsmt.com, and may be printed directly from the website. The Plan will notify the Member and provider of the Preauthorization determination.

   In making determinations of coverage, The Plan may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

   To determine which medications are subject to Preauthorization, the Member or provider should refer to the list of medications which applies to the Member's Plan on The Plan website at www.bcbsmt.com or call the Customer Service toll-free number identified on the Member's identification card or The Plan website at www.bcbsmt.com.

General Provisions Applicable to All Required Preauthorizations

1. **No Guarantee of Payment**

   Preauthorization does not guarantee payment of Benefits by The Plan. Even if the Benefit has been Preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date of service or the Member's Benefits may have changed as of the date the service.

2. **Request for Additional Information**

   The Preauthorization process may require additional documentation from the Member's health care provider or pharmacist. In addition to the written request for Preauthorization, the health care provider or pharmacist may be required to include pertinent documentation explaining the proposed services, the functional aspects of the treatment, the projected outcome, treatment plan and any other supporting documentation, study models, prescription, itemized repair and replacement cost statements, photographs, x-rays, etc., as may be requested by The Plan to make a determination of coverage pursuant to the terms and conditions of this Contract.

3. **Failure to Obtain Preauthorization**

   If the Member does not obtain Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Any treatment the Member receives which is not a covered service under this Contract, or is not determined to be Medically Necessary, or is not performed in the appropriate setting will be excluded from the Member's Benefits. This applies even if Preauthorization approval was requested or received.

Concurrent Review

Whenever it is determined by The Plan, that Inpatient care or an ongoing course of treatment may no longer meet medical necessity criteria or is considered Experimental/Investigational/Unproven (EIU), the Member, Member's Provider or the Member's authorized representative may submit a request to The Plan for continued services. If the Member, the Member's Provider or the Member's authorized representative requests to extend care beyond the approved time limit and it is a Request Involving Urgent Care, The Plan will make a determination on the request/appeal as soon as possible (taking into account medical exigencies) but no later than 72 hours after it receives the initial request, or within 48 hours after it receives the missing information (if the initial request is incomplete).

Care Management

The goal of Care Management is to help the Member receive the most appropriate care that is also cost effective. If the Member has an ongoing medical condition or a catastrophic illness, the Member should contact The Plan. If appropriate, a care manager will be assigned to work with the Member and the Member's providers to facilitate a treatment plan. Care Management includes Member education, referral coordination, utilization review and individual care planning. Involvement in Care Management does not guarantee payment by The Plan.

ELIGIBILITY AND ENROLLMENT

To be eligible for enrollment, the Applicant must and any Family Members for whom coverage is sought must:

1. Be a resident of the state of Montana.
2. Complete an application.

Eligibility for this coverage will be determined by the Exchange in accordance with applicable law. For questions regarding eligibility, refer to healthcare.gov.

Applying for Coverage

An Applicant may apply for coverage in a Qualified Health Plan (QHP) through the Exchange for himself/herself and/or any eligible Dependents (see below) by submitting the Application(s) for individual medical insurance form, along with any exhibits, appendices, addenda and/or other required information ("Application(s)") to Blue Cross and Blue Shield of Montana and the Exchange, as appropriate. The Application(s) for coverage may or may not be accepted.

No eligibility rules or variations in premium will be imposed based on health status, medical condition, claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability, disability, or any other health status related factor. Applicants will not be discriminated against for coverage under this Plan on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

Variation in the administration, processes or benefits of this policy that are based on clinically indicated, reasonable medical management practices, or are part of permitted wellness incentives, disincentives and/or other programs do not constitute discrimination.

An applicant may enroll in or change a QHP for himself/herself and/or any eligible Dependents during one of the Initial and Annual Enrollment Periods as set by the Exchange. The Effective Date will be determined by Blue Cross and Blue Shield of Montana and the Exchange, as appropriate, depending upon the date the application is received, payment of the initial premiums no later than the day before the Effective Date of coverage (unless any Advance Premium Tax Credit is greater than the initial premium), and other determining factors.

Annual Open Enrollment Period/Effective Date of Coverage

An Applicant may apply for or change coverage in a QHP through the Exchange for the Applicant and/or any Eligible Family Members during the annual open enrollment period designated by the Exchange.

When the Applicant enrolls during the annual open enrollment period, the Applicant's and/or any Eligible Family Members' effective date will be the following January 1, unless otherwise designated by the Exchange and Blue Cross and Blue Shield of Montana, as appropriate.

This section "Annual Open Enrollment Period/Effective Date of Coverage" is subject to change by the Exchange, Blue Cross and Blue Shield of Montana, and/or applicable law, as appropriate.

Special Enrollment Periods

Special enrollment periods have been designated during which the Member may apply for or change coverage in a QHP through the Exchange for himself/herself and/or any Eligible Family Members. Application must be made 60 days from the date of a special enrollment event.

Birth

Children born to a Member after the Effective Date of the Contract will be covered for a period of 31 days beginning at the moment of birth and including the day of birth, provided the Beneficiary Member remains covered under the Contract for those 31 days. Coverage will continue for the child after the 31 day period if within 60 days the Beneficiary Member:

1. Enrolls the child through the Exchange to continue the coverage; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if application to continue coverage is not received by the Exchange. If application to continue coverage is received between 32 and 60 days after the birth of the child, then coverage will be reinstated back to the date of birth. Dues must be paid for any coverage beyond the initial 31 days of coverage.

Limitations:

1. If the Beneficiary Member does not remain covered during the 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.
2. However, after 31 days, coverage will not continue for any newborn child of a covered Dependent child unless the Beneficiary Member adopts the newborn child or is the legal guardian of the newborn child.

Adopted Children or Children Placed for Adoption

Children will be covered for a period of 31 days upon adoption or placement for adoption, including the date of placement, provided the Beneficiary Member remains covered under the Contract for those 31 days. Coverage will continue for the child after the 31 day period if within 60 days the Beneficiary Member:

1. Enrolls the child through the Exchange to continue the coverage for the child; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if application to continue coverage is not received by the Exchange. If application to continue coverage is received between 32 and 60 days after the adoption or placement for adoption of the child, then coverage will be reinstated back to the date of the adoption or placement for adoption of the child. Dues must be paid for any coverage beyond the initial 31 days of coverage.

Limitations:

1. If the Beneficiary Member does not remain covered during the 31 days, the child placed for adoption will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.
2. In the event the placement is disrupted prior to legal adoption and the child is removed from placement, coverage shall cease upon the date the placement is disrupted.

Advance payments of any Advance Premium Tax Credit and cost-sharing reductions, if applicable, are not effective until the first day of the following month, unless the birth, adoption, or placement as a foster child or for adoption occurs on the first day of the month.

Marriage

In the case of marriage, the Effective Date will be the date of marriage if the completed request for enrollment (application) is made through the Exchange within 60 days after the date of marriage.

Loss of Minimum Essential Coverage

In the event the Member experiences a loss of minimum essential coverage, coverage will be effective no later than the first day of the month following the loss of coverage. A loss of coverage does not include:

1. Termination or loss due to a failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage; or
2. Situations allowing for a rescission (a cancellation or discontinuance of coverage that has a retroactive effect), as determined by the Exchange.

For purposes of this section, "Minimum Essential Coverage" means Health insurance coverage that is recognized as coverage that meets substantially all requirements under federal law pertaining to adequate individual, group or government health insurance coverage. For additional information on whether particular coverage is recognized as "Minimum Essential Coverage", please call the customer service number on the inside cover of this document or on the back of your ID card or visit www.cms.gov

Additional Special Enrollment Events

1. An individual gains status as a U.S. citizen(s), national(s), or lawfully present in the U.S. and gains such status.
2. Enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous as evaluated and determined by the Exchange and/or Blue Cross and Blue Shield of Montana, as appropriate.
3. An enrollee through the Exchange adequately demonstrates to the Exchange that the QHP in which he/she enrolled substantially violated a material provision of its contract in relation to the enrollee.
4. An individual is determined newly eligible or newly ineligible for an Advance Premium Tax Credit or has a change in eligibility for cost-sharing reductions, regardless of whether the individual already enrolled in a QHP.

   For purposes of this section, "Premium Tax Credit" means a refundable premium tax credit you may receive for taxable years ending after December 31, 2013, to the extent provided for under applicable law, where the credit is meant to offset all or a portion of the premium paid by you for coverage obtained through an Exchange during the preceding calendar year.

5. An individual gains access to new QHPs as a result of a permanent move.
6. An Indian, as defined by section 4 of the Indian Health Care Improvement Act. An Indian may enroll himself/herself and any eligible Dependents in a QHP or change from one QHP to another one time per month.
7. An individual demonstrates to the Exchange, in accordance with the guidelines issued by HHS, that he/she meets other exceptional circumstances as the Exchange may provide.
8. Loss of coverage due to voluntary or involuntary termination (other than for gross misconduct) and reduction in number of hours of employment;
9. Loss of coverage for Spouses of covered employees due to reasons that would make the employee eligible for COBRA; or loss of coverage due to the employee's death.
10. Loss of coverage for children of covered employees due to reasons that would make the employee eligible for COBRA, loss of coverage due to the employee's death, or loss of coverage due to the loss of Dependent status under the terms of The Plan.
11. Divorce or legal separation. Coverage will be effective on the first day of the month coinciding with or the next month following your divorce or legal separation date.
12. A Dependent is no longer considered a Dependent under The Plan because of age or work status.
13. Loss of coverage due to moving out of the QHP-issuer Network Service Area.
14. Loss of coverage because benefits are no longer offered by the QHP-issuer to the class of similarly situated individuals.
15. Such other events required by applicable law.

Coverage resulting from any of the special enrollment events outlined above is contingent upon timely completion of the application and remittance of the appropriate premiums in accordance with the guidelines as established by the Exchange and Blue Cross and Blue Shield of Montana, as appropriate.

Effective Date and Commencement of Benefits

Unless otherwise noted above, the Effective Date is as follows:

1. If an application was received on the 1st through the 14th of the month, the Effective Date will be no later than the first day of the following month.
2. If an application was received on the 15th through the 31st of the month, the Effective Date will be no later then the first day of the second following month.

The Member is entitled to the Benefits of this Contract from the Member's Effective Date.

Transfer of Plan Membership

Transfer of Membership for Family Members

The following persons may transfer membership to their own beneficiary membership Contract if application is made in writing to The Plan within 31 days of the date of termination of their membership under this Contract.

1. A Spouse of a Beneficiary Member who was enrolled as a Family Member and ceases to be a Family Member as defined due to divorce, annulment of marriage or legal separation.
2. Children of a Beneficiary Member who were enrolled as a Family Member and cease to be a Family Member as defined.
3. Family Members of a Beneficiary Member who has died.

Benefits to Member Hospitalized on Date of Transfer

If the Member is receiving Inpatient Care on the date of transfer of membership to another Blue Cross and Blue Shield of Montana Contract, the Member will continue to receive the Benefits payable under this Contract:

1. For 30 days; or
2. Until the Member is discharged from the Inpatient Care facility, whichever occurs first.

Child-Only Coverage

Child-only coverage is available to eligible children who:

1. Are residents of Montana; and
2. Have not attained age 21 prior to the first day of the plan year; and
3. Are a citizen, national, or noncitizen who is lawfully present in the United States; and
4. Are not incarcerated.

This Plan is considered child-only coverage and the following restrictions apply:

1. The parent or legal guardian is not covered and is not eligible for Benefits under this health Plan.
2. If a child is covered under this Contract and acquires a new eligible child of his/her own, then:

   Newborn children of the Member are covered under this Contract for the first 31 days after birth. If the Member does not remain covered for 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Member is covered. After 31 days, the newborn child of a Member may be enrolled in his/her own Plan coverage if application for coverage is made within 30 days.

   Children placed for adoption. Children will be covered upon placement for adoption. If the Member does not remain covered for 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered. Coverage will end for the child 31 days after placement for adoption. After 31 days, the child may be enrolled in his/her own Plan coverage if application for coverage is made within 30 days.

3. If a child is under the age of 18, his/her parent, legal guardian, or other responsible party must submit the application for child-only insurance form, along with any exhibits, appendices, addenda and/or other required information to The Plan and the Exchange, as appropriate. For any child under 18 covered under this health care Plan, any obligations set forth in this Plan, any exhibits, appendices, addenda and/or other required information will be the obligations of the parent, legal guardian, or other responsible party applying for coverage on the child's behalf. Application for child-only coverage will not be accepted for an adult child that has attained age 21 as of the beginning of the calendar year. Adult children (at least 18 years of age but no older than 20 years of age) who are applying for coverage under this Plan must apply for their own individual Plan and must sign or authorize the application(s).

TERMINATION OF COVERAGE

Termination When the Member is No Longer Eligible for Coverage

Coverage under this Contract for the Beneficiary Member, and any Family Members, will terminate at the end of the Month in which the Member becomes ineligible for coverage. However, a Spouse and any Family Members may be issued their own Contract. Please refer to the section entitled Transfer of Plan Membership.

If the Member is receiving Inpatient Care on the date coverage terminates, the Member will continue to receive the Benefits payable under this Contract:

1. For 30 days; or
2. Until the Member is discharged from the Inpatient Care facility, whichever occurs first.

Termination for Nonpayment of Dues or Other Reasons

Blue Cross and Blue Shield of Montana will terminate coverage due to fraud and/or intentional misrepresentation of material fact.

If the Member's dues are not paid when due, coverage will terminate automatically at midnight, Mountain Standard Time, on the last day of the Month for which dues are paid for the Beneficiary Member and Family Members.

Blue Cross and Blue Shield of Montana will provide notice of cancellation stating the date the cancellation will become effective, which may not be earlier than:

1. the beginning of the period for which premiums have not been paid in full if the notice of cancellation for nonpayment of premiums is mailed or delivered within 15 days after the due date of the missed premiums for that period;
2. the date of mailing or delivery of notice of cancellation for nonpayment of premiums if notice of cancellation for nonpayment of premiums is not mailed or delivered within 15 days after the premium due date for the applicable policy period; or
3. 90 days after the date of mailing or delivery of the notice of cancellation or refusal to renew for any reason other than nonpayment of premiums or a material misrepresentation contained in the application.

The time frames for the notices of cancellation outlined above run concurrently with the time frames included in the section entitled "Grace Period" under Payment of Dues.

A grace period of 31 days will be granted for the payment of each premium (dues) falling due after the first premium, during which grace period the Contract shall continue in force, however, Claim Payments for Covered Medical Expenses received during the grace period may be pended until full premium payment is made, and during the grace period pharmacies may require the Member to pay for the Member's prescription drug expenses in full.

If the Member pays the premium in full during the 31 day grace period, then the Member may submit a claim to Blue Cross and Blue Shield of Montana for any expenses that the Member paid to providers and pharmacies during the grace period. See the CLAIMS section for additional information.

If a Member fails to pay premiums in full to Blue Cross and Blue Shield of Montana and/or the Exchange within 31 days of the premium due date, this Contract will automatically terminate on the last day of the coverage period for which premiums have been paid in full. Claim Payments will not be provided for Covered Medical Expenses incurred during this 31 day grace period or thereafter unless the premiums are paid in full within this period. If coverage is terminated for non-payment of premium, any Claims received and paid for during the 31 day grece period will be billed to the Member.

For a Member receiving an Advance Premium Tax Credit, there is a three-month grace period for paying the full premiums falling due after the first premium is paid. If full premium is not paid for the Member and any covered Family Members within one month of the premium due date, Claim Payments for Covered Medical Expenses received during the second and third month's grace period under this Policy will be pended until full premium payment is received. If full payment of the premium is not received within the three month grace period, then coverage under this Contract will automatically terminate on the last day of the first month of the three-month grace period. Blue Cross and Blue Shield of Montana will not process any Claims for services after the date of termination.

Termination of Coverage of Children and Spouse

Coverage will terminate automatically at midnight Mountain Standard Time, on the last day of the Month in which a child reaches age 26 years. Coverage for a Spouse will terminate at midnight, Mountain Standard Time, on the last day of the Month in which the Spouse's marriage to the Beneficiary Member terminated. Please refer to the section entitled Transfer of Plan Membership.

Termination of Benefits on Termination of Coverage

When the membership of a Beneficiary Member and/or Family Member is terminated for any reason the Benefits of this Contract will no longer be provided and The Plan will not make payment for services provided to them after the date on which cancellation becomes effective. However, a Spouse and any Family Members may be issued their own Contract. Please refer to the section entitled Transfer of Plan Membership.

Certificate of Creditable Coverage

Even though this health plan does not have a preexisting condition exclusion period, The Plan will issue a Certificate of Creditable Coverage to the Member, upon request, following termination of coverage.

Reinstatement

If any renewal dues payment is not paid within the time granted the Member for payment, a subsequent acceptance of dues by The Plan without requiring in connection therewith an application for reinstatement, shall reinstate the Contract; provided, however, that if The Plan requires an application for reinstatement and issues a conditional receipt for the dues tendered, the Contract will be reinstated upon approval of such application by Blue Cross and Blue Shield of Montana or, lacking such approval, upon the 45th day following the date of such conditional receipt unless The Plan has previously notified the Member in writing of its disapproval of such application.

The reinstated Contract shall cover only loss resulting from such accidental injury as may be sustained after the date of reinstatement and loss due to such sickness as began more than ten days after such date. In all other respects, the Member and The Plan shall have the same rights thereunder as they had under the Contract immediately before the due date of the defaulted dues, subject to any provision endorsed hereon or attached hereto in connection with the reinstatement.

QUALIFIED MEDICAL CHILD SUPPORT ORDER (QMSCO)

Beneficiary Members and Family Members can obtain, without charge, a copy of the procedures governing Qualified Medical Child Support Order (QMCSO) determinations from Blue Cross and Blue Shield of Montana.

RENEWAL OF CONTRACT

Renewal of Contract by the Plan

This Contract will be renewed unless one of the following occurs:

1. Nonpayment of the required dues.
2. The Member has performed an act or practice that constitutes fraud or has made an intentional misrepresentation of a material fact with respect to coverage of individual insureds.
3. The Member is no longer eligible for coverage in a QHP offered through the Exchange.
4. This Contract is terminated or is decertified as a QHP.
5. The Member's coverage has been rescinded as described under the Rescission provision of this Policy.
6. The Member changes from QHP to another during an annual open enrollment period or special enrollment period.
7. Election by The Plan to:
   a. Cease offering a particular type of coverage in the individual market; or
   b. Cease offering all coverage in the individual market.

Termination of Contract by the Member

The Beneficiary Member may cancel this Contract by notifying Blue Cross and Blue Shield of Montana in writing. Notice of cancellation will terminate this Contract on the first of the Month following receipt of the Member's written notification to cancel.

BENEFITS

The Plan will pay for the following Benefits provided by a Covered Provider based on the Allowable Fee and subject to any Deductible, Copayment, Coinsurance and other provisions, as applicable.

Benefits outlined in this section are subject to the Plan's Medical Policy, any specific exclusions identified for that specific Benefit and to the exclusions and limitations outlined in the Exclusions and Limitations section.

Accident

Services which are provided for bodily injuries resulting from an Accident.

Acupuncture

Services provided by a licensed acupuncturist to treat illness or injury.

The Schedule of Benefits describes payment limitations for these services.

Advanced Practice Registered Nurses and Physician Assistants - Certified

Services provided by an Advanced Practice Registered Nurse or a physician assistant-certified who is licensed to practice medicine in the state where the services are provided and when payment would otherwise be made if the same services were provided by a Physician.

Ambulance

Licensed ground and air ambulance transport required for a Medically Necessary condition to the nearest appropriate site.

Anesthesia Services

Anesthesia services provided by a Physician (other than the attending Physician) or nurse anesthetist including the administration of spinal anesthesia and the injection or inhalation of a drug or other anesthetic agent.

The Plan will not pay for:

1. Hypnosis;
2. Local anesthesia or intravenous (IV) sedation that is considered to be an Inclusive Service/Procedure;
3. Anesthesia consultations before surgery that are considered to be Inclusive Services/Procedures because the Allowable Fee for the anesthesia performed during the surgery includes this anesthesia consultation; or
4. Anesthesia for dental services or extraction of teeth, except anesthesia provided at a Hospital in conjunction with dental treatment will be covered only when a nondental physical illness or injury exists which makes Hospital care Medically Necessary to safeguard the Member's health. Dental services and treatment are not a Benefit of this Contract, except as specifically included in the Dental Accident Benefit.

Approved Clinical Trials

Routine Patient Costs provided in connection with an Approved Clinical Trial.

Autism Spectrum Disorders

Diagnosis and treatment of autistic disorder, Asperger's Disorder or Pervasive Developmental Disorder.

Covered services include:

1. Habilitative Care or Rehabilitative Care, including, but not limited to, professional, counseling and guidance services and treatment programs; Applied Behavior Analysis (ABA), also known as Lovaas Therapy; discrete trial training, pivotal response training, intensive intervention programs, and early intensive behavioral intervention;
2. Medications;
3. Psychiatric or psychological care; and
4. Therapeutic care provided by a speech-language pathologist, audiologist, occupational therapist or physical therapist.

Note: Applied Behavior Analysis (ABA), also known as Lovaas Therapy, is only available for Members under age 19.

Birthing Centers

Services for the delivery of a newborn provided at a birthing center.

Blood Transfusions

Blood transfusions, including the cost of blood, blood plasma, blood plasma expanders and packed cells. Storage charges for blood are paid when a Member has blood drawn and stored for the Member's own use for a planned surgery.

Chemical Dependency

Benefits for Chemical Dependency will be paid as any other Illness.

Outpatient Services

Care and treatment for Chemical Dependency when the Member is not an Inpatient Member and provided by:

1. a Hospital;
2. a Mental Health Treatment Center;
3. a Chemical Dependency Treatment Center;
4. a Physician or prescribed by a Physician;
5. a psychologist;
6. a licensed social worker;
7. a licensed professional counselor;
8. an addiction counselor licensed by the state; or
9. a licensed psychiatrist.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Chemical Dependency; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by the Chemical Dependency.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Care Services

Care and treatment of Chemical Dependency, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity services provided at a Residential Treatment Center are Benefits of this Contract.

Preauthorization is required for Inpatient Care services and Residential Treatment services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Chemical Dependency, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization. Please refer to the section entitled Preauthorization.

Chemotherapy

The use of drugs approved for use in humans by the U.S. Food and Drug Administration and ordered by the Physician for the treatment of disease.

Chiropractic Services

Services of a licensed chiropractor.

The Schedule of Benefits describes payment limitations for these services.

Contraceptives

Services and supplies related to contraception, including but not limited to, oral contraceptives, contraceptive devices and injections, subject to the terms and limitations of the Contract. Oral contraceptives are paid as described in the Preventive Health Care section or under the Prescription Drugs section.

Deductible and Coinsurance do not apply to contraceptives covered under the Preventive Health Care Benefit, whether provided during an office visit or through the Prescription Drugs Benefit. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy.

Convalescent Home Services

Services of a Convalescent Home as an alternative to Hospital Inpatient Care. The Plan will not pay for custodial care.

NOTE: The Plan will not pay for the services of a Convalescent Home if the Member remains inpatient at the Convalescent Home when a skilled level of care is not Medically Necessary.

Preauthorization is required for Convalescent Home Services. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Dental Accident Services

Dental services provided by physicians, dentists, oral surgeons and/or any other provider are not covered under this Contract except that, Medically Necessary services for the initial repair or replacement of sound natural teeth which are damaged as a result of an Accident, are covered, except that orthodontics, dentofacial orthopedics, or related appliances are not covered, even if related to the Accident.

The Plan will not pay for services for the repair of teeth which are damaged as the result of biting and chewing.

Diabetic Education

Outpatient self-management training and education services for the treatment of diabetes provided by a Covered Provider with expertise in diabetes.

The Schedule of Benefits describes payment limitations for these services.

Diabetes Treatment (Office Visit)

Services and supplies for the treatment of diabetes provided during an office visit. For additional Benefits related to the treatment of diabetes, e.g., surgical services and medical supplies, refer to that specific Benefit.

Diagnostic Services

1. Diagnostic Imaging Procedures

   Diagnostic Imaging which includes Computerized Tomography Scan (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan).

2. All Other Covered Diagnostic Services

   a. X-rays and Other Radiology. Some examples of other radiology include:

   - Nuclear medicine
   - Ultrasound

b. Laboratory Tests. Some examples of laboratory tests include:

- Urinalysis
- Blood tests
- Throat cultures

c. Diagnostic Testing. Tests to diagnose an Illness or Injury. Some examples of diagnostic testing include:

- Electroencephalograms (EEG)
- Electrocardiograms (EKG or ECG)

This Benefit does not include diagnostic services such as biopsies which are covered under the surgery Benefit.

Durable Medical Equipment

The appropriate type of equipment used for therapeutic purposes **where the Member resides**. Durable medical equipment, which requires a written prescription, must also be:

1. able to withstand repeated use (consumables are not covered);
2. primarily used to serve a medical purpose rather than for comfort or convenience; and
3. generally not useful to a person who is not ill or injured.

The Plan will not pay for the following items:

1. exercise equipment;
2. car lifts or stair lifts;
3. biofeedback equipment;
4. self-help devices which are not medical in nature, regardless of the relief they may provide for a medical condition;
5. air conditioners and air purifiers;
6. whirlpool baths, hot tubs, or saunas;
7. waterbeds;
8. other equipment which is not always used for healing or curing;
9. Deluxe equipment. The Plan has the right to decide when deluxe equipment is required. However, upon such decision, payment for deluxe equipment will be based on the Allowable Fee for standard equipment.
10. computer-assisted communication devices;
11. durable medical equipment required primarily for use in athletic activities;
12. replacement of lost or stolen durable medical equipment;
13. repair to rental equipment; and
14. duplicate equipment purchased primarily for Member convenience when the need for duplicate equipment is no medical in nature.

Education Services

Education services, other than diabetic education, that are related to a medical condition.

Emergency Room Care

1. Emergency room care for an accidental Injury.
2. Emergency room care for Emergency Services.

Home Health Care

The following services, when prescribed and supervised by the Member's attending Physician provided in the Member's home by a licensed Home Health Agency and which are part of the Member's treatment plan:

1. Nursing services.
2. Home Health Aide services.

3. Hospice services.
4. Physical Therapy.
5. Occupational Therapy.
6. Speech Therapy.
7. Medical social worker.
8. Medical supplies and equipment suitable for use in the home.
9. Medically Necessary personal hygiene, grooming and dietary assistance.

The Plan will not pay for:

1. Maintenance or custodial care visits.
2. Domestic or housekeeping services.
3. "Meals-on-Wheels" or similar food arrangements.
4. Visits, services, medical equipment, or supplies not approved or included as part of the Member's treatment plan.
5. Services for the treatment of Mental Illness.
6. Services provided in a nursing home or skilled nursing facility.

Preauthorization is required for home health care. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Home Infusion Therapy Services

The preparation, administration, or furnishing of parenteral medications, or parenteral or enteral nutritional services to a Member by a Home Infusion Therapy Agency, including:

1. Education for the Member, the Member's caregiver, or a Family Member.
2. Pharmacy.
3. Supplies.
4. Equipment.
5. Skilled nursing services when billed by a Home Infusion Therapy Agency.

Home infusion therapy services must be ordered by a Physician and provided by a licensed Home Infusion Therapy Agency. A licensed Hospital, which provides home infusion therapy services, must have a Home Infusion Therapy Agency license or an endorsement to its Hospital facility license for home infusion therapy services.

Preauthorization is required for home infusion therapy services. Please refer to the section entitled Preauthorization.

Hospice Care

A coordinated program of home care and Inpatient Care that provides or coordinates palliative and supportive care to meet the needs of a terminally ill Member and the Member's Immediate Family. Benefits include:

1. Inpatient and Outpatient care;
2. Home care;
3. Nursing services - skilled and non-skilled;
4. Counseling and other support services provided to meet the physical, psychological, spiritual and social needs of the terminally ill Member; and
5. Instructions for care of the Member, counseling and other support services for the Member's Immediate Family.

Preauthorization is required for hospice care. Please refer to the section entitled Preauthorization.

Hospital Services - Facility and Professional

Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations

   a. Room and board, which includes special diets and nursing services.

b. Intensive care and cardiac care units which include special equipment and concentrated nursing services provided by nurses who are Hospital employees.

2. Miscellaneous Hospital Services

a. Laboratory procedures.
b. Operating room, delivery room, recovery room.
c. Anesthetic supplies.
d. Surgical supplies.
e. Oxygen and use of equipment for its administration.
f. X-ray.
g. Intravenous injections and setups for intravenous solutions.
h. Special diets when Medically Necessary.
i. Respiratory therapy, chemotherapy, radiation therapy, dialysis therapy.
j. Physical Therapy, Speech Therapy and Occupational Therapy.
k. Drugs and medicines which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
3. Require a Physician's written prescription.

Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.

Preauthorization is required for Inpatient care. Please refer to the section entitled Preauthorization.

Inpatient Care services are subject to the following conditions:

1. Days of care

a. The number of days of Inpatient Care provided is 365 days.
b. In computing the number of Inpatient Care days available, days will be counted according to the standard midnight census procedure used in most Hospitals. The day a Member is admitted to a Hospital is counted, but the day a Member is discharged is not. If a Member is discharged on the day of admission, one day is counted.
c. The day a Member enters a Hospital is the day of admission. The day a Member leaves a Hospital is the day of discharge.

2. The Member will be responsible to the Hospital for payment of its charges if the Member remains as an Inpatient Member when Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member. No Benefits will be paid for Inpatient Care provided primarily for diagnostic or therapy services.

3. Preauthorization is required for Inpatient Care. Please refer to the section entitled Preauthorization.

Inpatient Care Medical Services Billed by a Professional Provider

Nonsurgical services by a Covered Provider, Concurrent Care and Consultation Services.

Medical services do not include surgical or maternity services. Inpatient Care medical services are covered only if the Member is eligible for Benefits under the Hospital Services, Inpatient Care Services section for the admission.

Medical care visits are limited to one visit per day per Covered Provider unless a Member's condition requires a Physician's constant attendance and treatment for a prolonged period of time.

Observation Beds/Rooms

Payment will be made for observation beds when Medically Necessary.

Outpatient Hospital Services

Use of the Hospital's facilities and equipment for surgery, respiratory therapy, chemotherapy, radiation therapy and dialysis therapy.

Inborn Errors of Metabolism

Treatment under the supervision of a Physician of inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism and for which medically standard methods of diagnosis, treatment and monitoring exist. Benefits include expenses of diagnosing, monitoring, and controlling the disorders by nutritional and medical assessment, including but not limited to clinical services, biochemical analysis, medical supplies, prescription drugs, corrective lenses for conditions related to the inborn error of metabolism, nutritional management, and Medical Foods used in treatment to compensate for the metabolic abnormality and to maintain adequate nutritional status.

Infertility - Diagnosis and Treatment

The Plan will pay for:

The diagnosis and treatment of infertility, including:

- Medically Necessary evaluation to determine cause of infertility
- Artificial insemination (AI) or intrauterine insemination (IUI)
- Medically Necessary Reproductive procedures not related to in vitro fertilization.

The Plan will not pay for:

1. Prescription drugs used to treat infertility.
2. Services, supplies, drugs and devices related to in vitro fertilization.

Mammograms (Routine and Medical)

Mammography examinations.

The minimum mammography examination recommendations are:

1. One baseline mammogram for women ages 35 through 39.
2. One mammogram every two years for women ages 40 through 49, or more frequently as recommended by a Physician.
3. One mammogram every year for women age 50 or older.

Maternity Services - Professional and Facility Covered Providers

1. Prenatal and postpartum care.
2. Delivery of one or more newborns.
3. Hospital Inpatient Care for conditions related directly to pregnancy. Inpatient Care following delivery will be covered for whatever length of time is necessary and will be at least 48 hours following a vaginal delivery and at least 96 hours following a delivery by cesarean section. The decision to shorten the length of stay of Inpatient Care to less than that stated in the preceding sentence must be made by the attending health care provider and the mother.

   Under Federal law, Benefits may not be restricted for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, under Federal law, Covered Providers may not be required to obtain Preauthorization from The Plan for prescribing a length of stay not in excess of 48 hours (or 96 hours).
4. Payment for any maternity services by the professional provider is limited to the Allowable Fee for total maternity care, which includes delivery, prenatal and postpartum care.

Please refer also to the Newborn Initial Care section.

Medical Supplies

The following supplies for use outside of a Hospital:

1. Supplies for insulin pumps, syringes and related supplies for conditions such as diabetes.

2. Injection aids, visual reading and urine test strips, glucagon emergency kits for treatment of diabetes. One insulin pump for each warranty period is covered under the Durable Medical Equipment Benefit.
3. Sterile dressings for conditions such as cancer or burns.
4. Catheters.
5. Splints.
6. Colostomy bags and related supplies.
7. Supplies for renal dialysis equipment or machines.

Medical supplies are covered only when:

1. Medically Necessary to treat a condition for which Benefits are payable.
2. Prescribed by a Covered Provider.

Mental Health

Benefits provided for mental health are for the treatment of Mental Illness and Severe Mental Illness as defined in the section entitled "Definitions."

Benefits include but are not limited to, Inpatient Care services, Outpatient services, rehabilitation services and medication for the treatment of Mental Illness or Severe Mental Illness.

Payment for mental health Benefits will be made as for any other illness.

Outpatient Services

Care and treatment of Mental Illness or Severe Mental Illness if the Member is not an Inpatient Member and is provided by:

1. a Hospital;
2. a Physician or prescribed by a Physician;
3. a Mental Health Treatment Center;
4. a Chemical Dependency Treatment Center;
5. a psychologist;
6. a licensed social worker;
7. a licensed professional counselor;
8. a licensed addiction counselor; or
9. a licensed psychiatrist.
10. a licensed Advanced Practice Registered Nurse with a specialty in mental health.
11. a licensed Advanced Practice Registered Nurse with prescriptive authority and specializing in mental health.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Mental Illness or Severe Mental Illness; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by Mental Illness or Severe Mental Illness.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Services

Care and treatment of Mental Illness or Severe Mental Illness, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity residential services provided at a Residential Treatment Center are Benefits of this Contract.

Preauthorization is required for Inpatient Care services and Residential Treatment Center services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Mental Illness or Severe Mental Illness, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization. Please refer to the section entitled Preauthorization.

Naturopathy

Services provided by a licensed naturopathic provider are covered if such services are a Benefit of this Contract.

Newborn Initial Care

1. The initial care of a newborn at birth provided by a Physician.
2. Nursery Care - Hospital nursery care of newborn infants.

Office Visits

Covered services provided in a Covered Provider's office during a Professional Call and covered services provided in the home by a Covered Provider. Visits are limited to one visit per day per provider.

Oral Surgery

Benefits will be provided for the following:

- Excision or biopsy of tumors or cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth
- Excision of exostoses of the jaws and hard palate (provided that this procedure is not done in preparation for dentures or other prostheses)
- Treatment of fractures of facial bone
- External incision and drainage of cellulitis (not including treatment of dental abscesses)
- Incision of accessory sinuses, salivary glands or ducts
- Surgical removal of complete bony impacted teeth
- Reduction of dislocation of, or excision of, the temporomandibular joints.

Orthopedic Devices/Orthotic Devices

A supportive device for the body or a part of the body, head, neck or extremities, including but not limited to, leg, back, arm and neck braces. In addition, when Medically Necessary, Benefits will be provided for adjustments, repairs or replacement of the device because of a change in the Member's physical condition.

The Plan will not pay for foot orthotics defined as any in-shoe device designed to support the structural components of the foot during weight-bearing activities

Pediatric Vision Care

The following services only may be provided by a licensed ophthalmologist or optometrist operating within the scope of his or her license, or a dispensing optician to Members under 19 years of age:

1. One Routine vision exam per Benefit Period.
2. One pair of glasses (frames and lenses) or two boxes of contacts per Benefit Period.

The Plan will not pay for any vision service, treatment or materials not specifically listed above.

Physician Medical Services

Medical services by a Covered Provider for:

1. Inpatient Hospital Physician visits.
2. Convalescent Home facility Physician visits.
3. Surgical facility Physician services.

The Plan will not pay for pre- or postsurgical visits that are considered to be Inclusive Services/Procedures are included in the payment for the surgery.

This Benefit does not include services provided in the home or the Covered Provider's office.

Postmastectomy Care and Reconstructive Breast Surgery

Postmastectomy Care

Inpatient Care for the period of time determined by The Plan in consultation with the Attending Physician, and the Member, to be Medically Necessary following a mastectomy.

Reconstructive Breast Surgery

1. All stages of Reconstructive Breast Surgery after a mastectomy including, but not limited to:
   a. All stages of reconstruction of the breast on which a mastectomy has been performed.
   b. Surgery and reconstruction of the other breast to establish a symmetrical appearance.
   c. Chemotherapy.
   d. Prostheses and physical complications of all stages of a mastectomy and breast reconstruction, including lymphedemas.

   Coverage described in 1(a) through 1(d) will be provided in a manner determined in consultation with the Attending Physician and the patient.
2. Breast prostheses as the result of a mastectomy.

For specific Benefits related to postmastectomy care, refer to that specific Benefit, e.g., surgical services and Hospital services.

Prescription Drugs

Refer to the Prescription Drugs section in the Schedule of Benefits for specific information on the application of any Deductible, Copayment and/or Coinsurance.

The Prescription Drugs Benefit is for Prescription Drug Products which are self-administered. This Benefit does not include medications which are administered by a Covered Provider. If a medication is administered by a Covered Provider, the claim will process under the Member's medical Benefits. **Please refer to the Preauthorization section for complete information about the medications that are subject to the Member's medical Benefits, the process for requesting Preauthorization for medications subject to the Member's medical Benefits, and related Information.**

Subject to the terms, conditions, and limitations of this Contract, The Plan will pay for Prescription Drug Products, which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Require a Physician's written prescription; and
3. Are dispensed under federal or state law pursuant to a prescription order or refill.

Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.

Drug Lists

Covered drugs are selected by The Plan based upon the recommendations of a committee, which is made up of current and previously practicing physicians and pharmacists from across the country, some of which are employed by or affiliated with Blue Cross and Blue Shield of Montana. The committee considers drugs regulated by the FDA for inclusion on the Drug List. Some of the factors committee members evaluate include each drug's safety, effectiveness, cost, and how it compares with drugs currently on the Drug List. The committee considers drugs that are newly approved by the FDA, as well as those that have been on the market for some time. Entire drug classes are also regularly reviewed. Changes to the Drug List can be made from time to time.

The Plan may offer multiple Drug Lists. By accessing www.bcbsmt.com or www.myprime.com or calling the Customer Service toll-free number on the Member's identification card, the Member or provider can determine the Drug List that applies to the Member's Plan and whether a particular drug is on the Drug List.

The Member, or the Member's prescribing health care provider, can ask for a Drug List exception if the Member's drug is not on the Drug List (also known as a formulary). To request this exception, the Member or the Member's prescriber, can call the number on the back of the Member's ID card to ask for a review. If the Member has a health condition that may jeopardize his/her life, health or keep the Member from regaining function, or the Member's current drug therapy uses a non-covered drug, the Member or the Member's prescriber, may be able to ask for an expedited review process. Blue Cross and Blue Shield of Montana will notify the Member or the Member's prescriber, of the coverage decision within 24 hours after they receive the request for an expedited review. If the coverage request is denied, Blue Cross and Blue Shield of Montana will let the Member and the Member's prescriber, know why it was denied and offer the Member a covered alternative drug (if applicable). If the Member's exception is denied, the Member may appeal the decision according to the appeals process the Member will receive with the denial determination. The Member should call the number on the back of the ID card if the Member has any questions.

Covered Prescription Drug Products

The following Prescription Drug Products, obtained from a Participating Pharmacy, either retail or mail order, or a retail nonparticipating pharmacy, are covered:

1. Legend drugs - drugs requiring written prescriptions and dispensed by a licensed pharmacist for treatment of an illness or injury.
2. One prescription oral agent for controlling blood sugar levels for each class of drug approved by the United States food and drug administration.
3. Insulin on prescription.
4. Disposable insulin needles/syringes.
5. Test strips.
6. Lancets.
7. Oral contraceptives, contraceptive devices, implantables or injections prescribed by a Physician.
8. Smoking cessation products and over-the-counter smoking cessation aids/medications with a written prescription, as required by the Affordable Care Act. Tobacco counseling is available under the Preventive Health Care Benefit.

The Schedule of Benefits lists any Deductible, Copayment and/or Coinsurance that the Member is responsibility for and the payment limitations for these Prescription Drug Products.

Non-Covered Prescription Drug Products

The Plan will not pay for:

1. Nonlegend drugs other than insulin.
2. Compounded medications.
3. Anabolic Steroids.
4. Any drug used for the purpose of weight loss.
5. Fluoride supplements, except as required by the Affordable Care Act for children under age 6.
6. Drugs which are not approved by the FDA for a particular use or purpose or when used for a purpose other than the purpose for which the FDA approval is given, except as required by law or regulation. Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.

7. Over-the-counter drugs that do not require a prescription, except over-the-counter smoking cessation aids with a written prescription.
8. Prescription Drug Products for which there is an exact over-the-counter equivalent.
9. Prescription Drug Products for cosmetic purposes, including the treatment of alopecia (hair loss) (e.g., Minoxidil, Rogaine).
10. Therapeutic devices or appliances, including needles, syringes, support garments and other non-medicinal substances, regardless of intended use, except those otherwise covered under this section.
11. Prescription Drug Products used for erectile dysfunction.
12. Prescription Drug Products used for the treatment of infertility.
13. Insulin pumps and glucose meters. Insulin pumps and glucose meters are covered under the Durable Medical Equipment Benefit. Insulin pump supplies are covered under the Medical Supplies Benefit.
14. Drugs or items labeled "Caution - limited by federal law to investigational use," or experimental drugs, even though the Member is charged for the item.
15. Biological sera, blood, or blood plasma.
16. Prescription Drug Products which are to be taken by or administered to the Member, in whole or in part, while the Member is a patient in a licensed Hospital, rest home, sanitarium, extended care facility, convalescent hospital, nursing home, or similar institution which operates or allows to be operated on its premises, a facility for dispensing pharmaceuticals. Medication in these situations is part of the facility's charge.
17. Any Prescription Drug Product refilled in excess of the number specified by the Physician, or any refill dispensed after one year from the Physician's original order.
18. Replacement prescription drugs or Prescription Drug Products due to loss, theft or spoilage.
19. Prescription Drug Products obtained from a pharmacy located outside the United States for consumption within the United States.
20. Prescription Drug Products provided by a mail-order pharmacy that is not approved by The Plan.
21. Repackaged medications.
22. Non-sedating antihistamines.
23. Brand-Name Proton Pump Inhibitors (PPIs).
24. Prescription Drug Products determined by The Plan to have inferior efficacy or significant safety issues.

Controlled Substances Limitation

If The Plan determines that a Member may be receiving quantities of controlled substance medications not supported by FDA approved dosages or recognized treatment guidelines, any Benefits for additional drugs may be subject to a review for Medical Necessity, appropriateness and other restrictions.

Purchase and Payment of Prescription Drug Products

Prescription Drug Products may be obtained using an outpatient retail pharmacy or a mail-order pharmacy approved by The Plan. To use a mail-order pharmacy, the Member must send an order form with the prescription to the address listed on the mail-order service form and pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The address of each mail order pharmacy approved by The Plan is listed on the inside cover of this Contract.

If drugs or Prescription Drug Products are purchased at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the Member presents the Member's ID card at the time of purchase, the Member must pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The Member will only be required to pay the appropriate Deductible, Copayment and/or Coinsurance and the difference between the cost of the Brand-Name drug and the Generic equivalent if the amount can be determined by the pharmacy at the time of purchase.

Exceptions to this provision may be allowed for certain preventive medications (including prescription contraceptive medications) if the Member's health care Provider submits a request to The Plan indicating that the Generic drug

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would be medically inappropriate, along with supporting documentation. If The Plan grants the exception request, any difference between the cost of the Brand-Name drug and the Generic equivalent will be waived.

If the Member uses a Participating Pharmacy to fill a prescription, but elects to submit the claim directly to the Plan's Pharmacy Benefit Manager, instead of having the Participating Pharmacy submit the claim, the Member will be reimbursed for the prescription drug based on the amount that would have been paid to the Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance.

If drugs or Prescription Drug Products are purchased at a nonparticipating outpatient pharmacy, the Member must pay for the prescription at the time of dispensing and then file a prescription drug claim form with The Plan's Pharmacy Benefit Manager for reimbursement. The Member will be reimbursed for the prescription drug at 50% of the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance and any additional charge for the difference between the cost of the Brand-Name drug and the Generic equivalent.

Prescription Drug Products Subject to Preauthorization, Step Therapy or Quantity Limits

1. Prescription Drug Products subject to Preauthorization require prior approval from The Plan's Pharmacy Benefit Manager before they can qualify for coverage under The Plan. If the Member does not obtain Preauthorization before a Prescription Drug Product is dispensed, the Member may pay for the prescription and then pursue authorization of the drug from The Plan's Pharmacy Benefit Manager. If the authorization is approved by The Plan's Pharmacy Benefit Manager, the Member should then submit a claim for the prescription drug on a prescription claim form to The Plan's Pharmacy Benefit Manager for reimbursement.
2. Preauthorization does not guarantee payment of the Prescription Drug Product by The Plan. Even if the prescription drug has been preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date the drug is dispensed or the Member's Benefits may have changed as of the date the drug is dispensed.
3. A step therapy program is designed to help the Member use the lowest cost product(s) within a drug class. Drugs subject to step therapy are widely considered equivalent to other products within the class by both physicians and pharmacists. In order to obtain a medication within a step therapy program, the member must fail a first line drug. In general, first line products are usually generic medications. In some cases, a pharmacy policy will allow the step therapy to be waived. The pharmacy policies are located on The Plan website at www.bcbsmt.com.
4. A quantity limit is a limitation on the number or amount of a Prescription Drug Product covered within a certain time period. Quantity limits are established to ensure that prescribed quantities are consistent with clinical dosing guidelines, to control for billing errors by pharmacies, to encourage dose consolidation, appropriate utilization, and to avoid misuse/abuse of the medication. A prescription written for a quantity in excess of the established limit will require a Preauthorization before Benefits are available.

Certain Prescription Drug Products, such as those used to treat rheumatoid arthritis, growth hormone deficiency, hepatitis C, or more serious forms of anemia, hypertension, and epilepsy, are subject to Preauthorization, step therapy, or quantity limits. The Prescription Drug Products included in the prescription drug program are subject to change, and medications for other conditions may be added to the program.

If the Member's provider is prescribing a Prescription Drug Product subject to Preauthorization, step therapy, or quantity limits, the provider should fax the request for Preauthorization to The Plan's Pharmacy Benefit Administrator at the fax number listed on the inside cover of this Contract. The Member and provider will be notified of The Plan's Pharmacy Benefit Administrator's determination.

In making determinations of coverage, The Plan's Pharmacy Benefit Administrator may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, Pharmacy Benefit Manager evaluations, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

To find out more about Preauthorization/step therapy/quantity limits or to determine which Prescription Drug Products are subject to Preauthorization, step therapy or quantity limits, the Member or provider should refer to the Drug List which applies to the Member's Plan at www.bcbsmt.com or www.myprime.com or call the Customer Service toll-free number identified on the Member's identification card.

Specialty Medications

1. Specialty Medications are generally prescribed for individuals with complex or ongoing medical conditions such as multiple sclerosis, hemophilia, hepatitis C and rheumatoid arthritis. These high cost medications also have one or more of the following characteristics:
   a. Injected or infused, but some may be taken by mouth
   b. Unique storage or shipment requirements
   c. Additional education and support required from a health care professional
   d. Usually not stocked at retail pharmacies
2. For the highest level of Benefits, Specialty Medications must be acquired through The Plan's contracted Specialty Pharmacy listed on the inside cover of this Contract. A list of covered Specialty Medications may be found on The Plan website at www.bcbsmt.com. Registration and other applicable forms are also located on the website.

Preventive Health Care

Covered preventive services include, but are not limited to:

1. Services that have an "A" or "B" rating in the United States Preventive Services Task Force's current recommendations (additional information is provided by accessing http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm); and
2. Immunizations recommended by the Advisory Committee of Immunizations Practices of the Centers for Disease Control and Prevention; and
3. Health Resources and Services Administration (HRSA) Guidelines for Preventive Care & Screenings for Infants, Children, Adolescents and Women;

   In addition to the screening services recommended under the HRSA Guidelines, the following services are included:

   a. Lactation Services

      Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period. In addition, Benefits are provided for the purchase of manual or electric breast pumps or the rental of Hospital-grade pumps. The purchase of electric breast pumps is limited to two electric breast pumps per Benefit Period. Payment will be made according to the Preventive Health Care Benefit on the Schedule of Benefits.

   b. Contraceptives

      Food and Drug Administration approved contraceptive methods, including certain contraceptive products, sterilization procedures for women, and patient education and counseling for all women with reproductive capacity. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy; and
4. Current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention issued prior to or after November 2009.

Examples of Preventive Health Care services include, but are not limited to, physical examinations, colonoscopies, immunizations and vaccinations.

For more detailed information on all covered services, contact Customer Service or access www.bcbsmt.com.

Prostheses

The appropriate devices used to replace a body part missing because of an Accident, Injury, or Illness.

When placement of a prosthesis is part of a surgical procedure, it will be paid under Surgical Services.

Payment for deluxe prosthetics will be based on the Allowable Fee for a standard prosthesis.

The Plan will not pay for the following items:

1. computer-assisted communication devices;
2. replacement of lost or stolen prosthesis.

Note: The prosthesis will not be considered a replacement if the prosthesis no longer meets the medical needs of the Member due to physical changes or a deteriorating medical condition.

Radiation Therapy

The use of x-ray, radium, or radioactive isotopes ordered by the attending Physician and performed by a Covered Provider for the treatment of disease.

Rehabilitation – Facility and Professional

Rehabilitation Therapy and other covered services, as outlined in this Rehabilitation section, billed by a Rehabilitation Facility provider or a Professional Provider for services provided to a Member.

The Plan will not pay when the primary reason for Rehabilitation is any one of the following:

1. Custodial Care;
2. Diagnostic admissions;
3. Maintenance, nonmedical self-help, or vocational educational therapy;
4. Social or cultural rehabilitation;
5. Learning and developmental disabilities; and
6. Visual, speech, or auditory disorders because of learning and developmental disabilities or psychoneurotic and psychotic conditions.

Benefits will not be provided under this Rehabilitation section for treatment of Chemical Dependency or Mental Illness as defined in the Chemical Dependency and Mental Illness sections.

Benefits will be provided for services, supplies and other items that are within the scope of the Rehabilitation benefit described in this Rehabilitation section only as provided in and subject to the terms, conditions and limitations applicable to this Rehabilitation benefit section and other applicable terms, conditions and limitations of this Contract. Other Benefit sections of this Contract, such as but not limited to Hospital Services, do not include Benefits for any services, supplies or items that are within the scope of the Rehabilitation benefit as outlined in this section.

Rehabilitation Facility Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations
   a. Room and Board, which includes but is not limited to dietary and general, medical and rehabilitation nursing services.
2. Miscellaneous Rehabilitation Facility Services (whether or not such services are Rehabilitation Therapy or are general, medical or other services provided by the Rehabilitation Facility during the Member's admission), including but not limited to:
   a. Rehabilitation Therapy services and supplies, including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy.
   b. Laboratory procedures.
   c. Diagnostic testing.
   d. Pulmonary services and supplies, including but not limited to oxygen and use of equipment for its administration.
   e. X-rays and other radiology.
   f. Intravenous injections and setups for intravenous solutions.
   g. Special diets when Medically Necessary.
   h. Operating room, recovery room.
   i. Anesthetic and surgical supplies.

j. Drugs and medicines which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
3. Require a Physician's written prescription.

Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.

3. Rehabilitation Facility Inpatient Care Services do not include services, supplies or items for any period during which the Member is absent from the Rehabilitation Facility for purposes not related to rehabilitation, including but not limited to intervening inpatient admissions to an acute care Hospital.

Preauthorization is required for Rehabilitation Facility Inpatient Care. Please refer to the section entitled Preauthorization.

Rehabilitation Facility Inpatient Care is subject to the following conditions:

1. The Member will be responsible to the Rehabilitation Facility for payment of the Facility's charges if the Member remains as an Inpatient Member when Rehabilitation Facility Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member.
2. The term "Rehabilitation Facility" does not include:

a. A Hospital when a Member is admitted to a general medical, surgical or specialty floor or unit (other than a rehabilitation unit) for acute Hospital care, even though rehabilitation services are or may be provided as a part of acute care.
b. A nursing home;
c. A rest home;
d. Hospice;
e. A skilled nursing facility;
f. A Convalescent Home;
g. A place for care and treatment of Chemical Dependency;
h. A place for treatment of Mental Illness;
i. A long-term, chronic-care institution or facility providing the type of care listed above.

Rehabilitation Facility Inpatient Care Services Billed by a Professional Provider

All Professional services provided by a Covered Provider who is a physiatrist or other Physician directing the Member's Rehabilitation Therapy. Such professional services include care planning and review, patient visits and examinations, consultation with other physicians, nurses or staff, and all other professional services provided with respect to the Member. Professional services provided by other Covered Providers (i.e., who are not the Physician directing the Member's Rehabilitation Therapy) are not included in the rehabilitation Benefit, but are included to the extent provided in and subject to the terms, conditions and limitations of other contract benefits (e.g., Physician Medical Services).

Outpatient Rehabilitation

Rehabilitation Therapy provided on an outpatient basis by a facility or professional provider.

Surgical Services

Surgical Services Billed by a Professional Provider

Services by a professional provider for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery. The charge for a surgical suite outside of the Hospital is included in the Allowable Fee for the surgery.

Surgical Services Billed by an Outpatient Surgical Facility or Freestanding Surgery Centers

Services of a surgical facility or a freestanding surgery center licensed, or certified for Medicare, by the state in which it is located and have an effective peer review program to assure quality and appropriate patient care. The surgical

procedure performed in a surgical facility or a freestanding surgery center is recognized as a procedure which can be safely and effectively performed in an Outpatient setting.

The Plan will pay for a Recovery Care Bed when Medically Necessary and provided for less than 24 hours. Payment will not exceed the semiprivate room rate that would be billed for an inpatient stay.

Surgical Services Billed by a Hospital (Inpatient and Outpatient)

Services of a Hospital for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery.

Telemedicine

Benefits for services provided by Telemedicine when such services are Medically Necessary Covered Medical Expenses provided by a Covered Provider.

Therapies for Down Syndrome

Benefits will be provided for the diagnosis and treatment of Down syndrome for a covered child under 19 years of age. Covered services include:

- Medically Necessary Habilitative Care or Rehabilitative Care that is prescribed, provided, or ordered by a licensed Physician, including but not limited to professional, counseling, and guidance services and treatment programs. Habilitative Care and Rehabilitative Care includes Medically Necessary interactive therapies derived from evidence-based research, including intensive intervention programs and early intensive behavioral intervention.
- Medically Necessary therapeutic care that is provided by a licensed speech-language pathologist a physical therapist or an occupational therapist;

When treatment is expected to require extended services, Blue Cross and Blue Shield of Montana may request that the treating Physician provide a treatment plan based on evidence-based screening criteria. The treatment plan will consist of the diagnosis, proposed treatment by type and frequency, the anticipated duration of treatment, the anticipated outcomes stated as goals, and the reasons the treatment is Medically Necessary. Blue Cross and Blue Shield of Montana may request that the treatment plan be updated every 6 months.

Therapies - Outpatient

Services provided for Physical Therapy, Speech Therapy, cardiac therapy and Occupational Therapy, not including Rehabilitation Therapy.

Transplants

For certain transplants, Blue Cross and Blue Shield of Montana contracts with a number of Centers of Excellence that provide transplant services. Blue Cross and Blue Shield of Montana highly recommends use of the Centers of Excellence because of the quality of the outcomes at these facilities. Members being considered for a transplant procedure are encouraged to contact Blue Cross and Blue Shield of Montana Customer Service to discuss the possible benefits of utilizing the Centers of Excellence.

Transplant services include:

1. Organ procurement including transportation of the surgical/harvesting team, surgical removal of the donor organ, evaluation of the donor organ and transportation of the donor or donor organ to the location of the transplant operation.
2. Donor services including the pre-operative services, transplant related diagnostic lab and x-ray services, and the transplant surgery hospitalization. Transplant related services are covered for up to six months after the transplant.
3. Hospital Inpatient Care services.
4. Surgical services.
5. Anesthesia.
6. Professional provider and diagnostic Outpatient services.

7. Licensed ambulance travel or commercial air travel for the Member receiving the treatment to the nearest Hospital with appropriate facilities.

Payment by The Plan is subject to the following conditions:

1. When both the transplant recipient and donor are members, both will receive Benefits.
2. When the transplant recipient is a Member and the donor is not, both will receive Benefits to the extent that benefits for the donor are not provided under other hospitalization coverage.
3. When the transplant recipient is not a Member and the donor is, the donor will receive Benefits to the extent tha benefits are not provided to the donor by hospitalization coverage of the recipient.

The Plan will not pay for:

1. Experimental/Investigational/Unproven procedures.
2. Transplants of a nonhuman organ or artificial organ implant.
3. Donor searches.

Preauthorization is required for Transplants. Please refer to the section entitled Preauthorization.

Well-Child Care

Well-child care provided by a Physician or a health care professional supervised by a Physician.

Benefits shall include coverage for:

1. Histories;
2. Physical examinations;
3. Developmental assessments;
4. Anticipatory guidance;
5. Laboratory tests;
6. Routine immunizations.

EXCLUSIONS AND LIMITATIONS

All Benefits provided under this Contract are subject to the Exclusions and limitations in this section and as stated under the Benefit section. **The Plan will not pay for:**

1. All services, supplies, drugs and devices which are provided to treat any Illness or Injury arising out of employment when the Member's employer has elected or is required by law to obtain coverage for Illness or Injury under state or federal Workers' Compensation laws, occupational disease laws, or similar legislation, including employees' compensation or liability laws of the United States. This Exclusion applies to all services and supplies provided to treat such Illness or Injury even though:
   a. Coverage under the government legislation provides benefits for only a portion of the services incurred.
   b. The employer has failed to obtain such coverage required by law.
   c. The Member waives his or her rights to such coverage or benefits.
   d. The Member fails to file a claim within the filing period allowed by law for such benefits.
   e. The Member fails to comply with any other provision of the law to obtain such coverage or benefits.
   f. The Member was permitted to elect not to be covered by the Workers' Compensation Act but failed to properly make such election effective.

   This Exclusion will not apply if the Member is permitted by statute not to be covered and the Member elects not to be covered by the Workers' Compensation Act, occupational disease laws, or liability laws.

   This Exclusion will not apply if the Member's employer was not required and did not elect to be covered under any Workers' Compensation, occupational disease laws or employer's liability acts of any state, country, or the United States.

2. Services, supplies, drugs and devices which the Member is entitled to receive or does receive from TRICARE, the Veteran's Administration (VA), and Indian Health Services but not Medicaid. This Exclusion is not intended to exclude Covered Medical Expenses from coverage if a Member is a resident of a Montana State institution when Benefits are provided.

   Note: Under some circumstances, the law allows certain governmental agencies to recover for services rendered to the Member. When such a circumstance occurs, the Member will receive an explanation of benefits.

3. Services, supplies, drugs and devices to treat any Injury or Illness resulting from war, declared or undeclared, insurrection, rebellion, or armed invasion.

4. Any loss for which a contributing cause was commission by the Member of a felony, or attempt to commit a felony. This exclusion does not apply if the loss is related to being a victim of domestic violence or if the commission of the felony is related to a preexisting medical condition.

5. Services for which a Member is not legally required to pay or charges that are made only because Benefits are available under this Contract.

6. Services, supplies, drugs and devices provided to the Member before the Member's Effective Date or after the Member's coverage terminates.

7. Nonsurgical treatment for malocclusion of the jaw, including services for temporomandibular joint dysfunction, anterior or internal dislocations, derangements and myofascial pain syndrome, orthodontics (dentofacial orthopedics), or related appliances.

8. Orthodontics.

9. All dental services, including but not limited to ridge augmentation and vestibuloplasty, whether performed by Physicians, dentists, oral surgeons and/or any other provider, except for services provided as the result of a Dental Accident.

10. Vision services, including but not limited to prescription, fitting or provision of eyeglasses or contact lenses and Lasik Surgery, except for services covered under the Pediatric Vision Care Benefit. In addition, vision services may be covered for specific conditions in Medical Policy.

11. Hearing aids, except that Medically Necessary cochlear implants may be covered per Medical Policy.

12. Cosmetic services except when provided to correct a condition resulting from an Accident, a condition resulting from an Injury or to treat a congenital anomaly, as applicable in Medical Policy.

13. For travel by a Member or provider.

14. Any service or procedure which is determined by The Plan to be an Inclusive Service/Procedure.

15. Any services, supplies, drugs and devices which are:

    a. Experimental/Investigational/Unproven services, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.
    b. Not accepted standard medical practice. The Plan may consult with physicians or national medical specialty organizations for advice in determining whether the service or supply is accepted medical practice.
    c. Not a Covered Medical Expense.
    d. Not Medically Necessary.
    e. Not covered under applicable Medical Policy.

16. Any services, supplies, drugs and devices considered to be Experimental/Investigational/Unproven and which are provided during a Phase I or II clinical trial, or the experimental or research arm of a Phase III clinical trial, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial. This includes services, supplies, drugs and devices under study to determine the maximum tolerated dosage(s), toxicity, safety, efficacy or efficacy as compared with standard treatment, or for the diagnosis of the condition in question.

17. Transplants of a nonhuman organ or artificial organ implant.

18. Private duty nursing.

19. Procedures, equipment, services, supplies, or charges for abortions for which Federal funding is prohibited. Federal funding is allowed for abortions in the case of rape or incest, or for a pregnancy which, as certified by a physician, places the woman in danger of death unless an abortion is performed.

20. Reversal of an elective sterilization.

21. Services, supplies, drugs and devices related to in vitro fertilization.

22. Routine foot care for Members without co-morbidities, except Routine foot care is covered if a Member has co-morbidities such as diabetes.

23. Treatment of flat foot conditions and the prescription of supportive devices for such conditions and the treatment of subluxations of the foot.

24. Foot orthotics.

25. Services, supplies, drugs and devices related to treatment for psychological or psychogenic sexual dysfunctions.

26. Services, supplies, drugs and devices relating to any of the following treatments or related procedures:

- **a.** Homeopathy.
- **b.** Hypnotherapy.
- **c.** Rolfing.
- **d.** Holistic medicine.
- **e.** Religious counseling.
- **f.** Self-help programs.

27. Services provided by a massage therapist.

28. Sanitarium care, custodial care, rest cures, or convalescent care to help the Member with daily living tasks. Examples include but are not limited to, help in:

- **a.** Walking.
- **b.** Getting in and out of bed.
- **c.** Bathing.
- **d.** Dressing.
- **e.** Feeding.
- **f.** Using the toilet.
- **g.** Preparing special diets.
- **h.** Supervision of medication which is usually self-administered and does not require the continuous attention of medical personnel.

No payment will be made for admissions or parts of admissions to a Hospital, skilled nursing facility, or extended care facility for the types of care outlined in this exclusion.

29. Over-the-counter food supplements, formulas, and/or Medical Foods, regardless of how administered except when used for Inborn Errors of Metabolism.

30. Services, supplies, drugs and devices for the surgical treatment of any degree of obesity, whether provided for weight control or any medical condition.

31. Services, supplies, drugs and devices for weight reduction or weight control. This Exclusion does not include intensive behavioral dietary counseling when services are provided by a Physician, Physician Assistant or Nurse Practitioner.

32. Charges associated with health clubs, weight loss clubs or clinics.

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33. Services, supplies, drugs and devices for the treatment of Illness, Injury and/or complications resulting from services that are not Covered Medical Expenses, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.

34. Tutoring services.

35. Any services, supplies, drugs and devices not provided in or by a Covered Provider.

36. Services, supplies, drugs and devices primarily for personal comfort, hygiene, or convenience which are not primarily medical in nature.

37. Deluxe medical equipment including, but not limited to, durable medical equipment, prosthetics and communication devices except as included in the Durable Medical Equipment Benefit and the Prosthetic Benefit in the section entitled "Benefits."

38. All services, supplies, drugs and devices provided to treat any Illness or Injury arising out of employment as an athlete by or on a team or sports club engaged in any contact sport that includes significant physical contact between the athletes involved, including but not limited to football, hockey, roller derby, rugby, lacrosse, wrestling and boxing, where the Member's employer is not required by law to obtain coverage for Illness or Injury under state or federal workers' compensation, occupational disease or similar laws.

39. Applied Behavior Analysis (ABA) services, except as specifically included in this Contract under Autism Spectrum Disorders.

40. Services, supplies, drugs and devices provided outside of the United States, except if such services are provided as the result of an Emergency Medical Condition.

41. Services, supplies, drugs and devices which are not listed as a Benefit as described in this Contract.

CLAIMS

How to Obtain Payment for Covered Expenses for Benefits

1. If a Member obtains benefits from a Participating Provider, the Participating Provider will submit claims to The Plan for the Member. If a Member obtains benefits from a nonparticipating provider, the Member may be required to submit all claims to The Plan. All claims for services must be submitted on or before December 31 of the calendar year following the year in which services were received. All claims must provide enough information about the services for The Plan to determine whether or not they are a Covered Medical Expense. Submission of such information is required before payment will be made. In certain instances, Blue Cross and Blue Shield of Montana may require that additional documents or information including, but not limited to, accident reports, medical records, and information about other insurance coverage, claims, payments and settlements, be submitted within the timeframe requested for the additional documentation before payment will be made.

   However, claims for prescription drugs purchased from a nonparticipating pharmacy must be submitted within one year from the date of purchase.

2. If a Member purchases drugs or Prescription Drug Products at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the ID card is presented at the time of purchase, the Member must pay for the Prescription Drug Product and the Participating Pharmacy will submit a claim for the cost of the covered prescription drug or Prescription Drug Product to The Plan's Pharmacy Benefit Manager. The cost of the covered drug or Prescription Drug Product will then accumulate to the Member's Deductible and Out-of-Pocket Amount. Once the Deductible, if applicable, is met, the Member will only be required to pay the appropriate Copayment and/or Coinsurance if the amount can be determined by the pharmacy at the time of purchase.

   If a Member purchases drugs or Prescription Drug Products at a nonparticipating pharmacy, the Member must pay for the prescription at the time of dispensing and then within one year of the date of purchase submit a claim for the prescription drug on a form to The Plan's Pharmacy Benefit Manager for reimbursement. The Member

will be reimbursed for the prescription drug at 50% of the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance.

3. Claims must be submitted to the address listed on the inside cover of this Contract.

Prescription Drug Claims - Filling Prescriptions at a Retail Pharmacy

Outpatient prescription drugs are available through the Prime Therapeutics Prescription Drugs Benefit. Prime Therapeutics is the Pharmacy Benefit Manager.

1. Go to a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy that accepts Member ID cards. To find out if a pharmacy takes part in the program, ask the pharmacist. To find a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy nearest the Member, check the list on the website www.bcbsmt.com or call the pharmacy locator at the telephone number on the inside cover of this document.
2. Present the prescription and the Member's ID card to the pharmacist.
3. Make sure that the pharmacist has complete and correct information about the Member for whom the prescription is written, including sex and date of birth.
4. When the Member receives a prescription, he or she should sign the pharmacy log and pay his or her share of the cost.
5. If a Member purchases prescription drugs from a participating outpatient pharmacy or mail-service pharmacy approved by The Plan, the Member must pay for the Prescription Drug Product and the pharmacy will submit the prescription drug claims to Prime Therapeutics.
6. The Member must pay the difference between a Brand-Name drug and the Generic equivalent if the Member purchases a Brand-Name prescription drug when a Generic drug substitute is available.
7. The Plan makes use of a Drug List, which is a list of covered prescription drugs for dispensing to Members as appropriate.
8. For prescriptions filled at a pharmacy that is not part of the network, the Member will need to pay the pharmacist the entire cost of the prescription at the time the prescription is filled and dispensed and submit a paper claim to Prime Therapeutics for reimbursement. If a Member does not present his or her ID card at a Participating Pharmacy, a paper claim must be submitted by the Member to Prime Therapeutics for reimbursement. The Member will be reimbursed at 50% of the contracted rate minus Deductible, Copayment and/or Coinsurance, if applicable, in both situations. The Member will not receive the preferred pricing.
9. Prescriptions filled at Hospital pharmacies are not eligible for reimbursement unless they are listed as a network pharmacy.

Prime Therapeutics claim forms are available by calling The Plan at the telephone number on the inside cover of this document.

Mail-Service Pharmacy

A convenient way to get maintenance prescriptions is through the mail. Maintenance prescriptions are those that the Member expects to continue using for an extended period of time and for which a prescription can be written for up to a 90-day supply. Coverage for costly prescriptions should be verified prior to ordering. Specific Benefits are outlined in the Prescription Drugs section in this document.

Ordering prescriptions through the mail service pharmacy is very easy. To obtain a mail service claim form, call The Plan at the telephone number on the inside cover of this document.

To order a prescription:

1. Complete all sections and sign the Mail-Service order form.
2. Enclose the following:
   a. the original prescription written for a 90-day supply;
   b. the Member's current pharmacy telephone number, prescription numbers to be transferred; and
   c. the Member's telephone number.
3. Mail the form to the mail service pharmacy at the address listed on the form.

COORDINATION OF BENEFITS WITH OTHER INSURANCE

The Coordination of Benefits (COB) provision applies when a Member has health care coverage under more than one plan. "Plan" is defined below.

The order in which each plan will make payment for Covered Medical Expenses is governed by the order of benefit determination rules. The plan that pays first is called the primary plan. The primary plan must pay Covered Medical Expenses in accordance with its Contract terms without regard to the possibility that another plan may cover some expenses. The plan that pays after the primary plan is the secondary plan. The secondary plan may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Definitions

For the purpose of this section only, the following definitions apply:

Plan

Any of the following that provide benefits, or services, for medical or dental care or treatment include:

1. group and nongroup health insurance contracts;
2. health maintenance organization (HMO) contracts;
3. Closed Panel Plans or other forms of group or group type coverage (whether insured or uninsured);
4. medical care components of long-term care contracts, such as skilled nursing care; and
5. Medicare or any other federal governmental plan, as permitted by law.

The term plan does not include:

1. excepted benefits pursuant to 33-22-140(8)(a), (b), (c), (d), (e), (f), (g), (h), (j), and (k), MCA;
2. school accident type coverage;
3. benefits for non-medical components of long-term care policies; or
4. a governmental plan, which, by law, provides benefits that are in excess of those of any private insurance plan or other nongovernmental plan.

Each contract for coverage is a separate plan. If a plan has two parts and COB rules apply only to one of the two, each of the parts is treated as a separate plan.

This Plan

In a COB provision, "this plan" means that part of the Contract providing the health care benefits to which the COB provision applies and which may be reduced because of the benefits of other plans. Any other part of the Contract providing health care benefits is separate from this plan. A contract may apply one COB provision to certain benefits, such as dental benefits, coordinating only with similar benefits, and may apply another COB provision to coordinate other benefits.

Order of Benefit Determination Rules

The rules that determine whether this plan is a primary plan, or secondary plan, when the person has health care coverage under more than one plan.

1. When this plan is primary, it determines payment for Covered Medical Expenses first before those of any other plan without considering any other plan's benefits.
2. When this plan is secondary, it determines its benefits after those of another plan and may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Allowable Expense

A Covered Medical Expense, including deductibles, coinsurance and copayments, that is covered at least in part by any plan covering the Member. When a plan provides benefits in the form of services, the reasonable cash value of each service will be considered an allowable expense and a benefit paid. An expense that is not covered by any plan covering the Member is not an allowable expense. In addition, any expense that a provider by law or in accordance with a contractual agreement is prohibited from charging a Member is not an allowable expense.

The following are examples of expenses that are not allowable expenses:

1. The difference between the cost of a semi-private hospital room and a private hospital room is not an allowable expense, unless one of the plans provides coverage for private hospital room expenses.
2. If a Member is covered by two or more plans that compute their benefit payments on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology, any amount in excess of the highest reimbursement amount for a specific benefit is not an allowable expense.
3. If a Member is covered by two or more plans that provide benefits or services on the basis of negotiated fees, an amount in excess of the highest of the negotiated fees is not an allowable expense.
4. If a Member is covered by one plan that calculates its benefits or services on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology and another plan that provides its benefits or services on the basis of negotiated fees, the primary plan's payment arrangement shall be the allowable expense for all plans. However, if the provider has contracted with the secondary plan to provide the benefit or service for a specific negotiated fee or payment amount that is different than the primary plan's payment arrangement and if the provider's contract permits, the negotiated fee or payment shall be the allowable expense used by the Secondary plan to determine its benefits.
5. The amount of any benefit reduction by the primary plan because a Member has failed to comply with the plan provisions is not an allowable expense. Examples of these types of plan provisions include second surgical opinions, precertification of admissions, and preferred provider arrangements.

Closed Panel Plan

A plan that provides health care benefits to covered persons primarily in the form of services through a panel of providers that have contracted with or are employed by the plan, and that excludes coverage for services provided by other providers, except in cases of emergency or referral by a panel member.

Custodial Parent

The parent awarded custody by a court decree or, in the absence of a court decree, is the parent with whom the child resides more than one half of the calendar year excluding any temporary visitation.

Order of Benefit Determination Rules

When a Member is covered by two or more plans, the rules for determining the order of benefit payments are as follows:

1. The primary plan pays or provides its benefits according to its terms of coverage and without regard to the benefits of under any other Plan; and
2. Except as provided below, a plan that does not contain a COB provision that is consistent with this regulation is always primary unless the provisions of both plans state that the complying plan is primary.

   Coverage that is obtained by virtue of membership in a group that is designed to supplement a part of a basic package of benefits, and provides that this supplementary coverage, shall be excess to any other parts of the plan provided by the Group. Examples of these types of situations are major medical coverages that are superimposed over base plan hospital and surgical benefits, and insurance type coverages that are written in connection with a closed panel plan to provide out-of-network benefits.

3. A plan may consider the benefits paid or provided by another plan in calculating payment of its benefits only when it is secondary to that other plan.

4. Each plan determines its order of benefits using the first of the following rules that apply:

   Non-Dependent or Dependent.

   The plan that covers the person as an employee or retiree is the primary plan and the plan that covers the employee or retiree as a dependent is the secondary plan. However, if the person is a Medicare beneficiary and, as a result of federal law, Medicare is secondary to the plan covering the person as a dependent; and primary to the plan covering the person as other than a dependent (e.g., a retired employee); then the order of benefits between the two plans is reversed so that the plan covering the person as an employee or retiree is the secondary plan and the other plan is the primary plan.

Dependent Child Covered Under More Than One Plan.

Unless there is a court decree stating otherwise, when a dependent child is covered by more than one plan, the order of benefits is determined as follows:

1. **Dependent Child - Parents are married or are living together**

   a. The plan of the parent whose birthday falls earlier in the calendar year is the primary plan; or
   b. If both parents have the same birthday, the plan that has covered the parent the longest is the primary plan.

2. **Dependent Child - Parents are divorced or separated or not living together**

   a. If a court decree states that one of the parents is responsible for the dependent child's health care expenses or health care coverage and the plan of that parent has actual knowledge of those terms, that plan is primary. This rule applies to plan years commencing after the plan is given notice of the court decree;
   b. If a court decree states that both parents are responsible for the dependent child's health care expenses or health care coverage, the provisions of (a) above shall determine the order of benefits;
   c. If a court decree states that the parents have joint custody without specifying that one parent has responsibility for the health care expenses or health care coverage of the dependent child, the provisions of (a) above shall determine the order of benefits; or
   d. If there is no court decree allocating responsibility for the dependent child's health care expenses or health care coverage, the order of benefits for the child are as follows:

      - The plan covering the custodial parent;
      - The plan covering the Spouse of the custodial parent;
      - The plan covering the non-custodial parent; and then;
      - The plan covering the Spouse of the non-custodial parent.

3. **Dependent Child Covered Under More than One Plan of Individuals Who Are Not the Parents of the Child**

   The provisions of (1) or (2) above shall determine the order of benefits as if those individuals were the parents of the child.

4. **Active Employee or Retired or Laid-off Employee**

   The plan that covers a person as an active employee, that is, an employee who is neither laid off nor retired, (or is a dependent of such employee) is the primary plan. The plan covering that same person as a retired or laid-off employee (and the dependent of such employee) is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

5. **COBRA or State Continuation Coverage**

   If a person whose coverage is provided pursuant to COBRA or under a right of continuation provided by state or other federal law is covered under another plan, the plan covering the person as an employee or retiree or covering the person as a dependent of an employee or retiree is the primary plan and the COBRA or state or other federal continuation coverage is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

6. **Longer or Shorter Length of Coverage**

   The plan that covered the person as an employee or retiree longer is the primary plan and the plan that covered the person the shorter period of time is the secondary plan.

If the preceding rules do not determine the order of benefits, the allowable expenses shall be shared equally between the plans meeting the definition of plan. In addition, this plan will not pay more than it would have paid had it been the primary plan.

Effect on the Benefits of This Plan

When this plan is secondary, it may reduce its benefits so that the total benefits paid or provided by all plans during a plan year are not more than the total allowable expenses. In determining the amount to be paid for any claim, the secondary plan will calculate the benefits it would have paid in the absence of other health care coverage and apply that calculated amount to any allowable expense under its plan that is unpaid by the primary plan. The secondary plan may then reduce its payment by the amount so that, when combined with the amount paid by the primary plan, the total benefits paid or provided by all plans for the claim do not exceed the total allowable expense for that claim. In addition, the secondary plan shall credit to its plan deductible any amounts it would have credited to its deductible in the absence of other health care coverage.

If a covered person is enrolled in two or more closed panel plans and if, for any reason, including the provision of service by a non-panel provider, benefits are not payable by one closed panel plan, COB shall not apply between that plan and other closed panel plans.

Right to Receive and Release Needed Information

Certain facts about health care coverage and services are needed to apply these COB rules and to determine benefits payable under this plan and other plans. Blue Cross and Blue Shield of Montana may get the facts it needs from or give them to other organizations or persons for the purpose of applying these rules and determining benefits payable under this plan and other plans covering the Member claiming benefits. Blue Cross and Blue Shield of Montana need not inform, or get the consent of, any person to do this. Each Member claiming benefits under this plan must give Blue Cross and Blue Shield of Montana any facts it needs to apply those rules and determine benefits payable.

Facility of Payment

A payment made under another plan may include an amount that should have been paid under this plan. If it does, Blue Cross and Blue Shield of Montana may pay that amount to the organization that made that payment. That amount will then be treated as though it were a benefit paid under this plan. Blue Cross and Blue Shield of Montana will not have to pay that amount again. The term "payment made" includes providing benefits in the form of services, in which case "payment made" means the reasonable cash value of the benefits provided in the form of services.

Right of Recovery

If the amount of the payments made by Blue Cross and Blue Shield of Montana is more than it should have paid under this COB provision, it may recover the excess from one or more of the Members it has paid or for whom it has paid; or any other person or organization that may be responsible for the benefits or services provided for the Member. The "amount of the payments made" includes the reasonable cash value of any benefits provided in the form of services.

Coordination With Medicare

To the extent Medicare pays for benefits, then benefits paid under Medicare will be determined BEFORE Benefits are paid under this Contract. Benefits under this Contract are, therefore, SECONDARY to Medicare. If Medicare does not pay benefits, then this Contract will pay PRIMARY.

The combined payments by Medicare and The Plan will not exceed the charges for the covered services the Member receives.

Other Insurance

If a property or casualty insurer pays for services provided to the Member and coordination of benefits is not applicable, The Plan will credit the Member's Deductible, Copayment or Coinsurance, as applicable, if the Member notifies The Plan of the payment, within 12 months of the date of service.

Term

The term of this Contract is shown on the Schedule of Benefits. This Contract may be renewed as The Plan consents at dues set by The Plan.

Entire Contract; Changes

This Contract, including written riders, endorsements and attached papers, if any, constitutes the entire Contract between Blue Cross and Blue Shield of Montana and the Beneficiary Member. No change to this Contract is valid until made pursuant to the section entitled Modification of Contract.

Modification of Contract

The Plan may make administrative changes or changes in dues, terms or Benefits in this Contract by giving written notice to the Beneficiary Member at least 45 days before the Effective Date of the changes. Dues may not be increased more than once during a 12-month period, except as allowed by Montana law.

No other agent or representative or employee of The Plan may change any part of this Contract. No change in the Contract will be valid unless in writing and signed by the President of Blue Cross and Blue Shield of Montana.

Clerical Errors

No clerical error on the part of The Plan shall operate to defeat any of the rights, privileges, or Benefits of any Member covered under this Contract. Upon discovery of errors or delays, an equitable adjustment of charges and Benefits will be made. Clerical errors shall not prevent administration of the Contact in strict accordance with its terms.

Conformity With State Statutes

The provisions of this Contract conform to the minimum requirements of Montana law and have control over any conflicting statutes of any state in which the Beneficiary Member or any Dependent may have health services on or after the Effective Date of this Contract.

Forms for Proof of Loss

The Plan shall furnish, upon written request of a Member claiming to have a loss under this Contract, forms of proof of loss for completion by the Member. The Plan shall not, by reason of the requirement to furnish such forms, have any responsibility for or with reference to the completion of such form or the manner of any such completion or attempted completion.

Proofs of Loss

Written proof of loss must be furnished to The Plan at its said office in case of claim for loss for which this policy provides any periodic payment contingent upon continuing loss within 90 days after the termination of the period for which The Plan is liable and in case of claim for any other loss within 90 days after the date of such loss. Failure to furnish such proof within the time required shall not invalidate or reduce any claim if it was not reasonably possible to give proof within such time, provided such proof is furnished as soon as reasonably possible and in no event, except in the absence of legal capacity, later than 1 year from the time proof is otherwise required.

Time of Payment of Claims

Indemnities payable under this Contract for any loss other than loss for which this Contract provides any periodic payment will be paid immediately upon receipt of due written proof of such loss. Subject to due written proof of loss, all accrued indemnities for loss for which this Contract provides periodic payment will be paid monthly, and any balance remaining unpaid upon the termination of liability will be paid immediately upon receipt of due written proof.

Notices Under Contract

Any notice required by this Contract may be given by United States mail, postage paid. Notice to the Beneficiary Member will be mailed to the address appearing on the records of The Plan. Notice to The Plan must be sent to Blue Cross and Blue Shield of Montana at the address listed on the inside cover of this Contract. Any time periods included in a notice shall be measured from the date the notice was mailed.

A Beneficiary Member or Family Member may reasonably request, in writing, that any communication of the Member's health information be sent to an alternate address or by alternative means should disclosure of any of the Member's health information endanger the Member.

Notice of Annual Meeting

The Policyholder is hereby notified that the Policyholder is a Member of Health Care Service Corporation, a Mutual Legal Reserve Company, and is entitled to vote either in person, by proxy, at all meetings of Members of Blue Cross and Blue Shield. The annual meeting is held at our principal office at 300 East Randolph Street, Chicago, Illinois each year on the last Tuesday in October at 12:30 p.m.

The term "Member" as used above refers only to the person to whom this Contract has been issued. Under Family Coverage, the term "Member" does not include any person other than the Policyholder unless such person is acting upon the Policyholder's behalf.

Rescission of Contract

This Contract is subject to rescission if the Member commits an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of a material fact, concerning a Member's health, claims history, or current receipt of health care services.

Contract Not Transferable by the Member

No person, other than the Beneficiary Member or a Family Member listed on the subscriber application for membership and accepted by The Plan, is entitled to Benefits under this Contract. This Contract is not transferable to any other person.

Validity of Contract

If any part, term, or provision of this Contract is held by the courts to be illegal or in conflict with or not in compliance with any applicable law of the state of Montana or the United States, this Contract shall not be rendered invalid but shall be construed and applied in accordance with such provisions as would have applied had this Contract been in conformance with applicable law and the validity of the remaining portions or provisions shall not be affected. The rights and obligations of the parties shall be construed and enforced as if this Contract did not contain the particular part, term, or provision held to be invalid.

Execution of Papers

The Member agrees to execute and deliver any documents requested by The Plan which are necessary to administer the terms of this Contract.

Members Rights

Members have only those rights as specifically provided in this Contract. In addition, when requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

Alternate Care

The Plan may, at its sole discretion, make payment for services which are not listed as a Benefit of this Contract in order to provide quality care at a lesser cost. Such payments will be made only upon mutual agreement by the Member and The Plan.

Benefit Maximums

Once The Plan pays the maximum amount for a specific Benefit, no further payment will be made for that specific condition under any other provisions of this Contract.

Legal Actions

No action at law or inequity shall be brought to recover on this Contract prior to the expiration of 60 days after written Proof of Loss has been furnished in accordance with the requirements of this Contract. No such action shall be brought after the expiration of three years after the written Proof of Loss is required to be furnished.

Physical Examinations

Blue Cross and Blue Shield of Montana, at its own expense, shall have the right and opportunity to examine the person of a Member when and as often as it may reasonably require during the pending of a claim.

Pilot Programs

The Plan reserves the right to develop and enter into pilot programs under which health care services not normally covered under this Contract will be paid. The existence of a pilot program does not guarantee any Member the right to participate in the pilot program or that the pilot program will be permanent.

Fees

The Plan reserves the right to charge the Member a reasonable fee for providing information or documents to the Member which were previously provided in writing to the Member. Fees may be charged for the costs of copying labor, supplies and postage. Fees will not be charged for searching for and retrieving the requested information.

Time Limit on Certain Defenses

After two years from the date of issue of this Contract, no misstatements, except fraudulent misstatements, made by the applicant in the application for such Contract shall be used to void the Contract or to deny a claim for loss incurred commencing after the expiration of such two-year period.

Acceptance of this Contract

When The Plan approves the Member's application and the Member pays the first Month's dues, this Contract is accepted by both parties.

Previous Contract Superceded

This Contract voids any previous Contract between The Plan and the Member.

Subrogation

1. To the extent that Benefits have been provided or paid under this Contract, The Plan may be entitled to subrogation against a judgment or recovery received by a Member from a third party found liable for a wrongful act or omission that caused the Injury requiring payment for Benefits.
2. The Member will take no action through settlement or otherwise which prejudices the rights and interest of The Plan under this Contract.
3. If the Member intends to institute an action for damages against a third party, the Member will give The Plan reasonable notice of intention to institute the action. Reasonable notice will include information reasonably calculated to inform The Plan of facts giving rise to the third party action and of the prospects for recovery.
4. The Member may request that The Plan pay a proportional share of the reasonable costs of the third-party action, including attorney fees. If The Plan elects not to participate in the cost of the action, The Plan waives 50 percent of its subrogation interest.
5. The right of subrogation may not be enforced until the Member has been completely compensated for the injuries.

When the Member Moves Out of State

If the Member moves to an area served by another Blue Cross or Blue Shield plan, the Member's coverage will be transferred to the plan serving the new address. The new plan must offer coverage that is in compliance with the conversion laws of that state. This coverage is that which is normally provided to Members who leave a group and apply for new coverage as individuals. Although subject to the conversion laws of that state, such coverage is usually provided without a medical examination or health statement. If the Member accepts the conversion coverage, the new plan will credit the Member for the length of time of enrollment with Blue Cross and Blue Shield of Montana toward any of its own waiting periods. Any physical or mental conditions covered by The Plan will be covered by the new plan without a new waiting period if the new plan offers this feature to others carrying the same type of coverage. The premium rate and benefits available from the new plan may vary significantly from those offered by The Plan.

The new plan may also offer other types of coverage that are outside of the transfer program. This coverage may require a medical examination or health statement to exclude coverage for preexisting conditions and may not apply time enrolled in Blue Cross and Blue Shield of Montana to waiting periods.

Independent Relationship

Participating Providers furnishing care to a Member do so as independent contractors with The Plan; however, the choice of a provider is solely the Member's. Under the laws of Montana, The Plan cannot be licensed to practice medicine or surgery and The Plan does not assume to do so. The relationship between a provider and a patient is personal, private, and confidential. The Plan is not responsible for the negligence, wrongful acts, or omissions of any providers, or provider's employees providing services, or Member receiving services. The Plan is not liable for services or facilities which are not available to a Member for any reason.

Blue Cross and Blue Shield of Montana as an Independent Plan

The Member, hereby expressly acknowledges its understanding that this Contract constitutes a contract solely between the Member and The Plan, that The Plan is an independent corporation operating under a license with the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans (the "Association") permitting The Plan to use the Blue Cross and Blue Shield Service Mark in the state of Montana, and that The Plan is not contracting as the agent of the Association. The Member further acknowledges and agrees that it has not entered into this Contract based upon representations by any person other than The Plan and that no person, entity, or organization other than The Plan shall be held accountable or liable to the Member for any of The Plan's obligations to the Member created under this contract. This paragraph shall not create any additional obligations whatsoever on the part of The Plan other than those obligations created under other provisions of this Contract.

DEFINITIONS

This section defines certain words used throughout this Contract. These words are capitalized whenever they are used as defined.

ACCIDENT

An unexpected traumatic incident or unusual strain which is:

1. Identified by time and place of occurrence;
2. Identifiable by part of the body affected; and
3. Caused by a specific event on a single day.

Some examples include:

1. Fracture or dislocation.
2. Sprain or strain.
3. Abrasion, laceration.
4. Contusion.
5. Embedded foreign body.

6. Burns.
7. Concussion.

ADVANCED PRACTICE REGISTERED NURSE

Nurses who have additional professional education beyond the basic nursing degree required of a registered nurse and are considered Advanced Practice Registered Nurses by applicable state law. Advanced Practice Registered Nurses include nurse practitioners, nurse-midwives, nurse-anesthetists and clinical nurse specialists.

ALLOWABLE FEE

The Allowable Fee is based on, but not limited to, the following:

1. Medicare RBRVS based is a system established by Medicare to pay physicians for a "work unit." The RBRVS value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the Medicare RBRVS system can be considerably less than the nonparticipating providers' billed charge; or
2. Diagnosis-related group (DRG) methodology is a system used to classify hospital cases into one of approximately 500 to 900 groups that are expected to have similar hospital resource use. Payment for each DRG is based on diagnoses, procedures, age, sex, expected discharge date, discharge status, and the presence of complications. The amount of payment for each DRG is generally within a fixed range because each patient is expected to use the same level of hospital resources for the given DRG regardless of the actual hospital resources used. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the DRG system can be considerably less than the nonparticipating providers' billed charge; or
3. Billed charge is the amount billed by the provider; or
4. Case rate methodology is an all inclusive rate for an episode of care for a specific clinical condition paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the case rate system can be considerably less than the nonparticipating providers' billed charge; or
5. Per diem methodology is an all inclusive daily rate paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the per diem system can be considerably less than the nonparticipating providers' billed charge; or
6. Flat fee per category of service is a fixed payment amount for a category of service. For instance, a category of service could be a delivery, an imaging service, a lab service or an office visit. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the flat fee per category of service system can be considerably less than the nonparticipating providers' billed charge; or
7. Flat fee per unit of service fixed payment amount for a unit of service, For instance, a unit of service could be the amount of "work units" customarily required for a delivery, or an office visit, or a surgery. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the flat fee per unit system can be considerably less than the nonparticipating providers' billed charge; or
8. Percent off of billed charge is a payment amount where a percentage is deducted from the billed charges; or
9. A percentage of Medicare allowance is a payment amount where a percentage is deducted to the amount that Medicare would allow as payment for the service; or
10. The amount negotiated with the pharmacy benefit manager or manufacturer or the actual price for prescription or drugs; or
11. The American Society of Anesthesiologists' Relative Value Guide is a system established by the American Society of Anesthesiologists to pay anesthesiologists for a "work unit." The payment value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the system can be considerably less than the nonparticipating providers' billed charge.
12. For nonparticipating providers in Montana, the Allowable Fee is developed from base Medicare reimbursements, excluding any Medicare adjustments using information on the claim, and adjusted by a predetermined factor established by the Plan. Such factor will not be less than 100% of the base Medicare reimbursement rate. For services for which a Medicare reimbursement rate is not available, the Allowable

Fee for nonparticipating providers will represent an average contract rate for Participating Providers adjusted by a predetermined factor established by the Plan and updated on a periodic basis. Such factor shall not be less than 80% of the average contract rates and will be updated not less than every 2 years. Blue Cross and Blue Shield of Montana will utilize the same claim processing rules and/or edits that it utilizes in processing Participating Provider claims for processing claims submitted by nonparticipating providers which may also alter the Allowable Fee for a particular service. In the event the Plan does not have any claim edits or rules, the Plan may utilize the Medicare claim rules or edits that are used by Medicare in processing the claims. The Allowable Fee will not include any additional payments that may be permitted under the Medicare laws or regulations which are not directly attributable to a specific claim, including but not limited to, disproportionate share and graduate medical education payments.

Any change to the Medicare reimbursement amount will be implemented by the Plan within 90 days after the effective date that such change is implemented by the Centers for Medicaid and Medicare Services, or its successor.

In the event the nonparticipating Allowable Fee does not equate to the nonparticipating provider's billed charges, the Member will be responsible for the difference, along with any applicable Copayment, Coinsurance and Deductible amount. This difference may be considerable. To find out an estimate of the Plan's nonparticipating Allowable Fee for a particular service, Members may call the customer service number shown on the back of their Identification Card.

Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

APPLIED BEHAVIOR ANALYSIS (ABA) - (ALSO KNOWN AS LOVAAS THERAPY)

Medically Necessary interactive therapies or treatment derived from evidence-based research. The goal of ABA is to improve socially significant behaviors to a meaningful degree, including:

1. increase desired behaviors or social interaction skills;
2. teach new functional life, communication, or social, skills;
3. maintain desired behaviors, such as teaching self control and self-monitoring procedures;
4. appropriate transfer of behavior from one situation or response to another;
5. restrict or narrow conditions under which interfering behaviors occur;
6. reduce interfering behaviors such as self injury.

ABA therapy and treatment includes Pivotal Response Training, Intensive Intervention Programs, and Early Intensive Behavioral Intervention, and the terms are often used interchangeably. The ABA benefit also includes Discrete Trial Training, a single cycle of behaviorally based instruction routine that is a companion treatment with ABA.

Services must be provided by an appropriately certified provider.

APPROVED CLINICAL TRIAL

Approved clinical trial means a phase I, phase II, phase III, or phase IV, clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other Life-Threatening Condition. The trial must be:

1. Conducted under an investigational new drug application reviewed by the United States Food and Drug Administration;
2. Exempt from an investigational new drug application; or
3. Approved or funded by:

   - The National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, or a cooperative group or center of any of the foregoing entities;
   - A cooperative group or center of the United States Department of Defense or the United States Department of Veterans Affairs;
   - A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes for Health for center support groups; or
   - The United States Departments of Veterans Affairs, Defense, or Energy if the study or investigation has been reviewed and approved through a system of peer review determined by the United States

Secretary of Health and Human Services to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and provide unbiased scientific review by individuals who have no interest in the outcome of the review.

BENEFICIARY MEMBER

A person who has applied for, been accepted as a Member, and maintains membership in The Plan under the terms of this Contract.

BENEFIT

Services, supplies and medications that are provided to a Member and covered under this Contract as a Covered Medical Expense.

BENEFIT PERIOD

For the Contract - Is the period of time shown in the Schedule of Benefits.

For the Member - Is the same as for the Contract except if the Member's Effective Date is after the Effective Date of the Contract, the Benefit Period begins on the Member's Effective Date and ends on the same date the Contract Benefit Period ends. Thus, the Member's Benefit Period may be less than 12 months.

BEST EVIDENCE

Means evidence based on

1. Randomized Clinical Trials;
2. A Cohort Study or Case-Control Study, if randomized clinical trials are not available;
3. A Case Series, if Randomized Clinical Trials, Cohort Studies or Case-Control Studies are unavailable;
4. An Expert Opinion, if Randomized Clinical Trials, Cohort Studies, Case-Control Studies or Case Series are unavailable.

BLUE CROSS AND BLUE SHIELD OF MONTANA PRIME SPECIALTY NETWORK

Specialty Pharmacy providers who have entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

BRAND-NAME

A drug or product manufactured by a single manufacturer as defined by a nationally recognized provider of drug product database information. There may be some cases where two manufacturers will produce the same product under one license, known as a co-licensed product, which would also be considered as a Brand-Name drug. There may also be situations where a drug's classification changes from Generic to Preferred or Non-preferred Brand-Name due to a change in the market resulting in the Generic drug being a single source, or the drug product database information changing, which would also result in a corresponding change to your payment obligations from Generic to Preferred or Non-preferred Brand-Name.

CARE MANAGEMENT

A process that assesses and evaluates options and services required to meet the Member's health care needs. Care Management may involve a team of health care professionals, including Covered Providers, The Plan and other resources to work with the Member to promote quality, cost-effective care.

CASE-CONTROL STUDY

A retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

CASE SERIES

An evaluation of a series of patients with a particular outcome, without the use of a control group.

CHEMICAL DEPENDENCY

The uncontrollable or excessive use of addictive substances including but not limited to alcohol, morphine, cocaine, heroin, opium, cannabis, barbiturates, amphetamines, tranquilizers and/or hallucinogens, and the resultant physiological and/or psychological dependency which develops with continued use of such addictive substances requiring medical care as determined by a licensed addiction counselor or other appropriate medical practitioner.

CHEMICAL DEPENDENCY TREATMENT CENTER

A treatment facility that provides a program for the treatment of Chemical Dependency pursuant to a written treatment plan approved and monitored by a Physician or addiction counselor licensed by the state. The facility

must also be licensed or approved as a Chemical Dependency Treatment Center by the department of health and human services or must be licensed or approved by the state where the facility is located.

CLINICAL PEER

A physician or other health care provider who:

1. holds a nonrestricted license in a state of the United States, and
2. is trained or works in the same or a similar specialty to the specialty that typically manages the medical condition, procedure, or treatment under review.

COHORT STUDY

A prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

COINSURANCE

The percentage of the Allowable Fee payable by the Member for Covered Medical Expenses. The applicable Coinsurance for In-Network Covered Medical Expenses and Out-of-Network Covered Medical Expenses is stated in the Schedule of Benefits.

CONCURRENT CARE

Medical care rendered concurrently with surgery during one Hospital admission by a Physician other than the operating surgeon for treatment of a medical condition different from the condition for which surgery was performed; or

Medical care by two or more Physicians rendered concurrently during one Hospital admission when the nature or severity of the Member's condition requires the skills of separate Physicians.

CONSULTATION SERVICES

Services of a consulting Physician requested by the attending Physician. These services include discussion with the attending Physician and a written report by the consultant based on an examination of the Member.

CONTRACT

This Contract, the Member's application and any amendments, endorsements, riders, or modifications made to it by The Plan.

CONVALESCENT HOME

An institution, or distinct part thereof, other than a Hospital, which is licensed pursuant to state or local law. A Convalescent Home is:

1. a skilled nursing facility;
2. an extended care facility;
3. an extended care unit; or
4. a transitional care unit.

A Convalescent Home is primarily engaged in providing continuous nursing care by or under the direction and supervision of a registered nurse for sick or injured persons during the convalescent stage of their illness or injuries and is not, other than incidentally, a rest home or home for Custodial Care, or for the aged.

NOTE: A Convalescent Home shall not include an institution or any part of an institution otherwise meeting this definition, which is primarily engaged in the care and treatment of Mental Illness or Chemical Dependency.

COPAYMENT

The specific dollar amount payable by the Member for Covered Medical Expenses. The applicable Copayments are stated in the Schedule of Benefits.

COVERED MEDICAL EXPENSE

Expenses incurred for Medically Necessary services, supplies and medications that are based on the Allowable Fee and:

1. Covered under the Member Contract;
2. In accordance with Medical Policy; and
3. Provided to the Member by and/or ordered by a covered provider for the diagnosis or treatment of an active Illness or Injury or in providing maternity care.

In order to be considered a Covered Medical Expense, the Member must be charged for such services, supplies and medications.

COVERED PROVIDER

A participating or nonparticipating provider which has been recognized by Blue Cross and Blue Shield of Montana as a provider of services for Benefits described in this Contract. A provider may, because of the limited scope of practice, be covered only for certain services provided. To determine if a provider is covered, The Plan looks to the nature of the services rendered, the extent of licensure and The Plan's recognition of the provider.

Covered Providers include professional providers and facility providers including Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, nurse specialists, naturopathic physicians, Advanced Practice Registered Nurses, physician assistants, Hospitals and Freestanding Surgical Facilities.

CREDITABLE COVERAGE

Coverage that the Member had for medical benefits under any of the following plans, programs and coverages:

1. a group health plan
2. health insurance coverage
3. Title XVIII, part A or B, of the Social Security Act, 42 U.S.C. 1935c through 1395i-4 or 42 U.S.C. 1395j through 1395w-4 (Medicare)
4. Title XIX of the Social Security Act, 42 U.S.C. 1396a through 1396u, other than coverage consisting solely of a benefit under section 1928, 42 U.S.C. 1396s (Medicaid)
5. Title 10, chapter 55, United States Code (TRICARE)
6. a medical care program of the Indian Health Service or of a tribal organization
7. the Montana Comprehensive Health Association provided for in 33-22-1503 (MCHA)
8. a health plan offered under Title 5, chapter 89, of the United States Code (Federal Employee Health Benefits Program)
9. a public health plan
10. a health benefit plan under Section 5(e) of the Peace Corps Act, 22 U.S.C. 2504(e)
11. a high risk pool in any state

Creditable Coverage does not include coverage consisting solely of coverage of excepted Benefits.

DEDUCTIBLE

The dollar amount each Member must pay for In-Network Covered Medical Expenses and Out-of-Network Covered Medical Expenses incurred during the Benefit Period before The Plan will make payment for any Covered Medical Expense to which the Deductible applies. The In-Network and Out-of-Network Deductibles are separate and one does not accumulate to the other.

Only the Allowable Fee for Covered Medical Expenses is applied to the Deductible. Thus, Coinsurance, Copayment, noncovered services, and amounts billed by nonparticipating providers do not apply to the Deductible and are the Member's responsibility.

If two or more Members covered under the same Family Membership satisfy the family Deductible as shown on the Schedule of Benefits in a single Benefit Period, the Deductible does not apply for the remainder of that Benefit Period for any Member of the Family Membership.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, only one In-Network or Out-of-Network Deductible will be applied to that Hospital stay (facility charges only). If the Member satisfied the Member's Deductible prior to that Hospital stay, no Deductible will be applied to that stay.

DEPENDENT

1. the Beneficiary Member's Spouse;
2. the Beneficiary Member's unmarried or married child up to age 26, including an eligible foster child;
3. children for whom the Beneficiary Member becomes legally responsible by reason of placement for adoption, as defined in Montana law; or
4. an unmarried child of the Beneficiary Member who is 26 years of age or older and disabled.

For purposes of this Contract the unmarried child will be considered disabled if the child:

1. was covered under this Contract before age 26;
2. cannot support himself/herself because of intellectual disability or physical disability; and
3. is legally dependent on the Beneficiary Member for support.

Proof of those qualifications must be supplied to The Plan within 31 days following the child's 26th birthday. Although there is no limiting age for disabled children, The Plan reserves the right to require periodic certification from the Beneficiary Member of such incapacity and dependency. Certification will not be requested more frequently than annually after the two-year period following the child's 26th birthday.

DRUG LIST

A list that identifies those Prescription Drug Products that are covered by The Plan for dispensing to Members when appropriate. This list is reviewed quarterly and subject to modification. Details can be found on the pharmacy page at www.bcbsmt.com or by visiting www.myprime.com.

EFFECTIVE DATE

For a Member - the Effective Date of a Member's coverage means the date the Member:

1. has met the requirements of The Plan stated in this Contract; and
2. is shown on the records of The Plan to be eligible to receive Benefits.

For any endorsement, rider, or amendment - the Effective Date is the date shown on the Contract unless otherwise shown on the endorsement, rider and amendment.

EMERGENCY MEDICAL CONDITION

A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition that places the health of the individual in serious jeopardy, would result in serious impairment to bodily functions, or serious dysfunction of any bodily organ or part; or with respect to a pregnant woman having contractions, that there is inadequate time to safely transfer the woman to another hospital for delivery or that a transfer may pose a threat to the health or safety of the woman or the unborn fetus.

EMERGENCY SERVICES

Services, medicines or supplies furnished or required to evaluate and treat an Emergency Medical Condition.

EVIDENCE-BASED STANDARD

The conscientious, explicit, and judicious use of the current Best Evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

EXCHANGE (Health Insurance Marketplace)

A governmental agency or non-profit entity that meets the applicable Exchange standards, and other related standards established under the applicable law, and makes Qualified Health Plans (QHP) available to Qualified Individuals and qualified employers (as these terms are defined by the Marketplace). Unless otherwise identified, this term refers to the State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

EXCLUSION

A provision which states that The Plan has no obligation under this Contract to make payment.

EXPERT OPINION

A belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN

A drug, device, biological product or medical treatment or procedure is Experimental, Investigational and/or Unproven if **The Plan determines** that:

- The drug, device, biological product or medical treatment or procedure cannot be lawfully marketed without approval of the appropriate governmental or regulatory agency and approval for marketing has not been given at the time the drug, device, biological product or medical treatment or procedure is furnished; or

- The drug, device, biological product or medical treatment or procedure is the subject of ongoing phase I, II or III clinical trials, or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or
- The prevailing opinion among peer reviewed medical and scientific literature regarding the drug, device, biological product or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

FAMILY MEMBER

A Dependent who has been accepted as a Member of the plan and enrolled by a Beneficiary Member.

FAMILY MEMBERSHIP

The family unit including the Beneficiary Member and all Family Members who have been accepted as Members of The Plan.

FREESTANDING INPATIENT FACILITY

For treatment of Chemical Dependency, it means a facility which provides treatment for Chemical Dependency in a community-based residential setting for persons requiring 24-hour supervision and which is a Chemical Dependency Treatment Center. Services include medical evaluation and health supervision; Chemical Dependency education; organized individual, group and family counseling; discharge referral to Medically Necessary supportive services; and a client follow-up program after discharge.

For treatment of Mental Illness, it means a facility licensed by the state and specializing in the treatment of Mental Illness.

GENERIC

A drug that has the same active ingredient as a Brand-Name drug and is allowed to be produced after the Brand-Name drug's patent has expired. In determining the brand or generic classification for covered drugs, Blue Cross and Blue Shield of Montana uses the generic/brand status assigned by a nationally recognized provider of drug product database information. A list of Preferred Generic drugs is available on the Blue Cross and Blue Shield of Montana website at www.bcbsmt.com. The Member may also contact Customer Service for more information.

HABILITATIVE CARE

Coverage will be provided for Habilitative Care services when the Member requires help to keep, learn or improve skills and functioning for daily living. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. other services for people with disabilities. These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

HOME INFUSION THERAPY AGENCY

A health care provider that provides home infusion therapy services.

HOSPITAL

A facility providing, by or under the supervision of licensed Physicians, services for medical diagnosis, treatment, rehabilitation and care of injured, disabled, or sick individuals. A Hospital has an organized medical staff that is on call and available within 20 minutes, 24 hours a day, 7 days a week and provides 24-hour nursing care by licensed registered nurses.

ILLNESS

An alteration in the body or any of its organs or parts which interrupts or disturbs the performance of a vital function, thereby causing or threatening pain or weakness.

IN-NETWORK

Providers who are:

1. Participating Blue Cross and Blue Shield of Montana Professional Providers;
2. Participating Blue Cross and Blue Shield of Montana Facility Providers, except for Hospitals and surgery centers;
3. PPO Hospitals and surgery centers; or

4. Blue Cross and/or Blue Shield PPO providers outside of Montana.

INCLUSIVE SERVICES/PROCEDURES

A portion of a service or procedure which is necessary for completion of the service or procedure or a service or procedure which is already described or considered to be part of another service or procedure.

INJURY

Physical damage to an individual's body, caused directly and independent of all other causes. An Injury is not caused by an Illness, disease or bodily infirmity.

INPATIENT CARE

Care provided to a Member who has been admitted to a facility as a registered bed patient and who is receiving services, supplies and medications under the direction of a Covered Provider with staff privileges at that facility. Examples of facilities to which a Member might be admitted include:

1. Hospitals;
2. Transitional care units;
3. Skilled nursing facilities;
4. Convalescent homes;
5. Freestanding inpatient facilities.

INPATIENT MEMBER

A Member who has been admitted to a facility as a registered bed patient for Inpatient Care.

LIFE-THREATENING CONDITION

Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

MEDICAL FOODS

Nutritional substances in any form that are:

1. formulated to be consumed or administered enterally under supervision of a Physician;
2. specifically processed or formulated to be distinct in one or more nutrients present in natural food;
3. intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or certain nutrients contained in ordinary foodstuffs or who have other specific nutrient requirements as established by medical evaluation; and
4. essential to optimize growth, health, and metabolic homeostasis.

MEDICAL OR SCIENTIFIC EVIDENCE

Evidence found in the following sources:

1. peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
2. peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the national institutes of health's library of medicine for indexing in Index Medicus and Excerpta Medica, published by the Reed Elsevier group;
3. medical journals recognized by the secretary of health and human services under 42 U.S.C. 1395x(t)(2)(B) of the federal Social Security Act;
4. the following standard reference compendia:
   a. the American Hospital Formulary Service Drug Information;
   b. Drug Facts and Comparisons;
   c. the American Dental Association Guide to Dental Therapeutics; and
   d. the United States Pharmacopeia;
5. findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
   a. the federal agency for healthcare research and quality;
   b. the national institutes of health;
   c. the national cancer institute;

d. the national academy of sciences;
e. the centers for medicare and medicaid services;
f. the food and drug administration; and
g. any national board recognized by the national institutes of health for the purpose of evaluating the medical value of health care services; or

6. any other medical or scientific evidence that is comparable to the sources listed in subsection 4 or 5.

MEDICAL POLICY

The policy of The Plan which is used to determine if health care services including medical and surgical procedures, medication, medical equipment and supplies, processes and technology meet the following nationally accepted criteria:

1. final approval from the appropriate governmental regulatory agencies;
2. scientific studies showing conclusive evidence of improved net health outcome; and
3. in accordance with any established standards of good medical practice.

MEDICALLY NECESSARY (FOR AUTISM, ASPERGER'S DISORDER AND PERVASIVE DEVELOPMENTAL DISORDER)

Any care, treatment, intervention, service, or item that is prescribed, provided or ordered by a Physician or psychologist and that will or is reasonably expected to:

1. Prevent the onset of an Illness, condition, Injury, or disability;
2. Reduce or improve the physical, mental, or developmental effects of an Illness, condition, or Injury, or disability; or
3. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (FOR DOWN SYNDROME)

Any care, treatment, intervention, service, or item that is prescribed, provided, or ordered by a Physician licensed in this state and that will or is reasonably expected to:

1. Reduce or improve the physical, mental, or developmental effects of Down syndrome; or
2. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (MEDICAL NECESSITY)

Health care services that a Physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an Illness, Injury, disease or its symptoms, and that are:

1. in accordance with generally accepted standards of medical practice;
2. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's Illness, Injury or disease; and
3. not primarily for the convenience of the patient, Physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the view of Physicians practicing in relevant clinical areas and any other relevant factors.

The fact that services were recommended or performed by a Covered Provider does not automatically make the services Medically Necessary. The decision as to whether the services were Medically Necessary can be made only after the Member receives the services, supplies, or medications and a claim is submitted to The Plan. The Plan may consult with Physicians or national medical specialty organizations for advice in determining whether services were Medically Necessary.

MEMBER

Both the Beneficiary Member and Family Members.

MEMBER'S IMMEDIATE FAMILY
The Member's Spouse and children or parents and siblings who are caring for the hospice patient in that family.

MENTAL HEALTH TREATMENT CENTER
A treatment facility organized to provide care and treatment for Mental Illness through multiple modalities or techniques pursuant to a written treatment plan approved and monitored by an interdisciplinary team, including a licensed Physician, psychiatric social worker and psychologist. The facility must be:

1. licensed as a mental health treatment center by the state;
2. funded or eligible for funding under federal or state law; or
3. affiliated with a Hospital under a contractual agreement with an established system for patient referral.

MENTAL ILLNESS
A clinically significant behavioral or psychological syndrome or pattern that occurs in a person and that is associated with:

1. present distress or a painful symptom;
2. a disability or impairment in one or more areas of functioning; or
3. a significantly increased risk of suffering death, pain, disability, or an important loss of freedom.

Mental Illness must be considered as a manifestation of a behavioral, psychological, or biological dysfunction in a person.

Mental Illness does not include:

1. developmental disorders;
2. speech disorders;
3. psychoactive substance use disorders;
4. eating disorders (except for bulimia and anorexia nervosa);
5. impulse control disorders (except for intermittent explosive disorder and trichotillomania); or
6. Severe Mental Illness.

MONTH
For the purposes of this Contract, a Month has 30 days even if the actual calendar Month is longer or shorter.

MONTHLY DUES
The amount of money which must be paid monthly by the Beneficiary Member to keep this Contract in force.

MULTIDISCIPLINARY TEAM
A group of health service providers who are either licensed, certified, or otherwise approved to practice their respective professions in the state where the services are provided. Members of the Multidisciplinary Team may include, but are not limited to, a licensed psychologist, licensed speech therapist, registered physical therapist, or licensed occupational therapist.

OCCUPATIONAL THERAPY
Therapy involving the treatment of neuromusculoskeletal and psychological dysfunction through the use of speech tasks or goal-directed activities designed to improve the functional performance of an individual.

ORTHOPEDIC DEVICES
Rigid or semirigid supportive devices which restrict or eliminate motion of a weak or diseased body part. Orthopedic Devices are limited to braces, corsets and trusses.

OUT-OF-NETWORK
Providers who are:

1. Non-participating professional providers;
2. Non-participating facility providers;
3. Non-PPO Network Hospitals and surgery centers; or
4. Blue Cross and Blue Shield of Montana Participating Hospitals and surgery centers that are not in the PPO Network.

OUT OF POCKET AMOUNT

For the Member:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance each Member must pay for Covered Medical Expenses incurred during the Benefit Period. Once the Member has satisfied the applicable Out of Pocket Amount, the Member will not be required to pay the Member's Deductible, Coinsurance and Copayment for Covered Medical Expenses for the remainder of that Benefit Period. The Out of Pocket Amount for the Member is listed in the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, the Deductible and Coinsurance for the entire Hospital stay (facility charges only) will only apply to the Out of Pocket Amount of the Benefit Period in which the inpatient stay began. If the Member satisfied the Out of Pocket Amount prior to that Hospital stay, no Deductible or Coinsurance will be applied to that stay.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

For the Family:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance for Covered Medical Expenses a Family Membership must pay for services incurred during that Benefit Period. Once the Deductible, Coinsurance and Copayment paid by the Member during the Benefit Period for two or more Family Members covered under the same Family Membership total the applicable Out of Pocket Amount for the family, the Members covered under the same Family Membership will not be required to pay the Deductible, Coinsurance and Copayment for Covered Medical Expenses the remainder of that Benefit Period. The Out of Pocket Amount for the family is listed on the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other. For family coverage when only two Members are enrolled, the two Members each must meet their Individual Out of Pocket Amounts only.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

OUTPATIENT

Services or supplies provided to the Member by a Covered Provider while the Member is not an Inpatient Member.

PARTIAL HOSPITALIZATION

A time-limited ambulatory (Outpatient) program offering active treatment which is therapeutically intensive, encompassing structured clinical services within a stable, therapeutic program. The program can involve day, evening and weekend treatment. The underlying aim of this treatment is stabilization of clinical instability resulting from severe impairment and/or dysfunction in major life areas.

A Partial Hospitalization program should offer four to eight hours of therapy five days a week. The hours of therapy per day and the frequency of visits per week will vary depending on the clinical symptoms and progress being made with each individual.

PARTICIPATING PHARMACY

A pharmacy which has entered into an agreement with the pharmacy benefit manager to provide Prescription Drug Products to Members and has agreed to accept specified reimbursement rates. Participating Pharmacies may be Value Participating Pharmacies or Participating Pharmacies.

PARTICIPATING PROVIDER

A Participating Blue Cross and Blue Shield of Montana Professional Provider or a Participating Blue Cross and Blue Shield of Montana Facility Provider.

PHYSICAL THERAPY
Treatment of disease or injury by the use of therapeutic exercise and other interventions that focus on improving posture, locomotion, strength, endurance, balance, coordination, joint mobility, flexibility, functional activities of daily living and pain relief.

PHYSICIAN
A person licensed to practice medicine in the state where the service is provided.

PLAN - THE PLAN
Blue Cross and Blue Shield of Montana, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company.

POLICYHOLDER
The individual who has applied for and been accepted for coverage and to whom the Contract has been issued.

PPO-A PREFERRED PROVIDER ORGANIZATION
A provider or group of providers which have contracted with The Plan to provide services to Members covered under PPO Benefit Contracts.

PPO NETWORK
A provider or group of providers which have a PPO contract with Blue Cross Blue Shield of Montana. The Member may obtain a list of PPO providers from Blue Cross Blue Shield of Montana upon request. Payment to a non-PPO Network provider is subject to the non-PPO Network provider reduction shown in the Schedule of Benefits and the Special Provisions section of this document.

PREFERRED BRAND-NAME
A covered non-specialty Brand-Name drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Brand Name drug tier payment level.

PREFERRED GENERIC
A covered Generic drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Generic drug tier payment level.

PRESCRIPTION DRUG PRODUCT
A medication, product or device approved by the Food and Drug Administration.

PROFESSIONAL CALL
An interview between the Member and the professional provider in attendance. The professional provider must examine the Member and provide or prescribe medical treatment. "Professional Call" does not include telephone calls or any other communication where the Member is not examined by the professional provider, except as included in the Benefit section entitled Telemedicine.

PROOF OF LOSS
The documentation accepted by Blue Cross and Blue Shield of Montana upon which payment of Benefits is made.

QUALIFIED HEALTH PLAN (QHP)
A health care benefit program that has in effect a certification that it meets the applicable government standards, issued or recognized by each Exchange through which such program is offered.

QUALIFIED INDIVIDUAL (For an Approved Clinical Trial)
An individual with group health coverage or group or individual health insurance coverage who is eligible to participate in an Approved Clinical Trial according to the trial protocol for the treatment of cancer or other Life-Threatening Condition because:

1. The referring health care professional is participating in the clinical trial and has concluded that the individual's participation in the trial would be appropriate; or
2. The individual provides medical and scientific information establishing that the individual's participation in the clinical trial is appropriate because the individual meets the conditions described in the trial protocol.

RANDOMIZED CLINICAL TRIAL
A controlled, prospective study of patients who have been assigned at random to an experimental group or a

control group at the beginning of the study with only the experimental group of patients receiving a specific intervention. The term includes a study of the groups for variables and anticipated outcomes over time.

RECONSTRUCTIVE BREAST SURGERY

Surgery performed as a result of a mastectomy to reestablish symmetry between the breasts. The term includes augmentation mammoplasty, reduction mammoplasty, and mastopexy.

RECOVERY CARE BED

A bed occupied in an Outpatient surgical center for less than 24 hours by a patient recovering from surgery or other treatment.

REHABILITATION FACILITY

A facility, or a designated unit of a facility, licensed, certified or accredited to provide Rehabilitation Therapy including:

1. A facility that primarily provides Rehabilitation Therapy, regardless of whether the facility is also licensed as a Hospital or other facility type;
2. A freestanding facility or a facility associated or co-located with a Hospital or other facility;
3. A designated rehabilitation unit of a Hospital;
4. For purposes of the Rehabilitation Therapy Benefit, any facility providing Rehabilitation Therapy to a Member, regardless of the category of facility licensure.

REHABILITATION THERAPY

A specialized, intense and comprehensive program of therapies and treatment services (including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy) provided by a Multidisciplinary Team for treatment of an Injury or physical deficit. A Rehabilitation Therapy program is:

1. provided by a Rehabilitation Facility in an Inpatient Care or outpatient setting;
2. provided under the direction of a qualified Physician and according to a formal written treatment plan with specific goals;
3. designed to restore the patient's maximum function and independence; and
4. Medically Necessary to improve or restore bodily function and the Member must continue to show measurable progress.

REHABILITATIVE CARE

Coverage will be provided for Rehabilitative Care services when the Member requires help to keep, get back or improve skills and functioning for daily living that have been lost or impaired because the Member was sick, hurt or disabled. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. psychiatric rehabilitation.

These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

RESIDENTIAL TREATMENT CENTER

A facility setting offering a defined course of therapeutic intervention and special programming in a controlled environment which also offers a degree of security, supervision, structure and is licensed by the appropriate state and local authority to provide such service. It does not include half-way houses, wilderness programs, supervised living, group homes, boarding houses or other facilities that provide primarily a supportive environment and address long-term social needs, even if counseling is provided in such facilities. Patients are medically monitored with 24 hour medical availability and 24 hour onsite nursing service for patients with Mental Illness and/or Chemical Dependency. Requirements: Blue Cross and Blue Shield of Montana requires that any Mental Illness and/or Chemical Dependency Residential Treatment Center must be licensed in the state where it is located, or accredited by a national organization that is recognized by Blue Cross and Blue Shield of Montana as set forth in its current credentialing policy, and otherwise meets all other credentialing requirements set forth in such policy.

ROUTINE

Examinations or services provided when there is no objective indication of impairment of normal bodily function. Routine does not include the diagnosis or treatment of any Injury or Illness.

ROUTINE PATIENT COSTS

All items and services covered by a group health plan or a plan of individual or group health insurance coverage when the items or services are typically covered for a Qualified Individual who is not enrolled in an Approved Clinical Trial. The term does not include:

1. An investigational item, device, or service that is part of the trial;
2. An item or service provided solely to satisfy data collection and analysis needs for the trial if the item or service is not used in the direct clinical management of the patient; or
3. A service that is clearly inconsistent with widely accepted and established standards of care for the individual's diagnosis.

SEVERE MENTAL ILLNESS

The following disorders as defined by the American psychiatric association:

1. schizophrenia;
2. schizoaffective disorder;
3. bipolar disorder;
4. major depression;
5. panic disorder;
6. obsessive-compulsive disorder; and
7. autism.

Coverage for a child with autism who is 18 years of age or younger is provided under the Autism Spectrum Disorders Benefit if the child is diagnosed with:

1. Autistic Disorder;
2. Asperger's Disorder; or
3. Pervasive Developmental Disorder not otherwise specified.

SPECIALTY MEDICATIONS

High cost, hard to manage injectables, select orals, and/or infused therapies that are administered by the patient or Physician for the treatment of chronic illness.

SPECIALTY PHARMACY

A pharmacy which has entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

SPEECH THERAPY

The treatment of communication impairment and swallowing disorders.

SPOUSE

The opposite sex or the same sex person to whom the Beneficiary Member is legally married, based upon the law in effect at the time of and in the state or other appropriate jurisdiction in which the marriage was performed, recognized, or declared.

TELEMEDICINE

Telemedicine means the use of interactive audio, video, or other telecommunications technology that is:

1. Used by a health care provider or health care facility to deliver health care services at a site other than the site where the patient is located; and
2. Delivered over a secure connection that complies with the requirements of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.

The term includes the use of electronic media for consultation relating to the health care diagnosis or treatment of a patient in real time or through the use of store-and-forward technology. The term does not include the use of audio-only telephone, e-mail, or facsimile transmissions.

BLUE CROSS BLUE SHIELD OF MONTANA
A DIVISION OF HEALTH CARE SERVICE CORPORATION
A MUTUAL LEGAL RESERVE COMPANY

Michael E. Frank

By: Michael E. Frank
Plan President

Notice That Lifetime Limit No Longer Applies and Enrollment Opportunity

The lifetime limit on the dollar value of benefits under this health plan coverage no longer applies. Individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to reenroll in the plan. Individuals have 30 days beginning with the start of the plan year to request enrollment.

Notice of Opportunity to Enroll in connection with Extension of Dependent Coverage to Age 26

Children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage for children ended before attainment of age 26 are eligible to enroll in this health coverage, regardless of student status, financial dependency or marital status. Individuals may request enrollment for such children for 30 days beginning with the start of the plan year.

American Indian/Alaskan Native Cost-Sharing Notice

This Notice is hereby adopted and incorporated into your Contract.

This Notice only applies if you have enrolled in a Contract that includes Cost-sharing Reductions.

Please read it carefully.

If you are an American Indian/Alaskan Native enrolled under this Contract, the following variations in cost-sharing amounts will apply to your coverage under this Qualified Health Plan (QHP) offered on the Exchange:

If you have a household income of less than 300% of the Federal Poverty Level, you may be eligible for a Zero Cost Sharing (ZCS) Plan.

- If you are enrolled in a ZCS QHP with a non-participating benefit, you will have your cost-sharing for medical and drug Essential Health Benefits, as defined in this Contract, reduced to zero when the benefit is provided at both Participating and Non-Participating provider levels. Any Preauthorization requirements, balance billing/overage from Non-Participating providers, and any maximum benefit limitation or exclusions, will still apply.
- If you are enrolled in a ZCS QHP without a non-participating benefit (e.g. HMO), you will have your cost-sharing for medical and drug Essential Health Benefits, as defined in your benefit booklet, reduced to zero for participating services only. Your ZCS QHP does not provide benefits for services received from a Non-Participating provider, so you may be responsible for all costs associated for services obtained from such a provider. Any Preauthorization requirements, balance billing/overage from Non-Participating Providers, and any maximum benefit limitations or Exclusions, will still apply.

If you are not eligible for a ZCS Plan, you may be eligible for a Limited Cost Sharing (LCS) Plan.

- Under the LCS plans, you will have cost-sharing for medical and drug Essential Health Benefits, as defined in this Contract, reduced to zero when you receive services from an Indian Health Service provider, other tribal or urban Indian organization provider ("I/T/U providers"), or through a referral issued by an I/T/U provider under the Contract Health Service ("CHS") program. If you do not receive services from an I/T/U provider or through a CHS referral, you may be responsible for cost-sharing described in your benefit materials. Any applicable Preauthorization requirements, balance billing/overage from Non-participating providers, any maximum benefit limitations or exclusions, will still apply.

For information on whether a specific Provider is a Participating Provider or non-participating provider or whether a specific Provider is an IHS or other tribal or urban Indian organization provider, call a customer service representative at the number located on the back of your identification card.

For additional information regarding these notices, contact:

Blue Cross and Blue Shield of Montana
3645 Alice Street
Helena, MT 59601
1-800-447-7828

BlueCross BlueShield of Montana

If you, or someone you are helping, have questions, you have the right to get help and information in your language at no cost. To talk to an interpreter, call 855-258-8471.

العربية Arabic	إن كان لديك او لدى شخص تساعده اسئلة، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم فوري، اتصل على الرقم 855-258-8471.
繁體中文 Chinese	如果您, 或您正在協助的對象, 對此有疑問, 您有權利免費以您的母語獲得幫助和訊息. 洽詢一位翻譯員, 請撥電話 號碼 855-258-8471。
Français French	Si vous, ou quelqu'un que vous êtes en train d'aider, avez des questions, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 855-258-8471.
Deutsch German	Falls Sie oder jemand, dem Sie helfen, Fragen haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 855-258-8471 an.
Italiano Italian	Se tu o qualcuno che stai aiutando avete domande, hai il diritto di ottenere aiuto e informazioni nella tua lingua gratuitamente. Per parlare con un interprete, puoi chiamare il numero 855-258-8471.
日本語 Japanese	ご本人様、またはお客様の身の回りの方でも、ご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、855-258-8471までお電話ください。
한국어 Korean	만약 귀하 또는 귀하가 돕는 사람이 질문이 있다면 귀하는 무료로 그러한 도움과 정보를 귀하의 언어로 받을 수 있는 권리가 있습니다. 통역사가 필요하시면 855-258-8471로 전화하십시오.
Diné Navajo	T'áá ni, éí doodago ła'da bíká anánílwo'ígíí, na'ídíłkidgo, ts'ídá bee ná abóóti'i' t'áá níik'e níká a'doolwoł dóó bína'ídíłkidígíí bee nił hodoonih. Ata'dahalne'ígíí bich'į' hodíílnih kwe'é 855-258-8471.
Norsk Norwegian	Hvis du, eller noen du hjelper, har spørsmål, har du rett til å få hjelp og informasjon på ditt språk uten kostnad. For å snakke med en tolk, ring 855-258-8471.
Pennsilfaanisch Deitsch Pennsylvanian-Dutch	Wann du, odder ebber as du an helfe bischt, Questions hoscht, hoscht du's Recht fer Hilf un Information griege in dei eegni Schprooch as nix koschte zellt. Wann du mit en Interpreter schwetze wettscht, kannscht du 855-258-8471 uffrufe.
Русский Russian	Если у вас или человека, которому вы помогаете, возникли вопросы, у вас есть право на бесплатную помощь и информацию, предоставленную на вашем языке. Чтобы связаться с переводчиком, позвоните по телефону 855-258-8471.
Español Spanish	Si usted o alguien a quien usted está ayudando tiene preguntas, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 855-258-8471.
Tagalog Tagalog	Kung ikaw, o ang isang taong iyong tinutulungan ay may mga tanong, may karapatan kang makakuha ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang tagasalin-wika, tumawag sa 855-258-8471.
ไทย Thai	หากคุณ หรือคนที่คุณกำลังช่วยเหลือมีข้อสงสัยใด ๆ คุณมีสิทธิที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่มีค่าใช้จ่าย พูดคุยกับล่ามโดยติดต่อที่หมายเลข 855-258-8471.
Українська Ukrainian	Якщо у Вас чи у когось, хто отримує Вашу допомогу, виникають питання, у Вас є право отримати безкоштовну допомогу та інформацію Вашою рідною мовою. Щоб зв'язатись з перекладачем, зателефонуйте за номером 855-258-8471.
Tiếng Việt Vietnamese	Nếu quý vị, hoặc người mà quý vị đang giúp đỡ, có câu hỏi, thì quý vị có quyền được giúp và nhận thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 855-258-8471.

bcbsmt.com

IMPORTANT NOTICE TO PERSON ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance.

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- the benefits stated in the policy and coverage for the same event is provided by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- (outpatient prescription drugs if you are enrolled in Medicare Part D)
- other approved items and services

BEFORE YOU BUY THIS INSURANCE

1. Check the coverage in all health insurance policies you already have.
2. For more information about Medicare and Medicare Supplement insurance, review the "Guide to Health Insurance for People with Medicare," available from Blue Cross and Blue Shield of Montana.
3. For help in understanding your health insurance, contact your state insurance department or state health insurance assistance program (SHIP).

BlueCross BlueShield of Montana

Blue Cross and Blue Shield of Montana
3645 Alice Street
P.O. Box 4309
Helena, MT 59604-4309

BLUE PREFERRED GOLD PPO 104

BlueCross BlueShield of Montana

To learn more, call Blue Cross and Blue Shield of Montana at 800-447-7828 or your local agent

Outline of Coverage 2017

This plan does not have an Annual Out-of-Pocket Plan Maximum.

Benefit Period	January 1 – December 31		
Deductible *Copayments and coinsurance do not accumulate to the plan deductible.*	In-Network:	Individual: $1,400	Family: $2,800
	Out-of-Network:	Individual: $5,600	Family: $11,200
Out-of-Pocket Amount	In-Network:	Individual: $3,350	Family: $6,700
	Out-of-Network:	Individual: $13,400	Family: $26,800
Deductible Per Visit or Occurrence *These deductibles are in addition to the plan deductible and any coinsurance. Once the out-of-pocket amount is satisfied, plan deductible, per visit or occurrence deductibles and coinsurance and copayments do not apply.*	Emergency Room:	In-Network: $750	Out-of-Network: $750
	Inpatient Admission:	In-Network: $300	Out-of-Network: $1,500
	Outpatient Surgery:	In-Network: $200	Out-of-Network: $1,500
Coinsurance		In-Network: 20%	Out-of-Network: 50%
Copayment *Deductible and coinsurance do not apply to In-Network Services.*	Urgent Care:	In-Network: $20	Out-of-Network: No copayment; deductible and coinsurance apply
			(Emergency services pay as In-Network services.)
Deductible and Coinsurance Waived For:	In and Out-of-Network: Diabetic Education Benefit (the first $250) In-Network: Chemical Dependency and Mental Health Office Visits; Preventive Health Care; Routine and Diagnostic Mammograms; Hospice; Urgent Care; Well-Child Care; the first 3 Primary Care Provider (PCP) Office Visits Out-of-Network: The first $70 for Routine Mammograms; Well-Child Care. However, coinsurance applies to Well Child Care		

Blue Cross and Blue Shield of Montana (BCBSMT) Provider Networks

In-Network Providers - In-Network providers accept the BCBSMT allowable fee, in additional to the deductible, coinsurance and copayment, as payment in full for covered services. In-Network providers submit claims for you and BCBSMT pays In-Network providers directly. You will not be billed amounts over your deductible, coinsurance and copayment.

Preferred Provider Organization (PPO) - A network of hospitals and surgery centers across the state that accept lower payments for each service provided by a PPO Hospital or surgery center. Currently, all hospitals in Montana participate in this network.

Traditional Network Participating Providers - This is the most extensive provider network available in Montana, composed of professional providers and facility providers, other than hospitals and surgery centers which have contracted with BCBSMT to provide services at discounted rates. Approximately 95% off all physicians and 100% of hospitals in Montana participate in this network.

Out-of-Network Providers - Nonparticipating Providers have not contracted with BCBSMT to provide services at negotiated rates, and your out of pocket expenses can be significantly higher. These providers are under no obligation to submit claims for you and may bill you the difference between the allowable fee and their charge (balance billing), in addition to any deductible, coinsurance and copayment.

Emergency Services - Services provided for emergency medical condition which is a condition with symptoms of sufficient severity, including severe pain, that in the absence of immediate medical attention could reasonably be expected to result in: the Member's health being in serious jeopardy; the Member's bodily functions being seriously impaired; or a bodily organ or part being seriously damaged. These services pay as In-Network, even if provided Out-of-Network. An Out-of-Network provider may balance bill.

Finding Participating Providers—To locate In-Network providers in Montana check our on-line provider directory at www.bcbsmt.com or contact Customer Service at 1-800-447-7828.

Blue Cross of State Networks at Your Fingertips – The BlueCard program provides access to Participating Providers across the country. To find BlueCard Providers, visit the BlueCross and BlueShield Association website at http://provider.bcbs.com or call 1-800-810-BLUE (2593).

Deductible: The dollar amount each Member must pay for covered medical expenses incurred during the benefit period before BCBSMT will make payment for any covered medical expense to which the deductible applies. This plan has an In-Network deductible and separate Out-of-Network deductible.

Out-of-Pocket Amount: The total amount of deductible, coinsurance and copayment that each Member would pay in a single benefit period. Once the out-of-pocket amount is met, the Plan pays 100% of the allowable fee on covered services. However, any amount each Member pays for balances owed to nonparticipating providers and the Out-of-Network pharmacy 50% benefit reduction do not apply to the out-of-pocket amount. This plan has an In-Network out-of-pocket amount and a separate Out-of-Network out-of-pocket amount.

Coinsurance: The percentage of the allowable fee payable by the Member for covered medical expenses. This plan has an In-Network coinsurance and a separate Out-of-Network coinsurance.

Copayment: The specific dollar amount payable by the Member for covered medical expenses.

Rating Factors and Trend: The following rating factors are used: income and claims experience for the prior 12 months for the product being rated, the benefit difference for deductible, coinsurance and copayment for specific products in a category, projected claims, income and enrollment for the next 12-month rating period, projected expenses for the next rating period, and/or age of the applicant or subscriber, industry, and risk characteristics. The trend of premium increases during the preceding five years is:
2012 – 11%, 2013 – 13%, 2014 – 6.5%, 2015 -7.2%, 2016 – 21.8%
Your estimated premium will be _____.

Appeals section in the Contract contains information regarding utilization review procedures, including procedures for obtaining review of adverse determinations, and the Member's rights with respect to those procedures.

PET EXHIBIT 2-214

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Deductible, copayments and coinsurance apply to all services listed below, unless otherwise noted. This is only a summary of benefits and general provisions subject to the terms of the Contract. Preauthorization is not a guarantee of payment but is required for some services, supplies, treatments and prescription drugs to determine if services are medically necessary and a benefit of the Contract.

Professional Provider Services	Covered services include home and office calls, x-ray, lab and other services provided by a professional provider. . Deductible and coinsurance do not apply to the first three In-Network PCP office visits. The visit covers services provided during the visit. However, even if provided during that visit, the following services process under regular medical benefits: surgery, physical therapy, speech therapy, occupational therapy, chiropractic manipulation, diagnostic imaging, laboratory services and x-rays.
Preventive Health Care, Including Routine Mammograms and Well-Child Care	Services include: 1. Services that have an "A" or "B" rating in the United States Preventive Services Task Force's (USPSTF) current recommendations; and 2. Immunizations recommended by the Advisory Committee of Immunizations Practices of the Centers for Disease Control and Prevention; and 3. Health Resources and Services Administration (HRSA) Guidelines for Preventive Care & Screenings for Infants, Children, Adolescents and Women; and 4. Current recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued prior to November 2009. Examples of services include, but are not limited to, physical examinations, vaccinations, immunizations, lactation services, a breast pump (maximum of two electric), certain contraceptives and certain tobacco cessation products. Deductible, copayments and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network services, except for the first $70 for Out-of-Network routine mammograms. Deductible does not apply to Out-of-Network Well-Child Care.
Inpatient Hospital	Room and board, special care units, ancillary charges, and transplant coverage.
Outpatient Hospital	Accidental injury, x-ray/lab, surgery, chemotherapy, respiratory therapy, medical emergencies and other services.
Maternity Services	Professional and facility services are processed under regular medical benefits.
Emergency Room Care	Services provided for accidental injury and emergency services.
Transplants	Processed under regular medical benefits.
Convalescent Home	Skilled nursing facility, transitional care units and extended care facilities. 60 days per benefit period.
Chiropractic and Acupuncture Services	Chiropractic: 10 visit maximum per benefit period. Acupuncture: 12 visit maximum per benefit period.
Home Health Care	180 visit maximum per benefit period.
Hospice	Deductible and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network service
Individual Therapies	Outpatient physical, occupational, speech and cardiac rehabilitation therapies for professional and facility charges.
Rehabilitation Therapy	Inpatient and outpatient rehabilitation therapy services.
Durable Medical Equipment and Prostheses	Initial purchase, replacement, and repair.
Pediatric Vision (under 19 years of age)	Routine eye exam, deductible and coinsurance do not apply. Paid at 100% of the allowable fee. Lenses and frames processed under regular medical benefits.
Mental Illness	Mental Illness, including Severe Mental Illness, deductible and coinsurance do not apply to In-Network office visits which are paid at 100% of the allowable fee. Deductible and coinsurance apply to any other covered services provided In-Network and Out-of-Network.
Chemical Dependency	Deductible and coinsurance do not apply to In-Network office visits which are paid at 100% of the allowable fee. Deductible and coinsurance apply to any other covered services provided In-Network and Out-of-Network.
Autism Spectrum Disorder	Diagnosis and treatment of Autistic disorder, Asperger's disorder or pervasive developmental disorder. Applied Behavioral Analysis (ABA) therapy is only available to Members 0-18 years of age.
Mammograms (Medical/Diagnostic)	Deductible and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network service
Diagnostic Services	Processed under regular medical benefits.
Diabetic Education Benefit	Deductible and coinsurance do not apply to the first $250 per benefit period for outpatient services. After the first $250 in payment, deductible, copayment and coinsurance apply.

Prescription Drugs	**Value Participating Pharmacy Copayment/Coinsurance**	**Participating Pharmacy Copayment/Coinsurance**
Retail: 30-day supply	$0 preferred generic, $10 non-preferred generic, $50 preferred brand name, $100 non-preferred brand name	$5 preferred generic, $15 non-preferred generic, $60 preferred brand name, $110 non-preferred brand name
Retail: 90-day supply **Only available at Value Participating Pharmacies**	$0 preferred generic, $30 non-preferred generic, $150 preferred brand name, $300 non-preferred brand name	
Mail Order: 90-day supply	$0 preferred generic, $30 non-preferred generic, $150 preferred brand name, $300 non-preferred brand name	
Specialty Medications – 30-day supply	$250 when purchased at a participating Specialty Pharmacy. 50% coinsurance when purchased at any pharmacy other than a participating Specialty Pharmacy.	

Deductible: Does not apply
(The member must pay the difference between a brand name drug and the generic equivalent, in addition to the copayment, if the member chooses a brand name drug when a generic drug is available.)

Payment for Prescription Drugs purchased at a nonparticipating pharmacy will be reduced by 50% in addition to the Participating Network coinsurance. This 50% benefit reduction does not apply to the Out of Pocket Amount.

Specialty Medications, when purchased at any pharmacy other than a participating Specialty Pharmacy, are covered at 50% coinsurance. This 50% coinsurance does not apply to any Out of Pocket Amount.

Mail Order is only available through the Preferred Mail Order Pharmacy Network.

Member Rights – When requested by the Member or the Member's agent, BCBSMT is required to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider [illegible]

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AMENDMENT

This Amendment, effective 01/01/2017, is part of the Contract with Blue Cross and Blue Shield of Montana.

Include the following provision:

The Contract is an agreement between:

Blue Cross and Blue Shield of Montana
P.O. Box 4309
Helena, Montana 59604
and

Subscriber Name: BARRY J BRIGGS

This Amendment is subject to the terms of the base Contract and all provisions of the base Contract which do not conflict with this Amendment continue in full force. This Amendment will **automatically terminate** without notice when the base Contract terminates for any reason stated in the termination provisions.

BLUE CROSS BLUE SHIELD OF MONTANA
A DIVISION OF HEALTH CARE SERVICE CORPORATION
A MUTUAL LEGAL RESERVE COMPANY

Michael E. Frank

By: Michael E. Frank
Plan President

SUBSCRIBERNAME2012.A

WRITTEN NOTICE OF THE COVERAGE FOR MINIMUM HOSPITAL STAYS FOLLOWING CHILDBIRTH AS REQUIRED BY THE MONTANA INSURANCE CODE AND FEDERAL LAW.

Health insurance for maternity services, including benefits for childbirth, must provide coverage for at least 48 hours of inpatient hospital care following a vaginal delivery and at least 96 hours of inpatient care, following delivery by cesarean section for a mother and newborn infant in a health care facility.

Any decision to shorten the length of inpatient stay to less than that stated above must be made by the attending health care provider and the mother. A health benefit plan may not terminate the service of an attending health care provider or penalize or otherwise provide financial disincentives to an attending health care provider in response to orders by the attending health care provider for care consistent with these provisions. Under this same requirement a health plan may not require that the provider obtain authorization from the plan or the insurance issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

A health benefit plan that provides coverage for post-delivery care that is provided to a mother and newborn infant in the home may not be required to provide coverage of inpatient care unless the inpatient care is determined to be medically necessary by the attending health care provider.

For further information about this notice, please contact Customer Service at 1-800-447-7828 or visit our Website http://www.bcbsmt.com.

WRITTEN NOTICE OF THE WOMEN'S HEALTH AND CANCER RIGHTS ACT OF 1998 (WHCRA) AS REQUIRED BY FEDERAL LAW.

If you have had or are going to have a mastectomy, you may be entitled to certain benefits under WHCRA. For individuals receiving mastectomy-related benefits, coverage will be provided in a manner determined by the Plan in consultation with the attending physician and the patient, for:

1) All stages of reconstruction of the breast on which a mastectomy has been performed.
2) Surgery and reconstruction of the other breast to establish a symmetrical appearance.
3) Chemotherapy.
4) Prostheses and physical complications of all stages of a mastectomy and breast reconstruction, including lymphedemas.

These benefits will be provided subject to any deductible, coinsurance and/or copayment provisions of your health plan. For specific deductible, coinsurance and/or copayment information on your plan, please refer to your schedule of benefits.

For further information about this notice or the benefits provided under WHCRA, please contact Customer Service at 1-800-447-7828 or visit our Website http://www.bcbsmt.com.

WHCRA2012

NOTICE
OF PROTECTION PROVIDED BY
MONTANA LIFE AND HEALTH INSURANCE GUARANTY ASSOCIATION

This notice provides a **brief summary** of the Montana Life and Health Insurance Guaranty Association (the Association) and the protection it provides for policyholders. This safety net was created under Montana law, which determines who and what is covered and the amounts of coverage.

The Association was established to provide protection in the unlikely event that your life, annuity or health insurance company becomes financially unable to meet its obligations and is taken over by its Insurance Department. If this should happen, the Association will typically arrange to continue coverage and pay claims, in accordance with Montana law, with funding from assessments paid by other insurance companies.

The basic protections provided by the Association are:

- Life Insurance
  - $300,000 in death benefits
  - $100,000 in cash surrender or withdrawal values

- Health Insurance
  - $500,000 in hospital, medical and surgical insurance benefits
  - $300,000 in disability income insurance benefits
  - $300,000 in long-term care insurance benefits
  - $100,000 in other types of health insurance benefits

- Annuities
  - $250,000 in withdrawal and cash values

The maximum amount of protection is $300,000 in benefits with respect to any one life regardless of the number of policies or contracts, except with respect to hospital, medical, and surgical insurance benefits.

Note: Certain policies and contracts may not be covered or fully covered. For example, coverage does not extend to any portion(s) of a policy or contract that the insurer does not guarantee, such as certain investment additions to the account value of a variable life insurance policy or a variable annuity contract. There are also various residency requirements and other limitations under Montana law.

To learn more about the above protections, as well as protections relating to group contracts or retirement plans, please visit the Association's web site at www.mtlifega.org or contact:

Montana Life and Health Insurance Guaranty Association PO Box 951 Oconomowoc, WI 53066-0951 877-678-1048 or administrator@mtlifega.org	Montana Department of Insurance State Auditor's Office 840 Helena Ave. Helena, MT 59601 406-444-2040

Insurance companies and agents are not allowed by Montana law to use the existence of the Association or its coverage to encourage you to purchase any form of insurance. When selecting an insurance company, you should not rely on Association coverage.

If there is any inconsistency between this notice and Montana law, then Montana law will control.

Notice of Amendment and Adoption amending ARM 6.6.4601 and 6.6.4602, published in Montana Administrative Register 7/28/2011

350902.0714

BlueCross BlueShield of Montana

Blue Cross and Blue Shield of Montana (BCBSMT) is required to provide you a Notice of Privacy Practices to inform you of your rights under the law. This notice describes how BCBSMT can use or disclose your protected health information. Please take a few minutes and review this notice. You are encouraged to go to the Blue Access for Members (BAM) portal at BCBSMT.com to sign up to receive this notice electronically. Our contact information can be found at the end of the notice.

HIPAA NOTICE OF PRIVACY PRACTICES – Effective 9/23/13

YOUR RIGHTS. When it comes to your health information, you have certain rights. This section explains your rights and some of our responsibilities to help you.	
Get a copy of your health and claims records	• You can ask to see or get a copy of your health and claims records and other health information we have about you. Ask us how to do this by using the contact information at the end of this notice. • We will provide a copy or a summary of your health and claims records usually within 30 days of the request. We may charge a reasonable, cost-based fee.
Ask us to correct health and claims records	• You can ask us to correct your health and claims records if you think they are incorrect or incomplete. Ask us how to do this by using the contact information at the end of this notice. • We may say "no" to your request. We'll tell you why in writing within 60 days.
Request confidential communications	• You can ask us to contact you in a specific way or to send mail to a different address. Ask us how to do this by using the contact information at the end of this notice. • We will consider all reasonable requests, and must say "yes" if you tell us you would be in danger if we do not.
Ask us to limit what we use or share	• You can ask us **not** to share or use certain health information for treatment, payment or our operations. Ask how to do this by using the contact information at the end of this notice. • We are not required to agree to your request, and we may say "no" if it would affect your care.
Get a list of those with whom we've shared information	• You can ask for a list (accounting) for six years prior to your request date of when we shared your information, who we shared it with and why. Ask us how to do this by using the contact information at the end of this notice. • We will include all the disclosures except for those about treatment, payment, and our operations, and certain other disclosures (such as any you asked us to make). We will provide one accounting a year for free but we may charge a reasonable, cost-based fee if you ask for another one within 12 months.
Get a copy of this Notice	• You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. To request a copy of this notice, use the contact information at the end of this notice and we will send you one promptly.
Choose someone to act for you	• If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices for you. • We confirm this information before we release them any of your information.

BlueCross BlueShield of Montana

File a complaint if you feel your rights are violated	• You can complain if you feel we have violated your privacy rights by using the contact information at the end of this notice. • You can also file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by calling 1-877-696-6775; or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/ or by sending a letter to them at: 200 Independence Ave., SW, Washington, D.C. 20201. • We will not retaliate against you for filing a complaint.

YOUR CHOICES. For certain health information, you can tell us your choices about what we share.

If you have a clear preference on how you want us to share your information in the situations described below, tell us and we will follow your instructions. Use the contact information at the end of this notice.

In these cases, you have both the right and choice to tell us to:	• Share information with your family, close friends, or others involved in payment for your care • Share information in a disaster or relief situation • Contact you for fundraising efforts

If there is a reason you can't tell us who we can share information with, we may share it if we believe it is in your best interest to do so. We may also share information to lessen a serious or imminent threat to health or safety.

We never share your information in these situations unless you give us written permission	• Marketing purposes • Sale of your information

OUR USES AND DISCLOSURES. How do we use or share your health information?

We typically use or share your health information in the following ways.

Help manage the health care treatment you receive	• We can use your health information and share it with professionals who are treating you. *Example: A doctor sends us information about your diagnosis and treatment plan so we can arrange additional services.*
Run our organization	• We can use and disclose your information to run our organization and contact you when necessary. *Example: We use health information to develop better services for you.*

We can't use any genetic information to decide whether we will give you coverage except for long-term care plans.

Pay for your health Services	• We can use and disclose your health information since we pay for your health services. *Example: We share information about you with your dental plan to coordinate payment for your dental work.*
Administer your plan	• We may disclose your health information to your health plan sponsor for plan administration purposes. *Example: If your company contracts with us to provide a health plan, we may provide them certain statistics to explain the premiums we charge.*

BlueCross BlueShield of Montana

How else can we use or share your health information?

We are allowed or required to share your information in other ways, usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information go to: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html

Help with public health and safety issues	• We can share your health information for certain situations such as: – Preventing disease – Helping with product recalls – Reporting adverse reactions to medications – Reporting suspected abuse, neglect or domestic violence – Preventing or reducing a serious threat to anyone's health or safety
Do research	• We can use or share your information for health research.
Comply with the law	• We will share information about you when state or federal law requires it, including the Department of Health and Human Services if they want to determine that we are complying with federal privacy laws.
Respond to organ/tissue donation requests and work with certain professionals	• We can share health information about you with an organ procurement organization. • We can share information with a medical examiner, coroner or funeral director.
Address workers compensation, law enforcement, and Other government requests	• We can use or share health information about you: – For workers compensation claims – For law enforcement purposes or with a law enforcement official – With health oversight agencies for activities authorized by law – For special government functions such as military, national security, and presidential protective services or with prisons regarding inmates.
Respond to lawsuits And legal actions	• We can share health information about you in response to an administrative or court order, or in response to a subpoena.
Certain health information	• State law may provide additional protection on some specific medical conditions or health information. For example, these laws may prohibit us from disclosing or using information related to HIV/AIDS, mental health, alcohol or substance abuse and genetic information without your authorization. In these situations, we will follow the requirements of the state law.

OUR RESPONSIBILITIES. When it comes to your information, we have certain responsibilities.

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that compromises the privacy or security of your information.
- We must follow the duties and privacy practices described in this notice and give you a copy of it.
- We will not use or share your information other than as described here unless you tell us we can in writing.

You may change your mind at any time. Let us know in writing if you change your mind.

For more information: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp. html.**

BlueCross BlueShield of Montana

CHANGES TO THE NOTICE

We have the right to change the terms of this notice, and the changes we make will apply to all information we have about you. The new notice will be available upon request or from our website. We will also mail a copy of the new notices to you as required by law.

CONTACT INFORMATION

If you would like general information about your privacy rights or would like a copy of this notices, go to: http://www.bcbsmt.com/important_info/index.html

If you have specific questions about your rights or these notices, contact us in one of the following ways:

- Call us by using the toll-free number located on the back of your member identification card.
- Call us at 1-877-361-7594.
- Write us at Privacy Office Divisional Vice President
  Blue Cross and Blue Shield of Montana
  P.O. Box 804836
  Chicago, IL 60680-4110

REVISION DATE: 8/2014

BlueCross BlueShield
of Montana

P.O. Box 3236
Naperville, Illinois 60566-7236

Return Service Requested

BARRY BRIGGS
PO BOX 82
DILLON, MT 59725

5680114800-03-20838953

80345409

[redacted]

PET EXHIBIT 2-224

EXHIBIT

3

exhibitsticker.com

PET EXHIBIT 3-225

BlueCross BlueShield
of Montana

P.O. Box 3238
Naperville, IL 60566-7238
Address Service Requested

May 10, 2017

JOAN GROGAN
130 S MONTANA ST
DILLON, MT 59725

Patient Name:
Harold L. Grogan

Subject:
Your kit is enclosed

Member ID:
928019978

To contact us: 1-855-258-8471

Dear JOAN GROGAN,

Enclosed is the copy of the policy fulfillment kit you requested. The kit includes all the latest updated material.

Our goal is to serve your health insurance needs through all of life's changes. If you have any questions, feel free to call us at the number above.

Sincerely,

Your Customer Advocates
Blue Cross and Blue Shield of Montana

Enclosure

We're happy to provide our letters, at no cost, in Spanish, Tagalog, Chinese, Navajo, or Braille

- **Español:** Para asistencia en Español, por favor llame al numero ubicado en la parte posterior de su tarjeta de identificación.
- **Tagalog:** Upang humingi ng tulong sa Tagalog, paki tawagan ang numero na nakasulat sa inyong kard.
- **中文:** 如果需要中文幫助，請撥打您卡上的電話號碼。
- **Dine:** Dinék'ehjí áka'a'doowoołí biniiyé, t'áá shǫǫdi kojį' hodíilnih béésh bee hane'í bi numbo bee nééh ho'dólzinígíí biniiyé nanitnígíí bine'dęę' bikáá'

BlueCross BlueShield of Montana

Frequently Asked Questions

How do I make changes to my policy, plan or personal information?

If you bought your plan directly from us, you can call us at the Customer Service number listed on your member ID card. We can help you make the changes you need.

If you have a Marketplace plan, any changes will have to be made through the Marketplace. You can log into your account online at healthcare.gov or call the Marketplace toll free at 800-318-2596.

Some changes, such as adding or dropping a dependent, could change your monthly premium.

How do I sign up for Blue Access for Members℠?

Blue Access for Members gives you easy access to your account information.

1. Click on "Log In" at the top of our website at www.bcbsmt.com.
2. Click on "Register Now."
3. You'll need your member ID card, your ZIP code and your email address to sign up.

How do I make my monthly premium payment?

You can pay your premium by bank draft, with check or money order, using a debit card, or with cash. You can also set up automatic monthly payments using electronic funds transfer by calling Customer Service at the number listed on your member ID card. Find out how at www.bcbsmt.com/member/payment-options.

What is the "Standard Authorization Form to Use or Disclose Protected Health Information (PHI)"?

This form allows BCBSMT to disclose certain health information to the organization(s) or person(s) you name. For example, you may want to allow BCBSMT to provide your claims information to another person, such as a family member. You can sign the form for yourself or on behalf of a minor dependent child.

The form is included with your package for your convenience only. If you decide to use the form, please review it with care.

Am I covered when I travel?

Some BCBSMT plans offer coverage while traveling through BlueCard®, our unique program that gives members access to contracting doctors and hospitals outside a plan's service area, across the nation and around the world.

BlueCard coverage will differ based on your plan and on whether you choose a doctor or hospital in a BCBS network. Be sure to call Customer Service at the number on the back of your member ID card before your trip to find out what you can do if you need care while away from home. Log in to Blue Access for Members for details.

BlueCross BlueShield of Montana

At a Glance

Summary of your Blue Cross and Blue Shield of Montana health insurance coverage

Medical Plan Name: Blue Preferred Gold PPO
Network: Blue Preferred
Identification Number: 928019978
Coverage Date: 01/01/2017
Termination Date: 12/31/2017
Method of Payment: Monthly

Covered Members:
JOAN MAUREEN GROGAN
HAROLD LEE GROGAN

Translation and TTY services available for our members

To assist our members with special communication needs, and if your first language is not English, you can obtain assistance for the following:

- Members may ask to speak to a bilingual staff member (English or Spanish) by calling the Customer Service number on the back of your member ID card.
- Members may ask for access to a telephone-based translation service to assist with other languages.
- Some written forms and member materials are available in Spanish through our Customer Service
- BCBS provides TDD/TTY services and language assistance for incoming callers for deaf, hard-of-hearing and speech-disabled members:
    - Members can call 1-406-444-4212
    - Members can utilize their Teletypewriter (TTY) or Telecommunication Device (TDD) to access a teletype operator.

Deaf, hard-of-hearing and speech-disabled members:

- Members can utilize their Telecommunication Device (TDD) to access a teletype operator.

Thank you for choosing Blue Cross and Blue Shield of Montana.

BlueCross BlueShield of Montana

If you, or someone you are helping, have questions, you have the right to get help and information in your language at no cost. To talk to an interpreter, call 855-258-8471.

العربية Arabic	إن كان لديك أو لدى شخص تساعده أسئلة، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم فوري، اتصل على الرقم 855-258-8471.
繁體中文 Chinese	如果您, 或您正在協助的對象, 對此有疑問, 您有權利免費以您的母語獲得幫助和訊息 洽詢一位翻譯員, 請撥電話 號碼 855-258-8471。
Français French	Si vous, ou quelqu'un que vous êtes en train d'aider, avez des questions, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 855-258-8471.
Deutsch German	Falls Sie oder jemand, dem Sie helfen, Fragen haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 855-258-8471 an.
Italiano Italian	Se tu o qualcuno che stai aiutando avete domande, hai il diritto di ottenere aiuto e informazioni nella tua lingua gratuitamente. Per parlare con un interprete, puoi chiamare il numero 855-258-8471.
日本語 Japanese	ご本人様、またはお客様の身の回りの方でも、ご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、855-258-8471までお電話ください。
한국어 Korean	만약 귀하 또는 귀하가 돕는 사람이 질문이 있다면 귀하는 무료로 그러한 도움과 정보를 귀하의 언어로 받을 수 있는 권리가 있습니다. 통역사가 필요하시면 855-258-8471로 전화하십시오.
Diné Navajo	T'áá ni, éí doodago ła'da bíká anánílwo'ígíí, na'ídiłkidgo, ts'ídá bee ná ahóóti'i' t'áá níik'e níká a'doolwoł dóó bina'ídiłkidígíí bee nił hodoonih. Ata'dahalne'ígíí bich'į' hodíilnih kwe'é 855-258-8471.
Norsk Norwegian	Hvis du, eller noen du hjelper, har spørsmål, har du rett til å få hjelp og informasjon på ditt språk uten kostnad. For å snakke med en tolk, ring 855-258-8471.
Pennsilfaanisch Deitsch Pennsylvanian-Dutch	Wann du, odder ebber as du an helfe bischt, Questions hoscht, hoscht du's Recht fer Hilf un Information griege in dei eegni Schprooch as nix koschte zellt. Wann du mit en Interpreter schwetze wettscht, kannscht du 855-258-8471 uffrufe.
Русский Russian	Если у вас или человека, которому вы помогаете, возникли вопросы, у вас есть право на бесплатную помощь и информацию, предоставленную на вашем языке. Чтобы связаться с переводчиком, позвоните по телефону 855-258-8471.
Español Spanish	Si usted o alguien a quien usted está ayudando tiene preguntas, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 855-258-8471.
Tagalog Tagalog	Kung ikaw, o ang isang taong iyong tinutulungan ay may mga tanong, may karapatan kang makakuha ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang tagasalin-wika, tumawag sa 855-258-8471.
ไทย Thai	หากคุณ หรือคนที่คุณกำลังช่วยเหลือมีข้อสงสัยใด ๆ คุณมีสิทธิที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่มีค่าใช้จ่าย พูดคุยกับล่ามโดยติดต่อที่หมายเลข 855-258-8471.
Українська Ukrainian	Якщо у Вас чи у когось, хто отримує Вашу допомогу, виникають питання, у Вас є право отримати безкоштовну допомогу та інформацію Вашою рідною мовою. Щоб зв'язатись з перекладачем, зателефонуйте за номером 855-258-8471.
Tiếng Việt Vietnamese	Nêu quý vị, hoặc người mà quý vị đang giúp đỡ, có câu hỏi, thì quý vị có quyền được giúp và nhận thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 855-258-8471.

BlueCross BlueShield of Montana

Health care coverage is important for everyone.

We provide free communication aids and services for anyone with a disability or who needs language assistance.
We do not discriminate on the basis of race, color, national origin, sex, gender identity, age or disability.

To receive language or communication assistance free of charge, please call us at 855-710-6984.

If you believe we have failed to provide a service, or think we have discriminated in another way, contact us to file a grievance.

Office of Civil Rights Coordinator
300 E. Randolph St.
35th Floor
Chicago, Illinois 60601

Phone: 855-664-7270 (voicemail)
TTY/TDD: 855-661-6965
Fax: 855-661-6960
Email: CivilRightsCoordinator@hcsc.net

You may file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, at:

U.S. Dept. of Health & Human Services
200 Independence Avenue SW
Room 509F, HHH Building 1019
Washington, DC 20201

Phone: 800-368-1019
TTY/TDD: 800-537-7697
Complaint Portal: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf
Complaint Forms: http://www.hhs.gov/ocr/office/file/index.html

353049.1016

BlueCross BlueShield of Montana

EZ Blue Payment Option℠
Automatic Premium Payment Authorization Agreement

Take these simple steps for hassle-free monthly premium payments:

- Verify with your financial institution that it can accept automated electronic withdrawals.
- Complete this request online by going to bcbsmt.com and logging in to Blue Access for Members℠.
- If submitting by fax, please fax this form to **888-697-0686**.
- If submitting this form by mail, please use this address:

Blue Cross and Blue Shield of Montana
P.O. Box 3236
Naperville, IL 60566-9708

If you have any questions about this program, please call our Member Service Department toll-free at **855-258-8471**.

AGREEMENT

I request and authorize Blue Cross and Blue Shield of Montana (BCBSMT) and/or its designee to obtain payment of amounts becoming due by initiating charges to my account in the form of checks, share drafts, or electronic debit entries, and I request and authorize the Financial Institution named below to accept and honor the same to my account. As the account holder, by signing below, I also certify, in the event that this draft is being drawn from a company checking account, that I am authorized to approve this transaction, that the company is not paying any portion of the premium for this subscriber, either directly, or through reimbursement, and that the employer/company is not deducting any part of the premium from gross income under section 106 or section 162 of the Internal Revenue Code. I understand that both the financial institution and BCBSMT reserve the right to terminate this payment program and/or my participation therein. I also understand that I may discontinue this payment program at any time with at least 10 days advance notice to Blue Cross and Blue Shield of Montana by telephone prior to a scheduled withdrawal date.

Please complete the following:

☐ **Yes** ☐ **No** Deduct ongoing monthly premium payments only from my checking or savings account. Drafts will be drawn on the last day of each month, for the following month of coverage. If the draft date falls on a non-business day or a holiday, the premium payment will be deducted from my account on the next business day. Please ensure adequate funds are available at the time of application. Blue Cross and Blue Shield of Montana is not responsible for fees incurred due to insufficient funds. Select one of the following draft options.

☐ 1 MONTH BANK DRAFT PREMIUM AMOUNT EACH TIME
(12 PAYMENTS PER YEAR)

BCBSMT member ID/applicant's Social Security number: _____

Name of member/applicant: _____

Name of depositor(s) if other than the member/applicant: _____

Phone number of member/applicant/depositor: _____

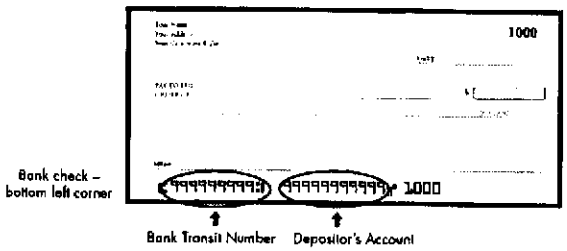
Name of bank, city and state where account is authorized: _____

_____

Please check one: ❑ Checking Account ❑ Savings Account

Bank Transit Number: _____

Depositor's Account Number: _____



I have read and accept the above agreement.

Please continue to pay your premiums by check or money order until you receive a confirmation letter from us stating the date automatic payments will begin.

Depositor's Signature: _____ Date: _____

BlueCross BlueShield of Montana

Standard Authorization Form To Use or Disclose Protected Health Information (PHI)

I. Individual (Name and information of person whose protected health information is being disclosed):

Name _____ Date of Birth _____

Group # _____ Identification/Subscriber # _____ Social Security Number _____

Address _____ City _____ State _____ ZIP _____

Area Code & Telephone Number _____

II. Authorization and Purpose:

I request and authorize Blue Cross and Blue Shield of Montana to disclose my protected health information as described below. **I understand that if the person/organization authorized to receive and use the information is not a health plan or health care provider, the disclosed information may no longer be protected by federal privacy regulations.**

Persons/Organizations authorized to receive your information _____ Relationship _____ Purpose _____

Address _____ City _____ State _____ ZIP _____

III. Specific Description of Information to be Used or Disclosed *(Please Complete **Parts A and B** in this Section)*

This Authorization CANNOT be used to disclose Psychotherapy Notes.

A. Release of Sensitive Protected Health Information Under State Law

You must check "yes" or "no" if you authorize the release of medical information, test results, records or communications specific to ***(note: "yes" means this information is included in the categories you designate in Part B below)*** :

- Human Immunodeficiency Virus (HIV) or HIV/Acquired Immune Deficiency Syndrome
- Sexually transmitted or "communicable" diseases (includes hepatitis, as well as venereal diseases);
- Drug, alcohol or substance abuse;
- Mental health or developmental disabilities (including mental retardation or similar disabilities, for example, those attributable to cerebral palsy, autism or neurological dysfunctions); and
- Genetic testing.

Yes ☐ **No** ☐

B. Release of Protected Health Information *(check one or more)*

			Dates of Services From:	To:
☐	Health Plan Benefit Information:	Includes information contained in your benefit booklet (i.e., copayments, coinsurance, eligibility and other benefit information).		
☐	Claims	Includes information related to payment of your claims for service you received, including pertinent information located on a claim form (i.e., billed amount, general procedure descriptions claim payment or denial reasons, etc.).		
☐	Service Determination Information:	Includes any information related to pre-service, concurrent and post-service decisions.		

A Division of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

☐ Premium Information: Includes information related to billing cycles, bank draft changes, etc.

☐ Services from (provider or supplier): Provider name: _____
(Includes information related to services rendered by a specific provider or supplier.)

☐ Other: _____
(Specify other information that is not listed in one of the categories

IV. Expiration and Revocation:

Expiration: This authorization will expire on (must choose one):

☐ 24 months from the date it is signed

☐ Other (insert date or event, not to exceed 24 months from the date it is signed): _____

Right to Revoke: I understand that I may revoke this authorization at any time by giving written notice to the address listed at the bottom of this form. **I understand that revocation of this authorization will not affect any action the above named entity took in reliance on this authorization before the above named entity received my written notice of revocation.**

V. Signature (this document must be signed by the individual, parent of minor child or the individual's personal representative)**:**

I understand that this authorization is voluntary and that the health plan cannot condition my eligibility for benefits, treatment, enrollment or payment of claims on the signing of this authorization. I understand that if I am signing on behalf of a minor child, this authorization will expire upon the child reaching the age of 18, unless there is proof of legal guardianship.

_____ _____
Signature **Date: month/day/year**

If you are signing as a Power of Attorney, Legal Guardian, Executor or Administrator complete the following and attach a copy of the Legal documents. You do NOT have to attach copies of these documents if they are already on file with Blue Cross and Blue Shield of Montana:

_____ _____
Personal Representative's Name **Relationship to Individual**

_____ _____ _____ _____
Personal Representative's Address **City** **State** **ZIP**

_____
Personal Representative's Area Code & Telephone Number

BEFORE RETURNING THIS FORM YOU SHOULD KEEP A COPY FOR YOUR RECORDS BY EITHER:

(1) MAKING A PHOTOCOPY OF THIS SIGNED AUTHORIZATION; OR
(2) COMPLETING THE DUPLICATE AUTHORIZATION FORM YOU RECEIVED OR PRINTED

Mail your completed signed authorization to:
Blue Cross and Blue Shield of Montana
P.O. Box 805107
Chicago, IL 60680-4112

If you need assistance completing the form, please refer to the instructions above or contact the Customer Service number listed on the back of your Member Identification Card.

Any changes to the format, content or branding of this form are strictly prohibited without review and approval ofthe HCSC Privacy Office. Please forward requests for changes to the Privacy_Office@bcbsil.com.

A Division of Health Care Service Corporation, a Mutual Legal Reserve Company an Independent Licensee of the Blue Cross and Blue Shield Association

BlueCross BlueShield of Montana

Make the Most of Your Blue Cross and Blue Shield of Montana (BCBSMT) Plan.

Now that you have your 2017 BCBSMT plan, here are some tips to help you make the most of your benefits this year.

Knowledge is key.

- **Know What's Covered**
  - Keep this book handy
  - Check your plan when you schedule visits, tests or procedures
- **Know Where to Go**
  - Remember, you may save time and money by visiting retail clinics and urgent care centers for nonemergencies
  - Go to the nearest ER for life-or-death illness or injury
- **Know the Costs**
  - Deductibles
  - Copays and/or coinsurance
  - Out-of-pocket maximum

Visit **www.bcbsmt.com/insurance-basics** for more details.

Blue Access for Members℠ (BAM)

The gateway to help manage your personal health information.

Log in and look.

- Access your health history
- Check your claims
- Find doctors and hospitals
- View your benefits
- Use our online tools

Registering for your BAM account is easy:*

1. Visit **www.bcbsmt.com/member**
2. Click on "Log In" in the upper right-hand side of the page
3. Click on "Register Now"
4. Use the information on your member ID card, your ZIP Code and your email address to complete the registration process

* Note: BCBSMT makes no representation or warranty with respect to the accuracy or completeness of information on BAM. The information on BAM is based upon information provided by you and claims received by BCBSMT, which information has not been independently verified.

Download the BCBSMT App

Carry your health plan with you wherever you go:

- Look up your ID
- Find providers in your network
- Check your benefits
- Track your claims

To download the app, go to Google Play or the App Store or text** BCBSMT to 33633.

** Message and data rates may apply. Terms and conditions and privacy policy at www.bcbsmt.com/mobile/text-messaging.

PET EXHIBIT 3-234

Where You Go for Care Matters

It's important to think where to go when you need medical care.

Thinking where to go when you have a health issue may make a difference in costs and time.

You have options.

	Average Costs	Average Wait Times	Examples of Health Issues
24/7 Nurseline Around the clock help 24 hours a day, 7 days a week	¢	17 seconds*	Registered nurses are on call to answer your health questions 24 hours a day, 7 days a week
Your Doctor Your first choice for nonemergency care	$	24 minutes*	• Cuts and scrapes • Fever, colds and flu • Minor burns • Ear or sinus pain • Shots • Eye swelling, pain • Sore throat • Stomach ache • Physicals • Minor allergic reactions
Retail Clinics For care when you can't see your doctor	$	15 minutes	• Infections • Minor injuries or pain • Flu shots • Skin problems • Bronchitis • Cold and flu • Sore and strep throat • Allergies
Urgent Care When it's not a true emergency, but you need help now	$ $ $ $	11-20 minutes**	• Migraines or headaches • Urinary tract infection • Back pain • Cuts that need stitches • Sprains or strains • Animal bites
Emergency Room When life is in danger from illness or injury	$ $ $ $ $ $	4 hours, 7 minutes†	• Chest pain, stroke • Head or neck injuries • Heart attack • Fainting, dizziness, weakness • Problems breathing • Seizures • Sudden or severe pain • Severe vomiting, diarrh • Uncontrolled bleeding • Broken bones

Key points to remember:

- **24/7 Nurseline.** You may call our 24/7 Nurseline at **877-213-2565**. Registered nurses can answer your general health questions and help you decide if you need care and where you could go. Have your member ID card ready before you call.
- **Use the ER for emergencies only.** When your injury or illness is serious, call 911 or go to the nearest emergency room. You don't need a referral. If it's not an emergency, you may be able to save money by seeing your regular doctor for colds, minor sprains and other less serious conditions.

* Medical Practice Pulse Report 2009, Press Ganey Associates. *http://helpandtraining.pressganey.com/Documents_secure/Pulse%20Reports/2009_ED_Pulse_Report.pd*

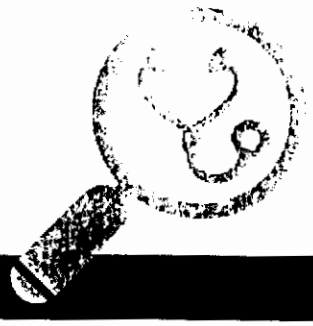
** Urgent Care Benchmarking Study Results. Journal of Urgent Care Medicine. January 2012.

† Emergency Department Pulse Report 2010 Patient Perspectives on American Health Care. Press Ganey Associates. *http://helpandtraining.pressganey.com/researchResources/hospitals/emergencyDepartment/emergencyPulsereport.aspx*

Provider Finder®

Easily search for physicians, specialists and hospitals in your plan's network.

Seeing providers in network helps you get the most from your benefits. Your out-of-pocket costs may be lower when you see in-network providers. Going to in-network hospitals may make a big difference in your costs also.



Check before any visit.

- Compare doctors and hospitals
- Get information on providers
- Get directions to provider locations
- Find out some wait times
- See awards and recognitions
- Read and write reviews
- See what languages the doctor speaks

1. Visit **www.bcbsmt.com**
2. Log in to BAM, go to the "Doctors and Hospitals" tab and click "Find a Doctor"
3. Search by network, doctor, hospital or area to find the most up-to-date listing of health care providers for your plan's network

Get ready before you see your doctor.

Notes can help you make the best use of your time with your doctor. Bring a pen and write as you talk.

Here is what your visit notes could include:

A list of symptoms:

- When did your health concern start?
- Where does it hurt?
- How badly does it hurt?
- Does it get better or worse with activity?
- Does rest help?
- Does what you eat matter?

Your health history:

- Past illnesses, injuries, diseases, allergies
- Your family's health history

Your list of questions:

- Some questions you know ahead of time.
- Some questions pop up as you talk with your doctor.

Current medication:

- A list of drugs OR
- Prescription and over-the-counter containers

Records:

- Records from previous tests or procedures, including X-rays
- Written test results and surgery reports

Learn more about taking care of your health

facebook.com/BCBSMT

youtube.com/bcbsmt

twitter.com/bcbsmt

connect.bcbsmt.com

PET EXHIBIT 3-236

Your Prescription Drug Coverage

Your prescription drug coverage has a network of pharmacies, online tools, and more.

The Drug List

The drug list is a list of covered medications available to BCBSMT members. If your drug is not on the list, check with your doctor for a covered alternative to consider.

Always check the list.

Once you have your prescription, you may save money by:

- Checking to see if your prescription is on the drug list at **www.bcbsmt.com/member/prescription-drug-plan-information/drug-lists**.
- Checking for a generic or lower-cost preferred brand drug. (Ask your doctor if these alternatives may be right for you.)
- Filling your prescriptions at a Value Pharmacy Network pharmacy. If you fill your prescription for a covered prescription drug at a non-Value Pharmacy Network pharmacy, you may pay more out of pocket.

Log in to your Blue Access for Members (BAM) account at **www.bcbsmt.com/member** to learn more about specific drug coverage on your prescription drug benefit.

Examples of Generic Drug Options for Common Drugs

Drug Class	Generic Options
Heartburn/Acid Reduction	lansoprazole, omeprazole, pantoprazole, rabeprazole, esomeprazole
Attention Deficit Hyperactivity Disorder	amphetamine/dextroamphetamine (ER), dexmethylphenidate, methylphenidate (ER)
Bipolar/Psychosis	olanzapine, quetiapine, risperidone, ziprasidone
Cholesterol Lowering	atorvastatin, fenofibric acid, fluvastatin, lovastatin, niacin, omega-3 fatty acids, pravastatin, simvastatin
Depression	bupropion (SR), citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine (ER), sertarline, venlafaxine (ER)
High Blood Pressure	atenolol, benazepril, benazepril (HCTZ), betaxolol, bisoprolol, candesartan, candesartan (HCTZ), enalapril, enalapril (HCTZ), irbesartan, irbesartan (HCTZ), lisinopril, lisinopril (HCTZ), losartan, losartan (HCTZ), metoprolol, metoprolol (ER), propranolol, ramipril, valsartan (HCTZ)
Osteoporosis	alendronate, ibandronate, raloxifen, zoledronic acid, risedronate
Sleep Aids	eszopiclone, zaleplon, zolpidem (ER)
Thyroid Replacement	levothyroxine, Levothroid, Levoxyl, Unithroid

This list is for example only and is not all-inclusive.

PET EXHIBIT 3-237

Value Pharmacy Network

Your prescription drug benefit may include a Value Pharmacy Network.

Check if your plan has a Value Pharmacy Network.

- **30-Day Supply:** If you fill a prescription for up to a 30-day supply of a covered prescription drug from a Value Pharmacy Network pharmacy, you may pay the lowest copay/coinsurance amount.
- **90-Day Supply:** You can also fill a prescription for up to a 90-day supply of a covered prescription drug at a participating Value Pharmacy Network pharmacy. You may pay the lowest copay/coinsurance amount for that quantity.
- Filling a prescription at a non-Value Pharmacy Network pharmacy may cost you more.

Visit Prime Therapeutics* at **myprime.com** to search for a Value Pharmacy Network pharmacy near you.

90-Day Supply Options

If you are taking medication on a routine basis, you may be able to get a 90-day supply.

Where can you get a 90-day supply?

- Through the mail order program
- At a participating retail pharmacy in the Value Pharmacy Network

You can find more information by logging in to your Blue Access for Members (BAM) account at **www.bcbsmt.com/member**.

Specialty Pharmacy Program

Your prescription drug benefit may include a specialty pharmacy program through Prime Therapeutics Specialty Pharmacy.

What are specialty medications?

Specialty medications are those used to treat serious or chronic conditions. Examples include:

- Hepatitis C
- Hemophilia
- Multiple sclerosis
- Rheumatoid arthritis

These drugs are typically given by injection, but may be topical or taken by mouth. They often require careful adherence to treatment plans, have special handling or storage requirements, and may not be stocked by retail pharmacies.

For more information, call Prime Therapeutics at **877-627-6337**.

Medical or Pharmacy Benefit?

- Specialty medications that require professional services for administration are usually covered under your medical benefit plan.
- Coverage for self-administered specialty medications is provided through your pharmacy benefit plan.

* Prime Therapeutics LLC is a separate pharmacy benefit management company, which also operates PrimeMail, a home delivery pharmacy service. Blue Cross and Blue Shield of Montana contracts with Prime Therapeutics to provide pharmacy benefit management and home delivery pharmacy services. Blue Cross and Blue Shield of Montana, as well as several other independent Blue Cross and Blue Shield Plans, has an ownership interest in Prime Therapeutics LLC.

Doctor's Orders: Some medicines on the drug list have special requirements.

What do I have to do to get my prescription?

Prior Authorization

Sometimes prior approval is needed before a drug may be covered.

- Your doctor will need to submit a prior authorization request to Prime Therapeutics.

Step Therapy

Some drugs may not be covered unless you try another preferred drug first.

- Ask your doctor if the preferred drug is right for you or have your doctor submit a prior authorization request for your other drug to Prime Therapeutics.

Quantity Limits

There may be dispensing limits on certain medicines. For example, a medication taken twice daily may be limited to 60 tablets for 30 days.

- If your doctor thinks you need more than the dispensing limit, he or she will need to ask for an override authorization from Prime Therapeutics.

Your doctor can call **888-723-7443** with questions or to ask for any forms.

Well onTarget®

Motivation and guidance for your health and wellness journey.

Whether you want to make a game plan, track your progress or get started on your journey, Well onTarget* provides tools and resources to help guide you toward your health and wellness goals.

Make a plan and track your progress.

Take your health assessment today! It shows you where you stand with issues like:

- Activity level
- Nutrition
- Weight, blood pressure, cholesterol metrics
- Stress management
- Tobacco use

Resources include:

- Online courses on topics related to any wellness goals identified by your health assessment
- Health trackers to track your progress toward any wellness goals identified by your health assessment
- A Blue Points℠ reward program**
  - The more you use the program, the more you earn
  - Redeem points for discounts on a wide range of products

Learn more at **wellontarget.com.**

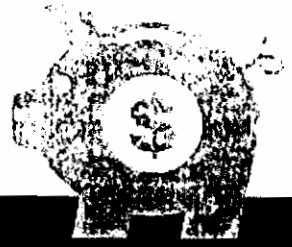
* Well onTarget is an informational resource provided to members and is not a substitute for the independent medical judgment of a health care provider. Members are instructed to consult with their health care provider before beginning their journey toward wellness.

** Blue Points Program Rules are subject to change without prior notice. See the Program Rules on the Well onTarget Member Wellness Portal at wellontarget.com for further information.

Blue365®

Save with the member discount program.

Blue365 is just one more advantage of being a BCBSMT member. Save money on health and wellness products and services that are often not covered by your benefit plan. There are no claims to file and no referrals or pre-certifications.



Shop and save.

Jenny Craig® | Seattle Sutton's® | Nutrisystem®

Save on:

- Healthy meals
- Membership fees (if applicable)
- Nutritional products and services

Reebok | SKECHERS®

- 20% off and free shipping
- Select Reebok athletic equipment for adults and kids
- Select SKECHERS Performance, Sport, Work and Corporate Casual styles

Snap Fitness™

- 50% discount off the best current enrollment offer (no processing fees)
- 5% discount off monthly dues
- Up to five personal training sessions for 10% off
- Free online workout tools
- One month online nutrition and meal planning
- Free fitness tests twice a year
- 30-day trial for $8.95

Dental Solutions℠ Discount Program

- $9.95 sign-up and $6 monthly fee
- Dental discount card
- Up to 50% discount at more than 61,000 dentists and 185,000 locations across the country

Retrofit℠

- 15% off private Expert 10 and Expert 15 weight loss coaching programs
- Private coaching
- Food and activity logging
- Seamless integration with Fitbit® activity trackers and wireless scales

TruHearing® | Beltone™

Save on:

- Hearing tests
- Hearing aids

Log in to BAM and click on "Member Discount Program" under "Quick Links," or visit **Blue365Deals.com/BCBSMT**. Once you sign up, weekly "Featured Deals" will be emailed to you. These deals offer special savings for a short period of time.

Value-added products and services may be discontinued or changed at any time and may be subject to geographical availability.

The relationship between these vendors and Blue Cross and Blue Shield of Montana (BCBSMT) is that of independent contractors

Blue365 is a discount program only for BCBSMT members. This is NOT insurance. Some of the services offered through this program may be covered under your health plan. Please check your benefit booklet or call the Customer Service number on the back of your ID card for specific benefit facts. Use of Blue365 does not change your monthly payment, nor do costs of the services or products count toward any maximums and/or plan deductibles. Discounts are only given through vendors who take part in this program. BCBSMT does not guarantee or make any claims or recommendations about the program's services or products. You may want to talk to your doctor before using these services and products. BCBSMT reserves the right to stop or change this program at any time without notice.

Blue Cross and Blue Shield of Montana, a Division of Health Care Service Corporation,
a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

PET EXHIBIT 3-240

BLUE PREFERRED GOLD PPO-104

INDIVIDUAL PLAN

THIS CONTRACT IS NOT A MEDICARE POLICY. If you are eligible for Medicare, review the Medicare Supplement Buyers Guide from Blue Cross and Blue Shield of Montana.

BlueCross BlueShield of Montana

FOR BCBSMT CUSTOMER SERVICE AND PREAUTHORIZATION

FOR CUSTOMER SERVICE
Call 1-855-258-8471

FOR PREAUTHORIZATION
Call 1-855-462-1782 or Fax 1-866-589-8253 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

FOR INPATIENT ADMISSIONS
Call 1-855-462-1782 or Fax 1-866-589-8253 for Non-Behavioral Health
Call 1-855-313-8909 or Fax 1-855-649-9681 for Behavioral Health

www.bcbsmt.com

- BCBSMT Provider Directory
- Wellness
- Customer Service
- Other Online Services and Information

BLUECARD® NATIONWIDE/WORLD WIDE COVERAGE PROGRAM
1-800-810-BLUE (2583) – http://provider.bcbs.com

FOR APPEALS
Send via fax to 1-866-589-8256
or mail to Blue Cross Blue Shield at:
PO Box 4309
Helena, MT 59604-4309

FOR URGENT CARE APPEALS
Call 1-855-258-8471

FOR PRESCRIPTION DRUG BENEFITS

Pharmacy Benefit Manager (PBM)	
• Prime Therapeutics	1-800-423-1973
• For preauthorizations, fax:	1-877-243-6930
PBM Website	www.myprime.com
Claim Forms	1-866-325-5230
Pharmacy Locator	1-866-325-5230
Specialty Care Pharmacy (BCBSMT Prime Specialty Network)	1-877-627-MEDS (6337)
• www.bcbsmt.com or www.myprime.com	1-877-828-3939
• Prescriber Fax	
Mail Order Services	
• **PrimeMail** PO Box 27836 Albuquerque, NM 87125-7836	1-866-325-5230
• **Ridgeway Mail-Order Pharmacy** 2824 US Hwy 93 North Victor, MT 59875	1-800-630-3214

Blue Cross and Blue Shield of Montana
3645 Alice Street
PO Box 4309
Helena, MT 59604-4309

FOR CLAIMS
Blue Cross and Blue Shield of Montana
PO Box 7982
Helena, MT 59604-7982

Certain terms in this Contract are defined in the Definitions section of this Contract. Defined terms are capitalized.

THIS CONTRACT

1. If the Member is not satisfied with this Contract for any reason, the Contract may be returned within 10 days of its delivery. The Plan will refund the amount of dues paid, thus voiding the Contract from the beginning.
2. The Plan agrees to pay for the Covered Medical Expenses as outlined in this Contract subject to the following conditions:
   a. All statements made in any application for membership or any statement of health must be correct.
   b. The Plan must receive the Monthly Dues on or before the time listed on the Member's bill. **Payment of monthly dues is a condition precedent to coverage under this Contract.**
3. Payment by The Plan will be subject to the terms, conditions and limitations of this Contract and any endorsements, amendments and/or riders.
4. Payment will only be made for services which are provided to Members after the Effective Date of this Contract and before the date on which this Contract terminates.

MEMBERS RIGHTS

When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

CONTINUITY OF CARE

If the Member's Participating Provider (professional) stops participating in the PPO network, the Member may request continued treatment from that provider for a period of time after the provider stops participating, except for pregnancy, the continuity of care period is 90 days or until the next policy renewal date, whichever is longer. For pregnancy, the continuity of care period is through the postpartum period. For the Member to qualify for continuity of care, the provider must: (1) agree that the Member is in an active course of treatment as defined by ARM 6.6.5908; (2) agree to accept the same allowed amount as the provider would have accepted if the provider had remained a Participating Provider; and (3) agree not to seek payment from the Member of any amount for which the Member would not have been responsible if the provider had remained a Participating Provider. Continuity of care protections are only for an active course of treatment and are not required for routine primary and preventive care.

PRIVACY OF INSURANCE AND HEALTH CARE INFORMATION

It is the policy of Blue Cross and Blue Shield of Montana to protect the privacy of Members through appropriate use and handling of private information. Further, appropriate handling and security of private information may be mandated by state and/or federal law.

The Beneficiary Member may receive a copy of Blue Cross and Blue Shield of Montana's "Notice of Privacy Practices," or other information about privacy practices, by calling the telephone number or writing to the address shown on the inside cover of this Contract.

PAYMENT OF DUES

Payment of Initial Dues

The first Month's dues must be paid to and accepted by The Plan before this Contract is in effect.

Payment of Monthly Dues

Dues are payable by each Beneficiary Member in advance, in the amounts and at the times shown on the Member's bill.

Payment Provisions

Blue Cross and Blue Shield of Montana only accepts premium (dues) and cost-sharing payments from:

1. The Member;
2. The Member's family;
3. Required Entities (the entities the law requires Blue Cross and Blue Shield of Montana to accept premium and cost-sharing payments from, which currently are Ryan White HIV/AIDS programs, under title XXVI of the Public Health Service Act, Indian tribes, tribal organizations and urban Indian organizations; and State and Federal government programs, as described in 45 C.F.R. § 156.1250); and
4. Private non-profit foundations that make premium or cost-sharing assistance available to the Member:
   a. for the entire coverage period of the Member's Contract;
   b. based solely on financial criteria;
   c. regardless of the Member's health status, and
   d. regardless of which issuer and/or benefit plan the Member chooses.

Blue Cross and Blue Shield of Montana does not accept premium and cost-sharing payments from any other third party. A violation of this policy may result in premium and cost-sharing payments paid by a third party not being credited to the Member's account or coverage or refunded to Member, which may result in the retroactive termination or cancellation of coverage.

Grace Period

Unless, not less than 30 days prior to the dues' due date, Blue Cross and Blue Shield of Montana has delivered to the Beneficiary Member or has mailed to the Member's last address as shown on the records of Blue Cross and Blue Shield of Montana, written notice of its intention not to renew this Contract beyond the period for which the dues have been accepted, a grace period of ten days will be granted for the payment of each Monthly Dues amount falling due after the first dues payment, during which grace period the Contract will continue in force.

IDENTITY THEFT SERVICES

Blue Cross and Blue Shield of Montana (BCBSMT) offers, at no additional cost to the Member, identity theft protection services, including credit monitoring, fraud detection, credit /identity repair and insurance to help protect the Member's information. These identity theft protection services are currently provided by BCBSMT's designated outside vendor and acceptance or declination of these services is optional to Member.

Members who wish to accept such identity theft protection services will need to individually enroll in the program online at www.bcbsmt.com or telephonically by calling the toll free telephone number on his/her identification card. Services may automatically end when the person is no longer an eligible Member. In addition, services may change or be discontinued at any time and BCBSMT does not guarantee that a particular vendor or service will be available at any given time. The services are provided as a convenience and are not considered covered benefits under this Contract.

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SCHEDULE OF BENEFITS

Blue Preferred Gold PPO 104

Annual and Lifetime Plan Maximum: None

Benefit Period: Calendar Year

The Benefits are subject to the Benefit Period unless otherwise specified.

	In-Network	Out-of-Network
Deductible:		
Individual	$1,400	$5,600
Family	$2,800	$11,200

The In-Network and Out-of-Network Deductibles are separate amounts and one does not accumulate to the other.

Any Copayments and Coinsurance do not accumulate to the Deductible.

Deductible per Visit or Occurrence:		
Emergency Room Care	$750*	$750*
Inpatient Admission	$300*	$1,500*
Outpatient Surgery	$200*	$1,500*

*These Per Occurrence Deductibles are in addition to Deductible and any Coinsurance.

Coinsurance:	20%	50%
Copayments:		
Urgent Care	$20	No Copayment; Deductible and Coinsurance Apply
Out of Pocket Amount:		
Individual	$3,350	$13,400
Family	$6,700	$26,800

The In-Network and Out-of-Network Out of Pocket Amounts are separate amounts and one does not accumulate to the other. Charges in excess of the Allowable Fee do not accumulate to help meet the Out of Pocket Amount.

Some Benefits may have payment limitations. Refer to the specific Benefit in this Schedule of Benefits for additional information. In addition:

- For Emergency Services provided by an Out-of-Network Provider, Benefits will be provided as if such services were provided by an In-Network provider.
- Out-of-Network providers may bill the Member the difference between the Allowable Fee and the provider's charge, in addition to any applicable Deductible, Copayment or Coinsurance even if Preauthorization is obtained for the service or treatment is provided for Emergency Services.

Term of Contract: Monthly

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Accident		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Acupuncture	20%	50%
Maximum Per Benefit Period – 12 Visits		
Ambulance	20%	20%
Autism Spectrum Disorders		
Services, except medications/prescription drugs and Applied Behavior Analysis (ABA) services that are described in the Benefit section entitled Autism Spectrum Disorders are covered under medical Benefits.		
Medications/prescription drugs are covered under Prescription Drugs.		
ABA services are only covered for Members under 19 years of age	20%	50%
Birthing Centers	20%	50%
Chemical Dependency		
Professional Provider Services		
Outpatient	20%*	50%
Inpatient	20%	50%
*Deductible and Coinsurance do not apply to Primary Care Provider (PCP) home and office visits for Chemical Dependency		
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Chiropractic Services	20%	50%
Maximum Benefit Per Benefit Period for Chiropractic Manipulations – 10 Visits		
Convalescent Home Services	20%	50%
Maximum Per Benefit Period – 60 Days		
Refer to Page 1 for the Inpatient Admissions Deductible.		
Diabetic Education Benefit		
The Deductible and Coinsurance do not apply to the Payment of the first $250. After the payment of $250, Deductible and Coinsurance will apply.		
First $250	Deductible and Coinsurance Do Not Apply	
After the first $250 in payment	20%	50%

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SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Diagnostic Services		
Diagnostic Imaging Services		
Computerized Tomography (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan)		
Professional Provider Services	20%	50%
Facility Services	20%	50%
All Other Covered Diagnostic Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Durable Medical Equipment		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Durable Medical Equipment	20%	50%
Education Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Emergency Room Care	20%	20%
Refer to Page 1 for the Emergency Room Deductible.		
Home Health Care	20%	50%
Maximum Per Benefit Period – 180 Visits		
Hospice Care		
Professional Provider Services	Deductible and Coinsurance Do Not Apply	50%
Facility Services	Deductible and Coinsurance Do Not Apply	50%
Hospital		
Professional Services (when the Professional Provider is employed by the Hospital)		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Mammograms		
Routine	Deductible and Coinsurance Do Not Apply	50%*
Medical	Deductible and Coinsurance Do Not Apply	50%
*Deductible and Coinsurance do not apply to the payment of the first $70 for Routine mammograms provided by an Out-of-Network provider.		

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION **Deductible applies to all services unless noted otherwise.**	**IN-NETWORK COINSURANCE/ COPAYMENT**	**OUT-OF-NETWORK COINSURANCE/ COPAYMENT**
Maternity Services		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Medical Supplies	20%	50%
Mental Health		
Professional Provider Services		
Outpatient	20%*	50%
Inpatient	20%	50%
*Deductible and Coinsurance do not apply to Primary Care Provider (PCP) home and office visits for Mental Illness.		
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Partial Hospitalization is covered under the Inpatient Treatment Benefit.		
Newborn Initial Care		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
The applicable Inpatient Admission Deductible and plan Deductible apply after the first 5 days of initial care.		
Office Visit		
Primary Care Provider (PCP)	20%*	50%
Deductible and Coinsurance do not apply to the first 3 In-Network PCP visits.		
However, Deductible and Coinsurance apply to the following covered services provided during those first 3 office visits: surgery, Physical Therapy, Speech Therapy, Occupational Therapy, Chiropractic Manipulation, Diagnostic Imaging, Laboratory Services and X-rays.		
Specialist	20%*	50%
*Deductible and Coinsurance do not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.		
Orthopedic Devices/Orthotic Devices	20%	50%
Other Facility Services – Inpatient and Outpatient	20%	50%
Pediatric Vision Care (For Members under 19 years of age)		
Routine Exam	Deductible and Coinsurance Do Not Apply	
Maximum Per Benefit Period – 1 Exam		
Frames and Lenses	20%	50%
Maximum Per Benefit Period – 1 Pair of Glasses or 2 boxes of Contact Lenses		
Physician Medical Services (Other than the Office Visit)	20%	50%

SCHEDULE OF BENEFITS, continued

BENEFIT INFORMATION Deductible applies to all services unless noted otherwise.	IN-NETWORK COINSURANCE/ COPAYMENT	OUT-OF-NETWORK COINSURANCE/ COPAYMENT
Prescription Drugs Refer to the last page of this Schedule of Benefits.		
Preventive Health Care		
Routine Services	Deductible and Coinsurance Do Not Apply	50%
Prostheses Benefit		
Rental (up to Purchase Price), Purchase and Repair and Replacement of Prosthetics	20%	50%
Rehabilitation Therapy		
Professional Services		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Surgery Center Services - Outpatient		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Refer to Page 1 for the Outpatient Surgery Deductible.		
Therapies – Outpatient		
Physical Therapy, Occupational Therapy, Speech Therapy, Cardiac Therapy		
Professional Provider Services	20%	50%
Facility Services	20%	50%
Transplants		
Professional Services		
Outpatient	20%	50%
Inpatient	20%	50%
Facility Services		
Outpatient	20%	50%
Inpatient	20%	50%
Refer to Page 1 for the Inpatient Admissions Deductible.		
Urgent Care *Copayment does not apply to In-Network Preventive Health Care services. Refer to the section entitled Preventive Health Care.	$20*, No Deductible	50%
Well-Child Care Services	Deductible and Coinsurance Do Not Apply	50%, No Deductible

SCHEDULE OF BENEFITS, continued

PRESCRIPTION DRUG INFORMATION	DEDUCTIBLE	COPAYMENT/ COINSURANCE
Prescription Drugs (The Prescription Drugs Benefit utilizes a Drug List.) Any Deductible, Copayment and/or Coinsurance do not apply to certain contraceptive products. Refer to the Preventive Health Care Benefit. Any Deductible, Copayment and/or Coinsurance also do not apply to smoking cessation products and over-the-counter aids/medications, for two 90-day treatment regimens.		
Deductible	Does Not Apply	
Retail Value Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
	Preferred Generic:	No Copayment
	Non-Preferred Generic:	$10
	Preferred Brand-Name:	$50
	Non-Preferred Brand-Name:	$100
Retail Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
	Preferred Generic:	$5
	Non-Preferred Generic:	$15
	Preferred Brand-Name:	$60
	Non-Preferred Brand-Name:	$110
Retail Non-Participating Pharmacy Prescriptions Copayments for a **30-day supply** are:		
	Preferred Generic:	$5
	Non-Preferred Generic:	$15
	Preferred Brand-Name:	$60
	Non-Preferred Brand-Name:	$110
Payment for Prescription Drug Products purchased at a Non-Participating Pharmacy will be reduced by 50%, in addition to any Copayment.		
Mail Service Maintenance Prescriptions Copayments for a **90-day supply** are:		
	Preferred Generic:	No Copayment
	Non-Preferred Generic:	$30
	Preferred Brand-Name:	$150
	Non-Preferred Brand-Name:	$300
Retail Value Participating Pharmacy Prescriptions Copayments for a **90-day supply** are:		
	Preferred Generic:	No Copayment
	Non-Preferred Generic:	$30
	Preferred Brand-Name:	$150
	Non-Preferred Brand-Name:	$300
Specialty Medications purchased at participating Specialty Pharmacies in the Blue Cross and Blue Shield of Montana Prime Specialty Network (30-day supply only)		$250*

***An Out-of-Network 50% Coinsurance applies to Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy.**

The Member must pay the difference between a Brand-Name drug and the Generic equivalent in addition to the Copayment and/or Coinsurance if the Member chooses a Brand-Name drug when a Generic drug is available.

Any Copayment and/or Coinsurance amounts paid for prescription drugs do not apply to the Deductible. The 50% benefit reduction for prescription drugs purchased at a Non-Participating Pharmacy does not apply to the Out-of-Pocket maximum. The 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy does not apply to any Out of Pocket Amount.

PROVIDERS OF CARE FOR MEMBERS

The participation or nonparticipation of providers from whom a Member receives services, supplies, and medication impacts the amount The Plan will pay and the Member's responsibility for payment. Professional providers and facility providers are either In-Network or Out-of-Network providers. In-Network providers include Participating Providers and Preferred Provider Organization (PPO) providers. Out-of-Network providers are nonparticipating and non-PPO providers.

In-Network and Out-of-Network Professional Providers and Facility Providers

Professional providers include, but are not limited to, Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, Advanced Practice Registered Nurses, physician assistants, naturopathic physicians, acupuncturists and physical therapists.

Primary Care Providers (PCPs) include general practitioners, family practitioners, internists, pediatricians, obstetricians and gynecologists, psychiatrists, psychologists, naturopaths, physicians' assistants, registered nurse practitioners, psychiatrists, psychologists, licensed addiction counselors, licensed clinical professional counselors and licensed clinical social workers.

A specialist is a Physician, not included in the list of PCPs, who provides medical services in any generally accepted medical specialty or sub-specialty.

PCPs and specialists do not include chiropractors, acupuncturists, speech therapists, physical therapists, or occupational therapists.

Facility providers include, but are not limited to, Hospitals, Rehabilitation Facilities, Home Health Agencies, Convalescent Homes, skilled nursing facilities, freestanding facilities for the treatment of Chemical Dependency or Mental Illness, and freestanding surgical facilities (surgery center).

The Member may obtain a list of Participating Providers from Blue Cross and Blue Shield of Montana free of charge by contacting The Plan at the number listed on the inside cover of this Contract.

PPO Providers

Blue Cross and Blue Shield of Montana has a PPO Network of Hospitals and surgery centers in Montana that is utilized under this Benefit Plan. Outside of the state of Montana, there are also Blue Cross and/or Blue Shield PPO Hospitals and surgery centers nationwide. The Member receives the In-Network Benefit when utilizing the PPO network or the nationwide Blue Cross and/or Blue Shield PPO Hospitals and surgery centers. If the Member obtains services or supplies from a non-PPO Network provider, the Out-of-Network Deductible, Coinsurance and Out-of-Pocket will apply as indicated on the Schedule of Benefits.

The exceptions to the Benefit reduction are:

- Emergency Services;
- Services that are unavailable within the PPO Network.

If a Member receives services from an out of state provider, then services must be provided by:

- Blue Cross and/or Blue Shield PPO facility providers; and/or
- Blue Cross and/or Blue Shield participating professional providers* or PPO professional providers.

*Some Blue Cross and/or Blue Shield Plans require services to be provided by a PPO professional provider for the Member to receive the highest level of Benefit. Contact The Plan for additional information on out of state services.

Emergency Services and services that are unavailable within the PPO Network will be covered as In Network. **However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if Preauthorization was obtained for such services.** The Member will be responsible for the balance of the nonparticipating provider's or non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment by the Member of any Deductible, Coinsurance and/or Copayment.

Out of PPO Network Referrals

There may be circumstances under which the most appropriate treatment for the Member's condition is not available through the PPO Network. When this occurs, it is recommended the Member's attending Physician contact The Plan for an out of PPO Network referral. If the referral is not approved, and the Member chooses to obtain services from a non-PPO Network provider, the Member will be responsible for the Out-of-Network Deductible and Coinsurance, in addition to any difference between the Blue Cross and Blue Shield of Montana Allowable Fee and the provider's billed charges.

If The Plan approves the referral, those services will process with the In-Network Deductible and Coinsurance. However, any nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment even if The Plan approves the referral.

How Providers are Paid by The Plan and Member Responsibility

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield of Montana for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

How Providers are Paid by The Plan and Member Responsibility Outside of Montana

Payment by The Plan for Benefits is based on the Allowable Fee and is impacted by the participation or nonparticipation of the provider in the Blue Cross and Blue Shield of Montana provider network in the state where serves are provided.

An **In-Network provider** agrees to accept payment of the Allowable Fee from Blue Cross and Blue Shield for Covered Medical Expenses, together with any Deductible, Coinsurance and/or Copayment from the Member, as payment in full. Generally, The Plan will pay the Allowable Fee for a Covered Medical Expense directly to the Participating Provider or PPO Provider. In any event, The Plan may, in its discretion, make payment to the Member, the provider, the Member and provider jointly, or any person, firm, or corporation who paid for the services on the Member's behalf.

Out-of-Network providers do not have to accept Blue Cross and Blue Shield payment as payment in full. Payment to a nonparticipating provider or a non-PPO provider for Covered Medical Expenses is based on the Allowable Fee. The nonparticipating provider or a non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield and provider charges plus Deductible, Coinsurance and/or Copayment. The Member will be responsible for the balance of the nonparticipating provider's or a non-PPO provider's charges after payment by Blue Cross and Blue Shield and payment of any Deductible, Coinsurance and/or Copayment.

For Prescription Drug Products, the Member will be responsible for paying the specific Copayment/Coinsurance as described in the Prescription Drugs section.

The Plan will not pay for any services, supplies or medications which are not a Covered Medical Expense, or for which a Benefit maximum has been met, regardless of whether provided by a Participating Provider or a nonparticipating provider. The Member will be responsible for all charges for such services, supplies, or medications.

MEMBERS RIGHTS AND RESPONSIBILITIES

A Member has the right to:

1. Receive information about The Plan, the quality assurance program, the Member's health Benefit Plan, the names of participating health care providers, and the Member's rights and responsibilities.
2. Be treated with respect and recognition of the Member's dignity and right to privacy.
3. Have a candid discussion of appropriate or Medically Necessary treatment options for the Member's condition, regardless of cost or Benefit coverage.
4. Participate with health care providers in decision-making regarding the Member's health care.
5. Voice complaints or appeals about the managed care organization, health care providers or the care provided.
6. Talk to the Member's health care provider and expect that the Member's records and conversations are kept confidential.
7. When requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

A Member has the responsibility to:

1. Provide, to the extent possible, information that The Plan and health care providers need in order to care for the Member.
2. Follow the treatment plans and instruction for care the Member has agreed upon with the Member's health care providers.

OUT-OF-AREA SERVICES – THE BLUECARD PROGRAM

Out-of-Area Services

Blue Cross and Blue Shield of Montana has a variety of relationships with other Blue Cross and/or Blue Shield Licensees. Generally, these relationships are called "Inter-Plan Arrangements." These Inter-Plan Arrangements work based on rules and procedures issued by the Blue Cross Blue Shield Association. Whenever a Member receives healthcare services outside of the Blue Cross and Blue Shield of Montana service area, the claims for those services may be processed through one of these Inter-Plan Arrangements. The Inter-Plan Arrangements are described below.

When a Member receives care outside of the Blue Cross and Blue Shield of Montana service area, the Member will receive care from one of two kinds of providers. Most providers ("participating providers") contract with the local Blue Cross and/or Blue Shield Licensee in that geographic area ("Host Blue"). Some providers ("nonparticipating providers") don't contract with the Host Blue. Blue Cross and Blue Shield of Montana explain below how we pay both kinds of providers.

1. **BlueCard® Program**

   Under the BlueCard® Program, when a Member receives Covered Medical Expenses within the geographic area served by a Host Blue, Blue Cross and Blue Shield of Montana will remain responsible for what we agreed to in the contract. However, the Host Blue is responsible for contracting with and generally handling all interactions with its participating healthcare providers.

   When the Member receives Covered Medical Expenses outside the Blue Cross and Blue Shield of Montana service area and the claim is processed through the BlueCard Program, the amount the Member pays for Covered Medical Expenses is calculated based on the lower of:

   - The billed covered charges for the Member's Covered Medical Expenses; or
   - The negotiated price that the Host Blue makes available to Blue Cross and Blue Shield of Montana.

Often, this "negotiated price" will be a simple discount that reflects an actual price that the Host Blue pays to the Member's healthcare provider. Sometimes, it is an estimated price that takes into account special arrangements with the Member's healthcare provider or provider group that may include types of settlements, incentive payments, and/or other credits or charges. Occasionally, it may be an average price, based on a discount that results in expected average savings for similar types of healthcare providers after taking into account the same types of transactions as with an estimated price.

Estimated pricing and average pricing, going forward, also take into account adjustments to correct for over- or underestimation of past pricing of claims, as noted above. However, such adjustments will not affect the price Blue Cross and Blue Shield of Montana uses for the Member's claim because they will not be applied after a claim has already been paid.

In some cases, Blue Cross and Blue Shield of Montana may, but is not required to, negotiate a payment with a non-participating healthcare provider on an exception basis.

Inter-Plan Programs: Federal/State Taxes/Surcharges/Fees

Federal or state laws or regulations may require a surcharge, tax or other fee. If applicable, Blue Cross and Blue Shield of Montana will include any such surcharge, tax or other fee as part of the claim charge passed on to the Member.

2. Non-Participating Healthcare Providers Outside of the Blue Cross and Blue Shield of Montana Service Area

a. Member Liability Calculation

When the Member incurs Covered Medical Expenses outside of the Blue Cross and Blue Shield of Montana service area for services provided by non-participating healthcare providers, the amount the Member pays for such services will generally be based on either the Host Blue's non-participating healthcare provider local payment or the pricing arrangements required by applicable state law. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph. Federal or state law, as applicable, will govern payments for out-of-network emergency services.

b. Exceptions.

In certain situations, Blue Cross and Blue Shield of Montana may use other payment bases, such as Covered Medical Expenses, the payment Blue Cross and Blue Shield of Montana would make if the healthcare services had been obtained within the Blue Cross and Blue Shield of Montana service area, or a special negotiated payment to determine the amount Blue Cross and Blue Shield of Montana will pay for services provided by non-participating healthcare providers. In these situations, the Member may be liable for the difference between the amount that the non-participating healthcare provider bills and the payment Blue Cross and Blue Shield of Montana will make for the Covered Medical Expenses as set forth in this paragraph.

3. BlueCard Worldwide® Program

If the Member is outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member may be able to take advantage of the BlueCard Worldwide® Program when accessing Covered Medical Expenses. The BlueCard Worldwide Program is unlike the BlueCard Program available in the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands in certain ways. For instance, although the BlueCard Worldwide Program assists the Member with accessing a network of inpatient, outpatient and professional providers, the network is not served by a Host Blue. As such, when the Member receive care from providers outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands, the Member will typically have to pay the providers and submit the claims himself/herself to obtain reimbursement for these services.

If the Member needs medical assistance services (including locating a doctor or hospital) outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands (hereinafter "BlueCard service area"), the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week. An assistance coordinator, working with a medical professional, will arrange a physician appointment or hospitalization, if necessary.

Benefits will not be provided for any services or supplies except for those provided for an Emergency Medical Condition and received through the Inter-Plan Arrangements, which includes the BlueCard program.

- **Inpatient Services**

  In most cases, if the Member contacts the BlueCard Worldwide Service Center for assistance, hospitals will not require the Member to pay for covered inpatient services, except for the cost-share amounts/deductibles, coinsurance, etc.. In such cases, the hospital will submit the Member's claims to the BlueCard Worldwide Service Center to begin claims processing. However, if the Member paid in full at the time of service, the Member must submit a claim to receive reimbursement for Covered Medical Expenses.

  The Member must contact Blue Cross and Blue Shield of Montana to obtain preauthorization to verify that Inpatient Services are for the treatment of an Emergency Medical Condition.

- **Outpatient Services**

  Outpatient Services are available for the treatment of an Emergency Medical Condition. Physicians, urgent care centers and other outpatient providers located outside the United States, the Commonwealth of Puerto Rico and the U.S. Virgin Islands will typically require the Member to pay in full at the time of service. The Member must submit a claim to obtain reimbursement for Covered Medical Expenses.

- **Submitting a BlueCard Worldwide Claim**

  When the Member pays for Covered Medical Services outside the BlueCard service area, the Member must submit a claim to obtain reimbursement. For institutional and professional claims, the Member should complete a BlueCard Worldwide International claim form and send the claim form the provider's itemized bill(s) to the BlueCard Worldwide Service Center (the address is on the form) to initiate claims processing. Following the instructions on the claim form will help ensure timely processing of the Member's claim. The claim form is available from Blue Cross and Blue Shield of Montana, the BlueCard Worldwide Service Center or online at www.bluecardworldwide.com. If the Member needs assistance with the Member claim submission, the Member should call the BlueCard Worldwide Service Center at 1.800.810.BLUE (2583) or call collect at 1.804.673.1177, 24 hours a day, seven days a week.

COMPLAINTS AND GRIEVANCES

Complaints and Grievances

The Plan has established a complaint and grievance process. A complaint involves a communication from the Member expressing dissatisfaction about The Plan's services or lack of action or disagreement with The Plan's response. A grievance will typically involve a complaint about a provider or a provider's office, and may include complaints about a provider's lack of availability or quality of care or services received from a provider's staff.

Most problems can be handled by calling Customer Service at the number appearing on the inside cover of this Contract. The Member may also file a written complaint or grievance with The Plan. The fax number, email address, and mailing address of The Plan appears on the inside cover of this Contract. Written complaints or grievances will be acknowledged within 10 days of receipt. The Member will be notified of The Plan's response within 60 days from receipt of the Member's written complaint or grievance.

APPEALS

Claims Procedures

Types of Claims

Claims are classified by type of claim and the timeline in which a decision must be decided and a notice provided depends on the type of claim involved. The initial benefit claim determination notice will be included in the Member's explanation of benefits (EOB) or in a letter from The Plan, whether adverse or not. There are five types of claims:

1. Pre-Service Claims

A pre-service claim is any claim for a Benefit that, under the terms of this Contract, requires authorization or approval from The Plan or The Plan's subcontracted administrator prior to receiving the Benefit.

2. Urgent Care Claims

An urgent care claim is any pre-service claim where a delay in the review and adjudication of the claim could seriously jeopardize the Member's life or health or ability to regain maximum function or subject the Member to severe pain that could not be adequately managed without the care or treatment that is the subject of the claim.

3. Post-Service Claims

A post-service claim is any claim for payment filed after a Benefit has been received and any other claim that is not a pre-service claim.

Rescission Claims

A rescission of coverage is considered a special type of claim. A rescission is defined as any cancellation or discontinuation of coverage that has a retroactive effect based upon the Member's fraud or an intentional misrepresentation of a material fact. A cancellation or discontinuance of coverage that has a retroactive effect is not a rescission if and to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage or to routine changed, such as eligibility updates. A cancellation or discontinuance with a prospective effect only is not a rescission.

5. Concurrent Care Claim

A concurrent care decision represents a decision of The Plan approving an ongoing course of medical treatment for the Member to be provided over a period of time or for a specific number of treatments. A concurrent care claim is any claim that relates to the ongoing course of medical or emergency treatment (and the basis of the approved concurrent care decision), such as a request by the Member for an extension of the number of treatments or the termination by The Plan of the previously approved time period for medical treatment.

Initial Claim Determination by Type of Claim

1. Pre-Service Claim Determination and Notice

a. Notice of Determination

Upon receipt of a pre-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial determination, but no later than 15 days after receiving the claim.

b. Notice of Extension

1. For reasons beyond the control of The Plan

The Plan may extend the 15-day time period for an additional 15 days for reasons beyond The Plan's control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision.

2. For receipt of information from the Member to decide the claim

If the extension is necessary due to the Member's failure to submit information necessary to decide the

claim, the extension notice will specifically describe the information needed, and the Member will be given 45 days from receipt of the notice within which to provide the specified information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

c. Notice of Improperly Submitted Claim

If a pre-service claim request was not properly submitted, The Plan will notify the Member about the improper submission as soon as practicable, but no later than 5 days after The Plan's receipt of the claim, and will advise the Member of the proper procedures to be followed for filing a pre-service claim.

2. Urgent Care Claim Determination and Notice

a. Designation of Claim

Upon receipt of a pre-service claim, The Plan will make a determination if the claim involves urgent care. If a physician with knowledge of the Member's medical condition determines the claim involves urgent care, The Plan will treat the claim as an urgent care claim.

b. Notice of Determination

If the claim is treated as an urgent care claim, The Plan will provide the Member with notice of the determination, either verbally or in writing, as soon as possible consistent with the Member's medical exigencies but no later than 72 hours from The Plan's receipt of the claim. If verbal notice is provided, The Plan will provide a written notice within 3 days after the date The Plan notified the Member.

c. Notice of Incomplete or Improperly Submitted Claim

If an urgent care claim is incomplete or was not properly submitted, The Plan will notify the Member about the incomplete or improper submission no later than 24 hours from The Plan's receipt of the claim. The Member will have at least 48 hours to provide the necessary information. The Plan will notify the Member of the initial claim determination no later than 48 hours after the earlier of the date The Plan receives the specific information requested or the due date for the requested information.

3. Post-Service Claim Determination and Notice

a. Notice of Determination

In response to a post-service claim, The Plan will provide timely notice of the initial claim determination once sufficient information is received to make an initial **determination, but no later than 30 days after receiving the claim.**

b. Notice of Extension

1. For reasons beyond the control of The Plan

The Plan may extend the 30-day timeframe for an additional 15-day period for reasons beyond The Plan's control. The Plan will notify the Member in writing of the circumstances requiring an extension and the date by which The Plan expects to render a decision in such case.

2. For receipt of information from the Member to decide the claim

If the extension is necessary due to the Member's failure to submit information necessary to decide the claim, the extension notice will specifically describe the information needed. The Member will be given 45 days from receipt of the notice to provide the information. The Plan will notify the Member of the initial claim determination no later than 15 days after the earlier of the date The Plan receives the specific information requested, or the due date for the information.

4. Concurrent Care Determination and Time Frame for Decision and Notice

a. Request for Extension of Previously Approved Time Period or Number of Treatments

1. In response to the Member's claim for an extension of a previously approved time period for treatments or number of treatments, and if the Member's claim involves urgent care, The Plan will review the claim and notify the Member of its determination no later than 24 hours from the date The Plan received the

Member's claim, provided the Member's claim was filed at least 24 hours prior to the end of the approved time period or number of treatments.

2. If the Member's claim was not filed at least 24 hours prior to the end of the approved time period or number of treatments, the Member's claim will be treated as and decided within the timeframes for an urgent care claim as described in the section entitled, "Initial Claim Determination by Type of Claim."
3. If the Member's claim did not involve urgent care, the time periods for deciding pre-service claims and post-service claims, as applicable, will govern.

b. Reduction or Termination of Ongoing Course of Treatment

Other than through a Plan amendment or termination, The Plan may not subsequently reduce or terminate an ongoing course of treatment for which the Member has received prior approval unless The Plan provides the Member with written notice of the reduction or termination and the scheduled date of its occurrence sufficiently in advance to allow the Member to appeal the determination and obtain a decision before the reduction or termination occurs.

5. Rescission of Coverage Determination and Notice of Intent to Rescind

If The Plan makes a decision to rescind the Member's coverage due to a fraud or an intentional misrepresentation of a material fact, The Plan will provide the Member with a Notice of Intent to Rescind at least thirty (30) days prior to rescinding coverage. The Notice of Intent to Rescind will include the following information:

a. The specific reason(s) for the rescission that show the fraud or intentional misrepresentation of a material fact;
b. The date when the notice period ends and the date to which coverage is to be retroactively rescinded;
c. A statement that the Member will have the right to appeal any final decision of The Plan to rescind coverage prior to or after the thirty (30) day period, and a description of The Plan's appeal procedures;
d. A reference to The Plan provision(s) on which the rescission is based;
e. A statement that the Member is entitled to receive upon request and free of charge reasonable access to, and copies of all documents and records and other information relevant to the rescission.

Notice of an Adverse Benefit Determination

An "adverse benefit determination" is defined as a rescission or a denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a Benefit. If The Plan's determination constitutes an adverse benefit determination, the notice to the Member will include:

1. Information sufficient to identify the benefit or claim involved, including, if applicable, the date of service, the health care provider, and the claim amount;
2. The reason(s) for the adverse benefit determination. If the adverse benefit determination is a rescission, the notice will include the basis for the fraud and/or intentional misrepresentation of a material fact;
3. A reference to the applicable Contract provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the adverse benefit determination is based;
4. A description of The Plan's internal appeal and external review procedures (and for urgent care claims only, a description of the expedited review process applicable to such claims), a description of and contact information for a consumer appeal assistance program, and if applicable, a statement of the Member's right to file a civil action under Section 502(a) of ERISA;
5. If applicable, a description of any additional information necessary to complete the claim and why the information is necessary;
6. If applicable, a statement that any internal Medical Policy or guideline or other medical information relied upon in making the adverse benefit determination, and an explanation for the same, will be provided, upon request and free of charge;
7. If applicable, a statement that an explanation for any adverse benefit determination that is based on an experimental treatment or similar exclusion or limitation or a medical necessity standard will be provided, upon request and free of charge;
8. If applicable, a statement that diagnosis and treatment codes will be provided, and their corresponding meanings, upon request and free of charge; and

9. A statement that reasonable access to and copies of all documents and records and other information relevant to the adverse benefit determination will be provided, upon request and free of charge.

How to File an Internal Appeal of an Adverse Benefit Determination

1. Time for Filing an Internal Appeal of an Adverse Benefit Determination

If the Member disagrees with an adverse benefit determination (including a rescission), the Member may appeal the determination within 180 days from receipt of the adverse benefit determination. With the exception of urgent care claims, The Member's appeal may be made verbally or in writing, should list the reasons why the Member does not agree with the adverse benefit determination, and must be sent to the address or fax number listed for appeals on the inside cover of this Contract. If the Member is appealing an urgent care claim, the Member may appeal the claim verbally by calling the telephone number listed for urgent care appeals on the inside cover of this Contract.

For additional assistance with an appeal, a Member may also contact the Commissioner of Securities and Insurance at: Montana Commissioner of Securities and Insurance, 804 Helena Ave., Helena, MT 59601 or call 1-800-332-6148 or 406-444-2040.

2. Access to Plan Documents

The Member may at any time during the filing period, receive reasonable access to and copies of all documents, records and other information relevant to the adverse benefit determination upon request and free of charge. Documents may be viewed at The Plan's office, at 3645 Alice Street, Helena, Montana, between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays. The Member may also request that Blue Cross and Blue Shield of Montana mail copies of all documentation to the Member free of charge.

3. Submission of Information and Documents

The Member may present written evidence and testimony, including any new or additional records, documents or other information that are relevant to the claim for consideration by The Plan until a final determination of the Member's appeal has been made.

4. Consideration of Comments

The review of the claim on appeal will take into account all evidence, testimony, new and additional records, documents, or other information the Member submitted relating to the claim, without regard to whether such information was submitted or considered in making the initial adverse benefit determination.

If The Plan considers, relies on or generates new or additional evidence in connection with its review of the Member's claim, The Plan will provide the Member with the new or additional evidence free of charge as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan. If The Plan relies on a new or additional rationale in denying the Member's claim on review, The Plan will provide the Member with the new or additional rationale as soon as possible and with sufficient time to respond before a final determination is required to be provided by The Plan.

5. Scope of Review

The person who reviews and decides the Member's appeal will be a different individual than the person who decided the initial adverse benefit determination and will not be a subordinate of the person who made the initial adverse benefit determination. The review on appeal will not give deference to the initial adverse benefit determination and will be made anew. The Plan will not make any decision regarding hiring, compensation, termination, promotion or other similar matters with respect to the individual selected to conduct the review on appeal based upon how the individual will decide the appeal.

6. Consultation with Medical Professionals

If the claim is, in whole or in part, based on medical judgment, The Plan will consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment. The health care professional will not have been involved in the initial adverse benefit determination (nor have been a subordinate of any person previously consulted). The Member may request information regarding the identity of any health care professional whose advice was obtained during the review of the Member's claim.

Time Period for Notifying Member of Final Internal Adverse Benefit Determination

The time period for deciding an appeal of an adverse benefit determination and notifying the Member of the final internal adverse benefit determination depends upon the type of claim. The chart below provides the time period in which The Plan will notify the Member of its final internal adverse benefit determination for each type of claim.

Type of Claim on Appeal	Time Period for Notification of Final Internal Adverse Benefit Determination
Urgent Care Claim	No later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency.
Pre-Service Claim	No later than 30 days from the date The Plan received the Member's appeal.
Post-Service Claim	No later than 60 days from the date The Plan received the Member's appeal.
Concurrent Care Claim	• If the Member's claim involved urgent care, no later than 72 hours from the date The Plan received the Member's appeal, taking into account the medical exigency. • If the Member's claim did not involve urgent care, the time period for deciding a pre-service (non-urgent care) claim or a post-service claim, as applicable, will govern.
Rescission Claim	No later than 60 days from the date The Plan received the Member's appeal.

Content of Notice of Final Internal Adverse Benefit Determination

If the decision on appeal upholds, in whole or in part, the initial adverse benefit determination, the final internal adverse benefit determination notice will include the following information:

1. Information sufficient to identify the claim involved in the appeal, including, as applicable, the date of service, the health care provider, and the claim amount;
2. The title and qualifying credentials of each health care professional participating in the appeal;
3. A statement from each health care professional participating in the appeal of his/her/their understanding of the basis for the Member's appeal;
4. The specific reason(s) for the final internal adverse benefit determination, including a discussion of the decision. If the final internal adverse benefit determination upholds a rescission, the notice will include the basis for the fraud or intentional misrepresentation of a material fact;
5. A reference to the applicable Contract provision(s), including identification of any standard relied upon in The Plan to deny the claim (such as a medical necessity standard), on which the final internal adverse benefit determination is based;
6. If applicable, a statement describing the Member's right to request an external review and the time limits for requesting an external review;
7. If applicable, a statement that any internal Medical Policy or guideline or medical information relied on in making the final internal adverse benefit determination will be provided, upon request and free of charge;
8. If applicable, an explanation of the scientific or clinical judgment for any final internal adverse benefit determination that is based on a medical necessity or an experimental treatment or similar exclusion or limitation as applied to the Member's medical circumstances;
9. If applicable, a statement that diagnosis and treatment codes will be provided, with their corresponding meanings, upon request and free of charge;
10. A description of and contact information for a consumer appeal assistance program and a statement of the Member's right to file a civil action under Section 502(a) of ERISA; and
11. A statement that reasonable access to and copies of all documents and records and other information relevant to the final internal adverse benefit determination will be provided, upon request and free of charge.

External Review Procedures – In General

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member may submit a request for external review. In addition, external review is limited to only those adverse benefit determinations that involve:

1. Rescissions of coverage; and
2. Medical judgment, including those adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit or adverse benefit determinations that certain treatments are experimental or investigational.

External review is not available for:

1. Adverse benefit determinations that are based on contractual or legal interpretations without any use of medical judgment; and
2. Adverse benefit determinations that are based on a failure to meet requirements for eligibility under a group health plan.

Standard External Review Procedures

There are two types of external review: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entitles the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

External reviews (standard or expedited) of adverse benefit determinations or final internal adverse benefit determinations based upon a determination that certain treatments are experimental or investigational are discussed in separate sections, following the section entitled Expedited External Review Procedures, below.

1. Request for a Standard External Review

The Member must submit a written request to The Plan for a standard external review within 4 months from the date the Member receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

The Plan must complete a preliminary review within 5 business days from receipt of the Member's request for a standard external review to determine whether:

a. The Member is or was covered under The Plan when the health care item or service was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care item or service was provided;
b. The adverse benefit determination or final internal adverse benefit determination relates to the Member's failure to meet The Plan's eligibility requirements;
c. The Member has exhausted (or is not required to exhaust) The Plan's internal appeals process;
d. The Member has provided all the information and forms required to process the external review.

Within 1 day after completing its review, The Plan will notify the Member in writing if the request is eligible for external review. If further information or materials are necessary to complete the review, the written notice will describe the information or materials and the Member will be given the remainder of the 4 month period or 48 hours after receipt of the written notice, whichever is later, to provide the necessary information or materials. If the request is not eligible for external review, The Plan will outline the reasons for ineligibility in the notice, include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance and provide the Member with contact information for the U.S. Employee Benefits Security Administration (toll free number 866.444.EBSA (3272) and contact information for the Commissioner's office.

3. Assignment of an IRO

If the Member's request is eligible for external review, The Plan will within 1 business day assign the request for external review on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Montana Commissioner of Securities and Insurance to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will also take into account other circumstances, including conflict of interest concerns.

4. Initiation of External Review and Opportunity to Submit Additional Documents

Within 1 business day of assigning the IRO, The Plan will notify the Member, in writing, or the Member's authorized representative, that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

5. Plan Submission of Documents to the IRO

Within 5 business days after the date the IRO is assigned, The Plan must submit the documents and any information considered in making the benefits denial to the IRO. The Plan's failure to timely provide such documents and information will not constitute cause for delaying the external review. If The Plan fails to timely provide the documents and information, the IRO may terminate the external review and reverse the adverse benefit determination or final internal adverse benefit determination. If the IRO does so, it must notify the Member and The Plan within 1 business day after making the decision.

6. Reconsideration by Plan

On receiving any information submitted by the Member, the IRO must forward the information to The Plan within 1 business day. The Plan may then reconsider its adverse benefit determination or final internal adverse benefit determination. If The Plan decides to reverse its adverse benefit determination or final internal adverse benefit determination, The Plan must provide written notice to the Member and IRO within 1 business day after making the decision. On receiving The Plan's notice, the IRO must terminate its external review.

7. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the following in reaching a decision:

a. The Member's medical records;
b. The Member's treating provider(s)'s recommendations;
c. Reports from appropriate health care professionals and other documents, opinions, and recommendations submitted by The Plan and the Member;
d. The terms and conditions of The Plan, including specific coverage provisions, to ensure that the IRO's decision is not contrary to the terms and conditions of The Plan, unless the terms and conditions do not comply with applicable law;
e. Appropriate practice guidelines, which must include applicable Evidence-Based Standards;
f. Any applicable clinical review criteria developed and used by The Plan unless the criteria are inconsistent with the terms and conditions of The Plan or do not comply with applicable law;
g. The applicable Medical Policies of The Plan;
h. The opinion of the IRO's clinical reviewer or reviewers after considering information described in this notice to the extent the information or documents are available and the clinical reviewer or reviewers consider them appropriate.

8. Written Notice of the IRO's Final External Review Decision

The IRO will send written notification of its decision to the Member and to The Plan within 45 days after the IRO's receipt of the request for external review. The notice will include:

a. A general description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;
b. The date the IRO received the assignment to conduct the external review and the date of the IRO's decision;
c. References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;
d. A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and any Evidence-Based Standards relied on in making the decision;

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e. A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;
f. A statement that judicial review may be available to the Member and The Plan; and
g. Contact information for a consumer appeal assistance program at the Commissioner of Securities and Insurance.

9. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan will immediately provide coverage or issue payment according to the written terms and benefits of the Contract.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that the timeframe for decisions and notifications is shorter.

1. Request for Expedited External Review

Under the following circumstances, the Member may request an expedited external review:

a. If the Member received an adverse benefit determination that denied the Member's claim and: (1) the Member filed a request for an internal urgent care appeal; and (2) the delay in completing the internal appeal process would seriously jeopardize the life or health of the Member or the Member's ability to regain maximum function; or
b. Upon receipt of a final internal adverse benefit determination which involves: (1) a medical condition of the Member for which a delay in completing the standard external review would seriously jeopardize the Member's life or health or the Member's ability to regain maximum function; or (2) an admission, availability of care, a continued stay, or a health care item or service for which the Member received emergency services, but has not been discharged from a facility.

2. Preliminary Review

Upon receiving the Member's request for expedited external review, The Plan will immediately determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section. After the preliminary review is complete, The Plan will immediately notify the Member or the Member's authorized representative in writing of its eligibility determination. If the Plan determines the Member's request is ineligible for review, the notice must include a statement informing the Member or the Member's authorized representative of the right to appeal The Plan's determination to the Commissioner of Securities and Insurance. The notice must also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If a request is eligible for expedited external review, The Plan will assign an IRO pursuant to and in compliance with the independence and other selection requirements set forth in the Assignment of an IRO paragraph, Standard External Review Procedures section. The Plan will transmit all documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO in as expeditious of a manner as possible (including by phone, facsimile, or electronically).

4. Standard of Review

In reaching its decision, the IRO will review the claim and will not be bound by any decisions or conclusions reached under The Plan's internal claims and appeals process. In addition to the documents and information timely received, and to the extent the information or documents are available, the IRO will consider the same documents and information set forth in the Standard of Review paragraph, Standard External Review Procedures section.

5. Notice of Final External Review Decision

The IRO will provide the Member and The Plan with notice of its final external review decision as expeditiously as the Member's medical condition or circumstances require, but not more than 72 hours after the IRO receives the expedited external review request. If the notice is not in writing, the IRO must provide written confirmation of its

decision to the Member and to The Plan within 48 hours after the date the IRO verbally conveyed the decision. The written notice will include:

- **a.** A description of the reason for the external review request, including information sufficient to identify the claim, and the reason for the prior denial;
- **b.** The date the IRO received the assignment to conduct the external review and the date of the IRO's decision;
- **c.** References to the evidence or documentation considered in reaching the decision, including specific coverage provisions and Evidence-Based Standards;
- **d.** A discussion of the principal reason(s) for the IRO's decision, including the rationale for its decision and any Evidence-Based Standards relied on in making the decision;
- **e.** A statement that the IRO's determination is binding, unless other remedies are available to The Plan or the Member under state or federal law;
- **f.** A statement that judicial review may be available to the Member or The Plan; and
- **g.** Contact information for the appropriate consumer appeal assistance program at the Commissioner of Securities and Insurance.

6. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan will immediately approve coverage that was the subject of the adverse benefit determination or final internal adverse benefit determination according to the written terms and benefits of the Contract.

7. Inapplicability of Expedited External Review

An expedited external review may not be provided for retrospective adverse benefit determinations or retrospective final internal adverse benefit determinations.

External Review Procedures – Experimental or Investigational

In most cases, and except as provided in the next two sections, the Member must follow and exhaust the internal appeals process outlined above before the Member or the Member's authorized representative may submit a request for external review. In addition, external review as outlined in the next two sections is limited to only those adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational.

Standard External Review Procedures

There are two types of external review of adverse benefit determinations or final internal adverse benefit determinations that certain treatments are experimental or investigational: a standard external review and an expedited external review. An expedited external review is generally based upon the seriousness of the Member's medical circumstances, and entitles the Member to an expedited notice and decision making process. The procedures for requesting standard (non-expedited) external reviews are discussed in this section. The procedures for requesting expedited external reviews are discussed in the next section.

1. Request for a Standard External Review

The Member or the Member's authorized representative must submit a written request to The Plan for a standard external review within 4 months from the date the Member or the Member's authorized representative receives an adverse benefit determination or a final internal adverse benefit determination.

2. Preliminary Review

Upon receipt of a request for standard external review, The Plan must complete a preliminary review within 5 business days to determine whether:

- **a.** The Member is or was covered under The Plan when the health care service or treatment was requested or, in the case of a retrospective review, whether the Member was covered under The Plan when the health care service or treatment was provided;
- **b.** The requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination: (i) is a covered benefit under the Member's health plan except for The Plan's determination that the health care service or treatment is experimental or investigational for a

particular medical condition; and (ii) is not explicitly listed as an excluded benefit under the Member's health plan;

c. The Member's treating health care provider has certified that one of the following situations is applicable: (i) standard health care services or treatments have not been effective in improving the condition of the Member; (ii) standard health care services or treatments are not medically appropriate for the Member; or (iii) there is no available standard health care service or treatment covered by The Plan that is more beneficial than the requested health care service or treatment;

d. (i) the Member's treating health care provider has recommended a health care service or treatment that the physician certifies, in writing, is likely to be more beneficial to the Member, in the physician's opinion, than any available standard health care services or treatments; or (ii) a physician who is licensed, board-certified, or eligible to take the examination to become board-certified and is qualified to practice in the area of medicine appropriate to treat the Member's condition has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care service or treatment requested by the Member who is subject to the adverse benefit determination or final internal adverse benefit determination is likely to be more beneficial to the Member than any available standard health care services or treatments; and

e. The Member has exhausted The Plan's internal appeals process or the Member is exempt from exhausting The Plan's internal appeals process.

Within 1 business day after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will within 1 business day assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day of assigning the IRO, The Plan will notify the Member or the Member's authorized representative in writing that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO within 10 business days following the date of receipt of the notice, for the IRO's consideration in its external review. The IRO may accept and consider additional information submitted after the 10 business days.

4. Plan Submission of Documents to the IRO

Within 5 business days after assigning an IRO, The Plan will provide to the assigned IRO any documents and information considered in making the adverse benefit determination or the final internal adverse benefit determination. Failure by the Plan to timely provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information within 5 business days, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan of its decision.

5. Reconsideration by The Plan

The IRO will forward any information submitted by Member or the Member's authorized representative to the Plan, within 1 business day of its receipt. The Plan may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by The Plan

may not delay or terminate the IRO's external review. The external review may be terminated only if The Plan decides, on completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage for the requested health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination. The Plan will notify the Member or the Member's authorized representative and the IRO immediately in writing of its decision. The IRO will terminate the external review on receipt of the notice from The Plan.

6. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. In selecting Clinical Peers to conduct the external review, the assigned IRO will select physicians or other health care providers who meet minimum statutorily prescribed qualifications and who, through clinical experience in the past 3 years, are experts in the treatment of the Member's condition and knowledgeable about the recommended or requested health care service or treatment. The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Within 20 days after selection, each Clinical Peer will provide an opinion to the assigned IRO on whether the requested health care service or treatment should be covered. In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached during The Plan's internal appeals process.

Each Clinical Peer's opinion will be in writing and include the following information:

- **a.** a description of the Member's medical condition;
- **b.** a description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that the requested health care service or treatment is more likely than not to be more beneficial to the Member than any available standard health care services or treatments and that the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments;
- **c.** a description and analysis of any Medical or Scientific Evidence considered in reaching the opinion;
- **d.** a description and analysis of any Evidence-Based Standard; and
- **e.** information on whether the clinical peer's rationale for the opinion is based on the Member's medical records and/or the attending provider's or health care professional's recommendation.

7. Written Notice of the IRO's Final External Review Decision

Within 20 days after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision and provide written notice of the decision to the Member or the Member's authorized representative and to The Plan.

If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should be covered, the IRO shall make a decision to reverse The Plan's adverse benefit determination or final internal adverse benefit determination. If a majority of the Clinical Peers respond that the recommended or requested health care service or treatment should not be covered, the IRO shall make a decision to uphold The Plan's adverse benefit determination or final internal adverse benefit determination. If the Clinical Peers are evenly split as to whether the recommended or requested health care service or treatment should be covered, the IRO shall obtain the opinion of an additional Clinical Peer. The additional Clinical Peer shall use the same information to reach an opinion as used by the Clinical Peers who have already submitted their opinions. The selection of the additional Clinical may not extend the time within which the assigned IRO is required to make a decision based on the opinions of the Clinical Peers.

The IRO will include in its written notice:

- **a.** a general description of the reason for the request for external review;
- **b.** the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;

c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

8. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Expedited External Review Procedures

In general, the same rules that apply to standard external review apply to expedited external review, except that requests for external review may be made differently and the timeframe for decisions and notifications is shorter.

1. Request for an Expedited External Review

The Member or the Member's authorized representative may make an oral or written request for an expedited external review of an adverse benefit determination or a final internal adverse benefit determination if the Member's treating health care provider certifies, in writing, that the recommended or requested health care service or treatment that is the subject of the request would be significantly less effective if not promptly initiated.

2. Preliminary Review

Upon receipt of a request for an expedited external review, The Plan must immediately complete a preliminary review to determine whether the request is eligible for external review, considering the same preliminary review requirements set forth in the Preliminary Review paragraph, Standard External Review Procedures section, above.

Immediately after completion of the preliminary review, The Plan will notify the Member or the Member's authorized representative in writing as to whether the request is complete and the request is eligible for external review.

If the request is not complete, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the information or materials that are needed to make the request complete. If the request is not eligible for external review, The Plan will inform the Member or the Member's authorized representative in writing and include in the notice the reasons for the request's ineligibility. The notice of initial determination will include a statement informing the Member or the Member's authorized representative of the right to appeal the determination of ineligibility to the Commissioner of Securities and Insurance. The notice will also provide contact information for the Commissioner's office.

3. Assignment of an IRO

If the request is eligible for external review, the Plan will immediately assign an IRO on a random basis, or using another method of assignment that ensures the independence and impartiality of the assignment process, from the list of approved IROs compiled and maintained by the Commissioner of Securities and Insurance, to conduct the external review. In making the assignment, The Plan will consider whether an IRO is qualified to conduct the particular expedited external review based on the nature of the health care service or treatment that is the subject of the adverse benefit determination or final internal adverse benefit determination and will also take into account other circumstances, including conflict of interest concerns.

Within 1 business day after assignment of the IRO, The Plan will notify the Member or the Member's authorized representative, in writing, that The Plan has initiated an external review and that the Member or the Member's authorized representative may submit additional information to the IRO for the IRO's consideration in its external review.

4. Plan Submission of Documents to the IRO

Upon assigning an IRO, The Plan will provide any documents and information considered in making the adverse benefit determination or the final internal adverse benefit determination to the assigned IRO electronically, by telephone, by facsimile, or by any other available expeditious method. Failure by the Plan to provide the documents and information may not delay the conduct of the external review. If the Plan fails to provide the documents and information upon IRO assignment, the assigned IRO may terminate the external review and decide to reverse the adverse benefit determination or final internal adverse benefit determination. Immediately

upon making such a determination, the IRO will notify the Member or the Member's authorized representative and The Plan accordingly.

5. Standard of Review

Within 1 business day after the receipt of the notice of assignment to conduct the external review, the assigned IRO will select a Clinical Peer, or multiple Clinical Peers if medically appropriate under the circumstances, to conduct the external review. The assigned IRO will select physicians or other health care providers using the same criteria as set forth in the Standard of Review paragraph in the Standard External Review Procedures, above, The choice of the physicians or other health care providers to conduct the external review may not be made by the Member or the Member's authorized representative or The Plan.

Each Clinical Peer selected pursuant will review and consider all of the information and documents considered by The Plan in making the adverse benefit determination or the final internal benefit determination and any other information submitted in writing by the Member or the Member's authorized representative.

Each Clinical Peer will provide an opinion to the assigned IRO as expeditiously and the Member's medical condition or circumstances require but no later than 5 calendar days after being selected as a Clinical Peer, on whether the requested health care service or treatment should be covered. If the Clinical Peer's opinion was initially made orally, the Clinical Peer shall provide the IRO written confirmation of the opinion within 48 hours after the opinion was initially made.

In reaching an opinion, Clinical Peers are not bound by any decisions or conclusions reached by The Plan. Each Clinical Peer's opinion may be rendered orally or in writing and will include the same information as set forth in the Standard of Review paragraph in the Standard External Review Procedures section, above.

6. Written Notice of the IRO's Final External Review Decision

Within 48 hours after the date of receiving the opinion of each Clinical Peer, the IRO shall make a decision based upon the recommendations of a majority of the Clinical Peers conducting the review, and will provide oral or written notice of the decision to the Member or the Member's authorized representative and to the Plan. If the IRO's notice is provided orally, the IRO will provide written confirmation of the decision within 48 hours of the initial oral notice.

The IRO will include in its written notice:

a. a general description of the reason for the request for external review;
b. the written opinion of each Clinical Peer, including the opinion of each Clinical Peer as to whether the recommended or requested health care service or treatment should be covered and the rationale for the reviewer's recommendation;
c. the date on which the IRO was assigned to conduct the external review;
d. the date of the IRO's decision; and
e. the principal rationale for the IRO's decision.

7. Compliance with IRO Decision

If the IRO reverses The Plan's adverse benefit determination or final internal adverse benefit determination, The Plan shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse benefit determination or final internal adverse benefit determination.

Deemed Exhaustion of Internal Appeal Process

1. The Member will be deemed to have exhausted the internal appeal process and may request external review or pursue any available remedies under state law or if applicable, a civil action under 502(a) of ERISA, if The Plan fails to comply with its claims and appeals procedures, except that claims and appeals procedures will not be deemed exhausted based on violations that are:

a. De minimis;
b. Non-prejudicial to the Member;
c. Attributable to good cause or matters beyond The Plan's control;
d. In the context of an ongoing, good faith exchange of information between the Member and The Plan; and
e. Not reflective of a pattern or practice of violations by The Plan.

2. Upon request of the Member, The Plan will provide an explanation of a violation within 10 days. The explanation will include a description of the basis for The Plan's assertion that the violation does not result in the deemed exhaustion of The Plan's internal claims and appeals procedures.
3. If the Member seeks external or judicial review based on deemed exhaustion of The Plan's internal claims and appeals procedures, and the external reviewer or court rejects the Member's request, The Plan will notify the Member within a reasonable period of time, not to exceed 10 days, of the Member's right to resubmit the Member's internal appeal. The timeframe for appealing the adverse benefit determination begins to run when the Member receives the notice of the right to resubmit the Member's internal appeal.

PREAUTHORIZATION

The Plan has designated certain covered services which require Preauthorization in order for the Member to receive the maximum Benefits possible under this Contract.

The Member is responsible for satisfying the requirements for Preauthorization. This means that the Member must request Preauthorization or assure that the Member's Physician, provider of services, the Member's authorized representative, or a Family Member complies with the requirements below. If the Member utilizes a Network Provider for covered services, that provider may request Preauthorization for the services. However, it is the Member's responsibility to assure that the services are preauthorized before receiving care.

To request Preauthorization, the Member or his/her Physician must call the Preauthorization number shown on the Member's Identification Card **before** receiving treatment. The Plan will assist in coordination of the Member's care so that his/her treatment is received in the most appropriate setting for his/her condition and that the Member receives the highest level of Benefits under this Contract.

Preauthorization does not guarantee that the care and services a Member receives are eligible for Benefits under the Contract. In addition, a nonparticipating provider or non-PPO provider can bill the Member for the difference between payment by Blue Cross and Blue Shield of Montana and provider charges plus Deductible, Coinsurance and/or Copayment even if the service is an Emergency Service or the if the service has been Preauthorized.

Preauthorization Process for Inpatient Services

For an Inpatient facility stay, the Member must request Preauthorization from The Plan **before** the Member's scheduled admission. The Plan will consult with the Member's Physician, Hospital, or other facility to determine if Inpatient level of care is required for the Member's illness or injury. The Plan may decide that the treatment the Member needs could be provided just as effectively in a different setting (such as the Outpatient department of the Hospital, an Ambulatory Surgical Facility, or the Physician's office).

If The Plan determines that the Member's treatment does not require Inpatient level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Unscheduled Inpatient admissions, such as admissions for Emergency Medical Conditions and maternity care should be preauthorized within two days after the admission.

Preauthorization Process for Mental Illness, Severe Mental Illness and Chemical Dependency Services

All Inpatient and partial hospitalization services related to treatment of Mental Illness, Severe Mental Illness and Chemical Dependency must be Preauthorized by The Plan. Preauthorization is also required for the following Outpatient Services and must be submitted no later than 15 business days before the service is provided:

- Electroconvulsive therapy;
- Intensive Outpatient Treatment;
- Neuropsychological testing;

- Psychological testing;
- Repetitive Transcranial Magnetic Stimulation.
- Applied Behavioral Analysis (ABA)

Preauthorization is not required for therapy visits to a Physician or other professional Provider licensed to perform covered services under this Contract. However, all services are subject to the provisions in the section entitled Concurrent Review.

If The Plan determines that the Member's treatment does not require Inpatient or partial hospital level of care, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with an Inpatient stay or partial hospital level of care, without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Preauthorization Process for Other Outpatient Services

In addition to the Preauthorization requirements outlined above, The Plan also requires Preauthorization, which must be submitted no later than 15 business days before the service is provided, for certain Outpatient services, including:

- Dialysis treatment - Out-of-Network;
- High-cost injections, including but not limited to IVIG, Avastin, Rituxan, and Remicade injections.
- Home Health Care;
- Home Hemodialysis;
- Home Infusion Therapy;
- Hospice Services;
- Molecular Genetic Testing;
- Outpatient elective surgery - Out-of-Network;
- Transplant Evaluations;
- Diagnostic sleep studies for Obstructive Sleep Apnea;
- Radiation Therapy

For additional information on Preauthorization, the Member or the Provider may call the Customer Service number on the Member's identification card.

It is NOT necessary to preauthorize standard x-ray and lab services or Routine office visits.

If The Plan does not approve the Outpatient Service, the Member and the Member's Provider will be notified of that decision. If the Member proceeds with the services without The Plan's approval, the Member may be responsible to pay the full cost of the services received.

If the Member does not request Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

The Benefits section of this Contract details the services which are subject to Preauthorization.

Preauthorization Request Involving Non-Urgent Care

Except in the case of a Preauthorization Request Involving Urgent Care (see below), The Plan will provide a written response to the Member's Preauthorization request no later than 15 days following the date we receive the Member's request. This period may be extended one time for up to 15 additional days, if we determine that additional time is necessary due to matters beyond our control.

If The Plan determines that additional time is necessary, The Plan will notify the Member in writing, prior to the expiration of the original 15-day period, that the extension is necessary, along with an explanation of the circumstances requiring the extension of time and the date by which The Plan expects to make the determination.

If an extension of time is necessary due to the need for additional information, The Plan will notify the Member of the specific information needed, and the Member will have 45 days from receipt of the notice to provide the additional information.

The Plan will provide a written response to the Member's request for Preauthorization within 15 days following receipt of the additional information. The procedure for appealing an adverse Preauthorization determination is set forth in the section entitled Complaints and Grievances.

Preauthorization Request Involving Urgent Care

A Preauthorization Request Involving Urgent Care is any request for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the Member or the ability of the Member to regain maximum function; or in the opinion of a Physician with knowledge of the Member's medical condition, would subject the Member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the Preauthorization request.

In case of a Preauthorization Request Involving Urgent Care, The Plan will respond to the Member no later than 72 hours after receipt of the request, unless the Member fails to provide sufficient information, in which case, the Member will be notified of the missing information within 24 hours and will have no less than 48 hours to provide the information. A Benefit determination will be made as soon as possible (taking into account medical exigencies) but no later than 72 hours after the initial request, or within 48 hours after the missing information is received (if the initial request is incomplete).

NOTE: The Plan's response to the Member's Preauthorization Request Involving Urgent Care, including an adverse determination, if applicable, may be issued orally. A written notice will also be provided within three days following the oral notification.

Preauthorization Request Involving Emergency Care

If the Member is admitted to the Hospital for Emergency Care and there is not time to obtain Preauthorization, the Member's Provider must notify The Plan within two working days following the Member's emergency admission.

Preauthorization Required For Certain Prescription Drug Products and Other Medications

Prescription Drug Products, which are self-administered, process under the Prescription Drugs section of this Contract. There are other medications that are administered by a Covered Provider which process under the medical Benefits.

1. **Prescription Drugs – Covered Under the Prescription Drugs Benefit**

   Certain prescription drugs, which are self-administered, require Preauthorization. Please refer to the Prescription Drugs section for complete information about the Prescription Drug Products that are subject to Preauthorization, step therapy, and quantity limits, the process for requesting Preauthorization, and related information.

2. **Other Medications – Covered Under Medical Benefits**

   Medications that are administered by a Covered Provider will process under the medical Benefits of this Contract. Certain medications administered by a Covered Provider require Preauthorization. The medications that require Preauthorization are subject to change by The Plan.

   For any medication that is subject to Preauthorization, the Member or provider should fax the request for Preauthorization to the Blue Cross and Blue Shield of Montana Medical Review Preauthorization Department at 1-855-313-8908. The Member or provider may also submit a written request for Preauthorization. Preauthorization forms are located on The Plan website at www.bcbsmt.com, and may be printed directly from the website. The Plan will notify the Member and provider of the Preauthorization determination.

   In making determinations of coverage, The Plan may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

   To determine which medications are subject to Preauthorization, the Member or provider should refer to the list of medications which applies to the Member's Plan on The Plan website at www.bcbsmt.com or call the Customer Service toll-free number identified on the Member's identification card or The Plan website at www.bcbsmt.com.

General Provisions Applicable to All Required Preauthorizations

1. **No Guarantee of Payment**

   Preauthorization does not guarantee payment of Benefits by The Plan Even if the Benefit has been Preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date of service or the Member's Benefits may have changed as of the date the service.

2. **Request for Additional Information**

   The Preauthorization process may require additional documentation from the Member's health care provider or pharmacist. In addition to the written request for Preauthorization, the health care provider or pharmacist may be required to include pertinent documentation explaining the proposed services, the functional aspects of the treatment, the projected outcome, treatment plan and any other supporting documentation, study models, prescription, itemized repair and replacement cost statements, photographs, x-rays, etc., as may be requested by The Plan to make a determination of coverage pursuant to the terms and conditions of this Contract.

3. **Failure to Obtain Preauthorization**

   If the Member does not obtain Preauthorization, The Plan will conduct a retrospective review after the claims have been submitted. If it is determined that the services were not Medically Necessary, were Experimental, Investigational or Unproven, were not performed in the appropriate treatment setting, or did not otherwise meet the terms and conditions of the Contract, the Member may be responsible for the full cost of the services.

Any treatment the Member receives which is not a covered service under this Contract, or is not determined to be Medically Necessary, or is not performed in the appropriate setting will be excluded from the Member's Benefits. This applies even if Preauthorization approval was requested or received.

Concurrent Review

Whenever it is determined by The Plan, that Inpatient care or an ongoing course of treatment may no longer meet medical necessity criteria or is considered Experimental/Investigational/Unproven (EIU), the Member, Member's Provider or the Member's authorized representative may submit a request to The Plan for continued services. If the Member, the Member's Provider or the Member's authorized representative requests to extend care beyond the approved time limit and it is a Request Involving Urgent Care, The Plan will make a determination on the request/appeal as soon as possible (taking into account medical exigencies) but no later than 72 hours after it receives the initial request, or within 48 hours after it receives the missing information (if the initial request is incomplete).

Care Management

The goal of Care Management is to help the Member receive the most appropriate care that is also cost effective. If the Member has an ongoing medical condition or a catastrophic illness, the Member should contact The Plan. If appropriate, a care manager will be assigned to work with the Member and the Member's providers to facilitate a treatment plan. Care Management includes Member education, referral coordination, utilization review and individual care planning. Involvement in Care Management does not guarantee payment by The Plan.

ELIGIBILITY AND ENROLLMENT

To be eligible for enrollment, the Applicant must and any Family Members for whom coverage is sought must:

1. Be a resident of the state of Montana.
2. Complete an application.

Eligibility for this coverage will be determined by the Exchange in accordance with applicable law. For questions regarding eligibility, refer to healthcare.gov.

Applying for Coverage

An Applicant may apply for coverage in a Qualified Health Plan (QHP) through the Exchange for himself/herself and/or any eligible Dependents (see below) by submitting the Application(s) for individual medical insurance form, along with any exhibits, appendices, addenda and/or other required information ("Application(s)") to Blue Cross and Blue Shield of Montana and the Exchange, as appropriate. The Application(s) for coverage may or may not be accepted.

No eligibility rules or variations in premium will be imposed based on health status, medical condition, claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability, disability, or any other health status related factor. Applicants will not be discriminated against for coverage under this Plan on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

Variation in the administration, processes or benefits of this policy that are based on clinically indicated, reasonable medical management practices, or are part of permitted wellness incentives, disincentives and/or other programs do not constitute discrimination.

An applicant may enroll in or change a QHP for himself/herself and/or any eligible Dependents during one of the Initial and Annual Enrollment Periods as set by the Exchange. The Effective Date will be determined by Blue Cross and Blue Shield of Montana and the Exchange, as appropriate, depending upon the date the application is received, payment of the initial premiums no later than the day before the Effective Date of coverage (unless any Advance Premium Tax Credit is greater than the initial premium), and other determining factors.

Annual Open Enrollment Period/Effective Date of Coverage

An Applicant may apply for or change coverage in a QHP through the Exchange for the Applicant and/or any Eligible Family Members during the annual open enrollment period designated by the Exchange.

When the Applicant enrolls during the annual open enrollment period, the Applicant's and/or any Eligible Family Members' effective date will be the following January 1, unless otherwise designated by the Exchange and Blue Cross and Blue Shield of Montana, as appropriate.

This section "Annual Open Enrollment Period/Effective Date of Coverage" is subject to change by the Exchange, Blue Cross and Blue Shield of Montana, and/or applicable law, as appropriate.

Special Enrollment Periods

Special enrollment periods have been designated during which the Member may apply for or change coverage in a QHP through the Exchange for himself/herself and/or any Eligible Family Members. Application must be made 60 days from the date of a special enrollment event.

Birth

Children born to a Member after the Effective Date of the Contract will be covered for a period of 31 days beginning at the moment of birth and including the day of birth, provided the Beneficiary Member remains covered under the Contract for those 31 days. Coverage will continue for the child after the 31 day period if within 60 days the Beneficiary Member:

1. Enrolls the child through the Exchange to continue the coverage; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if application to continue coverage is not received by the Exchange. If application to continue coverage is received between 32 and 60 days after the birth of the child, then coverage will be reinstated back to the date of birth. Dues must be paid for any coverage beyond the initial 31 days of coverage.

Limitations:

1. If the Beneficiary Member does not remain covered during the 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.
2. However, after 31 days, coverage will not continue for any newborn child of a covered Dependent child unless the Beneficiary Member adopts the newborn child or is the legal guardian of the newborn child.

Adopted Children or Children Placed for Adoption

Children will be covered for a period of 31 days upon adoption or placement for adoption, including the date of placement, provided the Beneficiary Member remains covered under the Contract for those 31 days. Coverage will continue for the child after the 31 day period if within 60 days the Beneficiary Member:

1. Enrolls the child through the Exchange to continue the coverage for the child; and
2. Pays the additional dues to continue coverage for the child.

Coverage will terminate after 31 days if application to continue coverage is not received by the Exchange. If application to continue coverage is received between 32 and 60 days after the adoption or placement for adoption of the child, then coverage will be reinstated back to the date of the adoption or placement for adoption of the child. Dues must be paid for any coverage beyond the initial 31 days of coverage.

Limitations:

1. If the Beneficiary Member does not remain covered during the 31 days, the child placed for adoption will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered.
2. In the event the placement is disrupted prior to legal adoption and the child is removed from placement, coverage shall cease upon the date the placement is disrupted.

Advance payments of any Advance Premium Tax Credit and cost-sharing reductions, if applicable, are not effective until the first day of the following month, unless the birth, adoption, or placement as a foster child or for adoption occurs on the first day of the month.

Marriage

In the case of marriage, the Effective Date will be the date of marriage if the completed request for enrollment (application) is made through the Exchange within 60 days after the date of marriage.

Loss of Minimum Essential Coverage

In the event the Member experiences a loss of minimum essential coverage, coverage will be effective no later than the first day of the month following the loss of coverage. A loss of coverage does not include:

1. Termination or loss due to a failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage; or
2. Situations allowing for a rescission (a cancellation or discontinuance of coverage that has a retroactive effect), as determined by the Exchange.

For purposes of this section, "Minimum Essential Coverage" means Health insurance coverage that is recognized as coverage that meets substantially all requirements under federal law pertaining to adequate individual, group or government health insurance coverage. For additional information on whether particular coverage is recognized as "Minimum Essential Coverage", please call the customer service number on the inside cover of this document or on the back of your ID card or visit www.cms.gov

Additional Special Enrollment Events

1. An individual gains status as a U.S. citizen(s), national(s), or lawfully present in the U.S. and gains such status.
2. Enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous as evaluated and determined by the Exchange and/or Blue Cross and Blue Shield of Montana, as appropriate.
3. An enrollee through the Exchange adequately demonstrates to the Exchange that the QHP in which he/she enrolled substantially violated a material provision of its contract in relation to the enrollee.
4. An individual is determined newly eligible or newly ineligible for an Advance Premium Tax Credit or has a change in eligibility for cost-sharing reductions, regardless of whether the individual already enrolled in a QHP.

   For purposes of this section, "Premium Tax Credit" means a refundable premium tax credit you may receive for taxable years ending after December 31, 2013, to the extent provided for under applicable law, where the credit is meant to offset all or a portion of the premium paid by you for coverage obtained through an Exchange during the preceding calendar year.

5. An individual gains access to new QHPs as a result of a permanent move.
6. An Indian, as defined by section 4 of the Indian Health Care Improvement Act. An Indian may enroll himself/herself and any eligible Dependents in a QHP or change from one QHP to another one time per month.
7. An individual demonstrates to the Exchange, in accordance with the guidelines issued by HHS, that he/she meets other exceptional circumstances as the Exchange may provide.
8. Loss of coverage due to voluntary or involuntary termination (other than for gross misconduct) and reduction in number of hours of employment;
9. Loss of coverage for Spouses of covered employees due to reasons that would make the employee eligible for COBRA; or loss of coverage due to the employee's death.
10. Loss of coverage for children of covered employees due to reasons that would make the employee eligible for COBRA, loss of coverage due to the employee's death, or loss of coverage due to the loss of Dependent status under the terms of The Plan.
11. Divorce or legal separation. Coverage will be effective on the first day of the month coinciding with or the next month following your divorce or legal separation date.
12. A Dependent is no longer considered a Dependent under The Plan because of age or work status.
13. Loss of coverage due to moving out of the QHP-issuer Network Service Area.
14. Loss of coverage because benefits are no longer offered by the QHP-issuer to the class of similarly situated individuals.
15. Such other events required by applicable law.

Coverage resulting from any of the special enrollment events outlined above is contingent upon timely completion of the application and remittance of the appropriate premiums in accordance with the guidelines as established by the Exchange and Blue Cross and Blue Shield of Montana, as appropriate.

Effective Date and Commencement of Benefits

Unless otherwise noted above, the Effective Date is as follows:

1. If an application was received on the 1st through the 14th of the month, the Effective Date will be no later than the first day of the following month.
2. If an application was received on the 15th through the 31st of the month, the Effective Date will be no later than the first day of the second following month.

The Member is entitled to the Benefits of this Contract from the Member's Effective Date.

Transfer of Plan Membership

Transfer of Membership for Family Members

The following persons may transfer membership to their own beneficiary membership Contract if application is made in writing to The Plan within 31 days of the date of termination of their membership under this Contract.

1. A Spouse of a Beneficiary Member who was enrolled as a Family Member and ceases to be a Family Member as defined due to divorce, annulment of marriage or legal separation.
2. Children of a Beneficiary Member who were enrolled as a Family Member and cease to be a Family Member as defined.
3. Family Members of a Beneficiary Member who has died.

Benefits to Member Hospitalized on Date of Transfer

If the Member is receiving Inpatient Care on the date of transfer of membership to another Blue Cross and Blue Shield of Montana Contract, the Member will continue to receive the Benefits payable under this Contract:

1. For 30 days; or
2. Until the Member is discharged from the Inpatient Care facility, whichever occurs first.

Child-Only Coverage

Child-only coverage is available to eligible children who:

1. Are residents of Montana; and
2. Have not attained age 21 prior to the first day of the plan year; and
3. Are a citizen, national, or noncitizen who is lawfully present in the United States; and
4. Are not incarcerated.

This Plan is considered child-only coverage and the following restrictions apply:

1. The parent or legal guardian is not covered and is not eligible for Benefits under this health Plan.
2. If a child is covered under this Contract and acquires a new eligible child of his/her own, then:

   Newborn children of the Member are covered under this Contract for the first 31 days after birth. If the Member does not remain covered for 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Member is covered. After 31 days, the newborn child of a Member may be enrolled in his/her own Plan coverage if application for coverage is made within 30 days.

   Children placed for adoption. Children will be covered upon placement for adoption. If the Member does not remain covered for 31 days, the newborn will only be covered for the amount of time (during the 31 days) that the Beneficiary Member is covered. Coverage will end for the child 31 days after placement for adoption. After 31 days, the child may be enrolled in his/her own Plan coverage if application for coverage is made within 30 days.

3. If a child is under the age of 18, his/her parent, legal guardian, or other responsible party must submit the application for child-only insurance form, along with any exhibits, appendices, addenda and/or other required information to The Plan and the Exchange, as appropriate. For any child under 18 covered under this health care Plan, any obligations set forth in this Plan, any exhibits, appendices, addenda and/or other required information will be the obligations of the parent, legal guardian, or other responsible party applying for coverage on the child's behalf. Application for child-only coverage will not be accepted for an adult child that has attained age 21 as of the beginning of the calendar year. Adult children (at least 18 years of age but no older than 20 years of age) who are applying for coverage under this Plan must apply for their own individual Plan and must sign or authorize the application(s).

TERMINATION OF COVERAGE

Termination When the Member is No Longer Eligible for Coverage

Coverage under this Contract for the Beneficiary Member, and any Family Members, will terminate at the end of the Month in which the Member becomes ineligible for coverage. However, a Spouse and any Family Members may be issued their own Contract. Please refer to the section entitled Transfer of Plan Membership.

If the Member is receiving Inpatient Care on the date coverage terminates, the Member will continue to receive the Benefits payable under this Contract:

1. For 30 days; or
2. Until the Member is discharged from the Inpatient Care facility, whichever occurs first.

Termination for Nonpayment of Dues or Other Reasons

Blue Cross and Blue Shield of Montana will terminate coverage due to fraud and/or intentional misrepresentation of material fact.

If the Member's dues are not paid when due, coverage will terminate automatically at midnight, Mountain Standard Time, on the last day of the Month for which dues are paid for the Beneficiary Member and Family Members.

Blue Cross and Blue Shield of Montana will provide notice of cancellation stating the date the cancellation will become effective, which may not be earlier than:

1. the beginning of the period for which premiums have not been paid in full if the notice of cancellation for nonpayment of premiums is mailed or delivered within 15 days after the due date of the missed premiums for that period;
2. the date of mailing or delivery of notice of cancellation for nonpayment of premiums if notice of cancellation for nonpayment of premiums is not mailed or delivered within 15 days after the premium due date for the applicable policy period; or
3. 90 days after the date of mailing or delivery of the notice of cancellation or refusal to renew for any reason other than nonpayment of premiums or a material misrepresentation contained in the application.

The time frames for the notices of cancellation outlined above run concurrently with the time frames included in the section entitled "Grace Period" under Payment of Dues.

A grace period of 31 days will be granted for the payment of each premium (dues) falling due after the first premium, during which grace period the Contract shall continue in force, however, Claim Payments for Covered Medical Expenses received during the grace period may be pended until full premium payment is made, and during the grace period pharmacies may require the Member to pay for the Member's prescription drug expenses in full.

If the Member pays the premium in full during the 31 day grace period, then the Member may submit a claim to Blue Cross and Blue Shield of Montana for any expenses that the Member paid to providers and pharmacies during the grace period. See the CLAIMS section for additional information.

If a Member fails to pay premiums in full to Blue Cross and Blue Shield of Montana and/or the Exchange within 31 days of the premium due date, this Contract will automatically terminate on the last day of the coverage period for which premiums have been paid in full. Claim Payments will not be provided for Covered Medical Expenses incurred during this 31 day grace period or thereafter unless the premiums are paid in full within this period. If coverage is terminated for non-payment of premium, any Claims received and paid for during the 31 day grace period will be billed to the Member.

For a Member receiving an Advance Premium Tax Credit, there is a three-month grace period for paying the full premiums falling due after the first premium is paid. If full premium is not paid for the Member and any covered Family Members within one month of the premium due date, Claim Payments for Covered Medical Expenses received during the second and third month's grace period under this Policy will be pended until full premium payment is received. If full payment of the premium is not received within the three month grace period, then coverage under this Contract will automatically terminate on the last day of the first month of the three-month grace period. Blue Cross and Blue Shield of Montana will not process any Claims for services after the date of termination.

Termination of Coverage of Children and Spouse

Coverage will terminate automatically at midnight Mountain Standard Time, on the last day of the Month in which a child reaches age 26 years. Coverage for a Spouse will terminate at midnight, Mountain Standard Time, on the last day of the Month in which the Spouse's marriage to the Beneficiary Member terminated. Please refer to the section entitled Transfer of Plan Membership.

Termination of Benefits on Termination of Coverage

When the membership of a Beneficiary Member and/or Family Member is terminated for any reason the Benefits of this Contract will no longer be provided and The Plan will not make payment for services provided to them after the date on which cancellation becomes effective. However, a Spouse and any Family Members may be issued their own Contract. Please refer to the section entitled Transfer of Plan Membership.

Certificate of Creditable Coverage

Even though this health plan does not have a preexisting condition exclusion period, The Plan will issue a Certificate of Creditable Coverage to the Member, upon request, following termination of coverage.

Blue Cross and Blue Shield of Montana will provide notice of cancellation stating the date the cancellation will become effective, which may not be earlier than:

1. the beginning of the period for which premiums have not been paid in full if the notice of cancellation for nonpayment of premiums is mailed or delivered within 15 days after the due date of the missed premiums for that period;
2. the date of mailing or delivery of notice of cancellation for nonpayment of premiums if notice of cancellation for nonpayment of premiums is not mailed or delivered within 15 days after the premium due date for the applicable policy period; or
3. 90 days after the date of mailing or delivery of the notice of cancellation or refusal to renew for any reason other than nonpayment of premiums or a material misrepresentation contained in the application.

The time frames for the notices of cancellation outlined above run concurrently with the time frames included in the section entitled "Grace Period" under Payment of Dues.

A grace period of 31 days will be granted for the payment of each premium (dues) falling due after the first premium, during which grace period the Contract shall continue in force, however, Claim Payments for Covered Medical Expenses received during the grace period may be pended until full premium payment is made, and during the grace period pharmacies may require the Member to pay for the Member's prescription drug expenses in full.

If the Member pays the premium in full during the 31 day grace period, then the Member may submit a claim to Blue Cross and Blue Shield of Montana for any expenses that the Member paid to providers and pharmacies during the grace period. See the CLAIMS section for additional information.

If a Member fails to pay premiums in full to Blue Cross and Blue Shield of Montana and/or the Exchange within 31 days of the premium due date, this Contract will automatically terminate on the last day of the coverage period for which premiums have been paid in full. Claim Payments will not be provided for Covered Medical Expenses incurred during this 31 day grace period or thereafter unless the premiums are paid in full within this period. If coverage is terminated for non-payment of premium, any Claims received and paid for during the 31 day grace period will be billed to the Member.

For a Member receiving an Advance Premium Tax Credit, there is a three-month grace period for paying the full premiums falling due after the first premium is paid. If full premium is not paid for the Member and any covered Family Members within one month of the premium due date, Claim Payments for Covered Medical Expenses received during the second and third month's grace period under this Policy will be pended until full premium payment is received. If full payment of the premium is not received within the three month grace period, then coverage under this Contract will automatically terminate on the last day of the first month of the three-month grace period. Blue Cross and Blue Shield of Montana will not process any Claims for services after the date of termination.

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Coverage will terminate automatically at midnight Mountain Standard Time, on the last day of the Month in which a child reaches age 26 years. Coverage for a Spouse will terminate at midnight, Mountain Standard Time, on the last day of the Month in which the Spouse's marriage to the Beneficiary Member terminated. Please refer to the section entitled Transfer of Plan Membership.

Termination of Benefits on Termination of Coverage

When the membership of a Beneficiary Member and/or Family Member is terminated for any reason the Benefits of this Contract will no longer be provided and The Plan will not make payment for services provided to them after the date on which cancellation becomes effective. However, a Spouse and any Family Members may be issued their own Contract. Please refer to the section entitled Transfer of Plan Membership.

Certificate of Creditable Coverage

Even though this health plan does not have a preexisting condition exclusion period, The Plan will issue a Certificate of Creditable Coverage to the Member, upon request, following termination of coverage.

Reinstatement

If any renewal dues payment is not paid within the time granted the Member for payment, a subsequent acceptance of dues by The Plan without requiring in connection therewith an application for reinstatement, shall reinstate the Contract; provided, however, that if The Plan requires an application for reinstatement and issues a conditional receipt for the dues tendered, the Contract will be reinstated upon approval of such application by Blue Cross and Blue Shield of Montana or, lacking such approval, upon the 45th day following the date of such conditional receipt unless The Plan has previously notified the Member in writing of its disapproval of such application.

The reinstated Contract shall cover only loss resulting from such accidental injury as may be sustained after the date of reinstatement and loss due to such sickness as began more than ten days after such date. In all other respects, the Member and The Plan shall have the same rights thereunder as they had under the Contract immediately before the due date of the defaulted dues, subject to any provision endorsed hereon or attached hereto in connection with the reinstatement.

QUALIFIED MEDICAL CHILD SUPPORT ORDER (QMSCO)

Beneficiary Members and Family Members can obtain, without charge, a copy of the procedures governing Qualified Medical Child Support Order (QMCSO) determinations from Blue Cross and Blue Shield of Montana.

RENEWAL OF CONTRACT

Renewal of Contract by the Plan

This Contract will be renewed unless one of the following occurs:

1. Nonpayment of the required dues.
2. The Member has performed an act or practice that constitutes fraud or has made an intentional misrepresentation of a material fact with respect to coverage of individual insureds.
3. The Member is no longer eligible for coverage in a QHP offered through the Exchange.
4. This Contract is terminated or is decertified as a QHP.
5. The Member's coverage has been rescinded as described under the Rescission provision of this Policy.
6. The Member changes from QHP to another during an annual open enrollment period or special enrollment period.
7. Election by The Plan to:
   a. Cease offering a particular type of coverage in the individual market; or
   b. Cease offering all coverage in the individual market.

Termination of Contract by the Member

The Beneficiary Member may cancel this Contract by notifying Blue Cross and Blue Shield of Montana in writing. Notice of cancellation will terminate this Contract on the first of the Month following receipt of the Member's written notification to cancel.

BENEFITS

The Plan will pay for the following Benefits provided by a Covered Provider based on the Allowable Fee and subject to any Deductible, Copayment, Coinsurance and other provisions, as applicable.

Benefits outlined in this section are subject to the Plan's Medical Policy, any specific exclusions identified for that specific Benefit and to the exclusions and limitations outlined in the Exclusions and Limitations section.

Accident

Services which are provided for bodily injuries resulting from an Accident.

Acupuncture

Services provided by a licensed acupuncturist to treat Illness or Injury.

The Schedule of Benefits describes payment limitations for these services.

Advanced Practice Registered Nurses and Physician Assistants - Certified

Services provided by an Advanced Practice Registered Nurse or a physician assistant-certified who is licensed to practice medicine in the state where the services are provided and when payment would otherwise be made if the same services were provided by a Physician.

Ambulance

Licensed ground and air ambulance transport required for a Medically Necessary condition to the nearest appropriate site.

Anesthesia Services

Anesthesia services provided by a Physician (other than the attending Physician) or nurse anesthetist including the administration of spinal anesthesia and the injection or inhalation of a drug or other anesthetic agent.

The Plan will not pay for:

1. Hypnosis;
2. Local anesthesia or intravenous (IV) sedation that is considered to be an Inclusive Service/Procedure;
3. Anesthesia consultations before surgery that are considered to be Inclusive Services/Procedures because the Allowable Fee for the anesthesia performed during the surgery includes this anesthesia consultation; or
4. Anesthesia for dental services or extraction of teeth, except anesthesia provided at a Hospital in conjunction with dental treatment will be covered only when a nondental physical Illness or Injury exists which makes Hospital care Medically Necessary to safeguard the Member's health. Dental services and treatment are not a Benefit of this Contract, except as specifically included in the Dental Accident Benefit.

Approved Clinical Trials

Routine Patient Costs provided in connection with an Approved Clinical Trial.

Autism Spectrum Disorders

Diagnosis and treatment of autistic disorder, Asperger's Disorder or Pervasive Developmental Disorder.

Covered services include:

1. Habilitative Care or Rehabilitative Care, including, but not limited to, professional, counseling and guidance services and treatment programs; Applied Behavior Analysis (ABA), also known as Lovaas Therapy; discrete trial training, pivotal response training, intensive intervention programs, and early intensive behavioral intervention;
2. Medications;
3. Psychiatric or psychological care; and
4. Therapeutic care provided by a speech-language pathologist, audiologist, occupational therapist or physical therapist.

Note: Applied Behavior Analysis (ABA), also known as Lovaas Therapy, is only available for Members under age 19.

Birthing Centers

Services for the delivery of a newborn provided at a birthing center.

Blood Transfusions

Blood transfusions, including the cost of blood, blood plasma, blood plasma expanders and packed cells. Storage charges for blood are paid when a Member has blood drawn and stored for the Member's own use for a planned surgery.

Chemical Dependency

Benefits for Chemical Dependency will be paid as any other Illness.

Outpatient Services

Care and treatment for Chemical Dependency when the Member is not an Inpatient Member and provided by:

1. a Hospital;
2. a Mental Health Treatment Center;
3. a Chemical Dependency Treatment Center;
4. a Physician or prescribed by a Physician;
5. a psychologist;
6. a licensed social worker;
7. a licensed professional counselor;
8. an addiction counselor licensed by the state; or
9. a licensed psychiatrist.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Chemical Dependency; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by the Chemical Dependency.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Care Services

Care and treatment of Chemical Dependency, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity services provided at a Residential Treatment Center are Benefits of this Contract.

Preauthorization is required for Inpatient Care services and Residential Treatment services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Chemical Dependency, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization. Please refer to the section entitled Preauthorization.

Chemotherapy

The use of drugs approved for use in humans by the U.S. Food and Drug Administration and ordered by the Physician for the treatment of disease.

Chiropractic Services

Services of a licensed chiropractor.

The Schedule of Benefits describes payment limitations for these services.

Contraceptives

Services and supplies related to contraception, including but not limited to, oral contraceptives, contraceptive devices and injections, subject to the terms and limitations of the Contract. Oral contraceptives are paid as described in the Preventive Health Care section or under the Prescription Drugs section.

Deductible and Coinsurance do not apply to contraceptives covered under the Preventive Health Care Benefit, whether provided during an office visit or through the Prescription Drugs Benefit. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy.

Convalescent Home Services

Services of a Convalescent Home as an alternative to Hospital Inpatient Care. The Plan will not pay for custodial care.

NOTE: The Plan will not pay for the services of a Convalescent Home if the Member remains inpatient at the Convalescent Home when a skilled level of care is not Medically Necessary.

Preauthorization is required for Convalescent Home Services. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Dental Accident Services

Dental services provided by physicians, dentists, oral surgeons and/or any other provider are not covered under this Contract except that, Medically Necessary services for the initial repair or replacement of sound natural teeth which are damaged as a result of an Accident, are covered, except that orthodontics, dentofacial orthopedics, or related appliances are not covered, even if related to the Accident.

The Plan will not pay for services for the repair of teeth which are damaged as the result of biting and chewing.

Diabetic Education

Outpatient self-management training and education services for the treatment of diabetes provided by a Covered Provider with expertise in diabetes.

The Schedule of Benefits describes payment limitations for these services.

Diabetes Treatment (Office Visit)

Services and supplies for the treatment of diabetes provided during an office visit. For additional Benefits related to the treatment of diabetes, e.g., surgical services and medical supplies, refer to that specific Benefit.

Diagnostic Services

1. Diagnostic Imaging Procedures

   Diagnostic Imaging which includes Computerized Tomography Scan (CT Scan), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET Scan).

2. All Other Covered Diagnostic Services

   a. X-rays and Other Radiology. Some examples of other radiology include:

   - Nuclear medicine
   - Ultrasound

b. Laboratory Tests. Some examples of laboratory tests include:

- Urinalysis
- Blood tests
- Throat cultures

c. Diagnostic Testing. Tests to diagnose an illness or injury. Some examples of diagnostic testing include:

- Electroencephalograms (EEG)
- Electrocardiograms (EKG or ECG)

This Benefit does not include diagnostic services such as biopsies which are covered under the surgery Benefit.

Durable Medical Equipment

The appropriate type of equipment used for therapeutic purposes **where the Member resides**. Durable medical equipment, which requires a written prescription, must also be:

1. able to withstand repeated use (consumables are not covered);
2. primarily used to serve a medical purpose rather than for comfort or convenience; and
3. generally not useful to a person who is not ill or injured.

The Plan will not pay for the following items:

1. exercise equipment;
2. car lifts or stair lifts;
3. biofeedback equipment;
4. self-help devices which are not medical in nature, regardless of the relief they may provide for a medical condition;
5. air conditioners and air purifiers;
6. whirlpool baths, hot tubs, or saunas;
7. waterbeds;
8. other equipment which is not always used for healing or curing;
9. Deluxe equipment. The Plan has the right to decide when deluxe equipment is required. However, upon such decision, payment for deluxe equipment will be based on the Allowable Fee for standard equipment.
10. computer-assisted communication devices;
11. durable medical equipment required primarily for use in athletic activities;
12. replacement of lost or stolen durable medical equipment;
13. repair to rental equipment; and
14. duplicate equipment purchased primarily for Member convenience when the need for duplicate equipment is not medical in nature.

Education Services

Education services, other than diabetic education, that are related to a medical condition.

Emergency Room Care

1. Emergency room care for an accidental Injury.
2. Emergency room care for Emergency Services.

Home Health Care

The following services, when prescribed and supervised by the Member's attending Physician provided in the Member's home by a licensed Home Health Agency and which are part of the Member's treatment plan:

1. Nursing services.
2. Home Health Aide services.

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3. Hospice services.
4. Physical Therapy.
5. Occupational Therapy.
6. Speech Therapy.
7. Medical social worker.
8. Medical supplies and equipment suitable for use in the home.
9. Medically Necessary personal hygiene, grooming and dietary assistance.

The Plan will not pay for:

1. Maintenance or custodial care visits.
2. Domestic or housekeeping services.
3. "Meals-on-Wheels" or similar food arrangements.
4. Visits, services, medical equipment, or supplies not approved or included as part of the Member's treatment plan.
5. Services for the treatment of Mental Illness.
6. Services provided in a nursing home or skilled nursing facility.

Preauthorization is required for home health care. Please refer to the section entitled Preauthorization.

The Schedule of Benefits describes payment limitations for these services.

Home Infusion Therapy Services

The preparation, administration, or furnishing of parenteral medications, or parenteral or enteral nutritional services to a Member by a Home Infusion Therapy Agency, including:

1. Education for the Member, the Member's caregiver, or a Family Member.
2. Pharmacy.
3. Supplies.
4. Equipment.
5. Skilled nursing services when billed by a Home Infusion Therapy Agency.

Home infusion therapy services must be ordered by a Physician and provided by a licensed Home Infusion Therapy Agency. A licensed Hospital, which provides home infusion therapy services, must have a Home Infusion Therapy Agency license or an endorsement to its Hospital facility license for home infusion therapy services.

Preauthorization is required for home infusion therapy services. Please refer to the section entitled Preauthorization.

Hospice Care

A coordinated program of home care and Inpatient Care that provides or coordinates palliative and supportive care to meet the needs of a terminally ill Member and the Member's Immediate Family. Benefits include:

1. Inpatient and Outpatient care;
2. Home care;
3. Nursing services - skilled and non-skilled;
4. Counseling and other support services provided to meet the physical, psychological, spiritual and social needs of the terminally ill Member; and
5. Instructions for care of the Member, counseling and other support services for the Member's Immediate Family.

Preauthorization is required for hospice care. Please refer to the section entitled Preauthorization.

Hospital Services - Facility and Professional

Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations
    a. Room and board, which includes special diets and nursing services.

b. Intensive care and cardiac care units which include special equipment and concentrated nursing services provided by nurses who are Hospital employees.

2. Miscellaneous Hospital Services

a. Laboratory procedures.
b. Operating room, delivery room, recovery room.
c. Anesthetic supplies.
d. Surgical supplies.
e. Oxygen and use of equipment for its administration.
f. X-ray.
g. Intravenous injections and setups for intravenous solutions.
h. Special diets when Medically Necessary.
i. Respiratory therapy, chemotherapy, radiation therapy, dialysis therapy.
j. Physical Therapy, Speech Therapy and Occupational Therapy.
k. Drugs and medicines which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
3. Require a Physician's written prescription.

Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.

Preauthorization is required for Inpatient care. Please refer to the section entitled Preauthorization.

Inpatient Care services are subject to the following conditions:

1. Days of care

a. The number of days of Inpatient Care provided is 365 days.
b. In computing the number of Inpatient Care days available, days will be counted according to the standard midnight census procedure used in most Hospitals. The day a Member is admitted to a Hospital is counted, but the day a Member is discharged is not. If a Member is discharged on the day of admission, one day is counted.
c. The day a Member enters a Hospital is the day of admission. The day a Member leaves a Hospital is the day of discharge.

2. The Member will be responsible to the Hospital for payment of its charges if the Member remains as an Inpatient Member when Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member. No Benefits will be paid for Inpatient Care provided primarily for diagnostic or therapy services.

3. Preauthorization is required for Inpatient Care. Please refer to the section entitled Preauthorization.

Inpatient Care Medical Services Billed by a Professional Provider

Nonsurgical services by a Covered Provider, Concurrent Care and Consultation Services.

Medical services do not include surgical or maternity services. Inpatient Care medical services are covered only if the Member is eligible for Benefits under the Hospital Services, Inpatient Care Services section for the admission.

Medical care visits are limited to one visit per day per Covered Provider unless a Member's condition requires a Physician's constant attendance and treatment for a prolonged period of time.

Observation Beds/Rooms

Payment will be made for observation beds when Medically Necessary.

Outpatient Hospital Services

Use of the Hospital's facilities and equipment for surgery, respiratory therapy, chemotherapy, radiation therapy and dialysis therapy.

Inborn Errors of Metabolism

Treatment under the supervision of a Physician of inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism and for which medically standard methods of diagnosis, treatment and monitoring exist. Benefits include expenses of diagnosing, monitoring, and controlling the disorders by nutritional and medical assessment, including but not limited to clinical services, biochemical analysis, medical supplies, prescription drugs, corrective lenses for conditions related to the inborn error of metabolism, nutritional management, and Medical Foods used in treatment to compensate for the metabolic abnormality and to maintain adequate nutritional status.

Infertility - Diagnosis and Treatment

The Plan will pay for:

The diagnosis and treatment of infertility, including:

- Medically Necessary evaluation to determine cause of infertility
- Artificial insemination (AI) or intrauterine insemination (IUI)
- Medically Necessary Reproductive procedures not related to in vitro fertilization.

The Plan will not pay for:

1. Prescription drugs used to treat infertility.
2. Services, supplies, drugs and devices related to in vitro fertilization.

Mammograms (Routine and Medical)

Mammography examinations.

The minimum mammography examination recommendations are:

1. One baseline mammogram for women ages 35 through 39.
2. One mammogram every two years for women ages 40 through 49, or more frequently as recommended by a Physician.
3. One mammogram every year for women age 50 or older.

Maternity Services - Professional and Facility Covered Providers

1. Prenatal and postpartum care.
2. Delivery of one or more newborns.
3. Hospital Inpatient Care for conditions related directly to pregnancy. Inpatient Care following delivery will be covered for whatever length of time is necessary and will be at least 48 hours following a vaginal delivery and at least 96 hours following a delivery by cesarean section. The decision to shorten the length of stay of Inpatient Care to less than that stated in the preceding sentence must be made by the attending health care provider and the mother.

   Under Federal law, Benefits may not be restricted for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, under Federal law, Covered Providers may not be required to obtain Preauthorization from The Plan for prescribing a length of stay not in excess of 48 hours (or 96 hours).

4. Payment for any maternity services by the professional provider is limited to the Allowable Fee for total maternity care, which includes delivery, prenatal and postpartum care.

Please refer also to the Newborn Initial Care section.

Medical Supplies

The following supplies for use outside of a Hospital:

1. Supplies for insulin pumps, syringes and related supplies for conditions such as diabetes.

2. Injection aids, visual reading and urine test strips, glucagon emergency kits for treatment of diabetes. One insulin pump for each warranty period is covered under the Durable Medical Equipment Benefit.
3. Sterile dressings for conditions such as cancer or burns.
4. Catheters.
5. Splints.
6. Colostomy bags and related supplies.
7. Supplies for renal dialysis equipment or machines.

Medical supplies are covered only when:

1. Medically Necessary to treat a condition for which Benefits are payable.
2. Prescribed by a Covered Provider.

Mental Health

Benefits provided for mental health are for the treatment of Mental Illness and Severe Mental Illness as defined in the section entitled "Definitions."

Benefits include but are not limited to, Inpatient Care services, Outpatient services, rehabilitation services and medication for the treatment of Mental Illness or Severe Mental Illness.

Payment for mental health Benefits will be made as for any other illness.

Outpatient Services

Care and treatment of Mental Illness or Severe Mental Illness if the Member is not an Inpatient Member and is provided by:

1. a Hospital;
2. a Physician or prescribed by a Physician;
3. a Mental Health Treatment Center;
4. a Chemical Dependency Treatment Center;
5. a psychologist;
6. a licensed social worker;
7. a licensed professional counselor;
8. a licensed addiction counselor; or
9. a licensed psychiatrist.
10. a licensed Advanced Practice Registered Nurse with a specialty in mental health.
11. a licensed Advanced Practice Registered Nurse with prescriptive authority and specializing in mental health.

Outpatient Benefits are subject to the following conditions:

1. the services must be provided to diagnose and treat recognized Mental Illness or Severe Mental Illness; and
2. the treatment must be reasonably expected to improve or restore the level of functioning that has been affected by Mental Illness or Severe Mental Illness.

The Plan will not pay for hypnotherapy or for services given by a staff member of a school or halfway house.

Inpatient Services

Care and treatment of Mental Illness or Severe Mental Illness, while the Member is an Inpatient Member, and which are provided in or by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Medically monitored and medically managed intensive Inpatient Care services and clinically managed high-intensity residential services provided at a Residential Treatment Center are Benefits of this Contract.

Preauthorization is required for Inpatient Care services and Residential Treatment Center services. Please refer to the section entitled Preauthorization.

Partial Hospitalization

Care and treatment of Mental Illness or Severe Mental Illness, while the Partial Hospitalization services are provided by:

1. a Hospital;
2. a Freestanding Inpatient Facility; or
3. a Physician.

Preauthorization is required for Partial Hospitalization. Please refer to the section entitled Preauthorization.

Naturopathy

Services provided by a licensed naturopathic provider are covered if such services are a Benefit of this Contract.

Newborn Initial Care

1. The initial care of a newborn at birth provided by a Physician.
2. Nursery Care - Hospital nursery care of newborn infants.

Office Visits

Covered services provided in a Covered Provider's office during a Professional Call and covered services provided in the home by a Covered Provider. Visits are limited to one visit per day per provider.

Oral Surgery

Benefits will be provided for the following:

- Excision or biopsy of tumors or cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth
- Excision of exostoses of the jaws and hard palate (provided that this procedure is not done in preparation for dentures or other prostheses)
- Treatment of fractures of facial bone
- External incision and drainage of cellulitis (not including treatment of dental abscesses)
- Incision of accessory sinuses, salivary glands or ducts
- Surgical removal of complete bony impacted teeth
- Reduction of dislocation of, or excision of, the temporomandibular joints.

Orthopedic Devices/Orthotic Devices

A supportive device for the body or a part of the body, head, neck or extremities, including but not limited to, leg, back, arm and neck braces. In addition, when Medically Necessary, Benefits will be provided for adjustments, repairs or replacement of the device because of a change in the Member's physical condition.

The Plan will not pay for foot orthotics defined as any in-shoe device designed to support the structural components of the foot during weight-bearing activities

Pediatric Vision Care

The following services only may be provided by a licensed ophthalmologist or optometrist operating within the scope of his or her license, or a dispensing optician to Members under 19 years of age:

1. One Routine vision exam per Benefit Period.
2. One pair of glasses (frames and lenses) or two boxes of contacts per Benefit Period.

The Plan will not pay for any vision service, treatment or materials not specifically listed above.

Physician Medical Services

Medical services by a Covered Provider for:

1. Inpatient Hospital Physician visits.
2. Convalescent Home facility Physician visits.
3. Surgical facility Physician services.

The Plan will not pay for pre- or postsurgical visits that are considered to be Inclusive Services/Procedures are included in the payment for the surgery.

This Benefit does not include services provided in the home or the Covered Provider's office.

Postmastectomy Care and Reconstructive Breast Surgery

Postmastectomy Care

Inpatient Care for the period of time determined by The Plan in consultation with the Attending Physician, and the Member, to be Medically Necessary following a mastectomy.

Reconstructive Breast Surgery

1. All stages of Reconstructive Breast Surgery after a mastectomy including, but not limited to:
   a. All stages of reconstruction of the breast on which a mastectomy has been performed.
   b. Surgery and reconstruction of the other breast to establish a symmetrical appearance.
   c. Chemotherapy.
   d. Prostheses and physical complications of all stages of a mastectomy and breast reconstruction, including lymphedemas.

   Coverage described in 1(a) through 1(d) will be provided in a manner determined in consultation with the Attending Physician and the patient.
2. Breast prostheses as the result of a mastectomy.

For specific Benefits related to postmastectomy care, refer to that specific Benefit, e.g., surgical services and Hospital services.

Prescription Drugs

Refer to the Prescription Drugs section in the Schedule of Benefits for specific information on the application of any Deductible, Copayment and/or Coinsurance.

The Prescription Drugs Benefit is for Prescription Drug Products which are self-administered. This Benefit does not include medications which are administered by a Covered Provider. If a medication is administered by a Covered Provider, the claim will process under the Member's medical Benefits. **Please refer to the Preauthorization sectic for complete information about the medications that are subject to the Member's medical Benefits, the process for requesting Preauthorization for medications subject to the Member's medical Benefits, and related information.**

Subject to the terms, conditions, and limitations of this Contract, The Plan will pay for Prescription Drug Products, which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Require a Physician's written prescription; and
3. Are dispensed under federal or state law pursuant to a prescription order or refill.

Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.

Drug Lists

Covered drugs are selected by The Plan based upon the recommendations of a committee, which is made up of current and previously practicing physicians and pharmacists from across the country, some of which are employed by or affiliated with Blue Cross and Blue Shield of Montana. The committee considers drugs regulated by the FDA for inclusion on the Drug List. Some of the factors committee members evaluate include each drug's safety, effectiveness, cost, and how it compares with drugs currently on the Drug List. The committee considers drugs that are newly approved by the FDA, as well as those that have been on the market for some time. Entire drug classes are also regularly reviewed. Changes to the Drug List can be made from time to time.

The Plan may offer multiple Drug Lists. By accessing www.bcbsmt.com or www.myprime.com or calling the Customer Service toll-free number on the Member's identification card, the Member or provider can determine the Drug List that applies to the Member's Plan and whether a particular drug is on the Drug List.

The Member, or the Member's prescribing health care provider, can ask for a Drug List exception if the Member's drug is not on the Drug List (also known as a formulary). To request this exception, the Member or the Member's prescriber, can call the number on the back of the Member's ID card to ask for a review. If the Member has a health condition that may jeopardize his/her life, health or keep the Member from regaining function, or the Member's current drug therapy uses a non-covered drug, the Member or the Member's prescriber, may be able to ask for an expedited review process. Blue Cross and Blue Shield of Montana will notify the Member or the Member's prescriber, of the coverage decision within 24 hours after they receive the request for an expedited review. If the coverage request is denied, Blue Cross and Blue Shield of Montana will let the Member and the Member's prescriber, know why it was denied and offer the Member a covered alternative drug (if applicable). If the Member's exception is denied, the Member may appeal the decision according to the appeals process the Member will receive with the denial determination. The Member should call the number on the back of the ID card if the Member has any questions.

Covered Prescription Drug Products

The following Prescription Drug Products, obtained from a Participating Pharmacy, either retail or mail order, or a retail nonparticipating pharmacy, are covered:

1. Legend drugs - drugs requiring written prescriptions and dispensed by a licensed pharmacist for treatment of an illness or injury.
2. One prescription oral agent for controlling blood sugar levels for each class of drug approved by the United States food and drug administration.
3. Insulin on prescription.
4. Disposable insulin needles/syringes.
5. Test strips.
6. Lancets.
7. Oral contraceptives, contraceptive devices, implantables or injections prescribed by a Physician.
8. Smoking cessation products and over-the-counter smoking cessation aids/medications with a written prescription, as required by the Affordable Care Act. Tobacco counseling is available under the Preventive Health Care Benefit.

The Schedule of Benefits lists any Deductible, Copayment and/or Coinsurance that the Member is responsibility for and the payment limitations for these Prescription Drug Products.

Non-Covered Prescription Drug Products

The Plan will not pay for:

1. Nonlegend drugs other than insulin.
2. Compounded medications.
3. Anabolic Steroids.
4. Any drug used for the purpose of weight loss.
5. Fluoride supplements, except as required by the Affordable Care Act for children under age 6.
6. Drugs which are not approved by the FDA for a particular use or purpose or when used for a purpose other than the purpose for which the FDA approval is given, except as required by law or regulation. Prescription Drug Products which are used in off-label situations may be reviewed for Medical Necessity.

7. Over-the-counter drugs that do not require a prescription, except over-the-counter smoking cessation aids with a written prescription.
8. Prescription Drug Products for which there is an exact over-the-counter equivalent.
9. Prescription Drug Products for cosmetic purposes, including the treatment of alopecia (hair loss) (e.g., Minoxidil, Rogaine).
10. Therapeutic devices or appliances, including needles, syringes, support garments and other non-medicinal substances, regardless of intended use, except those otherwise covered under this section.
11. Prescription Drug Products used for erectile dysfunction.
12. Prescription Drug Products used for the treatment of infertility.
13. Insulin pumps and glucose meters. Insulin pumps and glucose meters are covered under the Durable Medical Equipment Benefit. Insulin pump supplies are covered under the Medical Supplies Benefit.
14. Drugs or items labeled "Caution - limited by federal law to investigational use," or experimental drugs, even though the Member is charged for the item.
15. Biological sera, blood, or blood plasma.
16. Prescription Drug Products which are to be taken by or administered to the Member, in whole or in part, while the Member is a patient in a licensed Hospital, rest home, sanitarium, extended care facility, convalescent hospital, nursing home, or similar institution which operates or allows to be operated on its premises, a facility for dispensing pharmaceuticals. Medication in these situations is part of the facility's charge.
17. Any Prescription Drug Product refilled in excess of the number specified by the Physician, or any refill dispensed after one year from the Physician's original order.
18. Replacement prescription drugs or Prescription Drug Products due to loss, theft or spoilage.
19. Prescription Drug Products obtained from a pharmacy located outside the United States for consumption within the United States.
20. Prescription Drug Products provided by a mail-order pharmacy that is not approved by The Plan.
21. Repackaged medications.
22. Non-sedating antihistamines.
23. Brand-Name Proton Pump Inhibitors (PPIs).
24. Prescription Drug Products determined by The Plan to have inferior efficacy or significant safety issues.

Controlled Substances Limitation

If The Plan determines that a Member may be receiving quantities of controlled substance medications not supported by FDA approved dosages or recognized treatment guidelines, any Benefits for additional drugs may be subject to a review for Medical Necessity, appropriateness and other restrictions.

Purchase and Payment of Prescription Drug Products

Prescription Drug Products may be obtained using an outpatient retail pharmacy or a mail-order pharmacy approved by The Plan. To use a mail-order pharmacy, the Member must send an order form with the prescription to the address listed on the mail-order service form and pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The address of each mail order pharmacy approved by The Plan is listed on the inside cover of this Contract.

If drugs or Prescription Drug Products are purchased at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the Member presents the Member's ID card at the time of purchase, the Member must pay any required Deductible, Copayment and/or Coinsurance. In addition to any Deductible, Copayment and/or Coinsurance, if the Member chooses a Brand-Name drug for which a Generic substitute is available, the Member is required to pay the difference between the cost of the Brand-Name drug and the Generic equivalent. The Member will only be required to pay the appropriate Deductible, Copayment and/or Coinsurance and the difference between the cost of the Brand-Name drug and the Generic equivalent if the amount can be determined by the pharmacy at the time of purchase.

Exceptions to this provision may be allowed for certain preventive medications (including prescription contraceptive medications) if the Member's health care Provider submits a request to The Plan indicating that the Generic drug

would be medically inappropriate, along with supporting documentation. If The Plan grants the exception request, any difference between the cost of the Brand-Name drug and the Generic equivalent will be waived.

If the Member uses a Participating Pharmacy to fill a prescription, but elects to submit the claim directly to the Plan's Pharmacy Benefit Manager, instead of having the Participating Pharmacy submit the claim, the Member will be reimbursed for the prescription drug based on the amount that would have been paid to the Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance.

If drugs or Prescription Drug Products are purchased at a nonparticipating outpatient pharmacy, the Member must pay for the prescription at the time of dispensing and then file a prescription drug claim form with The Plan's Pharmacy Benefit Manager for reimbursement. The Member will be reimbursed for the prescription drug at 50% of the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance and any additional charge for the difference between the cost of the Brand-Name drug and the Generic equivalent.

Prescription Drug Products Subject to Preauthorization, Step Therapy or Quantity Limits

1. Prescription Drug Products subject to Preauthorization require prior approval from The Plan's Pharmacy Benefit Manager before they can qualify for coverage under The Plan. If the Member does not obtain Preauthorization before a Prescription Drug Product is dispensed, the Member may pay for the prescription and then pursue authorization of the drug from The Plan's Pharmacy Benefit Manager. If the authorization is approved by The Plan's Pharmacy Benefit Manager, the Member should then submit a claim for the prescription drug on a prescription claim form to The Plan's Pharmacy Benefit Manager for reimbursement.
2. Preauthorization does not guarantee payment of the Prescription Drug Product by The Plan. Even if the prescription drug has been preauthorized, coverage or payment can be affected for a variety of reasons. For example, the Member may have become ineligible as of the date the drug is dispensed or the Member's Benefits may have changed as of the date the drug is dispensed.
3. A step therapy program is designed to help the Member use the lowest cost product(s) within a drug class. Drugs subject to step therapy are widely considered equivalent to other products within the class by both physicians and pharmacists. In order to obtain a medication within a step therapy program, the member must fail a first line drug. In general, first line products are usually generic medications. In some cases, a pharmacy policy will allow the step therapy to be waived. The pharmacy policies are located on The Plan website at www.bcbsmt.com.
4. A quantity limit is a limitation on the number or amount of a Prescription Drug Product covered within a certain time period. Quantity limits are established to ensure that prescribed quantities are consistent with clinical dosing guidelines, to control for billing errors by pharmacies, to encourage dose consolidation, appropriate utilization, and to avoid misuse/abuse of the medication. A prescription written for a quantity in excess of the established limit will require a Preauthorization before Benefits are available.

Certain Prescription Drug Products, such as those used to treat rheumatoid arthritis, growth hormone deficiency, hepatitis C, or more serious forms of anemia, hypertension, and epilepsy, are subject to Preauthorization, step therapy, or quantity limits. The Prescription Drug Products included in the prescription drug program are subject to change, and medications for other conditions may be added to the program.

If the Member's provider is prescribing a Prescription Drug Product subject to Preauthorization, step therapy, or quantity limits, the provider should fax the request for Preauthorization to The Plan's Pharmacy Benefit Administrator at the fax number listed on the inside cover of this Contract. The Member and provider will be notified of The Plan's Pharmacy Benefit Administrator's determination.

In making determinations of coverage, The Plan's Pharmacy Benefit Administrator may rely upon pharmacy policies developed through consideration of peer reviewed medical literature, FDA approvals, accepted standards of medical practice in Montana, Pharmacy Benefit Manager evaluations, medical necessity, and Medical Policies. The pharmacy policies and Medical Policies are located on The Plan website at www.bcbsmt.com.

To find out more about Preauthorization/step therapy/quantity limits or to determine which Prescription Drug Products are subject to Preauthorization, step therapy or quantity limits, the Member or provider should refer to the Drug List which applies to the Member's Plan at www.bcbsmt.com or www.myprime.com or call the Customer Service toll-free number identified on the Member's identification card.

Specialty Medications

1. Specialty Medications are generally prescribed for individuals with complex or ongoing medical conditions such as multiple sclerosis, hemophilia, hepatitis C and rheumatoid arthritis. These high cost medications also have one or more of the following characteristics:
   a. Injected or infused, but some may be taken by mouth
   b. Unique storage or shipment requirements
   c. Additional education and support required from a health care professional
   d. Usually not stocked at retail pharmacies
2. For the highest level of Benefits, Specialty Medications must be acquired through The Plan's contracted Specialty Pharmacy listed on the inside cover of this Contract. A list of covered Specialty Medications may be found on The Plan website at www.bcbsmt.com. Registration and other applicable forms are also located on the website.

Preventive Health Care

Covered preventive services include, but are not limited to:

1. Services that have an "A" or "B" rating in the United States Preventive Services Task Force's current recommendations (additional information is provided by accessing http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm); and
2. Immunizations recommended by the Advisory Committee of Immunizations Practices of the Centers for Disease Control and Prevention; and
3. Health Resources and Services Administration (HRSA) Guidelines for Preventive Care & Screenings for Infants, Children, Adolescents and Women;

   In addition to the screening services recommended under the HRSA Guidelines, the following services are included:

   a. Lactation Services

      Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period. In addition, Benefits are provided for the purchase of manual or electric breast pumps or the rental of Hospital-grade pumps. The purchase of electric breast pumps is limited to two electric breast pumps per Benefit Period. Payment will be made according to the Preventive Health Care Benefit on the Schedule of Benefits.

   b. Contraceptives

      Food and Drug Administration approved contraceptive methods, including certain contraceptive products, sterilization procedures for women, and patient education and counseling for all women with reproductive capacity. For additional information, access www.bcbsmt.com and click on the Members tab and select Pharmacy; and
4. Current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention issued prior to or after November 2009.

Examples of Preventive Health Care services include, but are not limited to, physical examinations, colonoscopies, immunizations and vaccinations.

For more detailed information on all covered services, contact Customer Service or access www.bcbsmt.com.

Prostheses

The appropriate devices used to replace a body part missing because of an Accident, Injury, or Illness.

When placement of a prosthesis is part of a surgical procedure, it will be paid under Surgical Services.

Payment for deluxe prosthetics will be based on the Allowable Fee for a standard prosthesis.

The Plan will not pay for the following items:

1. computer-assisted communication devices;
2. replacement of lost or stolen prosthesis.

Note: The prosthesis will not be considered a replacement if the prosthesis no longer meets the medical needs of the Member due to physical changes or a deteriorating medical condition.

Radiation Therapy

The use of x-ray, radium, or radioactive isotopes ordered by the attending Physician and performed by a Covered Provider for the treatment of disease.

Rehabilitation – Facility and Professional

Rehabilitation Therapy and other covered services, as outlined in this Rehabilitation section, billed by a Rehabilitation Facility provider or a Professional Provider for services provided to a Member.

The Plan will not pay when the primary reason for Rehabilitation is any one of the following:

1. Custodial Care;
2. Diagnostic admissions;
3. Maintenance, nonmedical self-help, or vocational educational therapy;
4. Social or cultural rehabilitation;
5. Learning and developmental disabilities; and
6. Visual, speech, or auditory disorders because of learning and developmental disabilities or psychoneurotic and psychotic conditions.

Benefits will not be provided under this Rehabilitation section for treatment of Chemical Dependency or Mental Illness as defined in the Chemical Dependency and Mental Illness sections.

Benefits will be provided for services, supplies and other items that are within the scope of the Rehabilitation benefit described in this Rehabilitation section only as provided in and subject to the terms, conditions and limitations applicable to this Rehabilitation benefit section and other applicable terms, conditions and limitations of this Contract. Other Benefit sections of this Contract, such as but not limited to Hospital Services, do not include Benefits for any services, supplies or items that are within the scope of the Rehabilitation benefit as outlined in this section.

Rehabilitation Facility Inpatient Care Services Billed by a Facility Provider

1. Room and Board Accommodations
   a. Room and Board, which includes but is not limited to dietary and general, medical and rehabilitation nursing services.
2. Miscellaneous Rehabilitation Facility Services (whether or not such services are Rehabilitation Therapy or are general, medical or other services provided by the Rehabilitation Facility during the Member's admission), including but not limited to:
   a. Rehabilitation Therapy services and supplies, including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy.
   b. Laboratory procedures.
   c. Diagnostic testing.
   d. Pulmonary services and supplies, including but not limited to oxygen and use of equipment for its administration.
   e. X-rays and other radiology.
   f. Intravenous injections and setups for intravenous solutions.
   g. Special diets when Medically Necessary.
   h. Operating room, recovery room.
   i. Anesthetic and surgical supplies.

j. Drugs and medicines which:

1. Are approved for use in humans by the U.S. Food and Drug Administration; and
2. Are listed in the American Medical Association Drug Evaluation, Physicians' Desk Reference, or Drug Facts and Comparisons; and
3. Require a Physician's written prescription.

Drugs and medicines which are used in off-label situations may be reviewed for Medical Necessity.

3. Rehabilitation Facility Inpatient Care Services do not include services, supplies or items for any period during which the Member is absent from the Rehabilitation Facility for purposes not related to rehabilitation, including but not limited to intervening inpatient admissions to an acute care Hospital.

Preauthorization is required for Rehabilitation Facility Inpatient Care. Please refer to the section entitled Preauthorization.

Rehabilitation Facility Inpatient Care is subject to the following conditions:

1. The Member will be responsible to the Rehabilitation Facility for payment of the Facility's charges if the Member remains as an Inpatient Member when Rehabilitation Facility Inpatient Care is not Medically Necessary. No Benefits will be provided for a bed "reserved" for a Member.

2. The term "Rehabilitation Facility" does not include:

a. A Hospital when a Member is admitted to a general medical, surgical or specialty floor or unit (other than a rehabilitation unit) for acute Hospital care, even though rehabilitation services are or may be provided as a part of acute care.
b. A nursing home;
c. A rest home;
d. Hospice;
e. A skilled nursing facility;
f. A Convalescent Home;
g. A place for care and treatment of Chemical Dependency;
h. A place for treatment of Mental Illness;
i. A long-term, chronic-care institution or facility providing the type of care listed above.

Rehabilitation Facility Inpatient Care Services Billed by a Professional Provider

All Professional services provided by a Covered Provider who is a physiatrist or other Physician directing the Member's Rehabilitation Therapy. Such professional services include care planning and review, patient visits and examinations, consultation with other physicians, nurses or staff, and all other professional services provided with respect to the Member. Professional services provided by other Covered Providers (i.e., who are not the Physician directing the Member's Rehabilitation Therapy) are not included in the rehabilitation Benefit, but are included to the extent provided in and subject to the terms, conditions and limitations of other contract benefits (e.g., Physician Medical Services).

Outpatient Rehabilitation

Rehabilitation Therapy provided on an outpatient basis by a facility or professional provider.

Surgical Services

Surgical Services Billed by a Professional Provider

Services by a professional provider for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery. The charge for a surgical suite outside of the Hospital is included in the Allowable Fee for the surgery.

Surgical Services Billed by an Outpatient Surgical Facility or Freestanding Surgery Centers

Services of a surgical facility or a freestanding surgery center licensed, or certified for Medicare, by the state in which it is located and have an effective peer review program to assure quality and appropriate patient care. The surgical

procedure performed in a surgical facility or a freestanding surgery center is recognized as a procedure which can be safely and effectively performed in an Outpatient setting.

The Plan will pay for a Recovery Care Bed when Medically Necessary and provided for less than 24 hours. Payment will not exceed the semiprivate room rate that would be billed for an inpatient stay.

Surgical Services Billed by a Hospital (Inpatient and Outpatient)

Services of a Hospital for surgical procedures and the care of fractures and dislocations performed in an Outpatient or inpatient setting, including the usual care before and after surgery.

Telemedicine

Benefits for services provided by Telemedicine when such services are Medically Necessary Covered Medical Expenses provided by a Covered Provider.

Therapies for Down Syndrome

Benefits will be provided for the diagnosis and treatment of Down syndrome for a covered child under 19 years of age. Covered services include:

- Medically Necessary Habilitative Care or Rehabilitative Care that is prescribed, provided, or ordered by a licensed Physician, including but not limited to professional, counseling, and guidance services and treatment programs. Habilitative Care and Rehabilitative Care includes Medically Necessary interactive therapies derived from evidence-based research, including intensive intervention programs and early intensive behavioral intervention.
- Medically Necessary therapeutic care that is provided by a licensed speech-language pathologist a physical therapist or an occupational therapist;

When treatment is expected to require extended services, Blue Cross and Blue Shield of Montana may request that the treating Physician provide a treatment plan based on evidence-based screening criteria. The treatment plan will consist of the diagnosis, proposed treatment by type and frequency, the anticipated duration of treatment, the anticipated outcomes stated as goals, and the reasons the treatment is Medically Necessary. Blue Cross and Blue Shield of Montana may request that the treatment plan be updated every 6 months.

Therapies - Outpatient

Services provided for Physical Therapy, Speech Therapy, cardiac therapy and Occupational Therapy, not including Rehabilitation Therapy.

Transplants

For certain transplants, Blue Cross and Blue Shield of Montana contracts with a number of Centers of Excellence that provide transplant services. Blue Cross and Blue Shield of Montana highly recommends use of the Centers of Excellence because of the quality of the outcomes at these facilities. Members being considered for a transplant procedure are encouraged to contact Blue Cross and Blue Shield of Montana Customer Service to discuss the possible benefits of utilizing the Centers of Excellence.

Transplant services include:

1. Organ procurement including transportation of the surgical/harvesting team, surgical removal of the donor organ, evaluation of the donor organ and transportation of the donor or donor organ to the location of the transplant operation.
2. Donor services including the pre-operative services, transplant related diagnostic lab and x-ray services, and the transplant surgery hospitalization. Transplant related services are covered for up to six months after the transplant.
3. Hospital Inpatient Care services.
4. Surgical services.
5. Anesthesia.
6. Professional provider and diagnostic Outpatient services.

7. Licensed ambulance travel or commercial air travel for the Member receiving the treatment to the nearest Hospital with appropriate facilities.

Payment by The Plan is subject to the following conditions:

1. When both the transplant recipient and donor are members, both will receive Benefits.
2. When the transplant recipient is a Member and the donor is not, both will receive Benefits to the extent that benefits for the donor are not provided under other hospitalization coverage.
3. When the transplant recipient is not a Member and the donor is, the donor will receive Benefits to the extent that benefits are not provided to the donor by hospitalization coverage of the recipient.

The Plan will not pay for:

1. Experimental/Investigational/Unproven procedures.
2. Transplants of a nonhuman organ or artificial organ implant.
3. Donor searches.

Preauthorization is required for Transplants. Please refer to the section entitled Preauthorization.

Well-Child Care

Well-child care provided by a Physician or a health care professional supervised by a Physician.

Benefits shall include coverage for:

1. Histories;
2. Physical examinations;
3. Developmental assessments;
4. Anticipatory guidance;
5. Laboratory tests;
6. Routine immunizations.

EXCLUSIONS AND LIMITATIONS

All Benefits provided under this Contract are subject to the Exclusions and limitations in this section and as stated under the Benefit section. **The Plan will not pay for:**

1. All services, supplies, drugs and devices which are provided to treat any Illness or Injury arising out of employment when the Member's employer has elected or is required by law to obtain coverage for Illness or Injury under state or federal Workers' Compensation laws, occupational disease laws, or similar legislation, including employees' compensation or liability laws of the United States. This Exclusion applies to all services and supplies provided to treat such Illness or Injury even though:
   a. Coverage under the government legislation provides benefits for only a portion of the services incurred.
   b. The employer has failed to obtain such coverage required by law.
   c. The Member waives his or her rights to such coverage or benefits.
   d. The Member fails to file a claim within the filing period allowed by law for such benefits.
   e. The Member fails to comply with any other provision of the law to obtain such coverage or benefits.
   f. The Member was permitted to elect not to be covered by the Workers' Compensation Act but failed to properly make such election effective.

   This Exclusion will not apply if the Member is permitted by statute not to be covered and the Member elects not to be covered by the Workers' Compensation Act, occupational disease laws, or liability laws.

   This Exclusion will not apply if the Member's employer was not required and did not elect to be covered under any Workers' Compensation, occupational disease laws or employer's liability acts of any state, country, or the United States.

2. Services, supplies, drugs and devices which the Member is entitled to receive or does receive from TRICARE, the Veteran's Administration (VA), and Indian Health Services but not Medicaid. This Exclusion is not intended to exclude Covered Medical Expenses from coverage if a Member is a resident of a Montana State institution when Benefits are provided.

   Note: Under some circumstances, the law allows certain governmental agencies to recover for services rendered to the Member. When such a circumstance occurs, the Member will receive an explanation of benefits.

3. Services, supplies, drugs and devices to treat any Injury or Illness resulting from war, declared or undeclared, insurrection, rebellion, or armed invasion.

4. Any loss for which a contributing cause was commission by the Member of a felony, or attempt to commit a felony. This exclusion does not apply if the loss is related to being a victim of domestic violence or if the commission of the felony is related to a preexisting medical condition.

5. Services for which a Member is not legally required to pay or charges that are made only because Benefits are available under this Contract.

6. Services, supplies, drugs and devices provided to the Member before the Member's Effective Date or after the Member's coverage terminates.

7. Nonsurgical treatment for malocclusion of the jaw, including services for temporomandibular joint dysfunction, anterior or internal dislocations, derangements and myofascial pain syndrome, orthodontics (dentofacial orthopedics), or related appliances.

8. Orthodontics.

9. All dental services, including but not limited to ridge augmentation and vestibuloplasty, whether performed by Physicians, dentists, oral surgeons and/or any other provider, except for services provided as the result of a Dental Accident.

10. Vision services, including but not limited to prescription, fitting or provision of eyeglasses or contact lenses and Lasik Surgery, except for services covered under the Pediatric Vision Care Benefit. In addition, vision services may be covered for specific conditions in Medical Policy.

11. Hearing aids, except that Medically Necessary cochlear implants may be covered per Medical Policy.

12. Cosmetic services except when provided to correct a condition resulting from an Accident, a condition resulting from an Injury or to treat a congenital anomaly, as applicable in Medical Policy.

13. For travel by a Member or provider.

14. Any service or procedure which is determined by The Plan to be an Inclusive Service/Procedure.

15. Any services, supplies, drugs and devices which are:

    a. Experimental/Investigational/Unproven services, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.
    b. Not accepted standard medical practice. The Plan may consult with physicians or national medical specialty organizations for advice in determining whether the service or supply is accepted medical practice.
    c. Not a Covered Medical Expense.
    d. Not Medically Necessary.
    e. Not covered under applicable Medical Policy.

16. Any services, supplies, drugs and devices considered to be Experimental/Investigational/Unproven and which are provided during a Phase I or II clinical trial, or the experimental or research arm of a Phase III clinical trial, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial. This includes services, supplies, drugs and devices under study to determine the maximum tolerated dosage(s), toxicity, safety, efficacy or efficacy as compared with standard treatment, or for the diagnosis of the condition in question.

17. Transplants of a nonhuman organ or artificial organ implant.

18. Private duty nursing.

19. Procedures, equipment, services, supplies, or charges for abortions for which Federal funding is prohibited. Federal funding is allowed for abortions in the case of rape or incest, or for a pregnancy which, as certified by a physician, places the woman in danger of death unless an abortion is performed.

20. Reversal of an elective sterilization.

21. Services, supplies, drugs and devices related to in vitro fertilization.

22. Routine foot care for Members without co-morbidities, except Routine foot care is covered if a Member has co-morbidities such as diabetes.

23. Treatment of flat foot conditions and the prescription of supportive devices for such conditions and the treatment of subluxations of the foot.

24. Foot orthotics.

25. Services, supplies, drugs and devices related to treatment for psychological or psychogenic sexual dysfunctions.

26. Services, supplies, drugs and devices relating to any of the following treatments or related procedures:

- **a.** Homeopathy.
- **b.** Hypnotherapy.
- **c.** Rolfing.
- **d.** Holistic medicine.
- **e.** Religious counseling.
- **f.** Self-help programs.

27. Services provided by a massage therapist.

28. Sanitarium care, custodial care, rest cures, or convalescent care to help the Member with daily living tasks. Examples include but are not limited to, help in:

- **a.** Walking.
- **b.** Getting in and out of bed.
- **c.** Bathing.
- **d.** Dressing.
- **e.** Feeding.
- **f.** Using the toilet.
- **g.** Preparing special diets.
- **h.** Supervision of medication which is usually self-administered and does not require the continuous attention of medical personnel.

No payment will be made for admissions or parts of admissions to a Hospital, skilled nursing facility, or extended care facility for the types of care outlined in this exclusion.

29. Over-the-counter food supplements, formulas, and/or Medical Foods, regardless of how administered except when used for Inborn Errors of Metabolism.

30. Services, supplies, drugs and devices for the surgical treatment of any degree of obesity, whether provided for weight control or any medical condition.

31. Services, supplies, drugs and devices for weight reduction or weight control. This Exclusion does not include intensive behavioral dietary counseling when services are provided by a Physician, Physician Assistant or Nurse Practitioner.

32. Charges associated with health clubs, weight loss clubs or clinics.

33. Services, supplies, drugs and devices for the treatment of Illness, Injury and/or complications resulting from services that are not Covered Medical Expenses, except for any services, supplies, drugs and devices which are Routine Patient Costs incurred in connection with an Approved Clinical Trial.

34. Tutoring services.

35. Any services, supplies, drugs and devices not provided in or by a Covered Provider.

36. Services, supplies, drugs and devices primarily for personal comfort, hygiene, or convenience which are not primarily medical in nature.

37. Deluxe medical equipment including, but not limited to, durable medical equipment, prosthetics and communication devices except as included in the Durable Medical Equipment Benefit and the Prosthetic Benefit in the section entitled "Benefits."

38. All services, supplies, drugs and devices provided to treat any Illness or Injury arising out of employment as an athlete by or on a team or sports club engaged in any contact sport that includes significant physical contact between the athletes involved, including but not limited to football, hockey, roller derby, rugby, lacrosse, wrestling and boxing, where the Member's employer is not required by law to obtain coverage for Illness or Injury under state or federal workers' compensation, occupational disease or similar laws.

39. Applied Behavior Analysis (ABA) services, except as specifically included in this Contract under Autism Spectrum Disorders.

40. Services, supplies, drugs and devices provided outside of the United States, except if such services are provided as the result of an Emergency Medical Condition.

41. Services, supplies, drugs and devices which are not listed as a Benefit as described in this Contract.

CLAIMS

How to Obtain Payment for Covered Expenses for Benefits

1. If a Member obtains benefits from a Participating Provider, the Participating Provider will submit claims to The Plan for the Member. If a Member obtains benefits from a nonparticipating provider, the Member may be required to submit all claims to The Plan. All claims for services must be submitted on or before December 31 of the calendar year following the year in which services were received. All claims must provide enough information about the services for The Plan to determine whether or not they are a Covered Medical Expense. Submission of such information is required before payment will be made. In certain instances, Blue Cross and Blue Shield of Montana may require that additional documents or information including, but not limited to, accident reports, medical records, and information about other insurance coverage, claims, payments and settlements, be submitted within the timeframe requested for the additional documentation before payment will be made.

However, claims for prescription drugs purchased from a nonparticipating pharmacy must be submitted within one year from the date of purchase.

2. If a Member purchases drugs or Prescription Drug Products at a Value Participating Pharmacy, a Participating Pharmacy or a mail order pharmacy approved by The Plan, and the ID card is presented at the time of purchase, the Member must pay for the Prescription Drug Product and the Participating Pharmacy will submit a claim for the cost of the covered prescription drug or Prescription Drug Product to The Plan's Pharmacy Benefit Manager. The cost of the covered drug or Prescription Drug Product will then accumulate to the Member's Deductible and Out-of-Pocket Amount. Once the Deductible, if applicable, is met, the Member will only be required to pay the appropriate Copayment and/or Coinsurance if the amount can be determined by the pharmacy at the time of purchase.

If a Member purchases drugs or Prescription Drug Products at a nonparticipating pharmacy, the Member must pay for the prescription at the time of dispensing and then within one year of the date of purchase submit a claim for the prescription drug on a form to The Plan's Pharmacy Benefit Manager for reimbursement. The Member

will be reimbursed for the prescription drug at 50% of the amount that would have been paid to a Participating Pharmacy, less any Deductible, Copayment and/or Coinsurance.

3. Claims must be submitted to the address listed on the inside cover of this Contract.

Prescription Drug Claims - Filling Prescriptions at a Retail Pharmacy

Outpatient prescription drugs are available through the Prime Therapeutics Prescription Drugs Benefit. Prime Therapeutics is the Pharmacy Benefit Manager.

1. Go to a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy that accepts Member ID cards. To find out if a pharmacy takes part in the program, ask the pharmacist. To find a Prime Therapeutics Value Participating Pharmacy or a Participating Pharmacy nearest the Member, check the list on the website www.bcbsmt.com or call the pharmacy locator at the telephone number on the inside cover of this document.
2. Present the prescription and the Member's ID card to the pharmacist.
3. Make sure that the pharmacist has complete and correct information about the Member for whom the prescription is written, including sex and date of birth.
4. When the Member receives a prescription, he or she should sign the pharmacy log and pay his or her share of the cost.
5. If a Member purchases prescription drugs from a participating outpatient pharmacy or mail-service pharmacy approved by The Plan, the Member must pay for the Prescription Drug Product and the pharmacy will submit the prescription drug claims to Prime Therapeutics.
6. The Member must pay the difference between a Brand-Name drug and the Generic equivalent if the Member purchases a Brand-Name prescription drug when a Generic drug substitute is available.
7. The Plan makes use of a Drug List, which is a list of covered prescription drugs for dispensing to Members as appropriate.
8. For prescriptions filled at a pharmacy that is not part of the network, the Member will need to pay the pharmacist the entire cost of the prescription at the time the prescription is filled and dispensed and submit a paper claim to Prime Therapeutics for reimbursement. If a Member does not present his or her ID card at a Participating Pharmacy, a paper claim must be submitted by the Member to Prime Therapeutics for reimbursement. The Member will be reimbursed at 50% of the contracted rate minus Deductible, Copayment and/or Coinsurance, if applicable, in both situations. The Member will not receive the preferred pricing.
9. Prescriptions filled at Hospital pharmacies are not eligible for reimbursement unless they are listed as a network pharmacy.

Prime Therapeutics claim forms are available by calling The Plan at the telephone number on the inside cover of this document.

Mail-Service Pharmacy

A convenient way to get maintenance prescriptions is through the mail. Maintenance prescriptions are those that the Member expects to continue using for an extended period of time and for which a prescription can be written for up to a 90-day supply. Coverage for costly prescriptions should be verified prior to ordering. Specific Benefits are outlined in the Prescription Drugs section in this document.

Ordering prescriptions through the mail service pharmacy is very easy. To obtain a mail service claim form, call The Plan at the telephone number on the inside cover of this document.

To order a prescription:

1. Complete all sections and sign the Mail-Service order form.
2. Enclose the following:
   a. the original prescription written for a 90-day supply;
   b. the Member's current pharmacy telephone number, prescription numbers to be transferred; and
   c. the Member's telephone number.
3. Mail the form to the mail service pharmacy at the address listed on the form.

COORDINATION OF BENEFITS WITH OTHER INSURANCE

The Coordination of Benefits (COB) provision applies when a Member has health care coverage under more than one plan. "Plan" is defined below.

The order in which each plan will make payment for Covered Medical Expenses is governed by the order of benefit determination rules. The plan that pays first is called the primary plan. The primary plan must pay Covered Medical Expenses in accordance with its Contract terms without regard to the possibility that another plan may cover some expenses. The plan that pays after the primary plan is the secondary plan. The secondary plan may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Definitions

For the purpose of this section only, the following definitions apply:

Plan

Any of the following that provide benefits, or services, for medical or dental care or treatment include:

1. group and nongroup health insurance contracts;
2. health maintenance organization (HMO) contracts;
3. Closed Panel Plans or other forms of group or group type coverage (whether insured or uninsured);
4. medical care components of long-term care contracts, such as skilled nursing care; and
5. Medicare or any other federal governmental plan, as permitted by law.

The term plan does not include:

1. excepted benefits pursuant to 33-22-140(8)(a), (b), (c), (d), (e), (f), (g), (h), (j), and (k), MCA;
2. school accident type coverage;
3. benefits for non-medical components of long-term care policies; or
4. a governmental plan, which, by law, provides benefits that are in excess of those of any private insurance plan or other nongovernmental plan.

Each contract for coverage is a separate plan. If a plan has two parts and COB rules apply only to one of the two, each of the parts is treated as a separate plan.

This Plan

In a COB provision, "this plan" means that part of the Contract providing the health care benefits to which the COB provision applies and which may be reduced because of the benefits of other plans. Any other part of the Contract providing health care benefits is separate from this plan. A contract may apply one COB provision to certain benefits, such as dental benefits, coordinating only with similar benefits, and may apply another COB provision to coordinate other benefits.

Order of Benefit Determination Rules

The rules that determine whether this plan is a primary plan, or secondary plan, when the person has health care coverage under more than one plan.

1. When this plan is primary, it determines payment for Covered Medical Expenses first before those of any other plan without considering any other plan's benefits.
2. When this plan is secondary, it determines its benefits after those of another plan and may reduce payment for Covered Medical Expenses so that payment by all plans does not exceed 100% of the total allowable expense.

Allowable Expense

A Covered Medical Expense, including deductibles, coinsurance and copayments, that is covered at least in part by any plan covering the Member. When a plan provides benefits in the form of services, the reasonable cash value of each service will be considered an allowable expense and a benefit paid. An expense that is not covered by any plan covering the Member is not an allowable expense. In addition, any expense that a provider by law or in accordance with a contractual agreement is prohibited from charging a Member is not an allowable expense.

The following are examples of expenses that are not allowable expenses:

1. The difference between the cost of a semi-private hospital room and a private hospital room is not an allowable expense, unless one of the plans provides coverage for private hospital room expenses.
2. If a Member is covered by two or more plans that compute their benefit payments on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology, any amount in excess of the highest reimbursement amount for a specific benefit is not an allowable expense.
3. If a Member is covered by two or more plans that provide benefits or services on the basis of negotiated fees, an amount in excess of the highest of the negotiated fees is not an allowable expense.
4. If a Member is covered by one plan that calculates its benefits or services on the basis of usual and customary fees or relative value schedule reimbursement methodology or other similar reimbursement methodology and another plan that provides its benefits or services on the basis of negotiated fees, the primary plan's payment arrangement shall be the allowable expense for all plans. However, if the provider has contracted with the secondary plan to provide the benefit or service for a specific negotiated fee or payment amount that is different than the primary plan's payment arrangement and if the provider's contract permits, the negotiated fee or payment shall be the allowable expense used by the Secondary plan to determine its benefits.
5. The amount of any benefit reduction by the primary plan because a Member has failed to comply with the plan provisions is not an allowable expense. Examples of these types of plan provisions include second surgical opinions, precertification of admissions, and preferred provider arrangements.

Closed Panel Plan

A plan that provides health care benefits to covered persons primarily in the form of services through a panel of providers that have contracted with or are employed by the plan, and that excludes coverage for services provided by other providers, except in cases of emergency or referral by a panel member.

Custodial Parent

The parent awarded custody by a court decree or, in the absence of a court decree, is the parent with whom the child resides more than one half of the calendar year excluding any temporary visitation.

Order of Benefit Determination Rules

When a Member is covered by two or more plans, the rules for determining the order of benefit payments are as follows:

1. The primary plan pays or provides its benefits according to its terms of coverage and without regard to the benefits of under any other Plan; and
2. Except as provided below, a plan that does not contain a COB provision that is consistent with this regulation is always primary unless the provisions of both plans state that the complying plan is primary.

   Coverage that is obtained by virtue of membership in a group that is designed to supplement a part of a basic package of benefits, and provides that this supplementary coverage, shall be excess to any other parts of the plan provided by the Group. Examples of these types of situations are major medical coverages that are superimposed over base plan hospital and surgical benefits, and insurance type coverages that are written in connection with a closed panel plan to provide out-of-network benefits.

3. A plan may consider the benefits paid or provided by another plan in calculating payment of its benefits only when it is secondary to that other plan.

4. Each plan determines its order of benefits using the first of the following rules that apply:

   Non-Dependent or Dependent.

   The plan that covers the person as an employee or retiree is the primary plan and the plan that covers the employee or retiree as a dependent is the secondary plan. However, if the person is a Medicare beneficiary and, as a result of federal law, Medicare is secondary to the plan covering the person as a dependent; and primary to the plan covering the person as other than a dependent (e.g., a retired employee); then the order of benefits between the two plans is reversed so that the plan covering the person as an employee or retiree is the secondary plan and the other plan is the primary plan.

Dependent Child Covered Under More Than One Plan.

Unless there is a court decree stating otherwise, when a dependent child is covered by more than one plan, the order of benefits is determined as follows:

1. **Dependent Child - Parents are married or are living together**

   a. The plan of the parent whose birthday falls earlier in the calendar year is the primary plan; or

   b. If both parents have the same birthday, the plan that has covered the parent the longest is the primary plan.

2. **Dependent Child - Parents are divorced or separated or not living together**

   a. If a court decree states that one of the parents is responsible for the dependent child's health care expenses or health care coverage and the plan of that parent has actual knowledge of those terms, that plan is primary. This rule applies to plan years commencing after the plan is given notice of the court decree;

   b. If a court decree states that both parents are responsible for the dependent child's health care expenses or health care coverage, the provisions of (a) above shall determine the order of benefits;

   c. If a court decree states that the parents have joint custody without specifying that one parent has responsibility for the health care expenses or health care coverage of the dependent child, the provisions of (a) above shall determine the order of benefits; or

   d. If there is no court decree allocating responsibility for the dependent child's health care expenses or health care coverage, the order of benefits for the child are as follows:

   - The plan covering the custodial parent;
   - The plan covering the Spouse of the custodial parent;
   - The plan covering the non-custodial parent; and then;
   - The plan covering the Spouse of the non-custodial parent.

3. **Dependent Child Covered Under More than One Plan of Individuals Who Are Not the Parents of the Child**

   The provisions of (1) or (2) above shall determine the order of benefits as if those individuals were the parents of the child.

4. **Active Employee or Retired or Laid-off Employee**

   The plan that covers a person as an active employee, that is, an employee who is neither laid off nor retired, (or is a dependent of such employee) is the primary plan. The plan covering that same person as a retired or laid-off employee (and the dependent of such employee) is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

5. **COBRA or State Continuation Coverage**

   If a person whose coverage is provided pursuant to COBRA or under a right of continuation provided by state or other federal law is covered under another plan, the plan covering the person as an employee or retiree or covering the person as a dependent of an employee or retiree is the primary plan and the COBRA or state or other federal continuation coverage is the secondary plan. If the other plan does not have this rule, and as a result, the plans do not agree on the order of benefits, this rule is ignored. This rule does not apply if the section Non-Dependent or Dependent can determine the order of benefits.

6. **Longer or Shorter Length of Coverage**

   The plan that covered the person as an employee or retiree longer is the primary plan and the plan that covered the person the shorter period of time is the secondary plan.

If the preceding rules do not determine the order of benefits, the allowable expenses shall be shared equally between the plans meeting the definition of plan. In addition, this plan will not pay more than it would have paid had it been the primary plan.

Effect on the Benefits of This Plan

When this plan is secondary, it may reduce its benefits so that the total benefits paid or provided by all plans during a plan year are not more than the total allowable expenses. In determining the amount to be paid for any claim, the secondary plan will calculate the benefits it would have paid in the absence of other health care coverage and apply that calculated amount to any allowable expense under its plan that is unpaid by the primary plan. The secondary plan may then reduce its payment by the amount so that, when combined with the amount paid by the primary plan, the total benefits paid or provided by all plans for the claim do not exceed the total allowable expense for that claim. In addition, the secondary plan shall credit to its plan deductible any amounts it would have credited to its deductible in the absence of other health care coverage.

If a covered person is enrolled in two or more closed panel plans and if, for any reason, including the provision of service by a non-panel provider, benefits are not payable by one closed panel plan, COB shall not apply between that plan and other closed panel plans.

Right to Receive and Release Needed Information

Certain facts about health care coverage and services are needed to apply these COB rules and to determine benefits payable under this plan and other plans. Blue Cross and Blue Shield of Montana may get the facts it needs from or give them to other organizations or persons for the purpose of applying these rules and determining benefits payable under this plan and other plans covering the Member claiming benefits. Blue Cross and Blue Shield of Montana need not inform, or get the consent of, any person to do this. Each Member claiming benefits under this plan must give Blue Cross and Blue Shield of Montana any facts it needs to apply those rules and determine benefits payable.

Facility of Payment

A payment made under another plan may include an amount that should have been paid under this plan. If it does, Blue Cross and Blue Shield of Montana may pay that amount to the organization that made that payment. That amount will then be treated as though it were a benefit paid under this plan. Blue Cross and Blue Shield of Montana will not have to pay that amount again. The term "payment made" includes providing benefits in the form of services, in which case "payment made" means the reasonable cash value of the benefits provided in the form of services.

Right of Recovery

If the amount of the payments made by Blue Cross and Blue Shield of Montana is more than it should have paid under this COB provision, it may recover the excess from one or more of the Members it has paid or for whom it has paid; or any other person or organization that may be responsible for the benefits or services provided for the Member. The "amount of the payments made" includes the reasonable cash value of any benefits provided in the form of services.

Coordination With Medicare

To the extent Medicare pays for benefits, then benefits paid under Medicare will be determined BEFORE Benefits are paid under this Contract. Benefits under this Contract are, therefore, SECONDARY to Medicare. If Medicare does not pay benefits, then this Contract will pay PRIMARY.

The combined payments by Medicare and The Plan will not exceed the charges for the covered services the Member receives.

Other Insurance

If a property or casualty insurer pays for services provided to the Member and coordination of benefits is not applicable, The Plan will credit the Member's Deductible, Copayment or Coinsurance, as applicable, if the Member notifies The Plan of the payment, within 12 months of the date of service.

GENERAL PROVISIONS

Term

The term of this Contract is shown on the Schedule of Benefits. This Contract may be renewed as The Plan consents at dues set by The Plan.

Entire Contract; Changes

This Contract, including written riders, endorsements and attached papers, if any, constitutes the entire Contract between Blue Cross and Blue Shield of Montana and the Beneficiary Member. No change to this Contract is valid until made pursuant to the section entitled Modification of Contract.

Modification of Contract

The Plan may make administrative changes or changes in dues, terms or Benefits in this Contract by giving written notice to the Beneficiary Member at least 45 days before the Effective Date of the changes. Dues may not be increased more than once during a 12-month period, except as allowed by Montana law.

No other agent or representative or employee of The Plan may change any part of this Contract. No change in the Contract will be valid unless in writing and signed by the President of Blue Cross and Blue Shield of Montana.

Clerical Errors

No clerical error on the part of The Plan shall operate to defeat any of the rights, privileges, or Benefits of any Member covered under this Contract. Upon discovery of errors or delays, an equitable adjustment of charges and Benefits will be made. Clerical errors shall not prevent administration of the Contact in strict accordance with its terms.

Conformity With State Statutes

The provisions of this Contract conform to the minimum requirements of Montana law and have control over any conflicting statutes of any state in which the Beneficiary Member or any Dependent may have health services on or after the Effective Date of this Contract.

Forms for Proof of Loss

The Plan shall furnish, upon written request of a Member claiming to have a loss under this Contract, forms of proof of loss for completion by the Member. The Plan shall not, by reason of the requirement to furnish such forms, have any responsibility for or with reference to the completion of such form or the manner of any such completion or attempted completion.

Proofs of Loss

Written proof of loss must be furnished to The Plan at its said office in case of claim for loss for which this policy provides any periodic payment contingent upon continuing loss within 90 days after the termination of the period for which The Plan is liable and in case of claim for any other loss within 90 days after the date of such loss. Failure to furnish such proof within the time required shall not invalidate or reduce any claim if it was not reasonably possible to give proof within such time, provided such proof is furnished as soon as reasonably possible and in no event, except in the absence of legal capacity, later than 1 year from the time proof is otherwise required.

Time of Payment of Claims

Indemnities payable under this Contract for any loss other than loss for which this Contract provides any periodic payment will be paid immediately upon receipt of due written proof of such loss. Subject to due written proof of loss, all accrued indemnities for loss for which this Contract provides periodic payment will be paid monthly, and any balance remaining unpaid upon the termination of liability will be paid immediately upon receipt of due written proof.

Notices Under Contract

Any notice required by this Contract may be given by United States mail, postage paid. Notice to the Beneficiary Member will be mailed to the address appearing on the records of The Plan. Notice to The Plan must be sent to Blue Cross and Blue Shield of Montana at the address listed on the inside cover of this Contract. Any time periods included in a notice shall be measured from the date the notice was mailed.

A Beneficiary Member or Family Member may reasonably request, in writing, that any communication of the Member's health information be sent to an alternate address or by alternative means should disclosure of any of the Member's health information endanger the Member.

Notice of Annual Meeting

The Policyholder is hereby notified that the Policyholder is a Member of Health Care Service Corporation, a Mutual Legal Reserve Company, and is entitled to vote either in person, by proxy, at all meetings of Members of Blue Cross and Blue Shield. The annual meeting is held at our principal office at 300 East Randolph Street, Chicago, Illinois each year on the last Tuesday in October at 12:30 p.m.

The term "Member" as used above refers only to the person to whom this Contract has been issued. Under Family Coverage, the term "Member" does not include any person other than the Policyholder unless such person is acting upon the Policyholder's behalf.

Rescission of Contract

This Contract is subject to rescission if the Member commits an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of a material fact, concerning a Member's health, claims history, or current receipt of health care services.

Contract Not Transferable by the Member

No person, other than the Beneficiary Member or a Family Member listed on the subscriber application for membership and accepted by The Plan, is entitled to Benefits under this Contract. This Contract is not transferable to any other person.

Validity of Contract

If any part, term, or provision of this Contract is held by the courts to be illegal or in conflict with or not in compliance with any applicable law of the state of Montana or the United States, this Contract shall not be rendered invalid but shall be construed and applied in accordance with such provisions as would have applied had this Contract been in conformance with applicable law and the validity of the remaining portions or provisions shall not be affected. The rights and obligations of the parties shall be construed and enforced as if this Contract did not contain the particular part, term, or provision held to be invalid.

Execution of Papers

The Member agrees to execute and deliver any documents requested by The Plan which are necessary to administer the terms of this Contract.

Members Rights

Members have only those rights as specifically provided in this Contract. In addition, when requested by the insured or the insured's agent, Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

Alternate Care

The Plan may, at its sole discretion, make payment for services which are not listed as a Benefit of this Contract in order to provide quality care at a lesser cost. Such payments will be made only upon mutual agreement by the Member and The Plan.

Benefit Maximums

Once The Plan pays the maximum amount for a specific Benefit, no further payment will be made for that specific condition under any other provisions of this Contract.

Legal Actions

No action at law or inequity shall be brought to recover on this Contract prior to the expiration of 60 days after written Proof of Loss has been furnished in accordance with the requirements of this Contract. No such action shall be brought after the expiration of three years after the written Proof of Loss is required to be furnished.

Physical Examinations

Blue Cross and Blue Shield of Montana, at its own expense, shall have the right and opportunity to examine the person of a Member when and as often as it may reasonably require during the pending of a claim.

Pilot Programs

The Plan reserves the right to develop and enter into pilot programs under which health care services not normally covered under this Contract will be paid. The existence of a pilot program does not guarantee any Member the right to participate in the pilot program or that the pilot program will be permanent.

Fees

The Plan reserves the right to charge the Member a reasonable fee for providing information or documents to the Member which were previously provided in writing to the Member. Fees may be charged for the costs of copying labor, supplies and postage. Fees will not be charged for searching for and retrieving the requested information.

Time Limit on Certain Defenses

After two years from the date of issue of this Contract, no misstatements, except fraudulent misstatements, made by the applicant in the application for such Contract shall be used to void the Contract or to deny a claim for loss incurred commencing after the expiration of such two-year period.

Acceptance of this Contract

When The Plan approves the Member's application and the Member pays the first Month's dues, this Contract is accepted by both parties.

Previous Contract Superceded

This Contract voids any previous Contract between The Plan and the Member.

Subrogation

1. To the extent that Benefits have been provided or paid under this Contract, The Plan may be entitled to subrogation against a judgment or recovery received by a Member from a third party found liable for a wrongful act or omission that caused the Injury requiring payment for Benefits.
2. The Member will take no action through settlement or otherwise which prejudices the rights and interest of The Plan under this Contract.
3. If the Member intends to institute an action for damages against a third party, the Member will give The Plan reasonable notice of intention to institute the action. Reasonable notice will include information reasonably calculated to inform The Plan of facts giving rise to the third party action and of the prospects for recovery.
4. The Member may request that The Plan pay a proportional share of the reasonable costs of the third-party action, including attorney fees. If The Plan elects not to participate in the cost of the action, The Plan waives 50 percent of its subrogation interest.
5. The right of subrogation may not be enforced until the Member has been completely compensated for the injuries.

When the Member Moves Out of State

If the Member moves to an area served by another Blue Cross or Blue Shield plan, the Member's coverage will be transferred to the plan serving the new address. The new plan must offer coverage that is in compliance with the conversion laws of that state. This coverage is that which is normally provided to Members who leave a group and apply for new coverage as individuals. Although subject to the conversion laws of that state, such coverage is usually provided without a medical examination or health statement. If the Member accepts the conversion coverage, the new plan will credit the Member for the length of time of enrollment with Blue Cross and Blue Shield of Montana toward any of its own waiting periods. Any physical or mental conditions covered by The Plan will be covered by the new plan without a new waiting period if the new plan offers this feature to others carrying the same type of coverage. The premium rate and benefits available from the new plan may vary significantly from those offered by The Plan.

The new plan may also offer other types of coverage that are outside of the transfer program. This coverage may require a medical examination or health statement to exclude coverage for preexisting conditions and may not apply time enrolled in Blue Cross and Blue Shield of Montana to waiting periods.

Independent Relationship

Participating Providers furnishing care to a Member do so as independent contractors with The Plan; however, the choice of a provider is solely the Member's. Under the laws of Montana, The Plan cannot be licensed to practice medicine or surgery and The Plan does not assume to do so. The relationship between a provider and a patient is personal, private, and confidential. The Plan is not responsible for the negligence, wrongful acts, or omissions of any providers, or provider's employees providing services, or Member receiving services. The Plan is not liable for services or facilities which are not available to a Member for any reason.

Blue Cross and Blue Shield of Montana as an Independent Plan

The Member, hereby expressly acknowledges its understanding that this Contract constitutes a contract solely between the Member and The Plan, that The Plan is an independent corporation operating under a license with the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans (the "Association") permitting The Plan to use the Blue Cross and Blue Shield Service Mark in the state of Montana, and that The Plan is not contracting as the agent of the Association. The Member further acknowledges and agrees that it has not entered into this Contract based upon representations by any person other than The Plan and that no person, entity, or organization other than The Plan shall be held accountable or liable to the Member for any of The Plan's obligations to the Member created under this contract. This paragraph shall not create any additional obligations whatsoever on the part of The Plan other than those obligations created under other provisions of this Contract.

DEFINITIONS

This section defines certain words used throughout this Contract. These words are capitalized whenever they are used as defined.

ACCIDENT

An unexpected traumatic incident or unusual strain which is:

1. Identified by time and place of occurrence;
2. Identifiable by part of the body affected; and
3. Caused by a specific event on a single day.

Some examples include:

1. Fracture or dislocation.
2. Sprain or strain.
3. Abrasion, laceration.
4. Contusion.
5. Embedded foreign body.

6. Burns.
7. Concussion.

ADVANCED PRACTICE REGISTERED NURSE

Nurses who have additional professional education beyond the basic nursing degree required of a registered nurse and are considered Advanced Practice Registered Nurses by applicable state law. Advanced Practice Registered Nurses include nurse practitioners, nurse-midwives, nurse-anesthetists and clinical nurse specialists.

ALLOWABLE FEE

The Allowable Fee is based on, but not limited to, the following:

1. Medicare RBRVS based is a system established by Medicare to pay physicians for a "work unit." The RBRVS value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the Medicare RBRVS system can be considerably less than the nonparticipating providers' billed charge; or
2. Diagnosis-related group (DRG) methodology is a system used to classify hospital cases into one of approximately 500 to 900 groups that are expected to have similar hospital resource use. Payment for each DRG is based on diagnoses, procedures, age, sex, expected discharge date, discharge status, and the presence of complications. The amount of payment for each DRG is generally within a fixed range because each patient is expected to use the same level of hospital resources for the given DRG regardless of the actual hospital resources used. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the DRG system can be considerably less than the nonparticipating providers' billed charge; or
3. Billed charge is the amount billed by the provider; or
4. Case rate methodology is an all inclusive rate for an episode of care for a specific clinical condition paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the case rate system can be considerably less than the nonparticipating providers' billed charge; or
5. Per diem methodology is an all inclusive daily rate paid to a facility. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the per diem system can be considerably less than the nonparticipating providers' billed charge; or
6. Flat fee per category of service is a fixed payment amount for a category of service. For instance, a category of service could be a delivery, an imaging service, a lab service or an office visit. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to a nonparticipating providers under the flat fee per category of service system can be considerably less than the nonparticipating providers' billed charge; or
7. Flat fee per unit of service fixed payment amount for a unit of service, For instance, a unit of service could be the amount of "work units" customarily required for a delivery, or an office visit, or a surgery. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the flat fee per unit system can be considerably less than the nonparticipating providers' billed charge; or
8. Percent off of billed charge is a payment amount where a percentage is deducted from the billed charges; or
9. A percentage of Medicare allowance is a payment amount where a percentage is deducted to the amount that Medicare would allow as payment for the service; or
10. The amount negotiated with the pharmacy benefit manager or manufacturer or the actual price for prescription or drugs; or
11. The American Society of Anesthesiologists' Relative Value Guide is a system established by the American Society of Anesthesiologists to pay anesthesiologists for a "work unit." The payment value is determined by multiplying a "relative value" of the service by a "converter" to determine the value for a certain procedure. The amount of the payment is a fixed rate. Therefore, the amount paid by Blue Cross and Blue Shield of Montana to nonparticipating providers under the system can be considerably less than the nonparticipating providers' billed charge.
12. For nonparticipating providers in Montana, the Allowable Fee is developed from base Medicare reimbursements, excluding any Medicare adjustments using information on the claim, and adjusted by a predetermined factor established by the Plan. Such factor will not be less than 100% of the base Medicare reimbursement rate. For services for which a Medicare reimbursement rate is not available, the Allowable

Fee for nonparticipating providers will represent an average contract rate for Participating Providers adjusted by a predetermined factor established by the Plan and updated on a periodic basis. Such factor shall not be less than 80% of the average contract rates and will be updated not less than every 2 years. Blue Cross and Blue Shield of Montana will utilize the same claim processing rules and/or edits that it utilizes in processing Participating Provider claims for processing claims submitted by nonparticipating providers which may also alter the Allowable Fee for a particular service. In the event the Plan does not have any claim edits or rules, the Plan may utilize the Medicare claim rules or edits that are used by Medicare in processing the claims. The Allowable Fee will not include any additional payments that may be permitted under the Medicare laws or regulations which are not directly attributable to a specific claim, including but not limited to, disproportionate share and graduate medical education payments.

Any change to the Medicare reimbursement amount will be implemented by the Plan within 90 days after the effective date that such change is implemented by the Centers for Medicaid and Medicare Services, or its successor.

In the event the nonparticipating Allowable Fee does not equate to the nonparticipating provider's billed charges, the Member will be responsible for the difference, along with any applicable Copayment, Coinsurance and Deductible amount. This difference may be considerable. To find out an estimate of the Plan's nonparticipating Allowable Fee for a particular service, Members may call the customer service number shown on the back of their Identification Card.

Montana law requires Blue Cross and Blue Shield of Montana to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center, clinic or Hospital exceeds $500.

APPLIED BEHAVIOR ANALYSIS (ABA) - (ALSO KNOWN AS LOVAAS THERAPY)

Medically Necessary interactive therapies or treatment derived from evidence-based research. The goal of ABA is to improve socially significant behaviors to a meaningful degree, including:

1. increase desired behaviors or social interaction skills;
2. teach new functional life, communication, or social, skills;
3. maintain desired behaviors, such as teaching self control and self-monitoring procedures;
4. appropriate transfer of behavior from one situation or response to another;
5. restrict or narrow conditions under which interfering behaviors occur;
6. reduce interfering behaviors such as self injury.

ABA therapy and treatment includes Pivotal Response Training, Intensive Intervention Programs, and Early Intensive Behavioral Intervention, and the terms are often used interchangeably. The ABA benefit also includes Discrete Trial Training, a single cycle of behaviorally based instruction routine that is a companion treatment with ABA.

Services must be provided by an appropriately certified provider.

APPROVED CLINICAL TRIAL

Approved clinical trial means a phase I, phase II, phase III, or phase IV, clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other Life-Threatening Condition. The trial must be:

1. Conducted under an investigational new drug application reviewed by the United States Food and Drug Administration;
2. Exempt from an investigational new drug application; or
3. Approved or funded by:
   - The National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, or a cooperative group or center of any of the foregoing entities;
   - A cooperative group or center of the United States Department of Defense or the United States Department of Veterans Affairs;
   - A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes for Health for center support groups; or
   - The United States Departments of Veterans Affairs, Defense, or Energy if the study or investigation has been reviewed and approved through a system of peer review determined by the United States

Secretary of Health and Human Services to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and provide unbiased scientific review by individuals who have no interest in the outcome of the review.

BENEFICIARY MEMBER
A person who has applied for, been accepted as a Member, and maintains membership in The Plan under the terms of this Contract.

BENEFIT
Services, supplies and medications that are provided to a Member and covered under this Contract as a Covered Medical Expense.

BENEFIT PERIOD
For the Contract - Is the period of time shown in the Schedule of Benefits.

For the Member - Is the same as for the Contract except if the Member's Effective Date is after the Effective Date of the Contract, the Benefit Period begins on the Member's Effective Date and ends on the same date the Contract Benefit Period ends. Thus, the Member's Benefit Period may be less than 12 months.

BEST EVIDENCE
Means evidence based on

1. Randomized Clinical Trials;
2. A Cohort Study or Case-Control Study, if randomized clinical trials are not available;
3. A Case Series, if Randomized Clinical Trials, Cohort Studies or Case-Control Studies are unavailable;
4. An Expert Opinion, if Randomized Clinical Trials, Cohort Studies, Case-Control Studies or Case Series are unavailable.

BLUE CROSS AND BLUE SHIELD OF MONTANA PRIME SPECIALTY NETWORK
Specialty Pharmacy providers who have entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

BRAND-NAME
A drug or product manufactured by a single manufacturer as defined by a nationally recognized provider of drug product database information. There may be some cases where two manufacturers will produce the same product under one license, known as a co-licensed product, which would also be considered as a Brand-Name drug. There may also be situations where a drug's classification changes from Generic to Preferred or Non-preferred Brand-Name due to a change in the market resulting in the Generic drug being a single source, or the drug product database information changing, which would also result in a corresponding change to your payment obligations from Generic to Preferred or Non-preferred Brand-Name.

CARE MANAGEMENT
A process that assesses and evaluates options and services required to meet the Member's health care needs. Care Management may involve a team of health care professionals, including Covered Providers, The Plan and other resources to work with the Member to promote quality, cost-effective care.

CASE-CONTROL STUDY
A retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

CASE SERIES
An evaluation of a series of patients with a particular outcome, without the use of a control group.

CHEMICAL DEPENDENCY
The uncontrollable or excessive use of addictive substances including but not limited to alcohol, morphine, cocaine, heroin, opium, cannabis, barbiturates, amphetamines, tranquilizers and/or hallucinogens, and the resultant physiological and/or psychological dependency which develops with continued use of such addictive substances requiring medical care as determined by a licensed addiction counselor or other appropriate medical practitioner.

CHEMICAL DEPENDENCY TREATMENT CENTER
A treatment facility that provides a program for the treatment of Chemical Dependency pursuant to a written treatment plan approved and monitored by a Physician or addiction counselor licensed by the state. The facility

must also be licensed or approved as a Chemical Dependency Treatment Center by the department of health and human services or must be licensed or approved by the state where the facility is located.

CLINICAL PEER

A physician or other health care provider who:

1. holds a nonrestricted license in a state of the United States, and
2. is trained or works in the same or a similar specialty to the specialty that typically manages the medical condition, procedure, or treatment under review.

COHORT STUDY

A prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention.

COINSURANCE

The percentage of the Allowable Fee payable by the Member for Covered Medical Expenses. The applicable Coinsurance for In-Network Covered Medical Expenses and Out-of-Network Covered Medical Expenses is stated in the Schedule of Benefits.

CONCURRENT CARE

Medical care rendered concurrently with surgery during one Hospital admission by a Physician other than the operating surgeon for treatment of a medical condition different from the condition for which surgery was performed; or

Medical care by two or more Physicians rendered concurrently during one Hospital admission when the nature or severity of the Member's condition requires the skills of separate Physicians.

CONSULTATION SERVICES

Services of a consulting Physician requested by the attending Physician. These services include discussion with the attending Physician and a written report by the consultant based on an examination of the Member.

CONTRACT

This Contract, the Member's application and any amendments, endorsements, riders, or modifications made to it by The Plan.

CONVALESCENT HOME

An institution, or distinct part thereof, other than a Hospital, which is licensed pursuant to state or local law. A Convalescent Home is:

1. a skilled nursing facility;
2. an extended care facility;
3. an extended care unit; or
4. a transitional care unit.

A Convalescent Home is primarily engaged in providing continuous nursing care by or under the direction and supervision of a registered nurse for sick or injured persons during the convalescent stage of their Illness or injuries and is not, other than incidentally, a rest home or home for Custodial Care, or for the aged.

NOTE: A Convalescent Home shall not include an institution or any part of an institution otherwise meeting this definition, which is primarily engaged in the care and treatment of Mental Illness or Chemical Dependency.

COPAYMENT

The specific dollar amount payable by the Member for Covered Medical Expenses. The applicable Copayments are stated in the Schedule of Benefits.

COVERED MEDICAL EXPENSE

Expenses incurred for Medically Necessary services, supplies and medications that are based on the Allowable Fee and:

1. Covered under the Member Contract;
2. In accordance with Medical Policy; and
3. Provided to the Member by and/or ordered by a covered provider for the diagnosis or treatment of an active Illness or Injury or in providing maternity care.

In order to be considered a Covered Medical Expense, the Member must be charged for such services, supplies and medications.

COVERED PROVIDER

A participating or nonparticipating provider which has been recognized by Blue Cross and Blue Shield of Montana as a provider of services for Benefits described in this Contract. A provider may, because of the limited scope of practice, be covered only for certain services provided. To determine if a provider is covered, The Plan looks to the nature of the services rendered, the extent of licensure and The Plan's recognition of the provider.

Covered Providers include professional providers and facility providers including Physicians, doctors of osteopathy, dentists, optometrists, podiatrists, nurse specialists, naturopathic physicians, Advanced Practice Registered Nurses, physician assistants, Hospitals and Freestanding Surgical Facilities.

CREDITABLE COVERAGE

Coverage that the Member had for medical benefits under any of the following plans, programs and coverages:

1. a group health plan
2. health insurance coverage
3. Title XVIII, part A or B, of the Social Security Act, 42 U.S.C. 1935c through 1395i-4 or 42 U.S.C. 1395j through 1395w-4 (Medicare)
4. Title XIX of the Social Security Act, 42 U.S.C. 1396a through 1396u, other than coverage consisting solely of a benefit under section 1928, 42 U.S.C. 1396s (Medicaid)
5. Title 10, chapter 55, United States Code (TRICARE)
6. a medical care program of the Indian Health Service or of a tribal organization
7. the Montana Comprehensive Health Association provided for in 33-22-1503 (MCHA)
8. a health plan offered under Title 5, chapter 89, of the United States Code (Federal Employee Health Benefits Program)
9. a public health plan
10. a health benefit plan under Section 5(e) of the Peace Corps Act, 22 U.S.C. 2504(e)
11. a high risk pool in any state

Creditable Coverage does not include coverage consisting solely of coverage of excepted Benefits.

DEDUCTIBLE

The dollar amount each Member must pay for In-Network Covered Medical Expenses and Out-of-Network Covered Medical Expenses incurred during the Benefit Period before The Plan will make payment for any Covered Medical Expense to which the Deductible applies. The In-Network and Out-of-Network Deductibles are separate and one does not accumulate to the other.

Only the Allowable Fee for Covered Medical Expenses is applied to the Deductible. Thus, Coinsurance, Copayment, noncovered services, and amounts billed by nonparticipating providers do not apply to the Deductible and are the Member's responsibility.

If two or more Members covered under the same Family Membership satisfy the family Deductible as shown on the Schedule of Benefits in a single Benefit Period, the Deductible does not apply for the remainder of that Benefit Period for any Member of the Family Membership.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, only one In-Network or Out-of-Network Deductible will be applied to that Hospital stay (facility charges only). If the Member satisfied the Member's Deductible prior to that Hospital stay, no Deductible will be applied to that stay.

DEPENDENT

1. the Beneficiary Member's Spouse;
2. the Beneficiary Member's unmarried or married child up to age 26, including an eligible foster child;
3. children for whom the Beneficiary Member becomes legally responsible by reason of placement for adoption, as defined in Montana law; or
4. an unmarried child of the Beneficiary Member who is 26 years of age or older and disabled.

For purposes of this Contract the unmarried child will be considered disabled if the child:

1. was covered under this Contract before age 26;
2. cannot support himself/herself because of intellectual disability or physical disability; and
3. is legally dependent on the Beneficiary Member for support.

Proof of those qualifications must be supplied to The Plan within 31 days following the child's 26th birthday. Although there is no limiting age for disabled children, The Plan reserves the right to require periodic certification from the Beneficiary Member of such incapacity and dependency. Certification will not be requested more frequently than annually after the two-year period following the child's 26th birthday.

DRUG LIST

A list that identifies those Prescription Drug Products that are covered by The Plan for dispensing to Members when appropriate. This list is reviewed quarterly and subject to modification. Details can be found on the pharmacy page at www.bcbsmt.com or by visiting www.myprime.com.

EFFECTIVE DATE

For a Member - the Effective Date of a Member's coverage means the date the Member:

1. has met the requirements of The Plan stated in this Contract; and
2. is shown on the records of The Plan to be eligible to receive Benefits.

For any endorsement, rider, or amendment - the Effective Date is the date shown on the Contract unless otherwise shown on the endorsement, rider and amendment.

EMERGENCY MEDICAL CONDITION

A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition that places the health of the individual in serious jeopardy, would result in serious impairment to bodily functions, or serious dysfunction of any bodily organ or part; or with respect to a pregnant woman having contractions, that there is inadequate time to safely transfer the woman to another hospital for delivery or that a transfer may pose a threat to the health or safety of the woman or the unborn fetus.

EMERGENCY SERVICES

Services, medicines or supplies furnished or required to evaluate and treat an Emergency Medical Condition.

EVIDENCE-BASED STANDARD

The conscientious, explicit, and judicious use of the current Best Evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

EXCHANGE (Health Insurance Marketplace)

A governmental agency or non-profit entity that meets the applicable Exchange standards, and other related standards established under the applicable law, and makes Qualified Health Plans (QHP) available to Qualified Individuals and qualified employers (as these terms are defined by the Marketplace). Unless otherwise identified, this term refers to the State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

EXCLUSION

A provision which states that The Plan has no obligation under this Contract to make payment.

EXPERT OPINION

A belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN

A drug, device, biological product or medical treatment or procedure is Experimental, Investigational and/or Unproven if **The Plan determines** that:

- The drug, device, biological product or medical treatment or procedure cannot be lawfully marketed without approval of the appropriate governmental or regulatory agency and approval for marketing has not been given at the time the drug, device, biological product or medical treatment or procedure is furnished; or

- The drug, device, biological product or medical treatment or procedure is the subject of ongoing phase I, II or III clinical trials, or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or
- The prevailing opinion among peer reviewed medical and scientific literature regarding the drug, device, biological product or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

FAMILY MEMBER

A Dependent who has been accepted as a Member of the plan and enrolled by a Beneficiary Member.

FAMILY MEMBERSHIP

The family unit including the Beneficiary Member and all Family Members who have been accepted as Members of The Plan.

FREESTANDING INPATIENT FACILITY

For treatment of Chemical Dependency, it means a facility which provides treatment for Chemical Dependency in a community-based residential setting for persons requiring 24-hour supervision and which is a Chemical Dependency Treatment Center. Services include medical evaluation and health supervision; Chemical Dependency education; organized individual, group and family counseling; discharge referral to Medically Necessary supportive services; and a client follow-up program after discharge.

For treatment of Mental Illness, it means a facility licensed by the state and specializing in the treatment of Mental Illness.

GENERIC

A drug that has the same active ingredient as a Brand-Name drug and is allowed to be produced after the Brand-Name drug's patent has expired. In determining the brand or generic classification for covered drugs, Blue Cross and Blue Shield of Montana uses the generic/brand status assigned by a nationally recognized provider of drug product database information. A list of Preferred Generic drugs is available on the Blue Cross and Blue Shield of Montana website at www.bcbsmt.com. The Member may also contact Customer Service for more information.

HABILITATIVE CARE

Coverage will be provided for Habilitative Care services when the Member requires help to keep, learn or improve skills and functioning for daily living. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. other services for people with disabilities. These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

HOME INFUSION THERAPY AGENCY

A health care provider that provides home infusion therapy services.

HOSPITAL

A facility providing, by or under the supervision of licensed Physicians, services for medical diagnosis, treatment, rehabilitation and care of injured, disabled, or sick individuals. A Hospital has an organized medical staff that is on call and available within 20 minutes, 24 hours a day, 7 days a week and provides 24-hour nursing care by licensed registered nurses.

ILLNESS

An alteration in the body or any of its organs or parts which interrupts or disturbs the performance of a vital function, thereby causing or threatening pain or weakness.

IN-NETWORK

Providers who are:

1. Participating Blue Cross and Blue Shield of Montana Professional Providers;
2. Participating Blue Cross and Blue Shield of Montana Facility Providers, except for Hospitals and surgery centers;
3. PPO Hospitals and surgery centers; or

4. Blue Cross and/or Blue Shield PPO providers outside of Montana.

INCLUSIVE SERVICES/PROCEDURES
A portion of a service or procedure which is necessary for completion of the service or procedure or a service or procedure which is already described or considered to be part of another service or procedure.

INJURY
Physical damage to an individual's body, caused directly and independent of all other causes. An Injury is not caused by an Illness, disease or bodily infirmity.

INPATIENT CARE
Care provided to a Member who has been admitted to a facility as a registered bed patient and who is receiving services, supplies and medications under the direction of a Covered Provider with staff privileges at that facility. Examples of facilities to which a Member might be admitted include:

1. Hospitals;
2. Transitional care units;
3. Skilled nursing facilities;
4. Convalescent homes;
5. Freestanding inpatient facilities.

INPATIENT MEMBER
A Member who has been admitted to a facility as a registered bed patient for Inpatient Care.

LIFE-THREATENING CONDITION
Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

MEDICAL FOODS
Nutritional substances in any form that are:

1. formulated to be consumed or administered enterally under supervision of a Physician;
2. specifically processed or formulated to be distinct in one or more nutrients present in natural food;
3. intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or certain nutrients contained in ordinary foodstuffs or who have other specific nutrient requirements as established by medical evaluation; and
4. essential to optimize growth, health, and metabolic homeostasis.

MEDICAL OR SCIENTIFIC EVIDENCE
Evidence found in the following sources:

1. peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
2. peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the national institutes of health's library of medicine for indexing in Index Medicus and Excerpta Medica, published by the Reed Elsevier group;
3. medical journals recognized by the secretary of health and human services under 42 U.S.C. 1395x(t)(2)(B) of the federal Social Security Act;
4. the following standard reference compendia:
   a. the American Hospital Formulary Service Drug Information;
   b. Drug Facts and Comparisons;
   c. the American Dental Association Guide to Dental Therapeutics; and
   d. the United States Pharmacopeia;
5. findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
   a. the federal agency for healthcare research and quality;
   b. the national institutes of health;
   c. the national cancer institute;

d. the national academy of sciences;
e. the centers for medicare and medicaid services;
f. the food and drug administration; and
g. any national board recognized by the national institutes of health for the purpose of evaluating the medical value of health care services; or

6. any other medical or scientific evidence that is comparable to the sources listed in subsection 4 or 5.

MEDICAL POLICY

The policy of The Plan which is used to determine if health care services including medical and surgical procedures, medication, medical equipment and supplies, processes and technology meet the following nationally accepted criteria:

1. final approval from the appropriate governmental regulatory agencies;
2. scientific studies showing conclusive evidence of improved net health outcome; and
3. in accordance with any established standards of good medical practice.

MEDICALLY NECESSARY (FOR AUTISM, ASPERGER'S DISORDER AND PERVASIVE DEVELOPMENTAL DISORDER)

Any care, treatment, intervention, service, or item that is prescribed, provided or ordered by a Physician or psychologist and that will or is reasonably expected to:

1. Prevent the onset of an Illness, condition, Injury, or disability;
2. Reduce or improve the physical, mental, or developmental effects of an Illness, condition, or Injury, or disability; or
3. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (FOR DOWN SYNDROME)

Any care, treatment, intervention, service, or item that is prescribed, provided, or ordered by a Physician licensed in this state and that will or is reasonably expected to:

1. Reduce or improve the physical, mental, or developmental effects of Down syndrome; or
2. Assist in achieving maximum functional capacity in performing daily activities, taking into account both the functional capacity of the recipient and the functional capacities that are appropriate for a child of the same age.

MEDICALLY NECESSARY (MEDICAL NECESSITY)

Health care services that a Physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an Illness, Injury, disease or its symptoms, and that are:

1. in accordance with generally accepted standards of medical practice;
2. clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's Illness, Injury or disease; and
3. not primarily for the convenience of the patient, Physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the view of Physicians practicing in relevant clinical areas and any other relevant factors.

The fact that services were recommended or performed by a Covered Provider does not automatically make the services Medically Necessary. The decision as to whether the services were Medically Necessary can be made only after the Member receives the services, supplies, or medications and a claim is submitted to The Plan. The Plan may consult with Physicians or national medical specialty organizations for advice in determining whether services were Medically Necessary.

MEMBER

Both the Beneficiary Member and Family Members.

MEMBER'S IMMEDIATE FAMILY
The Member's Spouse and children or parents and siblings who are caring for the hospice patient in that family.

MENTAL HEALTH TREATMENT CENTER
A treatment facility organized to provide care and treatment for Mental Illness through multiple modalities or techniques pursuant to a written treatment plan approved and monitored by an interdisciplinary team, including a licensed Physician, psychiatric social worker and psychologist. The facility must be:

1. licensed as a mental health treatment center by the state;
2. funded or eligible for funding under federal or state law; or
3. affiliated with a Hospital under a contractual agreement with an established system for patient referral.

MENTAL ILLNESS
A clinically significant behavioral or psychological syndrome or pattern that occurs in a person and that is associated with:

1. present distress or a painful symptom;
2. a disability or impairment in one or more areas of functioning; or
3. a significantly increased risk of suffering death, pain, disability, or an important loss of freedom.

Mental Illness must be considered as a manifestation of a behavioral, psychological, or biological dysfunction in a person.

Mental Illness does not include:

1. developmental disorders;
2. speech disorders;
3. psychoactive substance use disorders;
4. eating disorders (except for bulimia and anorexia nervosa);
5. impulse control disorders (except for intermittent explosive disorder and trichotillomania); or
6. Severe Mental Illness.

MONTH
For the purposes of this Contract, a Month has 30 days even if the actual calendar Month is longer or shorter.

MONTHLY DUES
The amount of money which must be paid monthly by the Beneficiary Member to keep this Contract in force.

MULTIDISCIPLINARY TEAM
A group of health service providers who are either licensed, certified, or otherwise approved to practice their respective professions in the state where the services are provided. Members of the Multidisciplinary Team may include, but are not limited to, a licensed psychologist, licensed speech therapist, registered physical therapist, or licensed occupational therapist.

OCCUPATIONAL THERAPY
Therapy involving the treatment of neuromusculoskeletal and psychological dysfunction through the use of speech tasks or goal-directed activities designed to improve the functional performance of an individual.

ORTHOPEDIC DEVICES
Rigid or semirigid supportive devices which restrict or eliminate motion of a weak or diseased body part. Orthopedic Devices are limited to braces, corsets and trusses.

OUT-OF-NETWORK
Providers who are:

1. Non-participating professional providers;
2. Non-participating facility providers;
3. Non-PPO Network Hospitals and surgery centers; or
4. Blue Cross and Blue Shield of Montana Participating Hospitals and surgery centers that are not in the PPO Network.

UT OF POCKET AMOUNT
For the Member:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance each Member must pay for Covered Medical Expenses incurred during the Benefit Period. Once the Member has satisfied the applicable Out of Pocket Amount, the Member will not be required to pay the Member's Deductible, Coinsurance and Copayment for Covered Medical Expenses for the remainder of that Benefit Period. The Out of Pocket Amount for the Member is listed in the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other.

If a Member is in the Hospital on the last day of the Member's Benefit Period and continuously confined through the first day of the next Benefit Period, the Deductible and Coinsurance for the entire Hospital stay (facility charges only) will only apply to the Out of Pocket Amount of the Benefit Period in which the inpatient stay began. If the Member satisfied the Out of Pocket Amount prior to that Hospital stay, no Deductible or Coinsurance will be applied to that stay.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

For the Family:

The total amount of In-Network Deductible, Coinsurance and Copayment and the Out-of-Network Deductible and Coinsurance for Covered Medical Expenses a Family Membership must pay for services incurred during that Benefit Period. Once the Deductible, Coinsurance and Copayment paid by the Member during the Benefit Period for two or more Family Members covered under the same Family Membership total the applicable Out of Pocket Amount for the family, the Members covered under the same Family Membership will not be required to pay the Deductible, Coinsurance and Copayment for Covered Medical Expenses the remainder of that Benefit Period. The Out of Pocket Amount for the family is listed on the Schedule of Benefits. The In-Network and Out-of-Network Out of Pocket Amounts are separate and one does not accumulate to the other. For family coverage when only two Members are enrolled, the two Members each must meet their Individual Out of Pocket Amounts only.

Non-covered services, the non-participating pharmacy 50% benefit reduction, the 50% Coinsurance for Specialty Medications purchased at any pharmacy other than a participating Specialty Pharmacy and amounts over the allowed amount billed by a non-participating provider do not accumulate to the Out of Pocket Amount and are the Member's responsibility.

OUTPATIENT
Services or supplies provided to the Member by a Covered Provider while the Member is not an Inpatient Member.

PARTIAL HOSPITALIZATION
A time-limited ambulatory (Outpatient) program offering active treatment which is therapeutically intensive, encompassing structured clinical services within a stable, therapeutic program. The program can involve day, evening and weekend treatment. The underlying aim of this treatment is stabilization of clinical instability resulting from severe impairment and/or dysfunction in major life areas.

A Partial Hospitalization program should offer four to eight hours of therapy five days a week. The hours of therapy per day and the frequency of visits per week will vary depending on the clinical symptoms and progress being made with each individual.

PARTICIPATING PHARMACY
A pharmacy which has entered into an agreement with the pharmacy benefit manager to provide Prescription Drug Products to Members and has agreed to accept specified reimbursement rates. Participating Pharmacies may be Value Participating Pharmacies or Participating Pharmacies.

PARTICIPATING PROVIDER
A Participating Blue Cross and Blue Shield of Montana Professional Provider or a Participating Blue Cross and Blue Shield of Montana Facility Provider.

PHYSICAL THERAPY
Treatment of disease or injury by the use of therapeutic exercise and other interventions that focus on improving posture, locomotion, strength, endurance, balance, coordination, joint mobility, flexibility, functional activities of daily living and pain relief.

PHYSICIAN
A person licensed to practice medicine in the state where the service is provided.

PLAN - THE PLAN
Blue Cross and Blue Shield of Montana, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company.

POLICYHOLDER
The individual who has applied for and been accepted for coverage and to whom the Contract has been issued.

PPO-A PREFERRED PROVIDER ORGANIZATION
A provider or group of providers which have contracted with The Plan to provide services to Members covered under PPO Benefit Contracts.

PPO NETWORK
A provider or group of providers which have a PPO contract with Blue Cross Blue Shield of Montana. The Member may obtain a list of PPO providers from Blue Cross Blue Shield of Montana upon request. Payment to a non-PPO Network provider is subject to the non-PPO Network provider reduction shown in the Schedule of Benefits and the Special Provisions section of this document.

PREFERRED BRAND-NAME
A covered non-specialty Brand-Name drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Brand Name drug tier payment level.

PREFERRED GENERIC
A covered Generic drug product or other item that is identified on the Drug List as preferred and is subject to the Preferred Generic drug tier payment level.

PRESCRIPTION DRUG PRODUCT
A medication, product or device approved by the Food and Drug Administration.

PROFESSIONAL CALL
An interview between the Member and the professional provider in attendance. The professional provider must examine the Member and provide or prescribe medical treatment. "Professional Call" does not include telephone calls or any other communication where the Member is not examined by the professional provider, except as included in the Benefit section entitled Telemedicine.

PROOF OF LOSS
The documentation accepted by Blue Cross and Blue Shield of Montana upon which payment of Benefits is made.

QUALIFIED HEALTH PLAN (QHP)
A health care benefit program that has in effect a certification that it meets the applicable government standards, issued or recognized by each Exchange through which such program is offered.

QUALIFIED INDIVIDUAL (For an Approved Clinical Trial)
An individual with group health coverage or group or individual health insurance coverage who is eligible to participate in an Approved Clinical Trial according to the trial protocol for the treatment of cancer or other Life-Threatening Condition because:

1. The referring health care professional is participating in the clinical trial and has concluded that the individual's participation in the trial would be appropriate; or
2. The individual provides medical and scientific information establishing that the individual's participation in the clinical trial is appropriate because the individual meets the conditions described in the trial protocol.

RANDOMIZED CLINICAL TRIAL
A controlled, prospective study of patients who have been assigned at random to an experimental group or a

control group at the beginning of the study with only the experimental group of patients receiving a specific intervention. The term includes a study of the groups for variables and anticipated outcomes over time.

RECONSTRUCTIVE BREAST SURGERY

Surgery performed as a result of a mastectomy to reestablish symmetry between the breasts. The term includes augmentation mammoplasty, reduction mammoplasty, and mastopexy.

RECOVERY CARE BED

A bed occupied in an Outpatient surgical center for less than 24 hours by a patient recovering from surgery or other treatment.

REHABILITATION FACILITY

A facility, or a designated unit of a facility, licensed, certified or accredited to provide Rehabilitation Therapy including:

1. A facility that primarily provides Rehabilitation Therapy, regardless of whether the facility is also licensed as a Hospital or other facility type;
2. A freestanding facility or a facility associated or co-located with a Hospital or other facility;
3. A designated rehabilitation unit of a Hospital;
4. For purposes of the Rehabilitation Therapy Benefit, any facility providing Rehabilitation Therapy to a Member, regardless of the category of facility licensure.

REHABILITATION THERAPY

A specialized, intense and comprehensive program of therapies and treatment services (including but not limited to Physical Therapy, Occupational Therapy and Speech Therapy) provided by a Multidisciplinary Team for treatment of an Injury or physical deficit. A Rehabilitation Therapy program is:

1. provided by a Rehabilitation Facility in an Inpatient Care or outpatient setting;
2. provided under the direction of a qualified Physician and according to a formal written treatment plan with specific goals;
3. designed to restore the patient's maximum function and independence; and
4. Medically Necessary to improve or restore bodily function and the Member must continue to show measurable progress.

REHABILITATIVE CARE

Coverage will be provided for Rehabilitative Care services when the Member requires help to keep, get back or improve skills and functioning for daily living that have been lost or impaired because the Member was sick, hurt or disabled. These services include, but are not limited to:

1. physical and occupational therapy;
2. speech-language pathology; and
3. psychiatric rehabilitation.

These services may be provided in a variety of Inpatient and/or Outpatient settings as prescribed by a Physician.

RESIDENTIAL TREATMENT CENTER

A facility setting offering a defined course of therapeutic intervention and special programming in a controlled environment which also offers a degree of security, supervision, structure and is licensed by the appropriate state and local authority to provide such service. It does not include half-way houses, wilderness programs, supervised living, group homes, boarding houses or other facilities that provide primarily a supportive environment and address long-term social needs, even if counseling is provided in such facilities. Patients are medically monitored with 24 hour medical availability and 24 hour onsite nursing service for patients with Mental Illness and/or Chemical Dependency. Requirements: Blue Cross and Blue Shield of Montana requires that any Mental Illness and/or Chemical Dependency Residential Treatment Center must be licensed in the state where it is located, or accredited by a national organization that is recognized by Blue Cross and Blue Shield of Montana as set forth in its current credentialing policy, and otherwise meets all other credentialing requirements set forth in such policy.

ROUTINE

Examinations or services provided when there is no objective indication of impairment of normal bodily function. Routine does not include the diagnosis or treatment of any Injury or Illness.

ROUTINE PATIENT COSTS

All items and services covered by a group health plan or a plan of individual or group health insurance coverage when the items or services are typically covered for a Qualified Individual who is not enrolled in an Approved Clinical Trial. The term does not include:

1. An investigational item, device, or service that is part of the trial;
2. An item or service provided solely to satisfy data collection and analysis needs for the trial if the item or service is not used in the direct clinical management of the patient; or
3. A service that is clearly inconsistent with widely accepted and established standards of care for the individual's diagnosis.

SEVERE MENTAL ILLNESS

The following disorders as defined by the American psychiatric association:

1. schizophrenia;
2. schizoaffective disorder;
3. bipolar disorder;
4. major depression;
5. panic disorder;
6. obsessive-compulsive disorder; and
7. autism.

Coverage for a child with autism who is 18 years of age or younger is provided under the Autism Spectrum Disorders Benefit if the child is diagnosed with:

1. Autistic Disorder;
2. Asperger's Disorder; or
3. Pervasive Developmental Disorder not otherwise specified.

SPECIALTY MEDICATIONS

High cost, hard to manage injectables, select orals, and/or infused therapies that are administered by the patient or Physician for the treatment of chronic illness.

SPECIALTY PHARMACY

A pharmacy which has entered into an agreement with The Plan to provide Specialty Medications to Members and which has agreed to accept specified reimbursement rates.

SPEECH THERAPY

The treatment of communication impairment and swallowing disorders.

SPOUSE

The opposite sex or the same sex person to whom the Beneficiary Member is legally married, based upon the law in effect at the time of and in the state or other appropriate jurisdiction in which the marriage was performed, recognized, or declared.

TELEMEDICINE

Telemedicine means the use of interactive audio, video, or other telecommunications technology that is:

1. Used by a health care provider or health care facility to deliver health care services at a site other than the site where the patient is located; and
2. Delivered over a secure connection that complies with the requirements of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq.

The term includes the use of electronic media for consultation relating to the health care diagnosis or treatment of a patient in real time or through the use of store-and-forward technology. The term does not include the use of audio-only telephone, e-mail, or facsimile transmissions.

BLUE CROSS BLUE SHIELD OF MONTANA
A DIVISION OF HEALTH CARE SERVICE CORPORATION
A MUTUAL LEGAL RESERVE COMPANY

Michael E. Frank

By: Michael E. Frank
Plan President

Notice That Lifetime Limit No Longer Applies and Enrollment Opportunity

The lifetime limit on the dollar value of benefits under this health plan coverage no longer applies. Individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to reenroll in the plan. Individuals have 30 days beginning with the start of the plan year to request enrollment.

Notice of Opportunity to Enroll in connection with Extension of Dependent Coverage to Age 26

Children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage for children ended before attainment of age 26 are eligible to enroll in this health coverage, regardless of student status, financial dependency or marital status. Individuals may request enrollment for such children for 30 days beginning with the start of the plan year.

American Indian/Alaskan Native Cost-Sharing Notice

This Notice is hereby adopted and incorporated into your Contract.

This Notice only applies if you have enrolled in a Contract that includes Cost-sharing Reductions.

Please read it carefully.

If you are an American Indian/Alaskan Native enrolled under this Contract, the following variations in cost-sharing amounts will apply to your coverage under this Qualified Health Plan (QHP) offered on the Exchange:

If you have a household income of less than 300% of the Federal Poverty Level, you may be eligible for a Zero Cost Sharing (ZCS) Plan.

- If you are enrolled in a ZCS QHP with a non-participating benefit, you will have your cost-sharing for medical and drug Essential Health Benefits, as defined in this Contract, reduced to zero when the benefit is provided at both Participating and Non-Participating provider levels. Any Preauthorization requirements, balance billing/overage from Non-Participating providers, and any maximum benefit limitation or exclusions, will still apply.
- If you are enrolled in a ZCS QHP without a non-participating benefit (e.g. HMO), you will have your cost-sharing for medical and drug Essential Health Benefits, as defined in your benefit booklet, reduced to zero for participating services only. Your ZCS QHP does not provide benefits for services received from a Non-Participating provider, so you may be responsible for all costs associated for services obtained from such a provider. Any Preauthorization requirements, balance billing/overage from Non-Participating Providers, and any maximum benefit limitations or Exclusions, will still apply.

If you are not eligible for a ZCS Plan, you may be eligible for a Limited Cost Sharing (LCS) Plan.

- Under the LCS plans, you will have cost-sharing for medical and drug Essential Health Benefits, as defined in this Contract, reduced to zero when you receive services from an Indian Health Service provider, other tribal or urban Indian organization provider ("I/T/U providers"), or through a referral issued by an I/T/U provider under the Contract Health Service ("CHS") program. If you do not receive services from an I/T/U provider or through a CHS referral, you may be responsible for cost-sharing described in your benefit materials. Any applicable Preauthorization requirements, balance billing/overage from Non-participating providers, any maximum benefit limitations or exclusions, will still apply.

For information on whether a specific Provider is a Participating Provider or non-participating provider or whether a specific Provider is an IHS or other tribal or urban Indian organization provider, call a customer service representative at the number located on the back of your identification card.

For additional information regarding these notices, contact:

Blue Cross and Blue Shield of Montana
3645 Alice Street
Helena, MT 59601
1-800-447-7828

BlueCross BlueShield of Montana

If you, or someone you are helping, have questions, you have the right to get help and information in your language at no cost. To talk to an interpreter, call 855-258-8471.

العربية Arabic	إن كان لديك او لدى شخص تساعده اسئلة، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم فوري، اتصل على الرقم 855-258-8471.
繁體中文 Chinese	如果您, 或您正在協助的對象, 對此有疑問, 您有權利免費以您的母語獲得幫助和訊息 洽詢一位翻譯員, 請撥電話 號碼 855-258-8471。
Français French	Si vous, ou quelqu'un que vous êtes en train d'aider, avez des questions, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 855-258-8471.
Deutsch German	Falls Sie oder jemand, dem Sie helfen, Fragen haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 855-258-8471 an.
Italiano Italian	Se tu o qualcuno che stai aiutando avete domande, hai il diritto di ottenere aiuto e informazioni nella tua lingua gratuitamente. Per parlare con un interprete, puoi chiamare il numero 855-258-8471.
日本語 Japanese	ご本人様、またはお客様の身の回りの方でも、ご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、855-258-8471までお電話ください。
한국어 Korean	만약 귀하 또는 귀하가 돕는 사람이 질문이 있다면 귀하는 무료로 그러한 도움과 정보를 귀하의 언어로 받을 수 있는 권리가 있습니다. 통역사가 필요하시면 855-258-8471로 전화하십시오.
Diné Navajo	T'áá ni, éí doodago ła'da bíká anánílwo'ígíí, na'ídíłkidgo, ts'ídá bee ná ahóóti'i' t'áá níík'e níká a'doolwoł dóó bína'ídíłkidígíí bee nił hodoonih. Ata'dahalne'ígíí bich'į' hodíílnih kwe'é 855-258-8471.
Norsk Norwegian	Hvis du, eller noen du hjelper, har spørsmål, har du rett til å få hjelp og informasjon på ditt språk uten kostnad. For å snakke med en tolk, ring 855-258-8471.
Pennsilfaanisch Deitsch Pennsylvanian-Dutch	Wann du, odder ebber as du an helfe bischt, Questions hoscht, hoscht du's Recht fer Hilf un Information griege in dei eegni Schprooch as nix koschte zellt. Wann du mit en Interpreter schwetze wettscht, kannscht du 855-258-8471 uffrufe.
Русский Russian	Если у вас или человека, которому вы помогаете, возникли вопросы, у вас есть право на бесплатную помощь и информацию, предоставленную на вашем языке. Чтобы связаться с переводчиком, позвоните по телефону 855-258-8471.
Español Spanish	Si usted o alguien a quien usted está ayudando tiene preguntas, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 855-258-8471.
Tagalog Tagalog	Kung ikaw, o ang isang taong iyong tinutulungan ay may mga tanong, may karapatan kang makakuha ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang tagasalin-wika, tumawag sa 855-258-8471.
ไทย Thai	หากคุณ หรือคนที่คุณกำลังช่วยเหลือมีข้อสงสัยใด ๆ คุณมีสิทธิที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่มีค่าใช้จ่าย พูดคุยกับล่ามโดยติดต่อที่หมายเลข 855-258-8471.
Українська Ukrainian	Якщо у Вас чи у когось, хто отримує Вашу допомогу, виникають питання, у Вас є право отримати безкоштовну допомогу та інформацію Вашою рідною мовою. Щоб зв'язатись з перекладачем, зателефонуйте за номером 855-258-8471
Tiếng Việt Vietnamese	Nếu quý vị, hoặc người mà quý vị đang giúp đỡ, có câu hỏi, thì quý vị có quyền được giúp và nhận thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 855-258-8471.

bcbsmt.com

PET EXHIBIT 3-329

IMPORTANT NOTICE TO PERSON ON MEDICARE
THIS INSURANCE DUPLICATES SOME MEDICARE BENEFITS

This is not Medicare Supplement Insurance.

This insurance provides limited benefits if you meet the conditions listed in the policy. It does not pay your Medicare deductibles or coinsurance and is not a substitute for Medicare Supplement insurance.

This insurance duplicates Medicare benefits when it pays:

- the benefits stated in the policy and coverage for the same event is provided by Medicare

Medicare generally pays for most or all of these expenses.

Medicare pays extensive benefits for medically necessary services regardless of the reason you need them. These include:

- hospitalization
- physician services
- hospice
- (outpatient prescription drugs if you are enrolled in Medicare Part D)
- other approved items and services

BEFORE YOU BUY THIS INSURANCE

1. Check the coverage in all health insurance policies you already have.
2. For more information about Medicare and Medicare Supplement insurance, review the "Guide to Health Insurance for People with Medicare," available from Blue Cross and Blue Shield of Montana.
3. For help in understanding your health insurance, contact your state insurance department or state health insurance assistance program (SHIP).

BlueCross BlueShield
of Montana

Blue Cross and Blue Shield of Montana
3645 Alice Street
P.O. Box 4309
Helena, MT 59604-4309

BLUE PREFERRED GOLD PPO 104

BlueCross BlueShield of Montana

To learn more, call Blue Cross and Blue Shield of Montana at 800-447-7828 or your local agent

www.bcbsmt.com

Outline of Coverage

Benefit Period	January 1 – December 31		
Deductible *Copayments and coinsurance do not accumulate to the plan deductible.*	In-Network:	Individual: $1,400	Family: $2,800
	Out-of-Network:	Individual: $5,600	Family: $11,200
Out-of-Pocket Amount	In-Network:	Individual: $3,350	Family: $6,700
	Out-of-Network:	Individual: $13,400	Family: $26,800
Deductible Per Visit or Occurrence *These deductibles are in addition to the plan deductible and any coinsurance. Once the out-of-pocket amount is satisfied, plan deductible, per visit or occurrence deductibles and coinsurance and copayments do not apply.*	Emergency Room:	In-Network: $750	Out-of-Network: $750
	Inpatient Admission:	In-Network: $300	Out-of-Network: $1,500
	Outpatient Surgery:	In-Network: $200	Out-of-Network: $1,500
Coinsurance		In-Network: 20%	Out-of-Network: 50%
Copayment *Deductible and coinsurance do not apply to In-Network Services.*	Urgent Care:	In-Network: $20	Out-of-Network: No copayment; deductible and coinsurance apply (Emergency services pay as In-Network services.)
Deductible and Coinsurance Waived For:	**In and Out-of-Network:** Diabetic Education Benefit (the first $250) **In-Network:** Chemical Dependency and Mental Health Office Visits; Preventive Health Care; Routine and Diagnostic Mammograms; Hospice; Urgent Care; Well-Child Care; the first 3 Primary Care Provider (PCP) Office Visits **Out-of-Network:** The first $70 for Routine Mammograms; Well-Child Care. However, coinsurance applies to Well Child Care		

Blue Cross and Blue Shield of Montana (BCBSMT) Provider Networks

In-Network Providers - In-Network providers accept the BCBSMT allowable fee, in additional to the deductible, coinsurance and copayment, as payment in full for covered services. In-Network providers submit claims for you and BCBSMT pays In-Network providers directly. You will not be billed amounts over your deductible, coinsurance and copayment.

- **Preferred Provider Organization (PPO)** - A network of hospitals and surgery centers across the state that accept lower payments for each service provided by a PPO Hospital or surgery center. Currently, all hospitals in Montana participate in this network.
- **Traditional Network Participating Providers** - This is the most extensive provider network available in Montana, composed of professional providers and facility providers, other than hospitals and surgery centers which have contracted with BCBSMT to provide services at discounted rates. Approximately 95% off all physicians and 100% of hospitals in Montana participate in this network.

Out-of-Network Providers - Nonparticipating Providers have not contracted with BCBSMT to provide services at negotiated rates, and your out of pocket expenses can be significantly higher. These providers are under no obligation to submit claims for you and may bill you the difference between the allowable fee and their charge (balance billing), in addition to any deductible, coinsurance and copayment.

Emergency Services - Services provided for emergency medical condition which is a condition with symptoms of sufficient severity, including severe pain, that in the absence of immediate medical attention could reasonably be expected to result in: the Member's health being in serious jeopardy, the Member's bodily functions being seriously impaired; or a bodily organ or part being seriously damaged. These services pay as In-Network, even if provided Out-of-Network. An Out-of-Network provider may balance bill.

Finding Participating Providers – To locate In-Network providers in Montana check our on-line provider directory at www.bcbsmt.com or contact Customer Service at 1-800-447-7828.

Out of State Networks at Your Fingertips – The BlueCard program provides access to Participating Providers across the country. To find BlueCard Providers, visit the BlueCross and BlueShield Association website at http://provider.bcbs.com or call 1-800-810-BLUE (2593).

Deductible: The dollar amount each Member must pay for covered medical expenses incurred during the benefit period before BCBSMT will make payment for any covered medical expense to which the deductible applies. This plan has an In-Network deductible and separate Out-of-Network deductible.

Out-of-Pocket Amount: The total amount of deductible, coinsurance and copayment that each Member would pay in a single benefit period. Once the out-of-pocket amount is met, the Plan pays 100% of the allowable fee on covered services. However, any amount each Member pays for balances owed to nonparticipating providers and the Out-of-Network pharmacy 50% benefit reduction do not apply to the out-of-pocket amount. This plan has an In-Network out-of-pocket amount and a separate Out-of-Network out-of-pocket amount.

Coinsurance: The percentage of the allowable fee payable by the Member for covered medical expenses. This plan has an In-Network coinsurance and a separate Out-of-Network coinsurance.

Copayment: The specific dollar amount payable by the Member for covered medical expenses.

Rating Factors and Trend: The following rating factors are used: income and claims experience for the prior 12 months for the product being rated, the benefit difference for deductible, coinsurance and copayment for specific products in a category, projected claims, income and enrollment for the next 12-month rating period, projected expenses for the next rating period, and/or age of the applicant or subscriber, industry, and risk characteristics. The trend of premium increases during the preceding five years is:
2012 – 11%, 2013 – 13%, 2014 – 6.5%, 2015 -7.2%, 2016 – 21.8%
Your estimated premium will be _____.

The Appeals section in the Contract contains information regarding utilization review procedures, including procedures for obtaining review of adverse determinations, and the Member's rights with respect to those procedures.

Deductible, copayment and coinsurance apply to all services listed below, unless otherwise noted. This is only a summary of benefits. Benefits and general provisions are subject to the terms of the Contract. Preauthorization is not a guarantee of payment but is required for some services, supplies, treatments and prescription drugs to determine if services are Medically Necessary and a benefit of the Contract.

Professional Provider Services	Covered services include home and office calls, x-ray, lab and other services provided by a professional provider. Deductible and coinsurance do not apply to the first three In-Network PCP office visits. The visit covers services provided during the visit. However, even if provided during that visit, the following services process under regular medical benefits: surgery, physical therapy, speech therapy, occupational therapy, chiropractic manipulation, diagnostic imaging, laboratory services and x-rays.
Preventive Health Care, including Routine Mammograms and Well-Child Care	Services include: 1. Services that have an "A" or "B" rating in the United States Preventive Services Task Force's (USPSTF) current recommendations; and 2. Immunizations recommended by the Advisory Committee of Immunizations Practices of the Centers for Disease Control and Prevention and 3. Health Resources and Services Administration (HRSA) Guidelines for Preventive Care & Screenings for Infants, Children, Adolescents and Women, and 4. Current recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued prior to November 2009. Examples of services include, but are not limited to, physical examinations, vaccinations (immunizations), lactation services, a breast pump (maximum of two electric), certain contraceptives and certain tobacco cessation products. Deductible, copayments and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network services, except for the first $70 for Out-of-Network routine mammograms. Deductible does not apply to Out-of-Network Well-Child Care.
Inpatient Hospital	Room and board, special care units, ancillary charges, and transplant coverage.
Outpatient Hospital	Accidental injury, x-ray/lab, surgery, chemotherapy, respiratory therapy, medical emergencies and other services.
Maternity Services	Professional and facility services are processed under regular medical benefits.
Emergency Room Care	Services provided for accidental injury and emergency services
Transplants	Processed under regular medical benefits.
Convalescent Home	Skilled nursing facility, transitional care units and extended care facilities 60 days per benefit period.
Chiropractic and Acupuncture Services	Chiropractic: 10 visit maximum per benefit period. Acupuncture: 12 visit maximum per benefit period.
Home Health Care	180 visit maximum per benefit period.
Hospice	Deductible and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network services
Individual Therapies	Outpatient physical, occupational, speech and cardiac rehabilitation therapies for professional and facility charges.
Rehabilitation Therapy	Inpatient and outpatient rehabilitation therapy services.
Durable Medical Equipment and Prostheses	Initial purchase, replacement, and repair.
Pediatric Vision (under 19 years of age)	Routine eye exam, deductible and coinsurance do not apply. Paid at 100% of the allowable fee. Lenses and frames processed under regular medical benefits.
Mental Illness	Mental Illness, including Severe Mental Illness, deductible and coinsurance do not apply to In-Network office visits which are paid at 100% of the allowable fee. Deductible and coinsurance apply to any other covered services provided In-Network and Out-of-Network.
Chemical Dependency	Deductible and coinsurance do not apply to In-Network office visits which are paid at 100% of the allowable fee. Deductible and coinsurance apply to any other covered services provided In-Network and Out-of-Network.
Autism Spectrum Disorder	Diagnosis and treatment of Autistic disorder, Asperger's disorder or pervasive developmental disorder. Applied Behavioral Analysis (ABA) therapy is only available to Members 0-18 years of age.
Mammograms (Medical/Diagnostic)	Deductible and coinsurance do not apply to In-Network services which are paid at 100% of the allowable fee. Deductible and coinsurance apply to Out-of-Network services.
Diagnostic Services	Processed under regular medical benefits.
Diabetic Education Benefit	Deductible and coinsurance do not apply to the first $250 per benefit period for outpatient services. After the first $250 in payment, deductible, copayment and coinsurance apply.

Prescription Drugs	Value Participating Pharmacy Copayment/Coinsurance	Participating Pharmacy Copayment/Coinsurance
Retail: 30-day supply	$0 preferred generic, $10 non-preferred generic, $50 preferred brand name, $100 non-preferred brand name	$5 preferred generic, $15 non-preferred generic, $60 preferred brand name, $110 non-preferred brand name
Retail: 90-day supply Only available at Value Participating Pharmacies	$0 preferred generic, $30 non-preferred generic, $150 preferred brand name, $300 non-preferred brand name	
Mail Order: 90-day supply	$0 preferred generic, $30 non-preferred generic, $150 preferred brand name, $300 non-preferred brand name	
Specialty Medications – 30-day supply	$250 when purchased at a participating Specialty Pharmacy. 50% coinsurance when purchased at any pharmacy other than a participating Specialty Pharmacy.	

Deductible: Does not apply (The member must pay the difference between a brand name drug and the generic equivalent, in addition to the copayment, if the member chooses a brand name drug when a generic drug is available.)

Payment for Prescription Drugs purchased at a nonparticipating pharmacy will be reduced by 50% in addition to the Participating Network coinsurance. This 50% benefit reduction does not apply to the Out of Pocket Amount.

Specialty Medications, when purchased at any pharmacy other than a participating Specialty Pharmacy, are covered at 50% coinsurance. This 50% coinsurance does not apply to any Out of Pocket Amount.

Mail Order is only available through the Preferred Mail Order Pharmacy Network

Member Rights – When requested by the Member or the Member's agent, BCBSMT is required to provide a summary of a Member's coverage for a specific health care service or course of treatment when an actual charge or estimate of charges by a health care provider, surgical center or clinic or hospital exceeds $500.

AMENDMENT

This Amendment, effective 01/01/2017, is part of the Contract with Blue Cross and Blue Shield of Montana.

Include the following provision:

The Contract is an agreement between:

Blue Cross and Blue Shield of Montana
P.O. Box 4309
Helena, Montana 59604
and

Subscriber Name: JOAN MAUREEN GROGAN

This Amendment is subject to the terms of the base Contract and all provisions of the base Contract which do not conflict with this Amendment continue in full force. This Amendment will **automatically terminate** without notice when the base Contract terminates for any reason stated in the termination provisions.

BLUE CROSS BLUE SHIELD OF MONTANA
A DIVISION OF HEALTH CARE SERVICE CORPORATION
A MUTUAL LEGAL RESERVE COMPANY

Michael E. Frank

By: Michael E. Frank
Plan President

SUBSCRIBERNAME2012.A

WRITTEN NOTICE OF THE COVERAGE FOR MINIMUM HOSPITAL STAYS FOLLOWING CHILDBIRTH AS REQUIRED BY THE MONTANA INSURANCE CODE AND FEDERAL LAW.

Health insurance for maternity services, including benefits for childbirth, must provide coverage for at least 48 hours of inpatient hospital care following a vaginal delivery and at least 96 hours of inpatient care, following delivery by cesarean section for a mother and newborn infant in a health care facility.

Any decision to shorten the length of inpatient stay to less than that stated above must be made by the attending health care provider and the mother. A health benefit plan may not terminate the service of an attending health care provider or penalize or otherwise provide financial disincentives to an attending health care provider in response to orders by the attending health care provider for care consistent with these provisions. Under this same requirement a health plan may not require that the provider obtain authorization from the plan or the insurance issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

A health benefit plan that provides coverage for post-delivery care that is provided to a mother and newborn infant in the home may not be required to provide coverage of inpatient care unless the inpatient care is determined to be medically necessary by the attending health care provider.

For further information about this notice, please contact Customer Service at 1-800-447-7828 or visit our Website http://www.bcbsmt.com.

WRITTEN NOTICE OF THE WOMEN'S HEALTH AND CANCER RIGHTS ACT OF 1998 (WHCRA) AS REQUIRED BY FEDERAL LAW.

If you have had or are going to have a mastectomy, you may be entitled to certain benefits under WHCRA. For individuals receiving mastectomy-related benefits, coverage will be provided in a manner determined by the Plan in consultation with the attending physician and the patient, for:

1) All stages of reconstruction of the breast on which a mastectomy has been performed.
2) Surgery and reconstruction of the other breast to establish a symmetrical appearance.
3) Chemotherapy.
4) Prostheses and physical complications of all stages of a mastectomy and breast reconstruction, including lymphedemas.

These benefits will be provided subject to any deductible, coinsurance and/or copayment provisions of your health plan. For specific deductible, coinsurance and/or copayment information on your plan, please refer to your schedule of benefits.

For further information about this notice or the benefits provided under WHCRA, please contact Customer Service at 1-800-447-7828 or visit our Website http://www.bcbsmt.com.

NOTICE
OF PROTECTION PROVIDED BY
MONTANA LIFE AND HEALTH INSURANCE GUARANTY ASSOCIATION

This notice provides a **brief summary** of the Montana Life and Health Insurance Guaranty Association (the Association) and the protection it provides for policyholders. This safety net was created under Montana law, which determines who and what is covered and the amounts of coverage.

The Association was established to provide protection in the unlikely event that your life, annuity or health insurance company becomes financially unable to meet its obligations and is taken over by its Insurance Department. If this should happen, the Association will typically arrange to continue coverage and pay claims, in accordance with Montana law, with funding from assessments paid by other insurance companies.

The basic protections provided by the Association are:

- Life Insurance
  - $300,000 in death benefits
  - $100,000 in cash surrender or withdrawal values

- Health Insurance
  - $500,000 in hospital, medical and surgical insurance benefits
  - $300,000 in disability income insurance benefits
  - $300,000 in long-term care insurance benefits
  - $100,000 in other types of health insurance benefits

- Annuities
  - $250,000 in withdrawal and cash values

The maximum amount of protection is $300,000 in benefits with respect to any one life regardless of the number of policies or contracts, except with respect to hospital, medical, and surgical insurance benefits.

Note: Certain policies and contracts may not be covered or fully covered. For example, coverage does not extend to any portion(s) of a policy or contract that the insurer does not guarantee, such as certain investment additions to the account value of a variable life insurance policy or a variable annuity contract. There are also various residency requirements and other limitations under Montana law.

To learn more about the above protections, as well as protections relating to group contracts or retirement plans, please visit the Association's web site at www.mtlifega.org or contact:

Montana Life and Health Insurance Guaranty Association PO Box 951 Oconomowoc, WI 53066-0951 877-678-1048 or administrator@mtlifega.org	Montana Department of Insurance State Auditor's Office 840 Helena Ave. Helena, MT 59601 406-444-2040

Insurance companies and agents are not allowed by Montana law to use the existence of the Association or its coverage to encourage you to purchase any form of insurance. When selecting an insurance company, you should not rely on Association coverage.

If there is any inconsistency between this notice and Montana law, then Montana law will control.

Notice of Amendment and Adoption amending ARM 6.6.4601 and 6.6.4602, published in Montana Administrative Register 7/28/2011

350902.0714

PET EXHIBIT 3-337

BlueCross BlueShield of Montana

Blue Cross and Blue Shield of Montana (BCBSMT) is required to provide you a Notice of Privacy Practices to inform you of your rights under the law. This notice describes how BCBSMT can use or disclose your protected health information. Please take a few minutes and review this notice. You are encouraged to go to the Blue Access for Members (BAM) portal at BCBSMT.com to sign up to receive this notice electronically. Our contact information can be found at the end of the notice.

HIPAA NOTICE OF PRIVACY PRACTICES – Effective 9/23/13

YOUR RIGHTS. When it comes to your health information, you have certain rights.

This section explains your rights and some of our responsibilities to help you.

Get a copy of your health and claims records	• You can ask to see or get a copy of your health and claims records and other health information we have about you. Ask us how to do this by using the contact information at the end of this notice. • We will provide a copy or a summary of your health and claims records usually within 30 days of the request. We may charge a reasonable, cost-based fee.
Ask us to correct health and claims records	• You can ask us to correct your health and claims records if you think they are incorrect or incomplete. Ask us how to do this by using the contact information at the end of this notice. • We may say "no" to your request. We'll tell you why in writing within 60 days.
Request confidential communications	• You can ask us to contact you in a specific way or to send mail to a different address. Ask us how to do this by using the contact information at the end of this notice. • We will consider all reasonable requests, and must say "yes" if you tell us you would be in danger if we do not.
Ask us to limit what we use or share	• You can ask us **not** to share or use certain health information for treatment, payment or our operations. Ask how to do this by using the contact information at the end of this notice. • We are not required to agree to your request, and we may say "no" if it would affect your care.
Get a list of those with whom we've shared information	• You can ask for a list (accounting) for six years prior to your request date of when we shared your information, who we shared it with and why. Ask us how to do this by using the contact information at the end of this notice. • We will include all the disclosures except for those about treatment, payment, and our operations, and certain other disclosures (such as any you asked us to make). We will provide one accounting a year for free but we may charge a reasonable, cost-based fee if you ask for another one within 12 months.
Get a copy of this Notice	• You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. To request a copy of this notice, use the contact information at the end of this notice and we will send you one promptly.
Choose someone to act for you	• If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices for you. • We confirm this information before we release them any of your information.

BlueCross BlueShield of Montana

File a complaint if you feel your rights are violated	• You can complain if you feel we have violated your privacy rights by using the contact information at the end of this notice. • You can also file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by calling 1-877-696-6775; or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/ or by sending a letter to them at: 200 Independence Ave., SW, Washington, D.C. 20201. • We will not retaliate against you for filing a complaint.

YOUR CHOICES. For certain health information, you can tell us your choices about what we share.

If you have a clear preference on how you want us to share your information in the situations described below, tell us and we will follow your instructions. Use the contact information at the end of this notice.

In these cases, you have both the right and choice to tell us to:	• Share information with your family, close friends, or others involved in payment for your care • Share information in a disaster or relief situation • Contact you for fundraising efforts

If there is a reason you can't tell us who we can share information with, we may share it if we believe it is in your best interest to do so. We may also share information to lessen a serious or imminent threat to health or safety.

We never share your information in these situations unless you give us written permission	• Marketing purposes • Sale of your information

OUR USES AND DISCLOSURES. How do we use or share your health information?

We typically use or share your health information in the following ways.

Help manage the health care treatment you receive	• We can use your health information and share it with professionals who are treating you. *Example: A doctor sends us information about your diagnosis and treatment plan so we can arrange additional services.*
Run our organization	• We can use and disclose your information to run our organization and contact you when necessary. *Example: We use health information to develop better services for you.*

We can't use any genetic information to decide whether we will give you coverage except for long-term care plans.

Pay for your health Services	• We can use and disclose your health information since we pay for your health services. *Example: We share information about you with your dental plan to coordinate payment for your dental work.*
Administer your plan	• We may disclose your health information to your health plan sponsor for plan administration purposes. *Example: If your company contracts with us to provide a health plan, we may provide them certain statistics to explain the premiums we charge.*

BlueCross BlueShield of Montana

How else can we use or share your health information?

We are allowed or required to share your information in other ways, usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information go to: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html

Help with public health and safety issues	• We can share your health information for certain situations such as: – Preventing disease – Helping with product recalls – Reporting adverse reactions to medications – Reporting suspected abuse, neglect or domestic violence – Preventing or reducing a serious threat to anyone's health or safety
Do research	• We can use or share your information for health research.
Comply with the law	• We will share information about you when state or federal law requires it, including the Department of Health and Human Services if they want to determine that we are complying with federal privacy laws.
Respond to organ/tissue donation requests and work with certain professionals	• We can share health information about you with an organ procurement organization. • We can share information with a medical examiner, coroner or funeral director.
Address workers compensation, law enforcement, and Other government requests	• We can use or share health information about you: – For workers compensation claims – For law enforcement purposes or with a law enforcement official – With health oversight agencies for activities authorized by law – For special government functions such as military, national security, and presidential protective services or with prisons regarding inmates.
Respond to lawsuits And legal actions	• We can share health information about you in response to an administrative or court order, or in response to a subpoena.
Certain health information	• State law may provide additional protection on some specific medical conditions or health information. For example, these laws may prohibit us from disclosing or using information related to HIV/AIDS, mental health, alcohol or substance abuse and genetic information without your authorization. In these situations, we will follow the requirements of the state law.

OUR RESPONSIBILITIES. When it comes to your information, we have certain responsibilities.

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that compromises the privacy or security of your information.
- We must follow the duties and privacy practices described in this notice and give you a copy of it.
- We will not use or share your information other than as described here unless you tell us we can in writing.

You may change your mind at any time. Let us know in writing if you change your mind.

For more information: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp. html.**

BlueCross BlueShield of Montana

CHANGES TO THE NOTICE

We have the right to change the terms of this notice, and the changes we make will apply to all information we have about you. The new notice will be available upon request or from our website. We will also mail a copy of the new notices to you as required by law.

CONTACT INFORMATION

If you would like general information about your privacy rights or would like a copy of this notices, go to: http://www.bcbsmt.com/important_info/index.html

If you have specific questions about your rights or these notices, contact us in one of the following ways:

- Call us by using the toll-free number located on the back of your member identification card.
- Call us at 1-877-361-7594.
- Write us at Privacy Office Divisional Vice President
  Blue Cross and Blue Shield of Montana
  P.O. Box 804836
  Chicago, IL 60680-4110

REVISION DATE: 8/2014

BlueCross BlueShield
of Montana

P.O. Box 3236
Naperville, Illinois 60566-7236

Return Service Requested

JOAN GROGAN
130 S MONTANA ST
DILLON, MT 59725

5680114700-03-20838952

80345409

BlueCross BlueShield of Montana

P.O. Box 3236
Naperville, Illinois 60566-7236

Return Service Requested

JOAN GROGAN
130 S MONTANA ST
DILLON, MT 59725

5680114700-03-20838952

80345409

PET EXHIBIT 3-343

BlueCross BlueShield
of Montana

April 12, 2017

Dr. Roman Hendrickson
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Dr. Hendrickson:

Blue Cross and Blue Shield of Montana (BCBSMT) a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, periodically conducts audits of claims submitted by providers to help ensure that benefits are provided only for medically appropriate services that are included in our members' benefit plan as well as within BCBSMT's guidelines and Medical Policies.

It has come to our attention that your office has submitted claims for Artificial Pancreas Treatment (APT) that, upon review of the selected medical records and/ or additional information, were incorrectly billed as Evaluation and Management services, prolonged physician services, IV infusions, and/or lab services.

The rationale for this determination is that based upon the information reviewed, the claims appear to be for APT services but were billed using the incorrect procedure codes listed below:

Procedure Code	Procedure Code Description
36416	COLLECTION OF CAPILLARY BLOOD SPECIMEN (EG. FINGER, HEEL, EAR STICK)
80422	GLUCAGON TOLERANCE PANEL; FOR INSULINOMA THIS PANEL MUST INCLUDE THE FOLLOWING; GLUCOSE (82947 X 3) INSULIN (83525 X 3)
82947	GLUCOSE; QUANTITATIVE
82950	GLUCOSE; POST GLUCOSE DOSE (INCLUDES GLUCOSE)
82962	GLUCOSE, BLOOD BY GLUCOSE MONITORING DEVICE(S) CLEARED BY THE FDA SPECIFICALLY FOR HOME USE
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1 HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP

EXHIBIT
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exhibitsticker.com

99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
99355	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

decreasing hepatic glucose production. While patients with type-2 diabetes may be treated with various combinations of all three of the above classes of drugs, with or without additional insulin, patients with type-1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Large-scale randomized studies have established that tight glucose control is associated with a decreased incidence of microvascular complications of diabetes (i.e., nephropathy, neuropathy, and retinopathy). Currently, the American Diabetics Association recommends a target hemoglobin A1c (HbA1c) concentration of less than 7%.

CIIIT, also referred to as outpatient intravenous insulin therapy (OIVIT); pulsatile intravenous insulin therapy; hepatic activation; or metabolic activation, involves delivering insulin intravenously over a 6- to 7- hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT therapy is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al. proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that once weekly 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Regulatory Status

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process, as they

are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2006 and was regularly updated with searches of the MEDLINE database. No new relevant research studies were identified in the most recent literature review. Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

Does CIIIT improve glycemic control in diabetic patients?

Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) are necessary to validate treatment effectiveness. A MEDLINE literature search did not identify any blinded randomized clinical trials focusing on the efficacy of CIIIT for glucose control.

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the HbA1c levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1,2)

Aoki et al. also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures

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were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Does CIIIT reduce diabetic end-organ damage?

Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dailey et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

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vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

- Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

- A Randomized Controlled Trial to Evaluate Early Intermittent Intensive Insulin Therapy as an Effective Treatment of Type 2 Diabetes: REmission Studies Evaluating Type 2 DM – Intermittent Insulin Therapy (RESET-IT) (NCT01755468). This is a randomized, open-label trial to compare intermittent insulin therapy with continuous metformin therapy for patients with type 2 diabetes. Enrollment is planned for 148 subjects; the planned study completion date is December 2017.

Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

It is hypothesized that CIIIT improves hepatic glucose regulation. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. Two randomized trials report that CIIIT may moderate the progression of nephropathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). This evidence does not permit definitive conclusions regarding the health benefits of CIIIT. Therefore, the technique is considered experimental, investigational and/or unproven..

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIIT within each organization's clinical practice guidelines for diabetes. (6-8) The American College of Physicians published a clinical practice guideline in 2011 on the use of intensive insulin therapy for the management of glycemic control in hospitalized patients (9); the recommendations put forth in this guideline were based on earlier systematic review on this topic which did not include CIIIT. (10)

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Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

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HCPCS Codes
G9147, J1817, J7050
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
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Medicare Coverage:

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References:

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

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11. Chronic Intermittent Intervenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2014 July) Medicine 2.01.43

Policy History:

Date	Reason
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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BlueCross BlueShield
of Montana

April 12, 2017

Dianne Sawitke, NP
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Ms. Sawitke:

Blue Cross and Blue Shield of Montana (BCBSMT) a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, periodically conducts audits of claims submitted by providers to help ensure that benefits are provided only for medically appropriate services that are included in our members' benefit plan as well as within BCBSMT's guidelines and Medical Policies.

It has come to our attention that your office has submitted claims for Artificial Pancreas Treatment (APT) that, upon review of the selected medical records and/ or additional information, were incorrectly billed as Evaluation and Management services, prolonged physician services, IV infusions, and/or lab services.

The rationale for this determination is that based upon the information reviewed, the claims appear to be for APT services but were billed using the incorrect procedure codes listed below:

Procedure Code	Procedure Code Description
36416	COLLECTION OF CAPILLARY BLOOD SPECIMEN (EG. FINGER, HEEL, EAR STICK)
80422	GLUCAGON TOLERANCE PANEL; FOR INSULINOMA THIS PANEL MUST INCLUDE THE FOLLOWING; GLUCOSE (82947 X 3) INSULIN (83525 X 3)
82947	GLUCOSE; QUANTITATIVE
82950	GLUCOSE; POST GLUCOSE DOSE (INCLUDES GLUCOSE)
82962	GLUCOSE, BLOOD BY GLUCOSE MONITORING DEVICE(S) CLEARED BY THE FDA SPECIFICALLY FOR HOME USE
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1 HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP
99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES

	THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
99355	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) is **considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

decreasing hepatic glucose production. While patients with type-2 diabetes may be treated with various combinations of all three of the above classes of drugs, with or without additional insulin, patients with type-1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Large-scale randomized studies have established that tight glucose control is associated with a decreased incidence of microvascular complications of diabetes (i.e., nephropathy, neuropathy, and retinopathy). Currently, the American Diabetics Association recommends a target hemoglobin A1c (HbA1c) concentration of less than 7%.

CIIIT, also referred to as outpatient intravenous insulin therapy (OIVIT); pulsatile intravenous insulin therapy; hepatic activation; or metabolic activation, involves delivering insulin intravenously over a 6- to 7- hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT therapy is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al. proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that once weekly 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Regulatory Status

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process, as they

are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2005 and was regularly updated with searches of the MEDLINE database. No new relevant research studies were identified in the most recent literature review. Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

Does CIIIT improve glycemic control in diabetic patients?

Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) are necessary to validate treatment effectiveness. A MEDLINE literature search did not identify any blinded randomized clinical trials focusing on the efficacy of CIIIT for glucose control.

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the HbA1c levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1,2)

Aoki et al. also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures

PET EXHIBIT 4-361

were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Does CIIIT reduce diabetic end-organ damage?

Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dalley et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

• Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

• A Randomized Controlled Trial to Evaluate Early Intermittent Intensive Insulin Therapy as an Effective Treatment of Type 2 Diabetes: REmission Studies Evaluating Type 2 DM – Intermittent Insulin Therapy (RESET-IT) (NCT01755468). This is a randomized, open-label trial to compare intermittent insulin therapy with continuous metformin therapy for patients with type 2 diabetes. Enrollment is planned for 148 subjects; the planned study completion date is December 2017.

Summary

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References:

PET EXHIBIT 4-365

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

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BlueCross BlueShield
of Montana

April 12, 2017

Harold Laron Briggs
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

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J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosures: Medical Policy; Notice to Roman Hendrickson, MD; Notice to Dianne Sawitke, NP

HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

PET EXHIBIT 4-371

decreasing hepatic glucose production. While patients with type-2 diabetes may be treated with various combinations of all three of the above classes of drugs, with or without additional insulin, patients with type-1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Large-scale randomized studies have established that tight glucose control is associated with a decreased incidence of microvascular complications of diabetes (i.e., nephropathy, neuropathy, and retinopathy). Currently, the American Diabetics Association recommends a target hemoglobin A1c (HbA1c) concentration of less than 7%.

CIIIT, also referred to as outpatient intravenous insulin therapy (OIVIT); pulsatile intravenous insulin therapy; hepatic activation; or metabolic activation, involves delivering insulin intravenously over a 6- to 7- hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT therapy is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al. proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that once weekly 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Regulatory Status

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process, as they

Case 2:17-cv-00080-SEH Document 9-4 Filed 11/02/17 Page 30 of 48

are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2006 and was regularly updated with searches of the MEDLINE database. No new relevant research studies were identified in the most recent literature review. Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

Does CIIIT improve glycemic control in diabetic patients?

Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) are necessary to validate treatment effectiveness. A MEDLINE literature search did not identify any blinded randomized clinical trials focusing on the efficacy of CIIIT for glucose control.

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the HbA1c levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1,2)

Aoki et al. also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures

PET EXHIBIT 4-373

were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Does CIIIT reduce diabetic end-organ damage?

Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dailey et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

- Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

- A Randomized Controlled Trial to Evaluate Early Intermittent Intensive Insulin Therapy as an Effective Treatment of Type 2 Diabetes: REmission Studies Evaluating Type 2 DM – Intermittent Insulin Therapy (RESET-IT) (NCT01755468). This is a randomized, open-label trial to compare intermittent insulin therapy with continuous metformin therapy for patients with type 2 diabetes. Enrollment is planned for 148 subjects; the planned study completion date is December 2017.

Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

It is hypothesized that CIIIT improves hepatic glucose regulation. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. Two randomized trials report that CIIIT may moderate the progression of nephropathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). This evidence does not permit definitive conclusions regarding the health benefits of CIIIT. Therefore, the technique is considered experimental, investigational and/or unproven..

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIIT within each organization's clinical practice guidelines for diabetes. (6-8) The American College of Physicians published a clinical practice guideline in 2011 on the use of intensive insulin therapy for the management of glycemic control in hospitalized patients (9); the recommendations put forth in this guideline were based on earlier systematic review on this topic which did not include CIIIT. (10)

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been developed or changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov.

References:

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

3. Aoki TT, Grecu EO, Prendergast JJ et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. Diabetes Care 1995; 18(9):1260-5.

4. Dailey GE, Boden GH, Creech RH et al. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. Metabolism 2000; 49(11):1491-5.

5. Weinrauch LA, Sun J, Gleason RE et al. Pulsatile intermittent intravenous insulin therapy for attenuation of retinopathy and nephropathy in type 1 diabetes mellitus. Metabolism 2010; 59 (10):1429-34.

6. Handelsman Y, Mechanick JI, Blonde L et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract 2011; 17 Suppl 2:1-53.

7. Rodbard HW, Blonde L, Braithwaite SS et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Endocr Pract 2007; 13 Suppl 1:1-68.

8. American Diabetes Association. Clinical Practice Recommendations 2009. Diabetes Care 2009; 32(suppl 1). Available online at: http://care.diabetesjournals.org. Last accessed May, 2014.

9. Qaseem A, Humphrey LL, Chou R et al. Use of intensive insulin therapy for the management of glycemic control in hospitalized patients: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2011; 154 (4):260-7.

10. Kansagara D, Fu R, Freeman M et al. Intensive insulin therapy in hospitalized patients: a systematic review. Ann Intern Med 2011; 154(4):268-82.

11. Chronic Intermittent Intervenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2014 July) Medicine 2.01.43

Policy History:

Date	Reason
5/15/2016	Reviewed. No changes
8/16/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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BlueCross BlueShield of Montana

April 19, 2017

Kimberley Laden, NP
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Ms. Laden:

Blue Cross and Blue Shield of Montana (BCBSMT) a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, periodically conducts audits of claims submitted by providers to help ensure that benefits are provided only for medically appropriate services that are included in our members' benefit plan as well as within BCBSMT's guidelines and Medical Policies.

It has come to our attention that your office has submitted claims for Artificial Pancreas Treatment (APT) that, upon review of the selected medical records and/ or additional information, were incorrectly billed as Evaluation and Management services, prolonged physician services, IV infusions, and/or lab services.

The rationale for this determination is that based upon the information reviewed, the claims appear to be for APT services but were billed using the incorrect procedure codes listed below:

Procedure Code	Procedure Code Description
36416	COLLECTION OF CAPILLARY BLOOD SPECIMEN (EG. FINGER, HEEL, EAR STICK)
80422	GLUCAGON TOLERANCE PANEL; FOR INSULINOMA THIS PANEL MUST INCLUDE THE FOLLOWING; GLUCOSE (82947 X 3) INSULIN (83525 X 3)
82947	GLUCOSE; QUANTITATIVE
82950	GLUCOSE; POST GLUCOSE DOSE (INCLUDES GLUCOSE)
82962	GLUCOSE, BLOOD BY GLUCOSE MONITORING DEVICE(S) CLEARED BY THE FDA SPECIFICALLY FOR HOME USE
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1 HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP

99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
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99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
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J1815	INJECTION, INSULIN, PER 5 UNITS

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The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

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Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

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Case 2:17-cv-00080-SEH Document 9-4 Filed 11/02/17 Page 42 of 48

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Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dailey et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

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vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

- Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

- A Randomized Controlled Trial to Evaluate Early Intermittent Intensive Insulin Therapy as an Effective Treatment of Type 2 Diabetes: REmission Studies Evaluating Type 2 DM – Intermittent Insulin Therapy (RESET-IT) (NCT01755468). This is a randomized, open-label trial to compare intermittent insulin therapy with continuous metformin therapy for patients with type 2 diabetes. Enrollment is planned for 148 subjects; the planned study completion date is December 2017.

Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

It is hypothesized that CIIIT improves hepatic glucose regulation. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. Two randomized trials report that CIIIT may moderate the progression of nephropathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). This evidence does not permit definitive conclusions regarding the health benefits of CIIIT. Therefore, the technique is considered experimental, investigational and/or unproven..

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIIT within each organization's clinical practica guidelines for diabetes. (6-8) The American College of Physicians published a clinical practice guideline in 2011 on the use of intensive insulin therapy for the management of glycemic control in hospitalized patients (9); the recommendations put forth in this guideline were based on earlier systematic review on this topic which did not include CIIIT. (10)

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

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Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been developed or changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov.

References:

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

3. Aoki TT, Grecu EO, Prendergast JJ et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. Diabetes Care 1995; 18(9):1260-5.

4. Dailey GE, Boden GH, Creech RH et al. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. Metabolism 2000; 49(11):1491-5.

5. Weinrauch LA, Sun J, Gleason RE et al. Pulsatile intermittent intravenous insulin therapy for attenuation of retinopathy and nephropathy in type 1 diabetes mellitus. Metabolism 2010; 59 (10):1429-34.

6. Handelsman Y, Mechanick JI, Blonde L et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract 2011; 17 Suppl 2:1-53.

7. Rodbard HW, Blonde L, Braithwaite SS et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Endocr Pract 2007; 13 Suppl 1:1-68.

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9. Qaseem A, Humphrey LL, Chou R et al. Use of intensive insulin therapy for the management of glycemic control in hospitalized patients: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2011; 154 (4):260-7.

10. Kansagara D, Fu R, Freeman M et al. Intensive insulin therapy in hospitalized patients: a systematic review. Ann Intern Med 2011; 154(4):268-82.

11. Chronic Intermittent Intervenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2014 July) Medicine 2.01.43

PET EXHIBIT 4-390

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Policy History:

Date	Reason
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

EXHIBIT 5 exhibitsticker.com

decreasing hepatic glucose production. While patients with type-2 diabetes may be treated with various combinations of all three of the above classes of drugs, with or without additional insulin, patients with type-1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Large-scale randomized studies have established that tight glucose control is associated with a decreased incidence of microvascular complications of diabetes (i.e., nephropathy, neuropathy, and retinopathy). Currently, the American Diabetics Association recommends a target hemoglobin A1c (HbA1c) concentration of less than 7%.

CIIIT, also referred to as outpatient intravenous insulin therapy (OIVIT); pulsatile intravenous insulin therapy; hepatic activation; or metabolic activation, involves delivering insulin intravenously over a 6- to 7- hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT therapy is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al. proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that once weekly 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Regulatory Status

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process, as they

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are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2005 and was regularly updated with searches of the MEDLINE database. No new relevant research studies were identified in the most recent literature review. Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

Does CIIIT improve glycemic control in diabetic patients?

Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) are necessary to validate treatment effectiveness. A MEDLINE literature search did not identify any blinded randomized clinical trials focusing on the efficacy of CIIIT for glucose control.

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the HbA1c levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1,2)

Aoki et al. also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures

were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Does CIIIT reduce diabetic end-organ damage?

Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dailey et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

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vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

- Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

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Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

It is hypothesized that CIIIT improves hepatic glucose regulation. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. Two randomized trials report that CIIIT may moderate the progression of nephropathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). This evidence does not permit definitive conclusions regarding the health benefits of CIIIT. Therefore, the technique is considered experimental, investigational and/or unproven..

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIIT within each organization's clinical practice guidelines for diabetes. (6-8) The American College of Physicians published a clinical practice guideline in 2011 on the use of intensive insulin therapy for the management of glycemic control in hospitalized patients (9); the recommendations put forth in this guideline were based on earlier systematic review on this topic which did not include CIIIT. (10)

Contract:

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Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

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Case 2:17-cv-00080-SEH Document 9-5 Filed 11/02/17 Page 7 of 152

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
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CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
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Medicare Coverage:

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The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been developed or changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov.

References:

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

3. Aoki TT, Grecu EO, Prendergast JJ et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. Diabetes Care 1995; 18(9):1260-5.

4. Dailey GE, Boden GH, Creech RH et al. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. Metabolism 2000; 49(11):1491-5.

5. Weinrauch LA, Sun J, Gleason RE et al. Pulsatile intermittent intravenous insulin therapy for attenuation of retinopathy and nephropathy in type 1 diabetes mellitus. Metabolism 2010; 59 (10):1429-34.

6. Handelsman Y, Mechanick JI, Blonde L et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract 2011; 17 Suppl 2:1-53.

7. Rodbard HW, Blonde L, Braithwaite SS et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Endocr Pract 2007; 13 Suppl 1:1-68.

8. American Diabetes Association. Clinical Practice Recommendations 2009. Diabetes Care 2009; 32(suppl 1). Available online at: http://care.diabetesjournals.org. Last accessed May, 2014.

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10. Kansagara D, Fu R, Freeman M et al. Intensive insulin therapy in hospitalized patients: a systematic review. Ann Intern Med 2011; 154(4):268-82.

11. Chronic Intermittent Intervenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2014 July) Medicine 2.01.43

PET EXHIBIT 5-399

Case 2:17-cv-00080-SEH Document 9-5 Filed 11/02/17 Page 9 of 152

Policy History:

Date	Reason
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 06-01-2017

Coverage:

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

NOTE: This policy does not apply to use of intravenous insulin infusions in the inpatient setting (i.e., for the treatment of diabetic ketoacidosis or diabetic hyperosmolar coma).

Description:

Glucose Homeostasis

Insulin-mediated glucose homeostasis involves 3 primary functions which occur at 3 locations: 1) insulin secretion by the pancreas; 2) glucose uptake, primarily in the muscle, liver, gut, and fat; and 3) hepatic glucose production. In the fasting state, when insulin levels are low, most glucose uptake into cells is non-insulin-mediated. Glucose uptake is then balanced by liver production of glucose. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, marked hyperglycemia may result.

Medications for Glucose Homeostasis in Diabetes

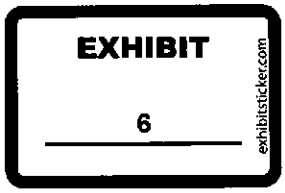
Diabetes is characterized by elevated blood glucose levels due to inadequate or absent insulin production (type 1 diabetes) or due to increased hepatic glucose production, decreased peripheral glucose uptake, and decreased insulin secretion (type 2 diabetes).

Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos], rosiglitazone [Avandia]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by decreasing hepatic glucose production. While patients with type 2 diabetes may be treated with various combinations of all 3 of these classes of drugs, with or without additional insulin, patients with type 1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Standard insulin management involves use of subcutaneous injection to mimic a physiologic insulin profile. Intravenous insulin is used in the acute inpatient setting to manage hyperglycemic emergencies (e.g., diabetic ketoacidosis).

Chronic Intermittent Insulin Therapy

Several forms of chronic intermittent insulin therapy, in which insulin is delivered intravenously or into the peritoneal space, have been evaluated.

Chronic intermittent intravenous insulin therapy (CIIIT) - also referred to as outpatient intravenous insulin therapy, pulsatile intravenous insulin therapy, hepatic activation therapy, or metabolic activation therapy - involves delivering insulin intravenously once weekly over several hours in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the doses based on frequent blood glucose monitoring. CIIIT is principally designed to normalize the hepatic metabolism of glucose. In 1993, Aoki et al. proposed that, in patients with



type 1 diabetes, lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) They stated: "We reasoned that if the liver of an IDDM [insulin-dependent diabetes mellitus; i.e., type 1 diabetes] patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that intermittent intravenous pulsatile infusions of insulin administered once weekly while the patient ingests a carbohydrate meal would increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin because it is delivered to the liver. The goal of this outpatient therapy is improved glucose control through improved hepatic activation.

Regulatory Status

Any insulin infusion pump can be used for the purposes of chronic intermittent intravenous insulin therapy. Infusion pumps have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2005 and has been updated regularly with searches of the MEDLINE database. The most recent literature review is through December 20, 2016.

Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end-organ damage associated with diabetes. Because of the many variables associated with management of diabetes, randomized controlled trials (RCTs) of CIIIT are necessary to permit conclusions about treatment effectiveness.

No studies were identified that investigated the proposed mechanism of action of CIIIT in humans.

CIIIT and Glycemic Control in Diabetic Patients

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. (1) All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which time appropriate adjustments in diet, insulin doses, and physical activity were made. While the study reported a decrease in the hemoglobin A1c (HbA1c) levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1, 2)

Aoki et al. (1995) also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1 diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomized to a control group or to a treatment group for 3 months and then crossed over for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin-converting enzyme inhibitors, calcium channel blockers, loop diuretics, alpha-2 agonists). The study was randomized, but not blinded, in that sham CIIIT procedures were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Section Summary: CIIIT and Glycemic Control in Diabetic Patients

One nonblinded RCT and 1 case series reporting on the effect of CIIIT on glycemic control in type 1 diabetic patients were identified. Both studies reported improvements: one in HbA1c compared with baseline, and the other in dose of antihypertensive medication in the treatment group compared with control. However, the lack of a blinded control comparator group in the RCT limits the conclusions that can be drawn.

In 2010, Weinrauch et al. published an RCT of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type 1 diabetes. (4) Patients were randomized to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29; control group) or to standard therapy plus weekly CIIIT (n=36; treatment group). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, control of HbA1c levels, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was smaller in the treatment group (0.09 mg/dL) than in the control group (0.39 mg/dL; p=0.035). While average creatinine clearance fell less in the treatment group (-5.1 mL/min), the difference versus standard therapy was not significant (-9.9 mL/min; p=0.30). Glycemic control did not vary significantly. The clinical significance of the difference in creatinine levels is unknown.

In 2000, Dailey et al. reported on a prospective, multicenter, controlled study of the effects of CIIIT on the progression of diabetic nephropathy. (5) They assessed 49 type 1 diabetes patients with nephropathy who were following the Diabetes Control and Complications Trial intensive therapy regimen. Of these, 26 were assigned to the control group, which continued intensive therapy, and 23 were assigned to the treatment group, which underwent weekly CIIIT plus intensive therapy. Both groups reported a significant decrease in HbA1c levels during the 18-month study period. Creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less than in the control group. The clinical significance of this finding is uncertain. Larger clinical trials that evaluate the end point of time to progression of renal failure are needed.

Section Summary: CIIIT and Reductions in Diabetic End-Organ Damage

Two controlled studies focusing on the efficacy of CIIIT for reducing diabetic end-organ complications were identified. Both reported significant improvements in intermediate measures of glycemic control in each group from pre- to postintervention, but did not consistently report differences in clinically meaningful outcomes from the beginning of the studies to the end. Similarly, there were no significant differences between treatment groups in the RCT.

Summary of Evidence

For individuals who have type 1 diabetes who receive chronic intermittent intravenous insulin therapy (CIIIT), the evidence includes 2 randomized controlled trials (RCTs) and uncontrolled studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. A limited number of uncontrolled studies have suggested that CIIIT might improve glycemic control. The 2 RCTs reported that CIIIT might moderate the progression of nephropathy or retinopathy. However, the published studies were small and reported improvements on intermediate outcomes only (i.e., changes in laboratory values). The clinical significance of the differences reported in these studies is uncertain. Additionally, most published evidence appeared between 1993 and 2000 and, as a result, does not account for recent improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association (updated in 2017) (6) and the American Association of Clinical Endocrinologists and American College of Endocrinology (updated in 2015), (7) have not included chronic intermittent intravenous insulin therapy (CIIIT) in guidelines for managing type 1 diabetes.

The American College of Physicians updated its Best Practice Advice in 2014 on inpatient glycemic control, which provided some recommendations on the use of intensive insulin therapy, including (8):

- "Best Practice Advice 1: Clinicians should target a blood glucose level of 7.8 to 11.1 mmol/L (140- 200 mg/dL) if insulin therapy is used in SICU [surgical intensive care unit]/MICU [medical intensive care unit] patients."

• "Best Practice Advice 2: Clinicians should aim to set targets less than 7.5 mmol/L (140 mg/dL) because harms are likely to increase with lower blood glucose targets."

Ongoing and Unpublished Clinical Trials

A currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01023165[a]	Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems	2000	Nov 2015 (unknown)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050

ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

References:

1. Aoki TT, Benbarka MM, Okimura MC, et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet. Aug 28 1993; 342(8870):515-518. PMID 8102666

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med. Dec 1995; 99(6):683-684. PMID 7503093

3. Aoki TT, Grecu EO, Prendergast JJ, et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. Diabetes Care. Sep 1995; 18(9):1260-1265. PMID 8612440

4. Weinrauch LA, Sun J, Gleason RE, et al. Pulsatile intermittent intravenous insulin therapy for attenuation of retinopathy and nephropathy in type 1 diabetes mellitus. Metabolism. Mar 1 2010; 59(10):1429-1434. PMID 20189608

5. Dailey GE, Boden GH, Creech RH, et al. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. Metabolism. Nov 2000; 49(11):1491-1495. PMID 11092517

6. American Diabetes Association (ADA). American Diabetes Association. Standards of Medical Care in Diabetes - 2017. Available at: <http://professional.diabetes.org> (accessed January 23, 2017).

7. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Cinical Endocrinologists and American College of Endocrinology - clinical practice guidelines for developing a diabetes mellitus comprehensive care plan - 2015. Endocr Pract. Apr 2015; 21 Suppl 1:1-87. PMID 25869408

8. Qaseem A, Chou R, Humphrey LL, et al. Inpatient glycemic control: best practice advice from the Clinical Guidelines Committee of the American College of Physicians. Am J Med Qual. Mar-Apr 2014; 29(2):95-98. PMID 23709472

9. Centers for Medicaid and Medicare Services. National Coverage Determination (NCD) for Outpatient Intravenous Insulin Treatment (40.7). 2009. Available at: <https://www.cms.gov> (accessed January 25, 2017).

10. Chronic Intermittent Intravenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2017 February) Medicine 2.01.43

Policy History:

Date	Reason
6/1/2017	Document updated with literature review. Coverage unchanged.
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-15-2016	05-31-2017
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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July 28, 2017

Sent via Certified Mail: 7015 1520 0000 8783 0092
Therese Anderson, CFE
Special Investigations Department
Blue Cross Blue Shield of Montana
P.O. Box 4309
Helena, MT 59604-4309

Re: Trina Health of Montana
Response to Cease and Desist Letters - April 12 and 19, 2017
Artificial Pancreas Treatment billing for BCBSMT Clients

Dear Ms. Anderson:

I am writing on behalf of Trina Health of Montana (Trina), to request that the "Cease and Desist" letters, dated April 12 and 19, 2017, that you sent to the three treating providers employed at Trina, be reconsidered, immediately. Those letters are enclosed herewith for your reference. Those letters demanded that the Trina providers "Cease and Desist" from billing Artificial Pancreas Treatment (APT) as any CPT/HCPCS (coding) and stated that Trina's providers must bill the treatment as G9147, which is the code for Outpatient Intravenous Insulin Treatment (OIVIT). The OIVIT style treatment is entirely different than APT treatment, and Trina believes that Blue Cross Blue Shield of Montana (BCBSMT) is mistaken in its billing direction and is inappropriately demanding that Trina providers bill the incorrect code.

Following receipt of your letters, Trina did direct its providers to discontinue billing BCBSMT, altogether, and it felt that its providers had been put "in between a rock and a hard spot" so to speak, as it could not bill the APT treatment under the G9147 code, since that would be incorrect, and there is no specific code for APT. Because there is no single code, at this time, for the APT treatment, Trina providers appropriately use the applicable outpatient coding under ICD-10 for the treatment.

Further, enclosed with your letters was the policy on Chronic Intermittent Intravenous Insulin Therapy (CIIIT), from HCSC Medical Policies, dated 05-15-2016. Trina also noticed that BCBSMT adopted the same exact policy on 06-01-2017. Both of those policies are enclosed herewith for your reference. My client has provided me the

EXHIBIT 7

information that shows how APT is distinguishable between CIIIT and APT and that establishes that the rationale behind the policy, as it is applied to APT, is faulty. The next couple of paragraphs contains that information from Trina.

CIIIT And APT Are Not the Same Treatments

There is a stark difference in the description of CIIIT and APT, as CIIIT is described in the HCSC and BCBSMT policies on CIIIT (Policy). According to the Policy:

> "Chronic Intermittent Insulin Therapy (CIIIT) – also referred to as outpatient intravenous insulin therapy, pulsatile intravenous insulin therapy, hepatic activation therapy, or metabolic activation therapy- involves delivering insulin intravenously …using a specialized pump controlled by a computerized program that adjusts the doses based on frequent blood glucose monitoring. CIIIT is principally designed to normalize the hepatic metabolism of glucose."

While, at the outset, it appears the two therapies may be alike, as both use insulin and a "specialized pump," the similarities end there. Artificial Pancreas Treatment (APT), utilizes a Microburst Insulin Infusion (MII) pump that does NOT rely on or even use a computer program, as indicated in your new policy. Rather, all adjustments are made manually for each individual patient, based upon a variety of factors.

Furthermore, unlike CIIIT, APT is not principally designed to normalize the hepatic metabolism of glucose. Rather, APT specifically targets system-wide metabolism, including neurological and skeletal, as well as hepatic. In addition, contrary to CIIIT programs, in which: "[a]ny insulin infusion pump can be used," ONLY the FDA cleared Bionica Microdose Infusion Pump can be used for APT. Probably most importantly, the Policy points out that, with CIIIT, "the evidence is insufficient to determine the effects of the technology on health outcomes." As set forth below, there is overwhelming evidence that health is improved as a result of APT. Thus, the Medical Policy for CIIIT does not apply to APT.

On July 14, 2017, the Journal of Diabetes, Metabolic Disorders & Control published: "Microbust Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization." The article is attached herewith for your reference. At the outset, the peer reviewed article explains how the treatment differs from other methods of therapeutic insulin administration because the Bionica Microdose Infusion Pump provides pulsatile administration of insulin in a manner that closely replicates natural pancreatic insulin secretion from beta cells in the body. None of the other conventional treatment regimens use this process. In fact, as set forth in the article, "the current methods of therapeutic insulin administration are not pulsatile."

Therese Anderson, CFE
Special Investigations Department
Blue Cross Blue Shield of Montana

Rationale for HCSC/BCBSMT Policy is Not Supported

The "Rationale" in the Policy as to APT, to the extent the Policy is applied to APT by BCBSMT is entirely inaccurate. That Rational in the Policy is, in short, that "No studies were identified that investigated the proposed mechanism of action of CIIIT in humans." The enclosed Journal report establishes that the Policy Rationale is not accurate and focuses on three major studies that establish the medical benefits of APT as it applies the MII treatment and related procedures. The studies referenced by the article can be summarized as follows:

Carbohydrate metabolism study
An examination of the effects of APT on metabolic rate measures as determined by indirect calorimetry concluded that oxygen consumption and energy expenditure significantly increased over the course of three treatment periods within each complete therapy session. This resulted in promoting a greater carbohydrate oxidation rate and an increased respiratory exchange ratio, while reducing lipolysis and lipid oxidation.

Painful diabetic neuropathy (PDN) study
Utilization of the microdose insulin infusion (APT) "showed a complete elimination or significant reduction of pain in 93% of PDN patients after 3 months of treatment – with complete resolution of pain in 47% of PDN patients."

Hospital and emergency room utilizations study
This two-year study was conducted at 14 centers, nationwide, and involved 1,524 Type 1 and Type 2 diabetic patients with two or more secondary complications of diabetes, including neuropathy, cardiomyopathy, retinopathy, hypertension, fibromyalgia, and hyperlipidemia, and histories of multiple hospitalizations and emergency department visits. The study concluded:

APT reduced hospitalizations to 1.65/1,000/year-as opposed to 46.7 patients per 1,000 over a one year period (National Hospital Discharge Survey (NHDS));

APT reduced emergency department visits to 2.3/1,000/year versus 58.4 (U.S. Agency for Healthcare Statistics (USAHS))

In other words, hospitalizations for diabetic patients are reduced for those undergoing MII treatment by 95.63% and emergency department visits are 94.66% fewer for those patients.

Of note to BCBSMT, the article went on to state: "This represents a significant reduction in hospital admissions and emergency department visits compared to normal rates-presumably generating substantial savings for the health care system."

The Policy that you used to support the "Cease and Desist" language in your letters and the rationale being used by BCBSMT, currently, to deny coverage for the treatments provided to BCBSMT insureds at Trina as of this April, is that the procedures does not work. The attached peer-reviewed medical journal article and the referenced studies show that APT is having astonishingly positive health effects on patients suffering from the most devastating co-morbidities of diabetes, and that, it does, in fact, work. As to your billing directive that Trina providers must us the G9147 code for (OIVIT), the attached Journal and the information provided in this letter should give you enough information to show that APT and OIVIT are not the same code. For that reason and under applicable laws, Trina providers absolutely cannot bill APT under the G9147 code designated for OIVIT treatment.

Trina and I believe that the above-stated information provides you the information you and the BCBSMT medical team need to understand that the CIIIT policy does not apply to the APT treatment. It also provides you the basis for rescinding the "Cease and Desist" directive given in your letters to the Trina providers. Your letters have put Trina in a position where it providers cannot bill BCBSMT, at all, because it cannot bill the APT procedure under OIVIT and your letter is preventing it from billing under the appropriate outpatient CPT codes.

As a result of your decision to refuse to reimburse for APT, Trina Health of Montana has been forced to suspend operations. Patients that relied on APT to stabilize and improve their diabetic complications and symptoms have been cut off from their life changing treatment. Patients who, prior to APT, were hospitalized and/or required emergency department admissions three (3), four (4), and even five (5) times each year, most of whom had zero hospitalizations and emergency department visits during APT, now face a daily and genuine fear that they are moving closer and closer to hospitalization. These rejected patients are painfully aware of the terrifying reality: that they may not survive long enough to, once again, undergo the treatment that allowed them to live a truly full and healthy life.

As such, I have been hired to request that BCBSMT immediately rescind the "Cease and Desist" directive and clarify that APT may be billed under reimbursable outpatient coding applicable to APT. In the event that BCBSMT does not do so within thirty (30) days of the date of this letter, I have been retained to file a declaratory action and move for a restraining order related to BCBSMT's billing directives and conclusions as to OIVIT, CIIIT and APT.

Time is of the essence for the patients served by Trina Health of Montana, and Trina Health of Montana must have the clarification in writing to ensure accuracy and appropriateness in its billing. Although, the patients referred to herein would prefer not to have to pursue a remedy in the courts, their options may be limited to that course of

action. They view your decision as one in which you will determine whether they live or die. They trust that you will thoughtfully consider their plight in reaching your decision.

Sincerely,

ERIN F. MacLEAN
for FREEMAN & MACLEAN, P.C.

EFM/tmr

cc: **Sent via Certified Mail: 7015 1520 0000 8783 0108**
Monica Berner, BCBSMT Chief Medical Officer and
Divisional Senior Vice President of Plan Operations
P.O. Box 4309
Helena, MT 59604-4309

BlueCross BlueShield of Montana

4/14/17 Received & faxed to Erin

April 12, 2017

Dr. Roman Hendrickson
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

COPY

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Dr. Hendrickson:

Blue Cross and Blue Shield of Montana (BCBSMT) a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, periodically conducts audits of claims submitted by providers to help ensure that benefits are provided only for medically appropriate services that are included in our members' benefit plan as well as within BCBSMT's guidelines and Medical Policies.

It has come to our attention that your office has submitted claims for Artificial Pancreas Treatment (APT) that, upon review of the selected medical records and/ or additional information, were incorrectly billed as Evaluation and Management services, prolonged physician services, IV infusions, and/or lab services.

The rationale for this determination is that based upon the information reviewed, the claims appear to be for APT services but were billed using the incorrect procedure codes listed below:

Procedure Code	Procedure Code Description
36416	COLLECTION OF CAPILLARY BLOOD SPECIMEN (EG. FINGER, HEEL, EAR STICK)
80422	GLUCAGON TOLERANCE PANEL; FOR INSULINOMA THIS PANEL MUST INCLUDE THE FOLLOWING; GLUCOSE (82947 X 3) INSULIN (83525 X 3)
82947	GLUCOSE; QUANTITATIVE
82950	GLUCOSE; POST GLUCOSE DOSE (INCLUDES GLUCOSE)
82962	GLUCOSE, BLOOD BY GLUCOSE MONITORING DEVICE(S) CLEARED BY THE FDA SPECIFICALLY FOR HOME USE
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1 HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP

99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
99355	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

BlueCross BlueShield of Montana

4/14/17 Received; faxed to Erin

April 12, 2017

Dianne Sawitke, NP
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

COPY

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Ms. Sawitke:

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94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
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96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP
99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES

	THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
99355	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

BlueCross BlueShield of Montana

April 19, 2017

Kimberley Laden, NP
Trina Health of Montana
530 N Montana St
Dillon, MT 59725-3315

VIA CERTIFIED MAIL

Re: Cease and Desist Billing for Artificial Pancreas Treatment as any CPT/HCPCS other than G9147

Dear Ms. Laden:

Blue Cross and Blue Shield of Montana (BCBSMT) a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, periodically conducts audits of claims submitted by providers to help ensure that benefits are provided only for medically appropriate services that are included in our members' benefit plan as well as within BCBSMT's guidelines and Medical Policies.

It has come to our attention that your office has submitted claims for Artificial Pancreas Treatment (APT) that, upon review of the selected medical records and/ or additional information, were incorrectly billed as Evaluation and Management services, prolonged physician services, IV infusions, and/or lab services.

The rationale for this determination is that based upon the information reviewed, the claims appear to be for APT services but were billed using the incorrect procedure codes listed below:

Procedure Code	Procedure Code Description
36416	COLLECTION OF CAPILLARY BLOOD SPECIMEN (EG. FINGER, HEEL, EAR STICK)
80422	GLUCAGON TOLERANCE PANEL; FOR INSULINOMA THIS PANEL MUST INCLUDE THE FOLLOWING; GLUCOSE (82947 X 3) INSULIN (83525 X 3)
82947	GLUCOSE; QUANTITATIVE
82950	GLUCOSE; POST GLUCOSE DOSE (INCLUDES GLUCOSE)
82962	GLUCOSE, BLOOD BY GLUCOSE MONITORING DEVICE(S) CLEARED BY THE FDA SPECIFICALLY FOR HOME USE
94681	OXYGEN UPTAKE, EXPIRED GAS ANALYSIS; INCLUDING CO2 OUTPUT, PERCENTAGE OXYGEN EXTRACTED
96360	IV INFUSION HYDRATION INITIAL 31 MIN-1 HOUR
96365	IV INFUSION THERAPY/PROPHYLAXIS /DX 1ST >1 HOUR
96366	IV INFUSION THERAPY PROPHYLAXIS/DX EA HOUR
96521	REFILLING AND MAINTENANCE OF PORTABLE PUMP

99204	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF A NEW PATIENT, WHICH REQUIRES THESE THREE KEY COMPONENTS; A COMPREHENSIVE HISTORY; A COMPREHENSIVE EXAMINATION; AND
99214	OFFICE OR OTHER OUTPATIENT VISIT FOR THE EVALUATION AND MANAGEMENT OF AN ESTABLISHED PATIENT, WHICH REQUIRES AT LEAST TWO OF THESE THREE KEY COMPONENTS; A DETAILED HISTORY; A DETAILED EXAMINATION; AND
99354	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
99355	PROLONGED PHYSICIAN SERVICE IN THE OFFICE OR OTHER OUTPATIENT SETTING REQUIRING DIRECT (FACE-TO-FACE) PATIENT CONTACT BEYOND THE USUAL SERVICE (EG, PROLONGED CARE AND TREATMENT OF AN ACUTE ASTHMATIC PATIENT IN AN OUTPATIENT SETTIN
J1815	INJECTION, INSULIN, PER 5 UNITS

BCBSMT/HCSC Medical Policy MED201.028 states that chronic intermittent intravenous insulin therapy (CIIIT) is considered experimental, investigational and/or unproven, and therefore, not covered by BCBSMT. A copy of Medical Policy 201.028 is included for your reference.

The 2017 HCPCS Level II manual lists HCPCS G9147 as, "Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine area nitrogen (UNN); and/or, arterial, venous or capillary glucose; and/or potassium concentration. According to Medical Policy MED201.028, HCPCS G9147 is the specific medical code for CIIIT procedures.

The BCBSMT website (www.bcbsmt.com) is available to providers to assist in reviewing BCBSMT's Medical Policies and Standards and Requirements.

Please cease and desist billing Artificial Pancreas Treatment as any CPT/HCPCS other than G9147. Any future claim audit(s) performed where the services billed are not supported by documentation, will be subject to recovery by Blue Cross and Blue Shield of Montana.

We request that you notify BCBSMT members in advance of services that APT is not covered and they will be fully responsible for the cost of such treatments.

Please be advised that effective immediately, BCBSMT will start conducting a pre-payment review of all claims submitted from your office to confirm appropriate claims coding.

Please continue to submit your claims as you ordinarily do. If BCBSMT requires additional information regarding a claim, such as the supporting medical records, you will be advised by letter. Please follow the directions on the letter regarding the address to which the medical records should be sent. As a reminder, as a BCBS contracting provider, submitting clinical and/or administrative records upon request is a condition of your network participation.

Please give careful consideration to the information contained herein. Should you have any questions regarding this letter, please contact me at 406.437.5230.

Sincerely,

Therese Anderson

Therese Anderson, CFE
Manager
Special Investigations Department
Blue Cross Blue Shield of Montana

Enclosure (1)

Cc: Harold Laron Briggs

HCSC Medical Policies

Medical Policies - Medicine

Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 05-15-2016

Coverage:

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

Description:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production. There are three main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: 1. insulin secretion by the pancreas; 2. glucose uptake, primarily in the muscle, liver, gut, and fat; and 3. hepatic glucose production. For example, in the fasting state, when insulin levels are low, the majority of glucose uptake is non-insulin mediated. Glucose uptake is then balanced by liver production of glucose, critical to nourish vital organs, such as the brain. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result. Different classes of diebetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®]; and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by

decreasing hepatic glucose production. While patients with type-2 diabetes may be treated with various combinations of all three of the above classes of drugs, with or without additional insulin, patients with type-1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Large-scale randomized studies have established that tight glucose control is associated with a decreased incidance of microvascular complications of diabetes (i.e., nephropathy, neuropathy, and retinopathy). Currently, the American Diabetics Association recommends a target hemoglobin A1c (HbA1c) concentration of less than 7%.

CIIIT, also referred to as outpatient intravenous insulin therapy (OIVIT); pulsatile intravenous insulin therapy; hepatic activation; or metabolic activation, involves delivering insulin intravenously over a 6- to 7- hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT therapy is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al. proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," end proposed that once weekly 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimetely results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Regulatory Status

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process, as they

are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2005 and was regularly updated with searches of the MEDLINE database. No new relevant research studies were identified in the most recent literature review. Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

Does CIIIT improve glycemic control in diabetic patients?

Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) are necessary to validate treatment effectiveness. A MEDLINE literature search did not identify any blinded randomized clinical trials focusing on the efficacy of CIIIT for glucose control.

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the HbA1c levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1,2)

Aoki et al. also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures

were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Does CIIIT reduce diabetic end-organ damage?

Because of the many variables associated with diabetic management, RCTs are necessary to validate treatment effectiveness. A MEDLINE literature search identified 2 RCTs focusing on the efficacy of CIIIT for reducing diabetic end organ complications.

In 2000, Dalley et al. reported on the effect of CIIIT on the progression of diabetic nephropathy. (4) A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1c during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al. published a study of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. (5) Patients were randomly allocated to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not

vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Ongoing Clinical Trials

A search of the online database ClinicalTrials.gov, identified the following studies evaluating the use of CIIIT.

- Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems (NCT01023165). This is a nonrandomized Phase 3 trial to evaluate outcomes related to quality of life and diabetic complications in patients with diabetic complications who undergo weekly bolus insulin sessions. Enrollment is planned for 2000 subjects; the planned study completion date is November 2015.

- A Randomized Controlled Trial to Evaluate Early Intermittent Intensive Insulin Therapy as an Effective Treatment of Type 2 Diabetes: REmission Studies Evaluating Type 2 DM – Intermittent Insulin Therapy (RESET-IT) (NCT01755468). This is a randomized, open-label trial to compare intermittent insulin therapy with continuous metformin therapy for patients with type 2 diabetes. Enrollment is planned for 148 subjects; the planned study completion date is December 2017.

Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

It is hypothesized that CIIIT improves hepatic glucose regulation. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. Two randomized trials report that CIIIT may moderate the progression of nephropathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). This evidence does not permit definitive conclusions regarding the health benefits of CIIIT. Therefore, the technique is considered experimental, investigational and/or unproven..

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIIT within each organization's clinical practice guidelines for diabetes. (6-8) The American College of Physicians published a clinical practice guideline in 2011 on the use of intensive insulin therapy for the management of glycemic control in hospitalized patients (9); the recommendations put forth in this guideline were based on earlier systematic review on this topic which did not include CIIIT. (10)

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been developed or changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov.

References:

1. Aoki TT, Benbarka MM, Okimura MC et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. Lancet 1993; 342(8870):515-8.

2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. Am J Med 1995; 99(6):683-4.

3. Aoki TT, Grecu EO, Prendergast JJ et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. Diabetes Care 1995; 18(9):1260-5.

4. Dailey GE, Boden GH, Creech RH et al. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. Metabolism 2000; 49(11):1491-5.

5. Weinrauch LA, Sun J, Gleason RE et al. Pulsatile intermittent intravenous insulin therapy for attenuation of retinopathy and nephropathy in type 1 diabetes mellitus. Metabolism 2010; 59 (10):1429-34.

6. Handelsman Y, Mechanick JI, Blonde L et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract 2011; 17 Suppl 2:1-53.

7. Rodbard HW, Blonde L, Braithwaite SS et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Endocr Pract 2007; 13 Suppl 1:1-68.

8. American Diabetes Association. Clinical Practice Recommendations 2009. Diabetes Care 2009; 32(suppl 1). Available online at: http://care.diabetesjournals.org. Last accessed May, 2014.

9. Qaseem A, Humphrey LL, Chou R et al. Use of intensive insulin therapy for the management of glycemic control in hospitalized patients: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2011; 154 (4):260-7.

10. Kansagara D, Fu R, Freeman M et al. Intensive insulin therapy in hospitalized patients: a systematic review. Ann Intern Med 2011; 154(4):268-82.

11. Chronic Intermittent Intervenous Insulin Therapy. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Manual (2014 July) Medicine 2.01.43

Policy History:

Date	Reason
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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Print

Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Number: MED201.028

Effective Date: 06-01-2017

Coverage:

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

Chronic intermittent intravenous insulin therapy (CIIIT) **is considered experimental, investigational and/or unproven.**

NOTE: This policy does not apply to use of intravenous insulin infusions in the inpatient setting (i.e., for the treatment of diabetic ketoacidosis or diabetic hyperosmolar coma).

Description:

Glucose Homeostasis

Insulin-mediated glucose homeostasis involves 3 primary functions which occur at 3 locations: 1) insulin secretion by the pancreas; 2) glucose uptake, primarily in the muscle, liver, gut, and fat; and 3) hepatic glucose production. In the fasting state, when insulin levels are low, most glucose uptake into cells is non-insulin-mediated. Glucose uptake is then balanced by liver production of glucose. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, marked hyperglycemia may result.

Medications for Glucose Homeostasis in Diabetes

Diabetes is characterized by elevated blood glucose levels due to inadequate or absent insulin production (type 1 diabetes) or due to increased hepatic glucose production, decreased peripheral glucose uptake, and decreased insulin secretion (type 2 diabetes).

Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos], rosiglitazone [Avandia]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by decreasing hepatic glucose production. While patients with type 2 diabetes may be treated with various combinations of all 3 of these classes of drugs, with or without additional insulin, patients with type 1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Standard insulin management involves use of subcutaneous injection to mimic a physiologic insulin profile. Intravenous insulin is used in the acute inpatient setting to manage hyperglycemic emergencies (e.g., diabetic ketoacidosis).

Chronic Intermittent Insulin Therapy

Several forms of chronic intermittent insulin therapy, in which insulin is delivered intravenously or into the peritoneal space, have been evaluated.

Chronic intermittent intravenous insulin therapy (CIIIT) - also referred to as outpatient intravenous insulin therapy, pulsatile intravenous insulin therapy, hepatic activation therapy, or metabolic activation therapy - involves delivering insulin intravenously once weekly over several hours in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the doses based on frequent blood glucose monitoring. CIIIT is principally designed to normalize the hepatic metabolism of glucose. In 1993, Aoki et al. proposed that, in patients with

type 1 diabetes, lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. (1) They stated: "We reasoned that if the liver of an IDDM [insulin-dependent diabetes mellitus; i.e., type 1 diabetes] patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that intermittent intravenous pulsatile infusions of insulin administered once weekly while the patient ingests a carbohydrate meal would increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin because it is delivered to the liver. The goal of this outpatient therapy is improved glucose control through improved hepatic activation.

Regulatory Status

Any insulin infusion pump can be used for the purposes of chronic intermittent intravenous insulin therapy. Infusion pumps have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the delivery of intravenous medications. FDA product code: IZG.

Rationale:

This policy was originally created in 2005 and has been updated regularly with searches of the MEDLINE database. The most recent literature review is through December 20, 2016.

Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end-organ damage associated with diabetes. Because of the many variables associated with management of diabetes, randomized controlled trials (RCTs) of CIIIT are necessary to permit conclusions about treatment effectiveness.

No studies were identified that investigated the proposed mechanism of action of CIIIT in humans.

CIIIT and Glycemic Control in Diabetic Patients

In 1993, Aoki et al. published a case series of 20 patients with "brittle" type 1 diabetes. (1) All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which time appropriate adjustments in diet, insulin doses, and physical activity were made. While the study reported a decrease in the hemoglobin A1c (HbA1c) levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT. (1, 2)

Aoki et al. (1995) also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1 diabetes and associated hypertension and nephropathy. (3) The 26 patients were randomized to a control group or to a treatment group for 3 months and then crossed over for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin-converting enzyme inhibitors, calcium channel blockers, loop diuretics, alpha-2 agonists). The study was randomized, but not blinded, in that sham CIIIT procedures were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Section Summary: CIIIT and Glycemic Control in Diabetic Patients

One nonblinded RCT and 1 case series reporting on the effect of CIIIT on glycemic control in type 1 diabetic patients were identified. Both studies reported improvements: one in HbA1c compared with baseline, and the other in dose of antihypertensive medication in the treatment group compared with control. However, the lack of a blinded control comparator group in the RCT limits the conclusions that can be drawn.

CIIIT and Reductions in Diabetic End-Organ Damage

In 2010, Weinrauch et al. published an RCT of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type 1 diabetes. (4) Patients were randomized to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29; control group) or to standard therapy plus weekly CIIIT (n=36; treatment group). Baseline demographic characteristics were similar between the 2 groups, as were age of onset, duration of diabetes, control of HbA1c levels, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was smaller in the treatment group (0.09 mg/dL) than in the control group (0.39 mg/dL; p=0.035). While average creatinine clearance fell less in the treatment group (-5.1 mL/min), the difference versus standard therapy was not significant (-9.9 mL/min; p=0.30). Glycemic control did not vary significantly. The clinical significance of the difference in creatinine levels is unknown.

In 2000, Dailey et al. reported on a prospective, multicenter, controlled study of the effects of CIIIT on the progression of diabetic nephropathy. (5) They assessed 49 type 1 diabetes patients with nephropathy who were following the Diabetes Control and Complications Trial intensive therapy regimen. Of these, 26 were assigned to the control group, which continued intensive therapy, and 23 were assigned to the treatment group, which underwent weekly CIIIT plus intensive therapy. Both groups reported a significant decrease in HbA1c levels during the 18-month study period. Creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less than in the control group. The clinical significance of this finding is uncertain. Larger clinical trials that evaluate the end point of time to progression of renal failure are needed.

Section Summary: CIIIT and Reductions in Diabetic End-Organ Damage

Two controlled studies focusing on the efficacy of CIIIT for reducing diabetic end-organ complications were identified. Both reported significant improvements in intermediate measures of glycemic control in each group from pre- to postintervention, but did not consistently report differences in clinically meaningful outcomes from the beginning of the studies to the end. Similarly, there were no significant differences between treatment groups in the RCT.

Summary of Evidence

For individuals who have type 1 diabetes who receive chronic intermittent intravenous insulin therapy (CIIIT), the evidence includes 2 randomized controlled trials (RCTs) and uncontrolled studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. A limited number of uncontrolled studies have suggested that CIIIT might improve glycemic control. The 2 RCTs reported that CIIIT might moderate the progression of nephropathy or retinopathy. However, the published studies were small and reported improvements on intermediate outcomes only (i.e., changes in laboratory values). The clinical significance of the differences reported in these studies is uncertain. Additionally, most published evidence appeared between 1993 and 2000 and, as a result, does not account for recent improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association (updated in 2017) (6) and the American Association of Clinical Endocrinologists and American College of Endocrinology (updated in 2015), (7) have not included chronic intermittent intravenous insulin therapy (CIIIT) in guidelines for managing type 1 diabetes.

The American College of Physicians updated its Best Practice Advice in 2014 on inpatient glycemic control, which provided some recommendations on the use of intensive insulin therapy, including (8):

- "Best Practice Advice 1: Clinicians should target a blood glucose level of 7.8 to 11.1 mmol/L (140- 200 mg/dL) if insulin therapy is used in SICU [surgical intensive care unit]/MICU [medical intensive care unit] patients."

• "Best Practice Advice 2: Clinicians should avoid targets less than 7.8 mmol/L (140 mg/dL) because harms are likely to increase with lower blood glucose targets."

Ongoing and Unpublished Clinical Trials

A currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01023165[a]	Multicenter Trial to Evaluate the Effects of Intensive Bolus Intravenous Insulin Delivery on Metabolic Integrity in Type 1 and Type 2 Diabetics Who Despite Tight Control and Proper Diet Still Suffer From Metabolic Problems	2000	Nov 2015 (unknown)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

The HCPCS code G9147 is specific to CIIIT. However, the following codes might be used to describe the various components of CIIIT, and some codes may be used more than once during a single session of CIIIT: 82948, 94681, 96365, 96366, 99070, 99211, J7050, J1817.

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
82948, 94681, 96365, 96366
HCPCS Codes
G9147, J1817, J7050

ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

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Policy History:

Date	Reason
6/1/2017	Document updated with literature review. Coverage unchanged.
5/15/2016	Reviewed. No changes
8/15/2015	Document updated with literature review. Coverage unchanged.
9/15/2014	Reviewed. No changes.
6/15/2013	Document updated with literature review. Coverage unchanged.
8/1/2011	Document updated with literature review. Coverage unchanged. CPT/HCPCS codes added.
9/1/2007	Revised/Updated Entire Document
5/1/2005	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-15-2016	05-31-2017
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-15-2015	05-14-2016
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-15-2014	08-14-2015
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	06-15-2013	09-14-2014
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	08-01-2011	06-14-2013
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	09-01-2007	07-31-2011
Chronic Intermittent Intravenous Insulin Therapy (CIIIT)	05-01-2005	08-31-2007

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Journal of Diabetes, Metabolic Disorders & Control

Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization

Background: Pulsed intravenous insulin therapy (PIVIT) has shown equivocal results in studies examining metabolic control. Microburst insulin infusion mimics the periodicity and amplitude of normal pancreatic function more closely than other previous pulsatile insulin therapeutic approaches.

Methods: Data from three observational, retrospective studies are reported: carbohydrate metabolism, painful diabetic neuropathy (PDN), and hospital/emergency department utilization. All studies utilized controlled microbursts of insulin via the Bionica Microdose system in patients with type 1 and type 2 diabetes. Indirect calorimetry was used to determine carbohydrate and metabolic rate measures (n=311). Painful Diabetic Neuropathy (PDN) diagnosis was assessed by the DN4 questionnaire and patients were categorized by neuropathic pain improvement (n=412). Finally, a two-year study of 1,524 diabetic patients was conducted to compare hospital admissions and emergency department visits to homologous patients.

Results: Microburst insulin infusion (MII) treatment increased oxygen consumption and energy expenditure by promoting a greater carbohydrate oxidation rate. Respiratory exchange ratio values increased significantly, reflecting a change toward carbohydrate oxidation, and resting metabolic rate increased 29%. Microburst therapy resulted in complete elimination or reduction of pain in 93% of PDN patients. Hospital admissions were reduced to 1.65/1,000/ year (versus National Hospital Discharge Survey reported rate of 46.7/1,000/year), and ED visits were reduced to 2.3/1,000/ year (versus US Healthcare Statistics rate of 58.4/1,000/year).

Conclusion: Microburst insulin therapy improved underlying carbohydrate metabolism, reduced neuropathic morbidity, and reduced ED visits and hospital admissions in patients with 2 or more diabetic morbidities. Microburst insulin therapy represents a new advance in the treatment of diabetes and the complications of diabetes.

Research Article

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Background

Recent research has demonstrated the burst insulin secretion of pancreatic beta cells in response to a carbohydrate load. A convincing body of evidence indicates that insulin is secreted in synchronized bursts from the pancreas into the hepatic portal vein [1-3]. Multiple studies in humans and animals have described the resulting oscillatory nature of systemic levels of blood glucose and insulin [4-7]. Moreover, the loss of pulsatile pancreatic activity and B-cell dysfunction may not only be initiating adverse events, but also contribute to the development of hepatic insulin resistance and progression of type 2 diabetes [8].

Providing insulin in a burst fashion using a device delivering small bursts of exogenous insulin would be expected to affect insulin target tissues more effectively by more closely mimicking the secretion of insulin observed in normal individuals. In previous studies, pulsed intravenous insulin delivery has shown encouraging, yet mixed results in lowering blood glucose levels compared to equal doses of continuously infused insulin [9,10]. Compared to standard therapy, burst therapy has shown promising, yet equivocal results in studies examining metabolic control, end-organ damage, and restoration of normal pulsatile pancreatic function in type 2 diabetes [11-13]. Perhaps the most encouraging study on the effects of pulsed therapy on end-organ damage showed a significant preservation of renal function by pulsatile insulin infusion [14].

These previous studies used earlier variations of what has been called pulsatile intravenous insulin therapy (PIVIT), which does not effectively mimic normal human insulin bursts. PIVIT, also referred to as outpatient intravenous insulin therapy (OIVIT),

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chronic intermittent intravenous insulin infusion (CIIIT), hepatic activation therapy (HAT), metabolic activation therapy (MAT) or the Harvard Protocol, does not replicate the periodicity and amplitude of normal pancreatic function, and was designed to deliver insulin in a series of increasing insulin peaks, producing successively increasing free insulin with limited clinical effectiveness.

In contrast, "microburst insulin infusion" (MII) via the Bionica Microdose Pump achieves the microburst of insulin causing oscillations with an amplitude of normal insulin secretion without an ever-increasing baseline of insulin – thus more closely mimicking natural burst insulin secretion.

In this report, we highlight data, which underscore the effectiveness of microburst insulin infusion in three observational, retrospective studies. These studies specifically focus on the effects of MII on metabolic rate measures, the potential attenuation and reversal of pain in patients with diabetic neuropathy, and on outcome measures as determined by hospital admissions and emergency department utilization.

Methods

All studies used MII which consisted of 3 one-hour insulin treatments, during which infused, controlled microbursts of IV insulin via the Bionica Microdose Pump, are given to match a pre-set measured oral ingestion of glucose equaling the average caloric need for that patient's weight during the period of treatment. A rest period of up to 30 minutes is given between the one-hour microburst infusions. The treatment was calculated and delivered according to the Bionica IV infusion device Supervisor's Guide and Trina Health protocols [15]. Patients in all 3 studies continued to receive their regular regimen of hypoglycemic medication either oral or insulin.

Restoration of more normal resting metabolism of carbohydrates was assessed using the Vacumed Vista-MX2 Metabolic Measurement System, a breath-by-breath mixing chamber measurement system of the volume of carbon dioxide produced at rest. The resting carbohydrate utilization measurements were taken 3 times per treatment day. The first measurement is before initiation of MII treatment, then midway in the treatment and the third measurement at the finish of the treatment regimen. Changes in VCO_2 are diagnostic, and are used to verify patient resting metabolism responses to the Trina Health protocol, and to determine the necessary treatment frequency (from once per week to once per three weeks or longer). Respiratory Quotients and VCO2 measurements were not used to guide and adjust treatment, but rather to determine the necessary frequency of treatment to maintain proper carbohydrate metabolism.

The individual treatment protocol for each patient continues until the patient's metabolic status is maintained over a personalized period of time as shown by the ability to quickly increase carbohydrate utilization in the presence of an oral glycemic load during the first hour of treatment. The first 2 treatments are given within 1-3 days of each other, and thereafter treatment is not continuous or pre-set as to the number of days between treatments.

Carbohydrate metabolism study

Indirect calorimetry is the primary method for metabolic rate measurement and involves measurement of oxygen consumption (VO_2) and carbon dioxide production (VCO_2) [16]. The relation between these gases and metabolic rate is defined by the respiratory exchange ratio (RER), Resting Metabolic Rate (RMR), and other measures. RER, which is a measurement of carbon dioxide produced per unit of oxygen (VCO_2/VO_2), varies with type of substrate (carbohydrate, fat, protein). An increased RER value is indicative of carbohydrate oxidation being favored over the oxidation of lipids for energy production. RMR is the measurement of energy required to maintain basic body functions while in a state of rest and accounts for 65% to 75% of total energy expenditure. The aim of this study was to examine the effects of MII therapy on metabolic rate measures as determined by indirect calorimetry.

Study methodology: This retrospective analysis included 311 patients treated at 12 centers, representing 7,583 individual microburst insulin treatments. Baseline and post-treatment VCO_2 and VO_2 metabolic measurement readings were taken for each individual treatment and comprehensive metabolic profiles were calculated. RER was determined by the respiratory exchange ratio (VCO2/VO2). Resting metabolic rate (RMR) was determined by the Weir equation [17]. The Jeukendrup & Wallis equation was used to calculate carbohydrate (CHO) oxidation [18]. Carbohydrate measures include % CHO oxidation of the total kcals expended, CHO kcals oxidized per liter of oxygen consumed, and CHO kcals oxidized per minute. Post-hoc analysis was performed using an orthogonal pair-wise contrasting process adjusted for within subject individual variances determined by the original repeated measures design.

Results: Oxygen consumption significantly changed over the three measurement periods (Table 1). Oxygen consumption increased from baseline to measurement periods 2 and 3 by 1.9% ($p=0.05$) and 4.4% ($p<0.0001$), respectively. Comparing oxygen consumption between measurements 2 and 3 showed that the period 3 measurement was greater by 2.5% ($p=0.015$). VCO_2 showed similar trends, but to a greater degree. Changes in VCO_2 production comparing baseline measurement periods 2 and 3 were 2.6% ($p=0.03$) and 9.7% ($p=0.001$), respectively. Comparing measurement periods 2 and 3, VCO_2 production increased 7.1% ($p<0.0001$). The RER values at baseline and across the other two measurement periods indicate that from baseline to period 2, the respective changes in oxygen consumption and the production of VCO_2 responded similarly. RER did not significantly change initially (Baseline RER = 0.91 ±0.11; Period 2 RER =0.92 ± 0.13, p=NS). However, due to a greater relative increase in VCO_2 production versus VO_2 consumption in the final measurements, period 3's RER significantly increased to both baseline and the period 2 measurement ($p<0.0001$). As a result, both the amount of CHO oxidized in kcals per minute and the CHO percentage of the total resting energy expenditure was significantly greater following both microhurst insulin infusion treatment periods. As a result of multiple microburst insulin infusions, carbohydrate oxidation in kcals per liter of O_2 increased for each measurement period (Figure 1). RMR values increased significantly from baseline to period 3 ($p<0.0001$) and also increased significantly from period

Citation: Elliott J, Zaias N, Escovar S, Deguzman L, Counce D et al. (2017) Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization. J Diabetes Metab Disord Control 4(4): 00118. DOI: 10.15406/jdmdc.2017.04.00118

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2 to period 3 (p=0.015). Baseline RMR values from the first visit to last visit over a period of 3 months were also compared in 27 patients in one clinic (Figure 2). Mean baseline RMR values increased from 1,475 to 1,904 (p<0.0001), an increase of 29%.

Table 1: Metabolic Effects of Multi-Micro Insulin Burst On VO_2, VCO_2, and Substrate Oxidation.

Variable	Baseline Mean (n =311)	95% CI	Period 2 Mean (n=73)	95% CI	Period 3 Mean (n = 311)	95% CI	Statistical Comparisons
VO2 (liters • min-1)	271.7	263.5-279.9	265.8	249.5-282.1	283.8	275.8-283.8	Baseline vs Period 2: p = 0.0460 Baseline vs Period 3: p< 0.0001 Period 2 vs Period 3: p = 0.0149
VCO2 (liters • min-1)	246.9	239.3-254.5	247.3	230.1-264.5	270.5	262.5-278.5	Baseline vs Period 2: p = 0.0303 Baseline vs Period 3: p< 0.0001 Period 2 vs Period 3: p <0.0001
RER (VCO2/ VO2)	0.91	0.90-0.93	0.93	0.90-0.96	0.96	0.95-0.97	Baseline vs Period 2: p = NS Baseline vs Period 3: p<0.0001 Period 2 vs Period 3: p<0.0001
CHO Oxidized (%)	66.1	63.2-68.9	72.3	67.1-77.6	78	75.8-80.3	Baseline vs Period 2: p = 0.0450 Baseline vs Period 3: p<0.0001 Period 2 vs Period 3: p = 0.001
CHO Oxidized (kcals/min-1)	0.871	0.827-0.916	0.962	0.867-1.057	1.095	1.051-1.140	Baseline vs Period 2: p = 0.0430 Baseline vs Period 3: p<0.0001 Period 2 vs Period 3: p<0.0001
Resting Metabolic Rate (kcals)	1,916	1,861-1,972	1,882	1,774-1,990	2,021	1,966-2,077	Baseline vs Period 2: p = 0.3672 Baseline vs Period 3: p<0.0001 Period 2 vs Period 3: p = 0.015

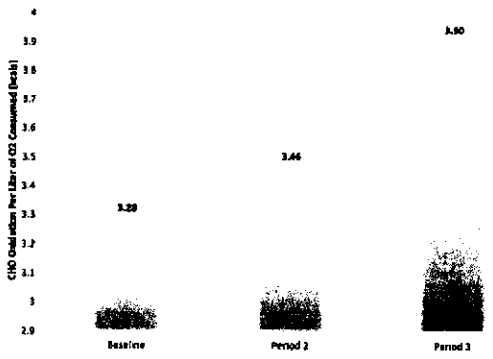

Figure 1: Effects of Microburst Insulin Infusion on Mean CHO Oxidation Over Time. Period 2 > Baseline = 5.5% (p=0.05), Period 3 > Baseline = 18.9% (p<0.0001), Period 3 > Period 2 = 12.7% (p<0.0001)

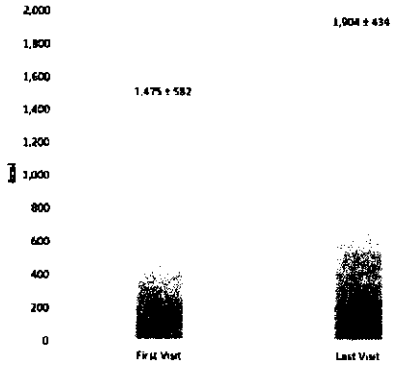

Figure 2: Comparison of Mean Resting Metabolic Rate (Baseline to Baseline).

Means ± SD Last Visit > First Visit = 29.1% (p<0.0001)

Study conclusion: MII treatment significantly increased oxygen consumption and energy expenditure by promoting a greater carbohydrate oxidation rate both in absolute (CHO oxidation in kcals per liter of O2 consumed and CHO oxidation in kcals per minute) and relative terms (percentage of CHO kcals expended relative the treatment groups total kcals expended per minute at rest). The increase in the respiratory exchange ratio soon after the introduction of microburst insulin therapy is to be expected, given the well-known actions of insulin on promoting glucose uptake and carbohydrate oxidation while reducing lipolysis and lipid oxidation [19], and these effects are reduced by insulin resistance, yet are still present in patients with type 2 diabetes [20]. A raised RER shows that insulin is favoring carbohydrate oxidation rather than lipids for energy production. Previous investigators have

Citation: Elliott J, Zalas N, Escovar S, Deguzman L, Counce D et al. (2017) Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization. J Diabetes Metab Disord Control 4(4): 00118. DOI: 10.15406/jdmdc.2017.04.00118

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reported decreases in resting metabolic rate over the short-term (2-8 days) in patients treated with insulin [21-23]. It is thought that the immediate decreases in RMR may be due to the short-term underlying effects of insulin on the reduction of energy-consuming processes such as proteolysis and gluconeogenesis [24]. We also report an immediate decrease in RMR in the second period following MII, consistent with previous findings. However, there was a subsequent increase in the last period, and a very significant increase of 29% in RMR values baseline-to-baseline over 3 months. These results suggest that MII has a dramatic effect on carbohydrate metabolism, overcoming the reduction of resting metabolic rate seen with conventional insulin treatments. This is of particular importance as the inability to properly metabolize carbohydrates represents a core dysfunction in diabetes. By preferentially converting energy production to carbohydrate metabolism, relative to lipids, diabetic patients avoid the consequences of elevated free fatty acids, which trigger a cascade of inflammatory processes.

Painful diabetic neuropathy study

Diabetic neuropathy is one of the most common microvascular complications of diabetes. Painful diabetic neuropathy (PDN) is reported in 16-34% of patients with diabetes [25]. The symptoms of PDN can be debilitating and can cause sleep disturbances, anxiety, and interfere with physical functioning [26]. The lack of normal sensation leads to injuries and eventually to amputation in many patients. PDN represents an ongoing therapeutic challenge and no single treatment exists to prevent or reverse neuropathic changes or to provide significant pain relief. Three classes of drugs are commonly used to treat diabetic neuropathy: tricyclic antidepressants, anticonvulsants, and selective serotonin-reuptake inhibitors. These compounds, however, have limited effectiveness, necessitating the need for additional pain management approaches [27]. This retrospective study analyzed the effects of MII on pain associated with diabetic neuropathy.

Study methodology: The study included 412 diabetic patients (81.1% Type 2 DM, and 19.9% Type 1 DM), there were 273 males and 204 females with a mean age of 58.3 years. These patients were being treated with MII therapy as previously described. Of these 412 patents, 299 patients (72.6%) were diagnosed as having significant Painful Diabetic Neuropathy (PDN). Patients with PDN were then treated with microburst insulin therapy once per week over a period of 3 months. The diagnosis of PDN was based on clinical findings: type of pain (burning discomfort, electric shock-like sensation, aching coldness in the lower limbs); time of occurrence (most bothersome at rest and at night); and abnormal or missing sensation (such as tingling or numbness) as determined by the DN4 questionnaire [28]. No neurological treatment other than MII treatment was provided, and no analgesic medications were used. Patients were then categorized based on neuropathic improvement (no improvement, significant improvement, and complete resolution), and percentages were compared (t-test, comparing percentages).

Results: After 3 months, 142 patients (47.5%) completely resolved all neuropathic symptoms, 136 patients (45.5%) reported significant improvement without complete resolution, and 21 patients (7.0%) reported no improvement (Table 2). There were significant differences (t-test) when comparing the percentages of both significantly improved and completely resolved patients to patients that were not improved ($p < .0001$).

Table 2: Neuropathic Improvement - One-sample t-test between percentages (n=299).

No Improvement	Significant Improvement
N=21 (7%)	N=136 (45.5%)
	p-value <.0001 (versus no improvement)

Study conclusion: Various symptomatic treatments have been proposed to manage neuropathic pain, but few have been found to be effective, with only three medications currently FDA approved for PDN. It is noteworthy that MII showed complete elimination or significant reduction of pain in 93% of PDN patients after 3 months treatment – with complete resolution of pain in 47% of PDN patients. Such significant reductions in pain may, in fact, be due to the mimicking of natural pancreatic function and restoration of carbohydrate metabolism by MII, but the exact mechanism requires further study. Given the lack of effective therapies for PDN and the encouraging findings reported in this study, additional studies on the effect of MII in PDN patients are warranted.

Hospital and emergency room utilization study

A retrospective analysis was conducted to determine if MII has a beneficial effect on patients with diabetes as determined by hospital and emergency room utilization when compared to matched National Hospital Discharge Survey and US Agency for Healthcare Statistics for homologous patients.

Methodology: This was a two-year retrospective study conducted at 14 centers involving 1,524 Type 1and Type 2 DM patients, with two or more secondary complications of diabetes (Table 3), and included patients with histories of multiple hospitalizations and emergency department visits prior to initiation of MII treatment. All study patients were treated with the MII protocol as described previously in addition to their regular hypoglycemic therapy.

Table 3: Comorbidities from Diabetes among study patients.

Diabetic Nephropathy, stages 1 – 4 (with and without dialysis)
Neuropathy, hands, feet, and other sites
Cardiomyopathy, CVD
Retinopathy, proliferative and other
Vascular dementia, (often associated with un-healing wounds)
Hypertension, (medication reductions)
Un-healing wounds, (with and without osteomyelitis)
Skin pigmentation
Sleeplessness, Restless Leg Syndrome
Functional energy loss
Fibromyalgia
Hyperlipidemia

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Hypoglycemia unawareness (T1DM)
Black toes and feet (avoided amputations)
Gastroparesis
Insulin resistance
Myasthenia gravis (MG) significant improvement
Balance disorders
Gait disorders, non-orthopedic
Erectile dysfunction
Cramping
Depression (related)
Depression by family/significant others

Results: During the two-year study period, there were a total of 5 admissions to the hospital for treatment (Table 4). The expected hospitalization rate for patients with diabetes and two or more morbidities as determined by the National Hospital Discharge Survey (NHDS) over a two-year study period is 96 per 1000 diabetic patients (47 per 1000 diabetic patients per year) [29]. There were a total of 7 visits to the emergency department (ED) for the same 1,524 patients over the 2-year study period (Table 5). The expected number of emergency department visits over two years is 116 per 1,000 diabetic patients (58 per 1,000 diabetic patients per year) as determined by the US Agency for Healthcare Statistics (USAHS) [30]. When comparing the rates of expected hospitalization and emergency department visits versus the actual number of visits for patients treated with MII treatment, there was a significant difference between the populations ($p < 0.0001$).

Table 4: Hospitalization Visits.

Comparison of Two Rates (Adjusted for 2 Years)		
	Study Visits	NHDS Rate
Numerator (e.g. number or events counted)	5	94
Denominator (e.g. total person-years)	1524	1000
Study incidence rate	0.003281	
95% Confidence Interval	0.001065 to 0.007656	
CDC incidence rate	0.047	
95% Confidence Interval	0.03453 to 0.0625	
Incidence rate difference	-0.04372	
95% Confidence Interval	-0.05517 to -0.03227	
P-value	P < 0.0001	

Table 5: Emergency Department Visits.

Comparison of Two Rates (Adjusted For 2 Years)		
	Study Visits	USAHS Rate
Numerator (e.g. number or events counted)	7	116
Denominator (e.g. total person-years)	1524	1000
Study incidence rate	0.004593	
95% Confidence Interval	0.001847 to 0.009464	
USAHS incidence rate	0.058	
95% Confidence Interval	0.04404 to 0.07498	
Incidence rate difference	-0.05341	
95% Confidence Interval	-0.06621 to -0.04061	
P-value	P < 0.0001	

Citation: Elliott J, Zaias N, Escovar S, Deguzman L, Counce D et al. (2017) Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization. J Diabetes Metab Disord Control 4(4): 00118. DOI: 10.15406/jdmdc.2017.04.00118

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Study conclusion: MII reduced hospitalization in a large group of diabetics with 2 or more serious co-morbidities to 1.65/1,000/year (versus NHDS estimated rate of 46.7/1,000/year) and emergency department visits to 2.3/1,000/year (versus US for Healthcare Statistics estimated rate of 58.4/1,000/year). This represents a significant reduction in hospital admissions and emergency department visits compared to normal rates-presumably generating substantial savings for the health care system.

Pulsatile intravenous insulin therapy (PIVIT), referred to by several different names, attempted to provide insulin in a novel way, a pulsatile pattern of insulin, which met with encouraging but limited success [13,31-32]. This therapy pre-dated widespread medical knowledge of how a normal pancreas secrets insulin in microbursts every 4-6 minutes [33]. An alternative approach, microburst insulin infusion (MII), has been developed that is more similar to physiologic insulin release, without an ever-increasing baseline of insulin that was inherent with previous approaches (PIVIT). MII differs from PIVIT and mimics both the periodicity and amplitude of normal pancreatic insulin release more closely. This novel therapy is used as a supplement to regular hypoglycemic therapy and provides advantages in managing patients with both type 1 and type 2 diabetes and associated secondary complications. In this study, we report the results of three observational studies that utilize MII in normal, clinical settings - the first focusing on metabolic rate measures related to carbohydrate metabolism, the second on neuropathy, a common microvascular complication, and the third on hospital admission/emergency department outcome data. Significant improvements in oxygen consumption and carbon dioxide production were shown consistently over 7,583 treatments in multiple clinics, reflecting underlying improvement in carbohydrate metabolism. As far as we know, this is also the first report of an insulin treatment regimen that actually increases the resting metabolic rate (RMR) over a longer term in patients with diabetes. The increase in RMR of 29% over a period of three months is most notable. The improvements in carbohydrate metabolism by MII treatment have several implications related to systemic inflammation. The conversion of energy production to carbohydrate substrates relative to lipids, minimizes the production of free fatty acids which trigger the inflammation cascade [34]. Inflammation affects insulin signaling and increases beta-cell death, and markers of inflammation such as elevated interleukin 6 (IL-6) and C-reactive protein (CRP) levels (Reference - Whitehall). Thus, MII may have considerable impact on the course of chronic inflammation in patients with diabetes. Future studies will further investigate the link between MII and inflammation, as well as the effects on markers of inflammation. Compared to traditional pharmaceutical treatment approaches for painful diabetic neuropathy, MII had notable results – with either complete elimination or significant reduction in pain in 93% of patients. These results are important as painful diabetic neuropathy (PDN) is common and is associated with significant impairment in the quality of life in patients with diabetes. Given the very few effective treatment options for patients with PDN, future studies are planned to both confirm these clinical results and investigate underlying mechanisms.

Assessment of the population health care impact of MII was demonstrated by the outcome data generated over two years, assessing hospital admissions and emergency department visits. Both these measures showed statistically significant reductions when compared to standard benchmarks, over the entire spectrum of secondary diabetes complications. Such reductions would presumably translate into substantial savings for the health care system at multiple levels. A limitation of these studies was the lack of double-blinded controls. This was deemed impractical due to the treatment duration of four hours, where glucose is given to diabetic patients with significant comorbidities. Hence, we used well-documented historical data from studies for comparative purposes. These retrospective studies we report here were typically conducted over a wide range of clinical settings and geographical locations.

In summary, conventional insulin therapy has achieved only partial success in the treatment of diabetes and prevention of chronic complications. Disappointing insulin efficacy in the treatment of diabetes may be less due to the quality of exogenous insulin than due to the possibility of physiologic "inadequacy" of its method of administration. Although insulin is secreted normally from pancreatic beta cells in a pulsatile manner, the current methods of therapeutic insulin administration are not pulsatile. Investigators have attempted to develop different methodologies to mimic normal pulsatile insulin delivery with limited success.

Microburst insulin therapy represents a new advance in the treatment of diabetes, due to its ability to closely replicate normal pancreatic function. Taken together, the rather dramatic reductions in neuropathic complications and hospital/emergency department visits, as well as the significant improvements in carbohydrate metabolism in these observational studies, may be due to the more precise mimicking of naturally pulsed insulin.

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BlueCross BlueShield of Montana

August 28, 2017

Ms. Erin MacLean
Freeman & MacLean, P.C.
P.O. Box 884
Helena, MT 59624

RE: Trina Health of Montana
BCBSMT Cease and Desist Letters dated April 12 and 19, 2017
Artificial Pancreas Treatment for BCBSMT Clients

Dear Ms. MacLean:

This will acknowledge receipt of your July 28, 2017, letter in the above matter. You requested that we (1) rescind our cease and desist letters and (2) cover Artificial Pancreas Treatment (APT) essentially on two grounds, respectively. First that the billing code we directed Trina Health's Montana providers to use to bill APT is not applicable to that procedure, and second that the medical policy we cited to deny coverage is not applicable to APT. We disagree with both of those assertions.

I.

In your letter, you state that APT is an entirely different treatment regimen than chronic intermittent insulin therapy (CIIIT, or its various synonyms such as outpatient intravenous insulin therapy (OIVIT), pulsatile intravenous insulin therapy (PIVIT), hepatic activation therapy (HAT) or metabolic activation therapy (MAT), etc.). While APT may have some functional differences, as you describe in your letter, it is at its basis a pulsatile insulin therapy and thus no different than CIIIT or any of the other names by which pulsatile-style insulin therapy is known.

The documentation you provided with your letter, along with numerous other documents, including materials from Trina Health itself, bear that fact out. For instance, the abstract of the article you provided with your letter states, in relevant part: "Microburst insulin infusion [MII] mimics the periodicity and amplitude of normal pancreatic function more closely than other previous pulsatile insulin therapeutic approaches." [Emphasis added]. *Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization.* Journal of Diabetes, Metabolic Disorders & Control (2017) at p. 1. The article further states: "In previous studies, pulsed intravenous insulin delivery has shown encouraging, yet mixed results in lowering blood glucose levels compared to equal doses of continuously infused insulin." *Id.* [Emphasis added]. The

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point of the article is that microburst insulin infusion (MII, or, APT) is a type of pulsatile insulin infusion that shows more encouraging results over other related pulsatile infusion therapies. It is not an entirely different treatment methodology as you otherwise suggested in your letter. I note that over half of the authors of the article are affiliated with various Trina Health offices. If APT was not a form of pulsatile intravenous insulin treatment, the authors would have clearly differentiated microburst insulin infusion from CIIIT/OIVIT/PIVIT. That they did not speaks volumes to the fact that APT is a form of pulsatile therapy as is CIIIT, not a separate treatment methodology.

Trina Health sources even more closely relate APT to CIIIT, PIVIT, et. al. For instance, Trina Health of Kansas' website includes a host of articles under the heading 'Please see the information below to learn more about Trina Health and APT', http://trinahealthks.com/providers (accessed August 18, 2017). One of the links is to an article by Dr. G. Ford Gilbert, founder of Trina Health and the developer of APT, entitled *The Omnipresent Medical Necessity of Mimicking Normal Human Burst Insulin via the Bionica Artificial Pancreas Treatment* Trina Health Wichita NW (2015). In chapter 13 of the article, Dr. Gilbert summarizes numerous relevant clinical trials and outcomes using APT treatment. Several of the summarized studies equate APT with CIIIT (see articles 9, 10 and 11 on pp. 37-39) and PIVIT (articles 14 and 19 on page 40 and 42). For instance, article no. 19 is entitled *Pulsatile Intravenous Insulin Therapy: The best practice to reverse diabetes complications? (Answer is Yes)*. The summary begins by stating:

> Although pulsatile insulin is found in normal subjects, currently used methods of insulin administration are not pulsatile. A lesser known therapy, known as PIVIT, CIIIT, HAT and other acronyms all are the same use of the Bionica Microdose burst IV insulin delivery system which mimics normal pancreatic insulin secretion to signal the liver[.]

[Emphasis added]

Additionally, Koya Diabetes Care, Trina Health's counterpart in India, describes at length the benefits of pulsatile intravenous insulin therapy on its website, and in that discussion states "The commercial name of PIVIT is Artificial Pancreas Treatment (APT)". http://koyadiabetescare.com/pulsatile_insulin_therapy_blog.html (accessed August 18, 2017).

Finally, I would note that both Blue Cross Blue Shield of Alabama's and Aetna's respective medical policies governing intermittent intravenous insulin therapy identify APT as a synonym for CIIIT, OIVIT, PIVIT, HAT, et.al. The Aetna medical policy specifically identifies APT as belonging to Trina Health. Copies of both medical policies are enclosed/attached for your reference.

Given the numerous sources available, including those from Trina Health itself, we are unpersuaded that CIIIT (or its various synonyms) is so different of a methodology from APT as to constitute an entirely separate therapy. According to the resources we reviewed, APT is at the very least either a variation of CIIIT or they are synonymous treatment methodologies.

On or about December 23, 2009, the Centers for Medicare and Medicaid Services issued a directive in conjunction with its National Coverage Determination announcing that OIVIT was a

non-covered service, directing providers to use a new billing HCPCS code of G9147 for that service. The directive noted that:

> OIVIT is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT) [sic], Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment (PIVIT), Pulse Insulin Therapy (PIT), and Pulsatile Therapy (PT).

CMS MLN Matters Number: MM6775. Copies of CMS' National Coverage Determination and its coding directive are enclosed/attached, for your reference.

Use of the new HCPCS G9147 code was made effective for claims with dates of service on or after April 5, 2010. You are correct in your letter that there is not a specific CPT code for APT. However, because G9147 is the code designated by CMS for CIIIT claims and because CIIIT and APT are synonymous or substantially similar, BCBSMT was correct in its cease and desist letters to instruct your client to use G9147 when coding claims for APT.

II.

As you point out in your letter, BCBSMT/HCSC has re-confirmed as of June 1, 2017, the use of its existing medical policy (MED201.028) regarding CIIIT. MED201.028 holds that CIIIT is considered experimental, investigational and/or unproven. Because of that determination/status, CIIIT is not covered by BCBSMT. I note that in support of its determination, MED201.028 indicates that CMS does not consider CIIIT to be a covered benefit. Even more telling, MED201.028 (fn6) cites to the American Diabetes Association's Standards of Medical Care in Diabetes – 2017 in which reference to CIIIT/APT, etc., is wholly absent as a treatment standard. The ADA's treatment standards are available at http://professional.diabetes.org (accessed August 18, 2017).

Notably, the article you provided with and cited in your letter, is equivocal on the results of MII, noting variously that: "[s]uch significant reductions in pain may, in fact, be due to the mimicking of natural pancreatic function and restoration of carbohydrate metabolism by MII, but the exact mechanism requires further study. Given the lack of effective therapies for PDN [painful diabetic neuropathy] and the encouraging findings reported in this study, additional studies on the effect of MII in PDN patients are warranted." Article, p.4. "Thus, MII may have considerable impact on the course of chronic inflammation in patients with diabetes. Future studies will further investigate the link between MII and inflammation, as well as the effects on markers of inflammation." Article, p. 6. "Given the very few effective treatment options for patients with PDN, future studies are planned to both confirm these clinical results and investigate underlying mechanisms." *Id.* [Emphasis added] The fact that further studies are both necessary and planned is a strong indication that MII's apparent promising results are not conclusive and in any event, does not support overturning BCBSMT's medical policy governing CIIIT.

III.

In closing, I did want to take the opportunity to clarify one matter from our April 2017 cease and desist letters. In our letters, we provided a table of procedure codes that your client has been billing in place of G9147. Our letters were not meant and should not be interpreted to mean that the procedure codes featured therein cannot be billed in addition to G9147. In fact, medical policy MED201.028 indicates that a variety of procedure codes may be utilized in addition to G9147 (which applies to the outpatient insulin component of CIIIT) for subsidiary services or supplies provided in connection with CIIIT/APT, including but not limited to 94681, 96365 and 96366. To the extent that our April letters are interpreted as a prohibition in that regard, consider them modified as per this paragraph.

Thank you for bringing this matter to BCBSMT's attention. It is my hope that this response adequately addresses your client's concerns. Please do not hesitate to contact me should you have any further questions in this matter.

Very truly yours,

Christopher M. Herriges
Assistant General Counsel

Enclosures (4)

cc: Dr. Monica Berner, Divisional Vice President, Chief Medical Officer
Mary Belcher, Vice President and General Counsel
Therese Anderson, Manager, Special Investigations Dept.

BlueCross BlueShield
of Alabama

Name of Policy:

Chronic Intermittent Intravenous Insulin Therapy

Policy #:	603	Latest Review Date:	February 2017
Category:	Medical	Policy Grade:	D

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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Description of Procedure or Service:

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

Glucose Homeostasis

There are 3 main sites of insulin-mediated glucose homeostasis that must function in a coordinated fashion to maintain euglycemia: (1) insulin secretion by the pancreas; (2) glucose uptake, primarily in the muscle, liver, gut, and fat; and (3) hepatic glucose production. In the fasting state, when insulin levels are low, most glucose uptake is non-insulin-mediated. Glucose uptake is then balanced by liver production of glucose. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, as can be seen in diabetic patients, marked hyperglycemia may result.

Medications Used for Glucose Homeostasis in Diabetes

Diabetes is characterized by elevated blood glucose levels due to inadequate or absent insulin production (type 1 diabetes) or due to a state of increased hepatic glucose production, decreased peripheral glucose update, and decreased insulin secretion (type 2 diabetes).

Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos®] and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by decreasing hepatic glucose production. While patients with type 2 diabetes may be treated with various combinations of all three of these classes of drugs, without or without additional insulin, patients with type 1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Standard insulin management involves the use of subcutaneous injection to mimic a physiologic insulin profile. Intravenous insulin is used in the acute, inpatient setting for the management of hyperglycemic emergencies (i.e., diabetic ketoacidosis).

Chronic Intermittent Insulin Therapy

Several forms of chronic intermittent insulin therapy in which insulin is delivered intravenously or into the peritoneal space have been evaluated.

CIIIT, also referred to as outpatient intravenous insulin therapy, pulsatile intravenous insulin therapy, pulsatile insulin, hepatic activation, or metabolic activation involves delivering insulin intravenously over a several hour period in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT is principally designed to normalize the hepatic metabolism of glucose. In a 1993 article describing the development of the technique, Aoki et al proposed that in patients with insulin-dependent diabetes mellitus (IDDM), lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. The authors state, "We reasoned that if the liver of an IDDM patient could be perfused with near-normal concentrations of insulin during meals, the organ could be

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reactivated," and proposed that once weekly intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal will increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin as it is delivered to the liver. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation.

CIIIT is typically delivered once weekly as outpatient therapy.

Policy:

Chronic intermittent intravenous insulin therapy does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

This policy does not apply to the use of intravenous insulin infusions in the inpatient setting (i.e., for the treatment of diabetic ketoacidosis or diabetic hyperosmolar coma).

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was based on a search of the MEDLINE database through December 20, 2016.

Following is a key summary of the literature to date, which primarily addresses whether chronic intermittent intravenous insulin therapy (CIIIT) improves glycemic control in diabetic patients and whether CIIIT reduces end organ damage associated with diabetes. Because of the many variables associated with diabetic management, randomized controlled trials (RCTs) of CIIIT are necessary to permit conclusions about treatment effectiveness.

No studies were identified that investigate the proposed mechanism of action of CIIIT in humans.

CIIIT and Glycemic Control in Diabetic Patients

In 1993, Aoki et al published a case series of 20 patients with "brittle" type 1 diabetes. All patients received four daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which appropriate adjustments in diet, insulin therapy, and activity were made. While the study reported a decrease in the hemoglobin A1C

(HbA1C) levels, the lack of a control group limits the interpretation of results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIIT.

Aoki et al (1995) also examined the effect of CIIIT with hypertensive medications in 26 patients with type 1diabetes and associated hypertension and nephropathy. The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional three months. At baseline, all patients were being treated with four daily insulin injections and had achieved acceptable HbA1C levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin converting enzyme inhibitors, calcium channel blockers, loop diuretics, and alpha-2 agonists). While the study was randomized, it was not blinded in that sham CIIIT procedures were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Section Summary: CIIT and Glycemic Control in Diabetic Patients
One nonblinded RCT and 1 cases series reporting on the effect of CIIT on glycemic control in type 1 diabetic patients were identified. Both studies reported improvements: one in HbA1c control compared with baseline, and the other in dose of antihypertensive medication in the treatment group compared with control. However, the lack of a blinded control comparator group limits the conclusions that can be drawn.

CIIIT and Reductions in Diabetic End-Organ Damage
In 2000, Dailey et al reported on prospective, multicenter, controlled study of the effects of CIIIT on the progression of diabetic nephropathy. A total of 49 patients with type 1 diabetes were included. Of these, 26 were assigned to the control group, and 23 were assigned to the treatment group that underwent weekly CIIIT. Both groups reported a significant decrease in HbA1C during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared with the control group. Again, the clinical significance of this finding is uncertain; larger clinical trials that look at the end point of time to progression of renal failure are needed.

In 2010, Weinrauch et al published an RCT of the effects of CIIIT on progression of nephropathy and retinopathy in 65 subjects with type I diabetes. Patients were randomly allocated to standard therapy of three to four daily subcutaneous insulin injections (n=29) or standard therapy plus weekly CIIIT (n=36). Baseline demographic characteristics were similar between the two groups, as were age of onset, duration of diabetes, diabetic control, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes that were adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was less in the treatment group (0.09 mg/dL vs 0.39 mg/dL, respectively; p=0.035). While average creatinine clearance fell less

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in the treatment group, the difference was not significant (-5.1 mL/min vs -9.9 mL/min, respectively; p=0.30). Glycemic control did not vary significantly. The clinical significance of the difference in creatinine levels is unknown and requires further evaluation in trials involving a larger number of patients.

Section Summary: CIIIT and Reductions in Diabetic End-Organ Damage
Two controlled studies focusing on the efficacy of CIIIT for reducing diabetic end-organ complications were identified. Both studies reported significant improvements in intermediate measures of glycemic control in each group from pre- to post intervention, but did not consistently report differences in clinically meaningful outcomes from the beginning of the studies to the end. Similarly, there were no significant differences between treatment groups in the RCT.

Summary of Evidence
For individuals who have type 1 diabetes who receive CIIT, the evidence includes 2 randomized controlled trials and uncontrolled studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. The 2 RCTs report that CIIIT may moderate the progression of nephropathy or retinopathy. However, the published studies are small and report benefits on intermediate outcomes only (i.e., changes in laboratory values). The clinical significance of the differences reported in the studies is uncertain. Additionally, most published evidence appeared between 1993 and 2000 and as a result, does not account for more recent improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
Clinical practice guidelines from professional associations, including the American Diabetes Association (updated in 2017) and the American Association of Clinical Endocrinologists (updated in 2015), do not include CIIIT in their guidelines for managing type 1 diabetes.

The American College of Physicians published Best Practice Advice in 2014 on inpatient glycemic control, which provided some recommendations about the use of intensive insulin therapy (IIT), including:

- "Best Practice Advice 1: Clinicians should target a blood glucose level of 7.8 to 11.1 mmol/L (140-200 mg/dL) if insulin therapy is used in SICU [surgical intensive care unit]/MICU [medical intensive care unit] patients."
- "Best Practice Advice 2: Clinicians should avoid targets less than 7.8 mmol/L (140 mg/dL) because harms are likely to increase with lower blood glucose targets."

U.S. Preventive Services Task Force Recommendations
Not applicable.

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Key Words:

CIIIT, variable dosage insulin, hepatic activation, Outpatient Intravenous Insulin Therapy, OIVIT, metabolic activation therapy, MAT®, pulsatile intravenous insulin therapy (PIVIT), pulsatile insulin therapy (PIT), Artificial Pancreas Treatment®, APT®

Approved by Governing Bodies:

Any insulin infusion pump can be used for the purposes of chronic intermittent intravenous therapy. Infusion pumps have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for the delivery of intravenous medications.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

There is no specific CPT code describing CIIIT. The following series of CPT codes and HCPCS J codes may be used to describe the various components of CIIIT. Some codes, such as the code for glucose testing, may be used more than once during a single session of CIIIT.

82948	Glucose; blood reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
94681	Oxygen uptake, expired gas analysis; including CO-2 output, percentage oxygen extracted
94690	Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one hour
96366	; each additional hour (List separately in addition to code for primary procedure)
99070	Supplies and materials provided by the physician
99211	Office or other outpatient visit
J7050	Infusion, normal saline solution, 250 cc
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units

In late 2009, a new HCPCS code was created specific to this therapy:

G9147	Outpatient intravenous insulin treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for:

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respiratory quotient, and/or, urine urea nitrogen (UUN), and/or, arterial, venous or capillary glucose, and/or potassium concentration.

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Policy History:

Medical Policy Panel, July 2015
Medical Policy Group, July 2015 (6): New policy, previously on Investigational Listing; remains investigational.
Medical Policy Administration Committee, July 2015
Available for comment July 21 through September 4, 2015
Medical Policy Group, October 2015 (6): Updates to Key Words and Coding; no change to policy statement
Medical Policy Panel, February 2016
Medical Policy Group, February 2016 (6): Updates to Key Points and Key Words; no change in policy statement.
Medical Policy Panel, February 2017
Medical Policy Group, February 2017 (6): Updates to Description, Key Points, Practice Guidelines and References. No change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.

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Intermittent Intravenous Insulin Therapy

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Number: 0742

Policy

Aetna considers intermittent intravenous insulin therapy (also known as hepatic activation therapy, metabolic activation therapy, pulse insulin therapy, pulsatile intravenous insulin therapy, and Trina Health artificial pancreas treatment) experimental and investigational for the management of diabetes mellitus and all other indications because its clinical value has not been established.

Aetna considers insulin potentiation therapy experimental and investigational for the treatment of arthritis, cancer (e.g., breast, prostate; not an all-inclusive list), infectious diseases, and other conditions because of insufficient evidence regarding its effectiveness.

Aetna considers diagnostic tests of blood glucose or potassium, respiratory quotient, and urine urea nitrogen experimental and investigational when performed in the context of intermittent intravenous insulin therapy because the clinical value of these tests in this context has not been established.

Note: This policy does not apply to the use of insulin infusions for treatment of diabetic ketoacidosis or hyperosmolar coma.

Background

According to Aoki and colleagues (1993), the limited success of conventional insulin therapy (IT) attained in the management of patients with diabetes mellitus (DM) and its complications suggested that there is a need for re-evaluation of the appropriateness of standard insulin administration protocols. Conventional subcutaneous IT produces slowly changing blood insulin levels and sub-optimal hepatocyte insulinization resulting in impaired hepatic capacity for processing incoming dietary glucose. Chronic intermittent intravenous insulin therapy (CIIIT), also known as hepatic activation therapy, metabolic activation therapy, and pulsatile intravenous insulin therapy (PIVIT), is an IT that delivers insulin in a pulsatile fashion and supposedly achieves physiological insulin concentration in the portal vein. The Trina Health Artificial Pancreas Treatment is intermittent

pulsatile intravenous insulin therapy that should be used in combination with standard hypoglycemic treatments for the treatment of type I and type II DM.

Chronic intermittent intravenous IT is usually performed as a weekly procedure in conjunction with daily intensive subcutaneous IT. According to the Aoki Diabetes Research Institute, a CIIIT treatment session entails a 6-hour period in an out-patient (or in-patient) setting. The patient receives intermittent pulses of insulin through an intravenous catheter in a peripheral vein in the hand or arm. The intermittent pulses are controlled by a computerized program, which produces the desired geometric waveforms and the doses are adjusted based on frequent monitoring of blood glucose levels, respiratory quotient response, and the timing of a glucose load ingested by the patient. Chronic intermittent intravenous IT has been reported to (i) improve significantly glycemic control while reducing the incidence of hypoglycemic events, (ii) improve hypertension control, (iii) slow the progression of overt diabetic nephropathy (DN), and (iv) reverse some manifestations of diabetic autonomic neuropathy including abnormal circadian blood pressure (BP) pattern, severe postural hypotension, and hypoglycemia unawareness (Aoki et al, 1995a; Aoki et al, 1995b; Aoki et al, 1995c; Aoki et al, 2001; Aoki Diabetes Research Institute, 2006)

Aoki and colleagues (1993) examined the effects of long-term CIIIT in patients with insulin-dependent diabetes mellitus (IDDM, also known as type 1 DM), with the aim of achieving high portal vein concentrations during and after a glucose meal. They studied 20 IDDM patients with brittle disease. Despite the use of a 4-injection regimen with manipulation of insulin doses, diet, and physical activity, as well as frequent clinic visits for at least a year, these patients still had wide fluctuations in blood glucose and frequent hypoglycemic reactions. Chronic intermittent intravenous IT consisted of 7 to 10 pulses of intravenous insulin, infused while the patient was ingesting carbohydrate (primarily glucose) during the first hour of a 3-hour treatment; 3 treatments were given in a day. After 2 consecutive days' treatment, patients were treated for 1 day per week. No patient withdrew from the study. At the time of this analysis the duration of intermittent treatment ranged from 7 to 71 months (mean of 41 [SE 5] months). Glycohemoglobin (HbA1C) concentrations declined from 8.5 (0.4) % at the end of the stabilization phase to 7.0 (0.2) % at the analysis point ($p = 0.0003$). During the same time the frequencies of major and minor hypoglycemic events also fell significantly (major 3.0 [1.1] to 0.1 [0], minor 13.0 [2.6] to 2.4 [0.8] per month; both $p < 0.0001$). Because the use of saline rather than insulin pulses would have led to unacceptable hyperglycemia, these investigators opted for a historical control design.

Gill and Williams (1993) noted that the most important drawback regarding the afore-mentioned study was the lack of a control treatment or control group rendering it impossible to ascribe any observed improvements to CIIIT. Moreover, since this regimen of IT was hospital-based and administered by high-level staff, subjects had support and care much in excess of routine diabetic clinical care; this in itself is likely to be beneficial on diabetic control, independent of any specific treatment given. Gill and Williams stated that improvements appeared to have occurred in the first few months of the study, and that there was no significant further drop in HbA1C after this time. This could be a consequence of the intensive interest and management received by these subjects, rather than a specific effect of CIIIT.

In a prospective, randomized, cross-over clinical trial, Aoki and colleagues (1995a) evaluated anti-hypertensive effects of CIIIT on IDDM subjects with hypertension and DN by monitoring the amount of anti-hypertensive medication (AHM) needed to maintain BP less than or equal to 140/90 mm Hg. After a stabilization period, 26 hypertensive IDDM subjects were randomly assigned to a control or treatment phase for 3 months and then cross-overed into the opposite phase for another 3 months. Addition of CIIIT during the treatment phase was the only procedural difference between the control

and treatment phases. The AHM dosage requirements for maintenance of the baseline BP levels decreased significantly (46 %; $p < 0.0001$) and linearly over time ($p < 0.0058$) during the treatment phase, while remaining essentially unchanged during the control phase. The authors concluded that these findings suggested that CIIIT markedly improves BP control, as evidenced by the significantly reduced AHM dosage requirements in subjects with IDDM and hypertension, possibly through an improvement in vascular reactivity.

In a 18-month multi-center, prospective, controlled study, Dailey et al (2000) evaluated the effects of PIVIT on the progression of DN in patients with type 1 DM. Of the 49 patients studied, 26 formed the control group (C), which continued on IT, while 23 formed the treatment group (T) and underwent, in addition to IT, weekly PIVIT. Blood pressure in all patients was maintained below 140/90 mm Hg on AHM, preferentially using angiotensin-converting enzyme (ACE) inhibitors. All subjects were seen in the clinic for 18 months, had monthly HbA1C; and every 3 months, 24-hour urinary protein excretion and creatinine clearance (CrCl) were measured. The HbA1C levels declined from 8.61 % +/- 0.33 % to 7.68 % +/- 0.31 % ($p = 0.0028$) in the T group and from 9.13 % +/- 0.36 % to 8.19 % +/- 0.33 % ($p = 0.0015$) in the C group during the study period. Creatinine clearance declined significantly in both groups, as expected, but the rate of CrCl decline in the T group (2.21 +/- 1.62 ml/min/year) was significantly less than in the C group (7.69 +/- 1.88 ml/min/year, $p = 0.0343$). The authors concluded that when PIVIT was added to IT in type 1 DM patients with DN, it appeared to markedly reduce the progression of DN. The effect appeared to be independent of ACE inhibitor therapy, BP, or glycemic control.

While the studies by Aoki et al (1993, 1995a, 1995b, and 1995c) as well as Dailey et al (2000) reported that CIIIT appeared to improve all problems associated with diabetes therapy, the results of a study by Heinemann et al (1989) were negative, and glucose tolerance of the patients was worse following CIIIT. These researchers examined the effects of insulin pulsing (10 i.v. pulses of human insulin of 0.035 U per kg body weight were given, each of 20-second duration, with intervals of 6 minutes, three times per day covered with adequate administration of glucose) on 2 successive days on glucose-tolerance in 9 well-controlled type 1 DM patients on continuous subcutaneous insulin infusion therapy (aged 26 (7) years, mean (SD); duration of diabetes 10 (7) years; body mass index 23.4 (2.3) kg per m2; HbA1c 6.0 (0.6) %). On the days before and after the insulin pulsing, the patients were subjected to metabolic assessments by an oral glucose tolerance test (1 g glucose per kg body weight) 30 minutes after the subcutaneous injection of 0.15 U per kg body weight regular human insulin and a subsequent bicycle-ergometer test. During these metabolic assessments, plasma free insulin concentrations, plasma glucagon and the non-protein respiratory quotient remained unaffected by the insulin pulsing. However, glucose tolerance deteriorated significantly (maximal glucose concentration 120 minutes after glucose load was 10.0 mmol/L before and 13.9 mmol/L after insulin pulsing, $p < 0.01$). The authors concluded that the pattern of insulin pulsing used in this study did not ameliorate oral glucose homeostasis in well-controlled type 1 DM patients.

In an analysis of CIIIT, Heinemann (2001) noted that most of the studies were uncontrolled, none was double-blinded, and some were under-powered. The author also stated that in studies comparing the effects of pulsatile and continuous intravenous insulin infusion, no overwhelming evidence was found for acute beneficial effects of pulsatile insulin infusion. Heinemann also questioned the measurement of respiratory quotient as an index of hepatic glucose production because respiratory quotient is known to be only of limited validity. The author concluded that "only when a controlled, double-blind, randomized study with a sufficient number of diabetic patients demonstrates that the CIIIT leads to beneficial results would I believe in this form of insulin therapy".

DeWitt and Hirsch (2003) reviewed the literature regarding insulin use in patients with type 1 and type 2 DM. A total of 28 studies for type 1 DM, 18 for type 2 DM, and 48 for insulin-oral combination met the selection criteria. In patients with type 1 DM, physiological replacement, with bed-time basal insulin and a meal-time rapid-acting insulin analog, results in fewer episodes of hypoglycemia than conventional regimens. Rapid-acting insulin analogs are preferred over regular insulin in patients with type 1 DM since they improve HbA1C and reduce episodes of hypoglycemia. In patients with type 2 DM, adding bed-time neutral protamine Hagedom (isophane) insulin to oral IT significantly improves glycemic control, especially when started early in the course of disease. Bed-time use of insulin glargine results in fewer episodes of night-time hypoglycemia than neutral protamine Hagedorn regimens. For patients with more severe insulin deficiency, a physiological insulin regimen should allow lower glycemic targets in the majority of patients. Adverse events associated with IT include hypoglycemia, weight gain, and worsening diabetic retinopathy if HbA1C levels decrease rapidly. The authors concluded that many options for IT are now available. Physiological IT with insulin analogs is now relatively simple to use and is associated with fewer episodes of hypoglycemia. There is no mentioning of the use of CIIIT in this review.

Bolli (2006) reviewed data from long-term intervention studies regarding therapy in type 1 DM and discussed strategies for preventing hypoglycemia and safely achieving glycemic goals in this patient population. The author noted that twice-daily injection of pre-mixed or self-mixed insulin is the most common IT; however, this therapeutic strategy is also a major contributor to hypoglycemia and, eventually, hypoglycemia unawareness. Hypoglycemia unawareness in patients with type 1 DM has been found to be largely reversible. Moreover, intensive IT may prevent hypoglycemia and maintain glycemic targets. The most physiological regimen of IT available is continuous subcutaneous insulin infusion with an insulin pump; however, insulin glargine is a useful alternative to pump therapy. The author concluded that use of today's rapid- and long-acting insulin analogs in intensive management protocols not only improves glycemic control but also lowers the risk of hypoglycemia. Again, the use of CIIIT was not discussed in this review

Furthermore, available guidelines and position statements from several specialty societies on the management of patients with DM did not discuss the use of CIIIT:

- The American Association of Clinical Endocrinologists/American College of Endocrinology's guideline for the management of DM (2002).
- The National Collaborating Center for Chronic Conditions' clinical guideline on the diagnosis and management of adults with type 1 DM (2004).
- The American Diabetes Association (ADA)'s position statement on care of children and adolescents with type 1 DM (Silverstein et al, 2005).
- The ADA's position statement on nutrition recommendations and interventions for DM (ADA, 2007).

In a pilot study, Weinrauch et al (2007) examined the effect of PIVIT on cardiovascular mechanisms that might contribute to attenuation of renal compromise in IDDM patients with proteinuria. The control group (n = 8) received subcutaneous insulin (3 to 4 injections per day). The experimental group (n = 10) received three 1-hour courses of PIVIT on a single day per week in addition to subcutaneous insulin. Laboratory measurements included 2-dimensional Doppler echocardiography, 24-hour ambulatory monitoring with heart rate variation analysis, platelet aggregation and adhesion, plasma fibrinogen, factor VII, von Willebrand factor, fibrinolytic activity, plasminogen activator inhibitor, and viscosity measured at baseline and 12 months. Blood pressure control was maintained preferentially with angiotensin-converting enzyme inhibitors. Ratio of carbon dioxide production to

oxygen utilization was measured with each infusion and showed rapid increase from 0.8 to 0.9 (p = 0.005) at weekly treatments through 12 months. These investigators observed an annualized decrease in creatinine clearance of 9.6 ml/min for controls versus 3.0 ml/min for PIVIT-treated patients. Annualized fall in blood hemoglobin was 1.9 versus 0.8 g/dL, respectively (p = 0.013). There were no differences between the control and PIVIT group with respect to glycohemoglobin, advanced glycated end products, cholesterol, or triglycerides. No differences between the study groups for hemodynamic or hemostatic factors were evident. Blood pressures were not significantly different at baseline or 12 months. The authors concluded that although preservation of renal function with attenuation of loss of blood hemoglobin during 12 months of PIVIT was associated with improvement in the efficiency of fuel oxidation as measured by respiratory quotient, this occurred without differences in metabolic/hemostatic factors, cardiac autonomic function, cardiac wall, or chamber size. The hypothesis that preservation of renal function in IDDM patients with proteinuria by weekly PIVIT involves mechanisms from the autonomic nervous system, cardiac size, and function, or elements of hemostasis was not confirmed.

A decision memo for outpatient intravenous insulin treatment (OIVIT) from the Centers for Medicare & Medicaid Services (2009) stated that the evidence does not show that the use of OIVIT is reasonable and necessary to treat diabetes or any other medical condition. It also noted that the evidence does not demonstrate that the diagnostic tests respiratory quotient, urine urea nitrogen, diagnostic blood glucose or potassium testing performed in the context of OIVIT provide results that can be reasonably used by a physician in managing a patient with diabetes.

Weinrauch et al (2010) examined if deterioration of renal and retinal function in patients with type 1 DM could be blunted by multiple daily insulin doses with or without the addition of weekly PIVIT. A total of 65 patients were evaluated prospectively in 7 centers; 36 participants were randomly allocated to the infusion group and 29 to the standard therapy group. Mean serum creatinine was 1.6 mg/dL in both groups. Subjects were excluded if clearance was less than 30 ml/min. There were no significant differences between the groups with respect to age, duration of diabetes, sex distribution, glycohemoglobin, BP, ACE inhibitor use, proteinuria, or baseline diabetic retinopathy (DR) severity level (all eyes exhibited DR; 8 were deemed technically not amenable to evaluation). Progression of DR was noted in 31.6 % of 57 patients (32.3 % treated, 30.8 % control; p = 1.0) with both eyes evaluable. For patients with 12 or more months of follow-up, 27.9 % of 43 patients demonstrated progression of DR (32.0 % treated, 22.2 % control; p = 0.57). There were no significant differences between study groups with respect to progression or marked progression, nor was there any influence of duration of follow-up. Progression of DR was noted in 18.8 % of 122 eyes that could be adequately evaluated (17.9 % of 67 treated, 20 % of 55 controls; p = 0.39). Serum creatinine increased to 1.7 mg/dL in the treatment group and to 1.9 mg/dL in the control group (p = 0.03). Statistically significant preservation of renal function by PIVIT was not matched by a statistically significant prevention of DR progression compared with standard diabetes care. The authors noted that inadequate statistical power or duration of the study, or lack of further benefit of PIVIT on the retina in the presence of ACE inhibition may be responsible.

Insulin potentiation therapy (IPT) is based on the assumption that intravenous insulin increases the effect of medications so that lower doses of these medications can be used. Advocates of IPT suggest that insulin "opens the pores" of cells throughout the body allowing certain drugs to enter more easily. While treatment of cancer is the main focus of IPT, this approach has also been employed for other diseases.

Lasalvia-Prisco et al (2004) noted that it has been reported that insulin increases the cytotoxic effect (in-vitro) of methotrexate by as much as 10,000-fold. In a prospective, randomized clinical trial,

these researchers examined the clinical value of insulin as a potentiator of methotrexate. A total of 30 women with metastatic breast cancer resistant to fluorouracil + adriamycin + cyclophosphamide and also resistant to hormone therapy with measurable lesions were included in this study. Three groups each of 10 patients received two 21-day courses of the following treatments: insulin + methotrexate, methotrexate, and insulin, respectively. In each patient, the size of the target tumor was measured before and after treatment according to the RECIST (Response Evaluation Criteria In Solid Tumors). The changes in the size of the target tumor in the 3 groups were compared statistically. Under the trial conditions, the methotrexate-treated group and the insulin-treated group responded most frequently with progressive disease. The group treated with insulin + methotrexate responded most frequently with stable disease. The median increase in tumor size was significantly lower with insulin + methotrexate than with each drug used separately. These findings confirmed in-vivo the results of previous in-vitro studies showing clinical evidence that insulin potentiates methotrexate under conditions where insulin alone does not promote an increase in tumor growth. Therefore, the chemotherapy anti-tumoral activity must have been enhanced by the biochemical events elicited in tumor cells by insulin. The authors concluded that in multidrug-resistant metastatic breast cancer, methotrexate + insulin produced a significant anti-tumoral response that was not seen with either methotrexate or insulin used separately. These findings need to be validated by well-designed studies with larger sample size and longer follow-up.

The American Cancer Society (2008) noted that 1 very small published study on IPT was done in Uruguay. It included 30 women with breast cancer that was resistant to mainstream therapies. Of these women, 10 received insulin, 10 took methotrexate, and 10 received IPT using both drugs. After 8 weeks, researchers reported that the women in the IPT group had smaller increases in tumor size than either of the other groups. Even though they used lower doses of methotrexate than usual, there were some side effects (mouth sores) noted in the IPT group. This study did not look at survival, quality of life, well-being, or lasting effects. No long-term improvements were shown by this study. Most of the information about IPT comes from individual reports. Even among those, however, there is no evidence that individuals who reported being helped by IPT were followed for long enough to learn whether the treatment worked. Despite supporters' claims that IPT has been well-researched, no scientific studies that show safety and effectiveness have been published in available peer-reviewed journals. These claims cannot be verified. Furthermore, there are concerns about using lower doses of chemotherapy drugs. When chemotherapy drugs are tested in clinical trials, their effects are carefully monitored to learn which dose will best balance the need to kill cancer cells with the goal of keeping side effects at a tolerable level. There is no evidence that chemotherapy at a fraction of the recommended and tested dose can produce the same effect as the full dose if used with insulin.

Damyanov et al (2012) evaluated the results and quality of life of patients with resistant of castration-resistant tumors previously treated with IPT combined with hormone therapy. A total of 16 patients with metastasis prostate tumors after bilateral castration, androgenic blockade, and progression of the disease were observed during the study. The patients were divided into 2 groups: (i) group A consisting of 8 patients treated with low-dose chemotherapy epirubicin, vinblastine, and cyclophosphamide combined with luteinizing hormone releasing hormone (LHRH) agonist; and (ii) group B consisting of another 8 patients treated with low-dose chemotherapy docetaxel combined with LHRH agonist. The overall (groups A and B) results concerning prostate specific antigens after the 6th IPT showed partial effect in 8 out of 16 (50 %) patients, stabilization in 4 out of 16 (25 %), and progression in 4 out of 16 (25 %). The median survival for all treated patients is 11.7 months (range of 3 to 30 months). During the treatment no significant side effects were observed, and no lethal cases occurred. The authors concluded that despite the small number of the treated patients with castration-resistant prostate tumors, the preliminary results were promising; giving hope and

expectations for future serious multi-center research over the possibilities for routine implementation of low-dose IPT.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

There are no specific codes for intermittent intravenous insulin therapy (also known as hepatic activation therapy, metabolic activation therapy, and pulsatile intravenous insulin therapy), Trina Health artificial pancreas:

CPT codes not covered for indications listed in the CPB [when performed in the context of intermittent intravenous insulin therapy]:

82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose; blood, reagent strip
82950	post glucose dose (includes glucose)
84132	Potassium; serum, plasma or whole blood
84133	Potassium; urine
84540	Urea nitrogen, urine

HCPCS codes not covered for indications listed in the CPB:

G9147	Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration

Other HCPCS codes related to the CPB:

J1815, J1817, S5550 - S5571	Insulin

ICD-10 codes not covered for indications listed in the CPB: (not all-inclusive):

A00.0 - B99.9	Certain infections and parasitic disease
C00.0 - D49.9	Neoplasms
M00.00 - M25.9	Arthropathies

The above policy is based on the following references:

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Policy History

- Last Review 10/21/2016
  Effective: 12/07/2007
  Next Review: 08/24/2017
- Review History
- Definitions

Additional Information

- Clinical Policy Bulletin Notes

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The following was seen at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=334&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCD&KeyWord=insulin&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAAAA%3d%3d&

National Coverage Determination (NCD) for Outpatient Intravenous INSULIN Treatment (40.7)

Publication Number	Manual Section Number	Manual Section Title
100-3	40.7	Outpatient Intravenous **INSULIN** Treatment

Version Number	Effective Date of this Version	Implementation Date
1	12/23/2009	4/5/2010

Description Information

Benefit Category
Diagnostic Tests (other)
Drugs and Biologicals
Physicians' Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description
A. General
The term outpatient intravenous (IV) **INSULIN** therapy (OIVIT) refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of **INSULIN** via any means, guided by the results of measurement of:

- respiratory quotient; and/or
- urine urea nitrogen (UUN); and/or
- arterial, venous, or capillary glucose; and/or
- potassium concentration; and

performed in scheduled recurring periodic intermittent episodes.

This regimen is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous **INSULIN** Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous **INSULIN** Treatment (PIVIT), Pulse **INSULIN** Therapy (PIT), and Pulsatile Therapy (PT).

In OIVIT, **INSULIN** is intravenously administered in the outpatient setting for a variety of indications. Most commonly, it is delivered in pulses, but it may be delivered as a more conventional drip solution. The **INSULIN** administration is adjunctive to the patient's routine diabetic management regimen (oral agent or **INSULIN**-based) or other disease management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits. Glucose or other carbohydrate is available ad libitum (in accordance with patient desire).

Indications and Limitations of Coverage

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after December 23, 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence is adequate to conclude that OIVIT does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act. Services comprising an Outpatient Intravenous **INSULIN** Therapy regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen (see subsection A. above).

D. Other

Individual components of OIVIT may have medical uses in conventional treatment regimens for diabetes and other conditions. Coverage for such other uses may be determined by other local or national Medicare determinations, and do not pertain to OIVIT. For example, see Pub. 100-03, NCD Manual, Section 40.2, Home Blood Glucose Monitors, Section 40.3, Closed-loop Blood Glucose Control Devices (CBGCD), Section 190.20, Blood Glucose Testing, and Section 280.14, Infusion Pumps, as well as Pub. 100-04, Claims Processing Manual, Chapter 18, Section 90, Diabetics Screening.

(This NCD last reviewed December 2009.)

Claims Processing Instructions

- TN 1913 (Medicare Claims Processing)
- TN 1923 (Medicare Claims Processing)
- TN 1930 (Medicare Claims Processing)

Transmittal Information

Transmittal Number

117

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R117NCD.pdf

Revision History

02/2010 - Effective Date: 12/23/2009. Implementation Date: 03/08/2010. (TN 112) (CR6775)

03/2010 - There was an error in the OIVIT policy language in the Business Requirements. All other information remains the same. (TN 114) (CR6775)

03/2010 - Transmittal 114, dated February 22, 2010, is being rescinded and replaced by Transmittal 117. The only change is the implementation date from March 8, 2010, to April 5, 2010. All other information remains the same. (TN 117) (CR6775)
03/2013 - CMS translated the information for this policy from ICD-9-CM/PCS to ICD-10-CM/PCS according to HIPAA standard medical data code set requirements and updated any necessary and related coding infrastructure. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 10/07/2013 Effective date: 10/1/2015. (TN 1199) (TN 1199) (CR 8197)
02/2017 - This change request (CR) is the 10th maintenance update of ICD-10 conversions and other coding updates specific to national coverage determinations (NCDs). These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received. Previous NCD coding changes appear in ICD-10 quarterly updates as follows: CR7818, CR8109, CR8197, CR8691, CR9087, CR9252, CR9540, CR9631, and CR9751, as well as in CRs implementing new policy NCDs. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases and individual CRs as appropriate. No policy-related changes are included with the ICD-10 quarterly updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. (TN 1792) (CR9861)
05/2017 - This change request (CR) constitutes a maintenance update of ICD-10 conversions and other coding updates specific to national coverage determinations (NCDs). These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received. Previous NCD coding changes appear in ICD-10 quarterly updates that can be found at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new policy NCDs. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases and individual CRs as appropriate. No policy-related changes are included with the ICD-10 quarterly updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. (TN 1854) (CR10086)

National Coverage Analyses (NCAs)

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- Original consideration for Outpatient Intravenous Insulin Treatment (Therapy) (CAG-00410N) opens in new window

MLN Matters® CMS
Information for Medicare Fee-for-Service Health Care Professionals

News Flash – The Centers for Medicare & Medicaid Services (CMS) would like to remind Physician Quality Reporting Initiative (PQRI) participants that there is a "Verify Report Portlet" look-up tool available on the PQRI Portal for Eligible Professionals (EPs) to verify if a 2007 re-run and/or 2008 PQRI feedback report exists for your organization's Tax Identification Number (TIN) or National Provider Identifier (NPI). The TIN or NPI must be the one used by the EP to submit Medicare claims and valid PQRI quality data codes. This tool is available at (***https://www.qualitynet.org/portal/server.pt***) on the internet. There are two ways to access 2007 re-run and/or 2008 PQRI feedback reports: 1) An individual EP can simply call their respective Carrier or A/B MAC provider contact center to request confidential 2007 PQRI re-run and/or 2008 PQRI feedback reports that will contain information based on their individual NPI, or 2) EPs can logon to the secure PQRI Portal on QualityNet at (***http://www.qualitynet.org/portal/server.pt***) to access their feedback report(s) based their TIN, or for a group.

MLN Matters® Number: MM6775 **Related Change Request (CR) #: 6775**

Related CR Release Date: March 9, 2010 **Effective Date: December 23, 2009**

Related CR Transmittal #: R117NCD and R1930CP **Implementation Date: April 5, 2010**

Outpatient Intravenous Insulin Treatment (Therapy)

Note: This article was revised on March 30, 2010, to correct the dates when contractors may adjust claims on page 4. The start date should be December 23, 2009. All other information remains the same.

Provider Types Affected

This article is for physicians, hospitals, and other providers who bill Medicare contractors (Fiscal Intermediaries (FI), carriers, or Medicare Administrative Contractors (A/B MACs)) for providing outpatient intravenous insulin therapy (OIVIT) to Medicare beneficiaries.

What You Need to Know

On December 23, 2009, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) announcing the non-coverage decision on the use of outpatient intravenous insulin therapy (OIVIT).

Specifically, CMS has determined (effective for claims with dates of service on or after December 23, 2009) that the evidence does not support a conclusion that

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OIVIT improve health outcomes in Medicare beneficiaries. Therefore, OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act and services comprising an OIVIT regimen are therefore nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen. You should ensure that your billing staffs are aware of this NCD.

Background

CMS (on December 23, 2009) issued a national non-coverage decision on the use of OIVIT. CR 6775, from which this article is taken, provides details about this decision.

The term OIVIT refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of insulin via any means guided by the results of measuring:

- Respiratory quotient; and/or
- Urine urea nitrogen (UUN); and/or
- Arterial, venous, or capillary glucose; and/or
- Potassium concentration; and
- Performed in scheduled recurring periodic intermittent episodes.

Most commonly delivered in pulses (but sometimes as a more conventional drip solution), the insulin administration is an adjunct to the patient's routine oral agent or insulin-based diabetic (or other disease) management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits.

Note: OIVIT is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment (PIVIT), Pulse Insulin Therapy (PIT), *and* Pulsatile Therapy (PT).

HCPCS Coding for OIVIT

For use with this non-coverage decision, effective April 5, 2010, CMS will create a new HCPCS code (G9147), that is to be implemented with the April 2010 Integrated Outpatient Code Editor (IOCE) and Medicare Physician Fee Schedule Database (MPFSDB). You should use this new code on claims that you submit for non-covered OIVIT and any services compromising an OIVIT regimen with dates of service on and after December 23, 2009.

Effective April 5, 2010, HCPCS code 99199 (Unlisted Special Service, Procedure, or Report) should not be used when billing non-covered OIVIT and any services

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comprising an OIVIT regimen. Your FI, carrier, or A/B MAC will return any such claims that you submit with 99199 unprocessable using the following messages:

- Claim Adjustment Reason Code (CARC) 189 (NOS or unlisted procedure code (CPT/HCPCS) was billed when there is a specific procedure code for this procedure/service.);
- Remittance Advice Remark Code (RARC) N56 (The procedure code billed is not correct/valid for the services billed or the date of service billed.); and
- RARC MA66 (Missing/incomplete/invalid principal procedure code).

Also, effective April 5, 2010, HCPCS code 94681 (exhaled air analysis O_2/CO_2) must not be used on claims billing for non-covered OIVIT and any services comprising an OIVIT regimen or for claims billing diabetes-related conditions 250.00-250.93. Such claims submitted with HCPCS code 94681 will also be returned as unprocessable using the following messages:

- CARC 11 (The diagnosis is inconsistent with the procedure.);
- RARC N56 (The procedure code billed is not correct/valid for the services billed or the date of service billed.); and
- RARC MA66 (Missing/incomplete/invalid principal procedure code).

Effective April 5, 2010, when HCPCS code G9147 is billed on claims for non-covered OIVIT and any services comprising an OIVIT regimen for dates of service on and after December 23, 2009, Medicare contractors will deny the claim with the following messages

- Medicare Summary Notice (MSN) 16.10: Medicare does not pay for these item(s) or service(s);
- CARC 96: Non-covered charge(s);
- CARC M51: Missing/Incomplete /Invalid Procedure Code(s); and
- RARC N386: This decision was based on an NCD. An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx on the CMS website. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Note: Prior to April 5, 2010, non-covered OIVIT claims with dates of service on and after December 23, 2009, should be processed as they currently are now using NOS code 99199 and HCPCS code 94681. On April 5, 2010, these codes should no longer be used for non-covered OIVIT claims and new HCPCS code G9147, created for this purpose, should be used in their place.

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Please remember that individual components of OIVIT may have medical uses in conventional treatment regimens for diabetes and other conditions; and in these contexts, coverage may be determined by other local or national Medicare determinations, and do not pertain to OIVIT.

For examples of these uses you might want to look at the *Medicare National Coverage Determinations Manual* Sections 40.2, (Home Glucose Monitors), Section 40.3 (Closed-loop Blood Glucose Control Devices), Section 190.20 (Blood Glucose Testing), and Section 280.14 (Infusion Pumps. You may also want to look at the *Medicare Claims Processing Manual*, Chapter 18, Section 90, on Diabetes Screening. These manuals are available at **http://www.cms.gov/Manuals/IOM/list.asp** on the CMS website.

In addition, you should know that your contractors will not automatically search their files for claims with dates of service between December 23, 2009, and April 5, 2010, but may go back and adjust claims that you bring to their attention.

Additional Information

You can find more information about non-coverage of OIVIT by going to CR 6775, which was issued via two transmittals. The first transmittal, located at **http://www.cms.gov/Transmittals/downloads/R117NCD.pdf**, contains the updated "Medicare National Coverage Determinations Manual" sections related to CR6775. The second transmittal, located at **http://www.cms.gov/Transmittals/downloads/R1930CP.pdf**, contains the updated sections of the "Medicare Claims Processing Manua"l.

If you have any questions, please contact your FI, carrier, or A/B MAC at their toll-free number, which may be found at **http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip** on the CMS website.

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September 13, 2017

Christopher M. Herriges
Assistant General Counsel
Blue Cross Blue Shield of Montana
P.O. Box 4309
Helena, MT 59604-4309

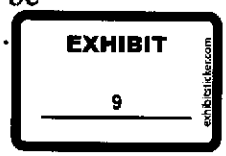
Re: Trina Health of Montana
Response to your letter, dated August 28, 2017
Artificial Pancreas Treatment billing for BCBSMT Clients

Dear Mr. Herriges:

I am writing on behalf of Trina Health of Montana (Trina), in response to your above-referenced response letter (Response). In your Response, you responded to my letter of July 28, 2017, in which I requested that the "Cease and Desist" letters, dated April 12 and 19, 2017, sent to Trina providers, be reconsidered.

In my July 28th letter, I provided you significant information that detailed the effectiveness of Alternative Pancreas Treatment© (APT), including a July 2017 article detailing the outcomes of a number of studies showing APT is effective on humans to treat diabetes and related diabetic conditions. The information that I provided you also clearly showed that Blue Cross Blue Shield of Montana's (BCBSMT) Chronic Intermittent Intravenous Insulin Therapy (CIIIT) was not applicable to APT, and, therefore, BCBSMT denying payment for APT under the CIIIT policy was an incorrect application of BCBSMT's CIIIT policy. I also detailed why the cease and desist letters from BCBSMT to Trina providers, directing Montana providers of APT to bill the treatment under the G9147 code for Outpatient Intravenous Insulin Therapy (OIVIT), were inappropriate, and I asked that BCBSMT rescind that directive. Finally, I clarified that since APT is not OIVIT and because there is no single code, at this time, for the APT treatment, Trina providers have been and should continue to be permitted to use the applicable outpatient coding for the Treatment.

Your letter of August 28, 2017 states that you understood the requests in my letter to be twofold: (1) rescind [BCBSMT's April] cease and desist letters, and (2) cover [APT].



You address these two requests in reverse order in your letter, and, as such, I will do so here, too.

BCBSMT Has Not Done an Objective Evaluation of APT

In the Response, you detail that CIIIT, OIVIT, pulsatile intravenous insulin therapy (PIVIT), hepatic activation therapy (HAT) and metabolic activation therapy (MAT), "etc." are "synonyms." My client would agree and would suggest that you neglected to add Aoki's "Harvard Protocol" to the list. You go on to state that "[w]hile APT may have some functional differences…it is at its basis a pulsatile insulin therapy and thus no different than CIIIT or any of the other names by which pulsatile-style therapy is known." This statement appears to be the basis of your later conclusion in the Response, which conclusion is stated by you as "because G9147 is the code designated by CMS for CIIIT claims and because CIIIT and APT are synonymous or substantially similar, BCBSMT was correct in its cease and desist letters to instruct your client to use G9147 when coding claims for APT."

From your letter, it appears that, medically speaking, you do not understand APT, its treatment process and/or how its process is entirely different from CIIIT and the other CIIIT-type therapies you reference (which Trina agrees are substantially similar to CIIIT). Your attempts to reference other BCBSMT policies that detail BCBSMT's review of CIIIT treatments do nothing show any appropriate application of those policies or BCBSMT's CIIIT policy to APT. Your references to portions of articles by Dr. G. Ford Gilbert provide no substance to support your conclusion that his articles "equate APT with CIIIT… and PIVIT…" The information that I have and continue to provide to you on APT wholly contradicts the conclusion reached in your Response in which you state that BCBSMT has determined that APT is "experimental, investigational and/or unproven" in the same manner as CIIIT-type treatments. Further, none of the materials referenced in your Response address APT, specifically, and/or its effectiveness, at all, and especially in relation to the other CIIIT-type treatments that you Reference in your letter. I submit to you that the substantial oversight in your apparently cursory review of APT and your lack of understanding of how APT is substantially different form CIIIT-type treatments led to your conclusion that APT is substantial similar to the CIIIT-type treatments that you reference, which is wholly unsupported and incorrect.

An independent, objective evaluation of APT does not appear to have been done by BCBSMT, as your Response provides no evidence that BCBSMT has done any independent medically-based evaluation of APT or specific process evaluation on the APT process incorporating any recent information on APT. Your attempt to discredit the peer reviewed article that I provided to you, detailing the effectiveness of APT in keeping patients out of the hospital, shows that BCBSMT has not considered either the findings detailed in the article or taken time to evaluate the outcomes of the underlying research specifically applicable to APT. BCBSMT has also not provided any evidence that

BCBSMT used any objective standards to determine what constitutes "substantially similar" or "substantially the same" when evaluating coverage for medical procedures, nor did you provide any evidence regarding how any such standards were applied to APT to reach the conclusions in your response.

BCBSMT's denial of coverage to its beneficiaries for APT resulting from BCBSMT's failure to reasonably and objectively evaluate APT, independent of CIIIT-type therapies, will lead to substantial negative health deterioration in patients who have purchased plans from BCBSMT and have relied upon BCBSMT doing a thorough job in independently and objectively evaluating treatments in order to provide coverage determinations. If BCBSMT continues to refuse to independently APT and its medical appropriateness to BCBSMT's beneficiaries in Montana, BCBSMT will have failed in its "obligation to act in good faith with its members." See Weber v. Blue Cross of Montana, 196 Mont. 454, 643 P.2d 198, 203, 39 St.Rep.245 (Mont., 1982)

APT is Substantially Different from CIIIT, OIVIT or Similar Therapies

As you know, I initially reached out to BCBSMT on behalf of Trina upon the belief that BCBSMT would act in good faith and do an independent and objective evaluation of the differences between CIIIT-type therapies and APT. I reached out to you knowing that if BCBSMT did an independent evaluation of the facts and a thorough medical review of the treatment, BCBSMT would make the correct determination that APT is not CIIIT. That, unfortunately, did not happen.

In order to see if we could give BCBSMT one more attempt to look further at APT, I conferred with Trina after review of your Response and asked if Trina could provide me additional, current information to show that APT is substantially different, not "substantially similar" to CIIIT. I received that information from Trina and permission from Trina to reach out to you one more time, prior to filing a lawsuit to have a court resolve the issue. Enclosed please find two letters written on behalf of APT providers, in 2016 and 2017, that should leave no doubt that APT is not CIIIT. The medical processes detailed in the September 1, 2016 letter "To Whom it May Concern" details the medical processes that make APT is substantially different from the CIIIT-type treatments, which are incorrectly described in your letter as being "substantially similar" to APT. Key, here, to your review is that the substantial difference in the medical process of APT from those CIIIT-type treatments causes APT to be effective where those treatments are not, and, in return, makes BCBSMT's CIIIT policy inapplicable to APT. This is especially true since BCBSMT's CIIIT policy states as its "Rationale" that "No studies were identified that investigated the proposed mechanism of action of CIIIT in humans." The second enclosed letter, August 16, 2017, addressed to "Dear....Colleagues" and redacted for confidentiality purposes, responds to similar confusion shown by another payor about the difference between CIIIT-type treatments and APT.

BCBSMT Should Cover APT, Until it Has Reasonably Evaluated APT independent of Other Therapies

The statements contained in your Response show that BCBSMT has not taken the time to reasonably evaluate the treatment process specific to APT. BCBSMT has also not shown that it has used any objective standards to independently evaluate APT's medical effectiveness on humans or to make a determination as to whether APT is "substantially similar" or substantially different, in relation to effectiveness in humans, to CIIIT-type treatments. For that reason, BCBSMT should, at a minimum, act in good faith to cover APT for its current beneficiaries, until it has independently evaluated the APT treatment under reasonable objective standards and communicated the findings of such a review and the objective standards used in the review to BCBSMT patients. BCBSMT has an obligation to do so, in order to act in good faith to the BCBSMT beneficiaries who are appropriate candidates for APT.

APT Cannot Be Coded as Demanded by BCBSMT

The unsupported conclusion in your Response that CIIIT and CIIIT-type therapies and APT are "synonymous or substantially," led you to a further incorrect conclusion that APT should coded as OIVIT under HCPCS G9147. Because APT is so substantially dissimilar to CIIIT and OIVIT and because APT's outcomes are so dissimilar to the outcomes of these other treatments – in that APT is shown to work in humans, there is simply no substantive reason for APT to ever be coded as OIVIT. This is especially true when one takes the time to review the 2009 decision by CMS that details the rationale behind its OIVIT related findings in comparison to the medical information that I have provided to you and that are additionally enclosed with this letter.

With regard to your attempt to modify the directives in the April cease and desist letters, your attempt to do so provided no substantive change to the demands made in those letters. Your Response states that additional codes can be used in conjunction with OIVIT to bill for "subsidiary services" to CIIIT-type treatments. However, you are not clear in how that coding would work or the exact coding process that you advise could or should be used.

Moreover, I understand that, since any treatments that are billed in conjunction with CIIIT-type treatments along with the OIVIT code of HCPCS G9147, will be denied as a result of them being connected with the OIVIT treatment, which you state is not covered by BCBSMT, your attempt to try to modify the April cease and desist letters not only falls short in providing any substantive guidance but appears to be wholly disingenuous and intended to lead APT providers into a billing trap, so to speak. I have consulted multiple billing and coding experts with regard to your assertions, and all of them have agreed that your Response does not substantively alter the directive given in the cease and desist letters, nor does it help guide APT providers utilize in using a billing and

coding system that would appropriately distinguish the APT treatment process from CIIIT-type or OIVIT treatments.

If BCBSMT Continues to Deny APT Coverage under CIIIT, It Does So in Bad Faith.

The information that I have provided you shows that APT is not CIIIT. Your response provides no showing of BCBSMT doing any independent evaluation of APT using objective standards to conduct a medical review of the effectiveness of APT in humans. Instead, your response shows that BCBSMT made a cursory review of CIIIT-type therapies and jumped directly to the assumption that APT is "substantially similar" to those therapies. As a result of BCBSMT failing to independently and objectively review the effectiveness of APT in humans using reasonable standard, BCBSMT's appears to be acting in bad faith toward its beneficiaries in its determination that APT is excluded from coverage under BCBSMT's CIIIT policy adopted in June of 2017. This is specifically true now, because the "Rationale" of BCBSMT's CIIIT policy is clearly stated in that policy as "[n]o studies were identified that investigated the proposed mechanism of action of CIIT in humans, and you have in your hands studies that show unequivocally that APT is effective in humans.

For the reasons stated in this letter, Trina requests that BCBSMT immediately reevaluate its position of APT's effectiveness in humans and the medical necessity of APT's specific treatment process using objective medical standards to identify whether APT is "substantially similar" to or substantially different from the CIIT-type polices that fall under BCBSMT's CIIIT policy. I ask that you detail to me the objective medical standards used in that evaluation, a description as to why the standards used were reasonable and a detailed analysis of the application of those standards in evaluating the APT treatment process for medical necessity in humans. Please provide a response to this request directed to my office providing this information no later than September 29, 2017. Thank you.

Sincerely,

ERIN F. MacLEAN
for FREEMAN & MACLEAN, P.C.

EFM/tmr
Enclosures

cc: Dr. Monica Berner, Divisional Vice President, Chief Medical Officer
Mary Belcher, Vice President and General Counsel
Therese Anderson, Manager, Special Investigations Dept.

TriNA HEALTH

September 1, 2016

To Whom It May Concern:

Re: History of OIVIT and Artificial Pancreas Treatment

Explanation of Non-Applicability of OIVIT to Artificial Pancreas Treatment® with Medical Necessity Information Not Contained in OIVIT NCDL 40.7.

Dear Sir or Madam:

Cases Have Decided, OIVIT is PIVIT, not the Artificial Pancreas Treatment.

It has already been determined, for all concerned, by Centers for Medicare and Medicaid (CMS) that the Artificial Pancreas Treatment® is not OIVIT as ruled in two legally determined ways:

a. The Medicare Appeals Court has spoken and found that OIVIT is PIVIT, an experimental attempt to obtain metabolic benefits, thereby excluding the Artificial Pancreas Treatment®. This appeal was final, has not been contested, and thus is dispositive on the subject.

b. The second confirmation of the difference is found in the treatments themselves and their patents, documents and procedures. Multiple publications and independent expert opinions are all consistent and dispositive.

Either one of the above two facts alone mandates that OIVIT does not apply to the Artificial Pancreas Treatment®. Together they are more conclusive and not subject to any contra argument. In fact, not one single physician nor one single historical fact suggests otherwise, so completely is the issue resolved.

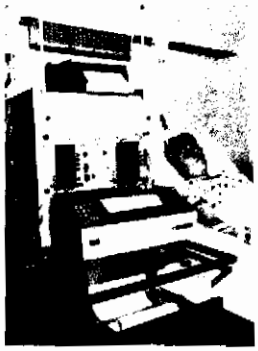
Accordingly, the Artificial Pancreas Treatment® is 1) legally and 2) factually not OIVIT and NCDL 40.7 does not apply. However, since the matter has been raised, the following is a complete (exhaustive) history of the facts:

1. PIVIT History (OIVIT), versus the Artificial Pancreas Treatment®.

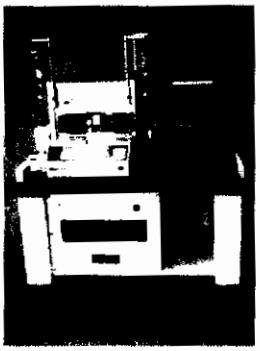
This is the legal history of two (2) independent approaches to treating diabetes and other diseases of metabolism, relating date back to 1982 and 1989 respectively. One, OIVIT or PIVIT was the so called "Harvard" approach. The other approach is the Artificial Pancreas Treatment® microburst of insulin by the Bionica Microdose. These two approaches have been confused because both are intravenous, but have little else in common.

2. **The so called "Harvard Protocol,"** originally was developed at Harvard (Joslin Diabetes Center) by Anton H. Clemens of Miles Laboratory, the inventor of the Miles Biostator® This device was granted FDA clearance K-780393 on June 19, 1978.

The original Biostator was able to provide a measured amount of insulin, IV glucose and required a keep vein open (KVO) flow of normal saline.



This device was then modified by Clemens to allow customized infusions of insulin, without glucose, keeping the KVO. (The black line is the addition of a floppy drive to modify delivery).



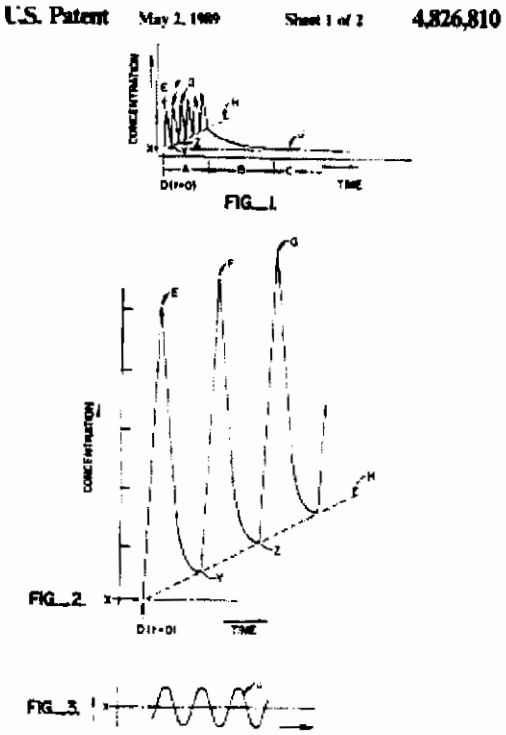
Anton Clemens and others at Miles Laboratories worked on the project for over several years before receiving their FDA clearance. The device was never a commercial product, but rather a research system to study glucose and to "clamp" the amount of blood glucose in the patient's blood through insulin.

The protocol for the Biostator® before modification was simple, it infused insulin with a slow peristaltic pump in an amount designed to keep blood glucose in a physiological range and constantly monitored blood glucose. Unfortunately, it took full time oversight and the final review stated: "...practical work with the Biostator is burdened with technical difficulties and considerable costs in comparison to a manual glucose clamp technique. The use of the Biostator® for the glucose clamp technique is not mandatory, but, the use of this machine makes it possible to perform glucose clamp studies under standardized and reproducible conditions."

The benefit of the modified Biostator® was that it could be used for experimentation, which is what Clements performed at Harvard in the late 1970's and early 1980's.
The Biostator® was not an artificial pancreas as it could not do what a pancreas does, nor could it deliver insulin the means by which a pancreas delivers insulin (in microbursts separated by 4-6 minutes).

The Biostator® was able to smoothly increase the baseline of insulin delivered by virtue of programming (algorithms). The Biostator required a continuous glucose monitor of venous blood to achieve either euglycemia or for OIVIT, relative insulin increases.

The modified Biostator® was used by multiple physicians at Harvard (including Dr. Thomas Aoki) to prepare their approach to the FDA application "A system used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma."



That approach led to a patent by Dr. Aoki issued on May 2, 1989, US Patent Number 4,826,810 which was and is the basis for the "Harvard Protocol."

As shown here, the "Harvard Protocol" patent calls for insulin infusion "thereby producing in the blood supply to said body tissues a series of peaks in the free insulin concentration, said prearranged time periods selected to produce successively increasing free insulin concentration minima between said peaks" (ie: ever increasing peaks of free insulin).

Thus, the Harvard Protocol was and is distinctive. It was never fully successful because the basic problem was the increased level of free insulin, and perhaps most importantly, because it did NOT replicate a normal microburst of insulin as if found in normal many.

Every claim in this Harvard Protocol (now OIVIT) patent sets forth the requirement that insulin is delivered in a "series of peaks…producing successively increasing free insulin…" (all claims, US 4,826,810). This "Harvard Protocol" was legally determined in prior Medicare Appeal, OIVIT where the appeal decision referred to it as OIVIT, "a unique concept which bases the insulin on Respiratory Quotient." Thus, the proof that OIVIT is indeed the OIVIT "Harvard Protocol" is found in both the patents and the findings of CMS after a series of lengthy hearings at the ALJ level.

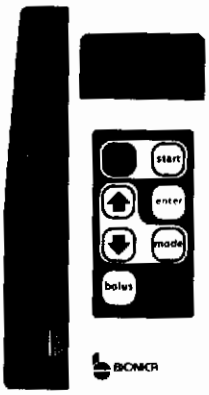
To be redundant, it is both legally and factually incontrovertible that this approach is the "Harvard Protocol" of increased baselines of free insulin, and this approach was never used with the Bionica Microdose of Microbursts of insulin called the Artificial Pancreas Treatment®. In fact, the only known use of the OIVIT Harvard Protocol was by Dr. Aoki and a few others, including Dr. Nathan Nachlas, in Florida, all of which were in experimental

settings (Aoki Diabetes Research Institute, and Advanced Diabetes Treatment Centers "ADTC"). This work was reported and published on ClinicalTrials.Gov, and is still on the site for anyone to verity. Thus, OIVIT was agreed to be, by the parties and by CMS to be an experimental means of pulses of insulin which uses Respiratory Quotients to adjust therapy.

3. Next Generation of Harvard Protocol Device.

After the use of the Miles Biostator® was concluded, American Hospital Supply commissioned Mcgaw (pump company) to attach a small computer to their Accupro pump which allowed for the ever increasing baseline of free insulin (OIVIT) to be delivered. This device was made specifically for the Aoki patent 4,826,810 above. This device was (is) a peristaltic pump which does not deliver microbursts, but rather treats from a hanging bag of insulin and saline (as per NCDL 40.7). (see right) This device was developed for American Hospital Supply (now Baxter) as an experimental unit (with New Device Application to the FDA). This was designed for and used by Dr. Aoki, and was not ever part of the Artificial Pancreas Treatment®. The benefit of the Mcgaw Accupro pump was with the computer, it could be programmed to give ever increasing amounts of insulin to achieve "ever increasing baseline" of insulin per the Harvard Protocol (OIVIT).

The NDA application to the FDA was withdrawn from use by American Hospital Supply when Baxter bought the company.



Accupro not an insulin pump, used a peristaltic rotating cam to squeeze fluid forward, and was fed by a hanging bag.

The Bionica Microdose ambulatory insulin pump (see left) is completely different and cannot deliver "ever increasing baselines" of insulin without complete modification of the 5 setting every 5 minutes, (which has never been done or reported). This pump computes the concentration and provides even doses of insulin every 4-6 minutes delivering level insulin in response to a fixed glucose load exactly like is seen in normal man.

4. **Prior ALJ and Medicare Appeals Council Case; Harvard PIVIT is OIVIT**: The fact that the Harvard Protocol is also known as OIVIT is clearly set forth in the August 28, 2009 Decision of Medicare Appeals Council, ALJ (1-392893626 re Advanced Diabetes Treatment Centers).
The Medicare Appeal on Page 8 recited the fact:

> "Between January 2008 and April 30 2008 the appellant provided multiple services to 348 beneficiaries as part of a clinical trial involving PIVIT" [now known as OIVIT]. "The appellate [ADTC] submitted assigned claims for these services to Medicare, including claims for "respiratory quotient" or "RQ" testing..."

On Page 9 the Council states:

> "The issue in this appeal concerns whether Medicare Part B payment is warranted for six respiratory quotient (RQ) tests per treatment episode, claimed under HCPCS code 94681 provided to multiple Medicare beneficiaries enrolled in a clinical trial involving pulsatile intravenous insulin therapy ("PIVIT"), where RQ testing is a routine cost of clinically appropriate monitoring of the effects of the PIVIT treatment, in accordance with the Medicare National Coverage Determination (NCD 310.1)"

[NCD 301.1 is the "Medicare Deemed Studies" system to pay for experimental studies which a) require an IRB to review, b) require clinical trial reporting to Clinical Trials.Gov, c) require an informed consent where the patient is informed of the experimental nature of the treatment and its potential side effects) and d) the right to participate with Medicare (CMS) payment of routine costs in those "deemed" clinical trials. At this point PIVIT (the Harvard Protocol) of Dr. Aoki was thus admittedly experimental and PIVIT was being studied.]

On Page 9 the Council states:

> "The ALJ next stated that [t]he clinical trials at issue are designed to monitor the effects of the Pulsatile IV insulin therapy through respiratory quotient (RQ) testing and frequent fingerstick testing." (Finding 6)"

On Page 9 the Council states:

> "The ALJ finally found that "frequent monitoring of RQ is necessary as these levels change rapidly depending on the fuel being utilized by the body. IV insulin given in pulses shifts metabolism to primary glucose metabolism. (Finding 10)"

On Page 10 the Council states:

> "In his analysis, the ALJ noted that PIVIT treatment was pioneered by Thomas Aoki MD at Harvard University and was known as "*the Harvard protocol.*" (Dec at 8)
> The ALJ reasoned that the trials at issue for their review were designed to "monitor the effects of Pulsatile Insulin therapy thorough respiratory quotient (RQ) testing and frequent fingerstick testing."

The official findings of the Medicare Appeal Council found:

> "The Council therefore finds that the ALJ erred in finding that the evidence, including testimony, established that "the RQ testing procedure…is not a component of the PIVIT.: Dec. at 10 ***RQ testing was provided during each session for purposes of determining whether the amount of insulin and/or carbohydrate provided should be altered during subsequent PIVIT sessions. The purpose and outcome of the RQ tests were critical components of PIVIT and affected clinical decisions during the process.*** Such services do not fall within the definition of "monitoring" the subject of a clinical trial for Medicare coverage of routine costs under NCD 310." (emphasis added)

The context of this Decision of the Medicare Appeals Council is important. NCD 310 pays for Clinical Trials (deemed studies) which are services to CMS beneficiaries, as Clinical Trials are for services which are of an "experimental or investigational" nature and thus do not necessarily rise to the level of medically necessary for beneficiaries.

PIVIT was thus both legally and finally determined to be experimental, a treatment that uses RQ as "a critical component" of the PIVIT a clinical trial with increased baselines of insulin. It was thus agreed and factually determined that PIVIT was an investigational treatment based upon RQ and the Harvard Protocol.

Nothing can be more clear, more well documented or more certain. The Dr. Aoki PIVIT is expressly the "Harvard Protocol" which uses RQ as its determination of for decision making treatment process. These facts were never contested, never controverted nor appealed. The only question was not about the definition of OIVIT or the experimental/investigational nature of the PIVIT treatment but solely: "what routine costs should be paid?"

5. Court Documents show No Crossover in Approaches. As further context to the two different approaches, it is important to note that as of 2003 the work of Aoki and the work of Bionica Microdose (Bionica Inc., Sacramento, CA) were totally distinct and separate. This too is indisputable due to the court actions of Dr. Aoki after he had been sued by one of his contracting parities. In that suit Dr. Aoki filed a cross-claim against Bionica Inc. (Second Judicial District Court of the State of Nevada, County of Washoe, Case No. CV03-04790, Metabolic Industries, etc., and Thomas T. Aoki, M.D., Cross-claimants vs. Bionica, Inc.)

The case documents demonstrate that there was an ongoing dispute between Dr. Aoki and Bionica Inc. which was finally determined when Dr. Aoki's company dismissed Bionica Inc. Dr. Aoki was a full time professor at UC Davis, not working at or with Bionica, and the dismissal showing that Bionica Inc. et al. confirms that he had no rights in or to Bionica or its pump. In all the various lawsuits that Dr. Aoki was involved in, he never claimed to have anything to do with the Bionica Microdose. Bionica and Dr. Aoki were thus not working in any way when the PIVIT (now OIVIT) clinical trials took place. Thus, it is shown that not

only were there were two very different protocols, the "Harvard Protocol" and the Artificial Pancreas Treatment® using the Bionica Microdose protocols, but that Dr. Aoki had nothing to do with the microburst or Bionica Inc. device.

6. Design Criteria. Furthermore, the design criteria for the Bionica Microdose does not support the Harvard Protocol. In fact, the design criteria was developed by G. Ford Gilbert, and the Bionica engineers in Australia (where it received the design of the year). The two approaches are not the same due to the nature of the microburst of insulin delivered which is so minuscule that it is delivered at 30 to 60 psi without vein change! It is also accurate from microburst to microburst, never "averaging" as other pumps do with their "smoothing algorithm."

As shown in the "Supervisor's Guide" instruction manual for the Bionica Microdose, the insulin is delivered in microbursts without reference to the prior amount (i.e. no increased free insulin baseline). Not only does the Bionica Artificial Pancreas Treatment® NOT have the Aoki - Harvard "ever increasing baseline of free insulin." it does not have a way to program to attain such increases. The increased free insulin approach used by Dr. Aoki also invites the potentially dangerous condition of hypoglycemia. Increased free insulin will automatically increase the likelihood of hypoglycemia.

Also, using the Bionica Microdose, the RQ is not a valid means to measure or treat, and the Artificial Pancreas Treatment®. Not only is the RQ not "a critical component" as in OIVIT, the Artificial Pancreas Treatment® does not use RQ for <u>any</u> treatment purposes whatsoever.

7. NCDL 40.7 is Very Clear, and Confirms that it applies to the Harvard Protocol. (and correctly names it OIVIT).

CMS covers and pays for the vast majority of Trina Health Treatments as overseen by other intermediaries because they understand that the NCDL does not apply to the Treatment delivered in hospitals and clinics associated with Trina Health. The NCDL is very specific, it only applies to the Harvard Protocol, PIVIT a specific outpatient "regimen" under the specific terms:

> **"Outpatient Intravenous Insulin Treatment (Effective December 23, 2009)**
> **(Rev. 117, Issued: 03-09-10, Effective Date: 12-23-09; Implementation Date: 04-05-10)**
>
> A. General
> The term outpatient intravenous (IV) insulin therapy (OIVIT) refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of insulin via any means, guided by the results of measurement of:
> • respiratory quotient; and/or
> • urine urea nitrogen (UUN); and/or
> • arterial, venous, or capillary glucose; and/or
> • potassium concentration;
> and performed in scheduled recurring periodic intermittent episodes.

This regimen is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment (PIVIT), Pulse Insulin Therapy (PIT), and Pulsatile Therapy (PT).

In OIVIT, insulin is intravenously administered in the outpatient setting for a variety of indications. Most commonly, it is delivered in pulses, but it may be delivered as a more conventional drip solution. The insulin administration is adjunctive to the patient's routine diabetic management regimen (oral agent or insulin-based) or other disease management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits. Glucose or other carbohydrate is available ad libitum (in accordance with patient desire)."

8. **NCDL 40.7 Is Equally Clear that it Does Not Apply to APT**. The above statement of treatment modality does not apply to the Bionica Microdose – Artificial Pancreas Treatment® (APT) and the OIVIT regimen is now outdated because the entire field of medicine has improved to the point of general acceptance of an Artificial Pancreas. The Trina-Bionica Artificial Pancreas Treatment® is a COMPLETELY different regimen from that described above. ***So different are the two approaches they do not even share the same physiological approach or treatment goals.***

What the NCDL expressly reviewed was only the Dr. Aoki (Harvard Protocol) which focuses on a program using Respiratory Quotients and "ad lib" glucose, which is not the Trina – Bionica Artificial Pancreas Treatment®. The mistake in identification is understandable because a few of the published clinical trials were with the Bionica Microdose burst insulin infusion device, not OIVIT. However, Dr. Aoki tried to use his patent, with his approach of "ever increasing baselines" and this was the regimen that the NCDL reviewed.

How could anyone disagree with the finding of "experimental or investigational" for OIVIT when it was part of a then ongoing published clinical trial? (ClinicalTrials.gov). And we too agree that the OIVIT with RQ use and increasing free insulin is just not physiologically defensible. The issue can be stated: "Why would any protocol use ever-increasing baselines of insulin and modulated by an RQ when the normal body does not do that?"

To use the phrases of the Bionica Inc. team, ***"The Harvard protocol is plainly egocentric on the part of the designers. They elect to oppose natural insulin release by using an increased baseline of insulin when that mode of insulin delivery is never found in man or animal, and by using a meaningless RQ."***

The basic difference between the two approaches is so basic that one is "physically illogical" and the other "physiologically normal." The Harvard OIVIT approach is backwards when compared to normal insulin. OIVIT gives insulin with an "ad lib" amount of glucose to cover an artificially ever increasing free insulin base, and then changes that treatment on the basis of the RQ. As the NCDL writer correctly shows, that is <u>not</u> how a normal body works. Rather, when a body receives carbohydrates, the pancreas senses the level of glucose in the

blood from the GI track and secretes, in 4-6 minute spaced microbursts of insulin, an amount of insulin to cover that glucose load. This is the way that the Artificial Pancreas Treatment® approaches the restoration of carbohydrate metabolism, mimicking normal.

Conversely, with the Harvard Protocol, the insulin is given "in ever-increasing baseline" which is not what the normal pancreas secrets, and glucose is used to cover the ever-increasing baseline of insulin in an "ad lib" way, using the RQ (Respiratory Quotient) to modify the glucose (not the insulin).

Simply put, the Harvard Protocol is backwards when compared to the Artificial Pancreas Treatment®. With the Harvard – Aoki protocol, Glucose is given ad libitum to meet an increasing baseline of insulin via RQ calculations, instead of the way the body normally works where the insulin is given to meet the glucose load. Further, the body senses glucose to determine insulin amounts, not an RQ which is a ratio of carbohydrate to lipid metabolism. That is why the two approaches are so completely different and why the Artificial Pancreas Treatment® does not use RQ in any way (supra). That is also why NCDL 40.7 is both correct and does not apply to the Artificial Pancreas Treatment®.

In fact, the NCDL 40.7 was a direct result of the work being done by Advanced Diabetes Treatment Centers which was in a contest with First Coast Service Options brought on by the fact that Advanced Diabetes Treatment Centers never published any of its findings using the Harvard Protocol. First Coast became tired of paying for "routine costs related to clinical trials under NCD 310" when ADTC never published any results or outcomes. Again, we do not disagree with the First Coast assessment either.

9. Significant Differences Between Treatments:

The Trina Health Treatment using the Bionica Microdose microburst insulin infusion device must be prescribed by a physician or licensed provider. The provider must make independent assessment of the need, and if appropriate, and provided the secondary complications of the patient exist from the failure of conventional therapy, the Treatment is given, but not as listed above in the OIVIT decision and description. A more complete discussion of the treatment follows, but for brevity;

a. The Trina – Bionica Artificial Pancreas Treatment® is not delivered in ever increasing pulses, (per above). That Harvard approach has been tried at least twice and because of hypoglycemia tendencies of increasing insulin, and the need for ad lib glucose, does not work well. Rather, the Artificial Pancreas Treatment® infuses microburst insulin every 6 minutes with no infusion between bursts. The infusion is in combination with a weight adjusted (not RQ adjusted) measured oral dextrose amount. The dextrose is in a philologically correct amount (not ad lib) for normal microbursts of insulin. The dextrose is based on weight and provides calories (kilocalories) for two meals (approximately 240 to 300 grams of dextrose), and is never delivered in "a conventional drip solution" (NCDL 40.7 above). The Artificial Pancreas Treatment® does not provide ad libitum glucose (NCDL 40.7). The Bionica Microdose device

provides a calculated concentration for the microburst infusion as part of its FDA registration, and this is never "drip."

b. The Artificial Pancreas Treatment® is not delivered on an "intermittent basis." (per NCDL 40.7 above). The treatment is given starting twice in two to four days, then once weekly until metabolism is restored (which is highly individual) and then extending to once every 2-3 or 4 weeks depending upon the patient outcomes until the individual therapeutic goal is reached. Some goals are the restoration of heart ejection fractions, some are the resolution of an un-healing wound, some the cessation of retinal laser photo coagulations, some to reduce kidney creatinine levels, some to restore brain metabolism, etc. All of these comorbidities and all of the various body types require individual treatment regimens and individual lengths between treatment based on the metabolic integrity and ability to convert carbohydrates as shown by conventional metabolic measurement (VCO_2). This is not the RQ or Respiratory Quotient as described later.

c. The Artificial Pancreas Treatment® is not delivered "chronologically" (per NCDL 40.7 above). Any regimen of chronological increasing waves or pulses can help, but does not necessarily achieve normal carbohydrate metabolism. The Artificial Pancreas Treatment® is prescribed based upon the provider's assessment of need, and based on the patient responses and improved ability to convert carbohydrates.

d. The Artificial Pancreas Treatment® is not delivered "without duration limits" (per NCDL 40.7 above). The provider's prescription determines the duration which is set, and verified each treatment. When the patient returns to normal functionality or the outcomes are met, the treatment is discontinued unless and until the patient has reoccurring complications and is unable to process carbohydrates properly, at which time the next assessment is given. Patients "graduate" from needing treatment and continue with their restored health, making the Artificial Pancreas Treatment® anything but "without duration limits." per NCDL 40.7 above. With the Trina – Bionica Artificial Pancreas Treatment® the duration is determined by the restoration and reversal of diabetic complications, which is not like the OIVIT regimen described above.

10. Comparing Each Element of the Decision In Order: The following specifically takes each element (bullet point) of the NCDL 40.7 in order and shows why it does not apply to the Artificial Pancreas Treatment®:

The NCDL: "Outpatient Intravenous Insulin Therapy [OIVIT]…**pulsatile or continuous intravenous infusion of insulin via any means, guided by the results of measurement of:**"

"• respiratory quotient; and/or"

There is a reason that RQ is the first mentioned aspect of OIVIT treatment. It is the basis for the treatment as shown above. (Harvard Protocol). It is a "critical component" of the

OIVIT system. So replete is the focus on RQ use for guiding treatment, the NCDL 40.7 addresses this use more than any other definition of OIVIT:

a. Decision: The first measurement mentioned is "RQ." (p.1)
b. Background: The first measurement mentioned is "RQ." (p.1)
c. Scope of this Decision: RQ is the first measurement mentioned (p.2)
d. Diabetes and Metabolic Measurement: RQ, the first mentioned (p.5)
e. Outpatient Intravenous Insulin Therapy (OIVIT): RQ is the first measurement mentioned (p.6)
f. Elements of OIVIT: measurement of RQ is required for adjustment (p.7)

In fact, RQ is the most quoted measurement in the entire NCDL, and this underscores the fact that the reviewer took issue with using RQ as a means of adjustment (as do we).

We also agree that there is no therapeutic need to use the RQ. The Respiratory Quotient test only shows the type of metabolism, which is whether the patient is burning lipids or carbohydrates, or storing fats, and not the amount or level of metabolism. RQ is a ratio of Oxygen consumed to Carbon dioxide produced. This is a true ratio, and for example the ratio of 5/10 is the same ratio as the ratio of 5,000/10,000. Raising the amount of resting metabolism is not reflected by RQ and that amount is what diabetes inhibits. Thus, by mathematical fact, the Artificial Pancreas Treatment® does not, can not, and should not be guided by RQ information. Only the amount of carbohydrate metabolism is relevant. The Artificial Pancreas Treatment® is absolutely not guided by the results of the Respiratory Quotient. Use of any metabolic measurement in reference to diabetes is only meaningful if the device is to determine the amount of carbohydrate metabolism that is achieved by the treatment, much like lab tests are conducted to determine the need for a medicine. The metabolic measurement machine is used as a patient health testing device, to determine when a patient is no longer normal, and not as a treatment device.

The Trina Health Treatment does not use the "Respiratory Quotient" in the "integration of insulin by any means." Nor is Treatment "guided by the results of measurement of " any of those factors.

This provides the undeniable conclusion that the RQ does not guide the Trina Artificial Pancreas Treatment®, and is thus not the regimen that is referred to in the NCDL.

Parenthetically, there can be a use for the Respiratory Quotient (RQ) test, it can used as a test to diagnose metabolic conditions and nutritional abnormalities. This test can, with proper need, be used as a periodic test. However, the RQ number does not show the amount of carbohydrate metabolism, nor is any expired gas used to guide the Artificial Pancreas Treatment®.

To diagnose diabetes, the best method is an Oral Glucose Tolerance Test (OGTT) which often follows a first alert of a problem when an abnormal fasting glucose is above 120 mg/dl, or the result of a HbA1c is > 6.0-6.2 percent. The OGTT provides the amount of glucose in the blood after one and/or two hours. One can also gain some background information as to the basic diagnosis of diabetic versus impaired glucose intolerant (or pre-diabetes) by looking at their

Respiratory Quotient (RQ) which in the presence of glucose should be ~ .90 (this is a ratio). The normal ratio is ~.85 and a person with impaired glucose processing might often have the highest ratio of ~.75…clearly deficient. None of these ratios are used in the Trina Artificial Pancreas Treatment® but can be used for diagnosis.

Specifically, as shown by the information above, as to the NCDL, the Artificial Pancreas Treatment® never infuses or treats "guided by the results of measurement of RQ. The unqualified answer is that it does not and not only is RQ not necessary, it is not helpful and not even logical. Thus, it is an undisputed fact by any logic.

11. Pulses of Insulin Are Conceded to be Normal. The NCDL 40.7 makes an attempt to discuss normal, but it failed to focus on the most important role of insulin in reference to the liver. The first-in-time act of the pancreas is to deliver microbursts of insulin to stimulate the liver to produce enzymes. The non-diabetic pancreas does just that, but the diabetic pancreas does not produce microbursts of insulin every 4-6 minutes and thus does not provide the oscillations to the body. This directly causes abnormal metabolism.

The NCDL 40.7 provides a minor treatise on "Physiology of Insulin Secretion" which is an entire heading and chapter. It states:

> "In the following section, we describe the physiology of insulin secretion. We believe this is important because some proponents of OIVIT cite the importance of mimicking the endogenous release of insulin in support of their claims."

It is not just OIVIT and Bionica proponents who cite the importance of insulin release, it is now mainstream medicine (see post-2009 publication). So, while the NCDL writer referred to this issue, the writer failed to anticipate the importance of normal as has now been accepted by all. Then, the writer goes on to recite many aspects of insulin secretion. However, any review of this letter must be very skilled to finding the most important aspect of the report, as it is hidden in a compound sentence:

> "Intravenous administration can approximate these levels of hepatic exposure to insulin only if systemic venous insulin levels (and the risk of hypoglycemia) are also high. Nonetheless, some investigators have proposed these alternative routes of insulin administration."

This infers that OIVIT can cause hypoglycemia, and we must agree. While there is true for the Harvard Protocol = Dr. Aoki patent of ever increasing free insulin (insulin which is available in blood) it is not true of the Bionica Microdose Artificial Pancreas Treatment® Inc. The Artificial Pancreas Treatment® providers are the most accomplished providers of IV Insulin in the world, with over 200,000 infusions without a single adverse reaction. (see Affidavit of No Adverse Reactions). They uniformly agree that this is the most important function of normal insulin to mimic. While we have no opinion as how the Harvard Protocol OIVIT "approximates these levels" (above) this statement clearly does not apply to the Artificial Pancreas Treatment®.

The NCDL writer obviously was not addressing the Artificial Pancreas Treatment® Bionica Microdose because the writer reviewed the FDA and thus personally knew that there is no logical

reason to claim "(and the risk of hypoglycemia) are also high" for anything other than the Harvard ever-increasing baseline of insulin (the Bionica Infusion device has never had an adverse reaction as shown on the FDA website). Therefore the writer is showing that the NCDL does not and cannot be referring to the Artificial Pancreas Treatment®.

On other matters, the writer's advocacy against what is natural shows one of two realities:

a. Either the writers of NCDL 40.7 did not know that that hypoglycemia requires a certain long-term (as opposed to burst) infusion without covering glucose, or;

b. The writers of NCDL 40.7 chose to eliminate references to normal proven physiology that support the logic of the Artificial Pancreas Treatment® IV insulin treatments.

There is no basis for the writer of the NCDL to claim that insulin must be dangerously high to be effective when the writer has absolutely no direct information on that point and should also know that the Artificial Pancreas Treatment® has proven otherwise.

Not only are there over 25 publications showing that insulin is normally secreted by the pancreas in microbursts every 4-6 minutes, there are NO publications that such microburst secretion is not totally normal, even in animals. Understanding the fluid levels gives perspective to how important this function is. The pancreas secretes approximately ½ gallon of liquid per day, but only a miniscule (in microburst) amount of insulin. The fact that insulin is given in microburst is likely the only fluidic way for insulin to be "recognized."

Under the heading "Diabetes and Standard Insulin Therapy" the NCDL writer describes the typical route of subcutaneous insulin therapy, and claim that it can be "self-administered unlike IV insulin." Again, the writer is indicating a sole focus on OIVIT as if the writer were referring to the Artificial Pancreas Treatment® that would be patently wrong. The writer reviewed the FDA allowance of the Bionica Microdose IV insulin infusion pump (Artificial Pancreas Treatment®) device which shows that it is "Ambulatory." which means that it can be safely used at home. In fact, if the writer had wished to further understand the safety facts on the Bionica Microdose the writer would have been provided even more safety data showing a lack of adverse reactions even with home use. This safety record is verified by the US FDA. Just as there are no reports of adverse reactions in all of the clinical trials using the Bionica, and all of the patent treatments in what are now 19 clinics, there are no reports of significant hypoglycemic reactions from home use.

Physiologically, a person treated with the Artificial Pancreas Treatment® will withstand downward pressures of insulin and avoid adverse reactions because the treatment generates glucose storage in the liver (and muscle) which is available to counteract any hypoglycemia. It is well known that the alpha cells in the pancreas produce glucagon which mobilizes glucose, and it is only because diabetic people have unavailable glucose that hypoglycemia takes place. With the Artificial Pancreas Treatment® patient, there is an avoidance of hypoglycemia (see published study)

There is no real need to point out other issues with the background material as NCDL 40.7 obviously does not seek to apply to the Artificial Pancreas Treatment® using the Bionica Microdose since there is no examination, no dialog, no trier of fact, no independent reviewer, no endocrinologists or the likes referring to Artificial Pancreas Treatment®.

By contrast attached is an independent endocrinologist opinion on the medical necessity of normalizing metabolism by mimicking the normal liver. This is consistent with the other physicians involved (see advisory board).

No fiscal intermediary should apply the 2009 NCD to Artificial Pancreas Treatment® since the people who are most knowledgeable about that (Bionica –Trina users) were not part of that NCD as it was reviewing the Harvard Protocol and Dr. Aoki, and not Artificial Pancreas Treatment®. If intermediaries were not recompensed from money denied to beneficiaries, the potential for misapplication might not be so great. The fact that none of these responding parties were part of the NCDL hearings just underscores that fact.

The simple and undeniable facts are that the NCDL 40.7, even with a somewhat flawed factual background, did conclude correctly that PIVIT is OIVIT, did correctly conclude that the RQ is not a valid approach to adjusting insulin or treatment, and did correctly conclude that PIVIT is investigational (which it even claimed to be under the deemed studies). Thankfully the letter formal decision was sufficiently detailed and specific that it eliminates any application of 40.7 to the Artificial Pancreas Treatment®.

12. Summary of the Artificial Pancreas Treatment® (This information is confidential):

Treatments: The patient is processed into the clinic, and vitals taken. An interview with the licensed practitioner (MD, DO, NP) takes place and an encounter history etc. is taken and recorded.

Prior to initiating treatment, the customary labs are taken as part of the H&P, so that anything unusual can be identified. No part of the treatment is guided by the results of measurement of the labs, except that if a patient were to have unusual labs the practitioner could elect not to treat. Labs are definitely not part of the treatment, and are generally performed the usual "once quarterly."

The patient's insulin dose is not determined by their history as in OIVIT. The Bionica Microdose computes the insulin concentration based on the patient's weight. The Artificial Pancreas Treatment® normal amount of dextrose is computed to be the necessary amount to fill the liver based on weight based calculations (unlike OIVIT).

Assuming the physician decides that the patient qualifies as having significant secondary complications or is in danger of ketoacidosis, then the Trina Treatment is initiated.

The patient weight is determined along with the vital signs. Their weight determines what a customary "meal" will be using carbohydrates.

The goal and delivery of the Artificial Pancreas Treatment® is:

a. to **provide 800 to 1500 calories of dextrose,** while

b. at the same time to provide **micro bursts of insulin** which start with the minimum level allowed by the Bionica pump. *The concentration is computed by the pump and has nothing to do with RQ.*

c. The total amount of dextrose including any IV dextrose for those with gastric dysfunction is determined by weight and thus reduced for smaller sized people. The amount of dextrose is the amount that a person of that body habitus would need for two meals. The dextrose in calories (kCal) is not fewer than 800 calories nor more than 1,200 kCal. The glucose treatment formula reduces the total calories for patients who are smaller in size. The ratio is:

> An average person of 200 pounds (91 kilograms) will require approximately 300 grams of dextrose (1200 kCal) to fully glycosylate his/her liver and muscle.
>
> An average person of 140 pounds (65 kilograms) will only require 240 grams of dextrose (960 kCal) to fully glycosylate their liver. Women are thus more likely to need fewer grams of glucose. No further reduction in grams is necessary.

d. Patients are started with a fraction of their normal insulin (10 miliUnits = 1/100 of a Unit/kg) because the storage of glucose in liver is depressed in patients with diabetes.

e. Insulin dose in micro bursts (Bionica Microdose) is from 10 mU/kg to 35 mU/kg average with a maximum of 70 mU/kg. With dextrose pre-loading, the Artificial Pancreas Treatment® does not result in hypoglycemia.

f. The Artificial Pancreas Treatment® improves a patient's metabolic abilities and over time insulin resistance is reduced. Accordingly, the amount of insulin is adjusted over time, however this is <u>not</u> in reference to the RQ.

g. The insulin is adjusted for the patient which is entirely different from OIVIT and not related to an RQ. OIVIT is basically backwards and inappropriate in its insulin delivery (ever increasing baselines) where insulin is given, and glucose adjusted to respond. That is not the way a normal pancreas works.

h. The Artificial Pancreas Treatment® takes its logic from normal man. The normal insulin level fluctuations of a day are from 5 to 40 mU/Ml which is what is used by the Artificial Pancreas Treatment®. This is far different from OIVIT.

i. The patient sits in a chair, walks as needed to the bathroom or elsewhere, and stays in the clinic for approximately 4 hours while receiving measured IV insulin via the Bionica

Insulin pump, and the patient's calculated dextrose (240 to 300 grams) by mouth. (the patient is not tied to an IV pole infusion device which increases insulin as in OIVIT).

j. APT is not a hyperinsulinemia treatment: Only a very small amount of insulin is given. For example, a 70 kilogram person with 10mU/kg Dose will only receive per burst 70x10/1000 of unit, or only seven tenths (7/10) of a single Unit of Insulin. For reference, most type 2 diabetic people use over 50 units a day, many over 100.

k. With the range of oral dextrose of from 200 to 300 grams per session, (each gram is 3.85 kcal – calories) the patient receives approximately 800 to 1,200 calories total. Again, this is not a large number of calories and is not a large amount of insulin either. However, because Artificial Pancreas Treatment® mimics the normal micro bursts of pancreatic insulin, the results are remedial as published.

l. The above are all part of the pump computer programming which automatically calculates the concentration of insulin. **None of the NCDL listed items or RQ are part of that calculation**. (end of treatment summary)

13. Continuing with the elements of NCDL decision criteria: The treatment is guided by:

"• urine urea nitrogen (UUN); and/or"

Answer: Urine, urea nitrogen are not used or part of the treatment.

"• arterial, venous, or capillary glucose; and/or"

Arterial, venous or capillary glucose does not guide the treatment. In OIVIT the use of home glucose monitors is urged in addition to RQ. We agree that blood glucose management is a daily and sometimes hourly pursuit for any person with diabetes, but it is not part of the treatment, as is every other type of homeostasis. However, this is not the case with the Harvard Protocol, which must provide ad lib oral glucose due to the ever-increasing baseline of free insulin.

Also, unlike OIVIT, the amount of **oral** dextrose (as opposed to arterial, venous or capillary glucose) is pre-determined to meet the physiological requirements of a person of that size. The concentration of insulin is determined by the Bionica device, and the oral glucose amount is determined by the weight of the patient (equaling approximately 1200 calories, adjusted for size.)

"• potassium concentration;"

Answer: Potassium concentration is not part of the treatment (and it is shown in attached clinical trials and publications that small amounts of burst insulin does not affect potassium as does an insulin drip commonly found in hospitals.) It is with this worry too that the Harvard Protocol of OIVIT must contend, but not the Artificial

Pancreas Treatment®.

"and performed in scheduled recurring periodic intermittent episodes."

Answer: The treatment is not "scheduled recurring episodes" either intermittent or not. While the phrase is difficult to understand (how something can be "scheduled on an intermittent basis") the point trying to be made is that with OIVIT treatments scheduling is on an artificial timing, not related to the patient outcomes. For OIVIT this is true, but for the Artificial Pancreas Treatment® nothing could be further from the truth. The scheduling is not recurring or artificially timed, it is in strictly accordance with the patient needs. A patient may have a few treatments to heal an un-healing wound, or several treatments to regain ejection fractions from cardiovascular disease.

One thing is universally known, patients will not pay for and will not keep returning to have an IV therapy that is not making a meaningful change in their health. They will "vote with their feet."

The OIVIT NCDL 40.7 shows the difference.

OIVIT: is "typically delivered as a series of fixed duration infusion and frequently performed on a perpetual basis." (p.6) This clearly does not apply to the Artificial Pancreas Treatment® as the measurement of VCO_2 and the patient outcomes decide the number of treatments.

OIVIT: "the RQ, which may or may not include a measure UUN component is claimed to be used as a determination of the patient's carbohydrate oxidative efficiency." (p.6) This too does not have anything to do with the Artificial Pancreas Treatment®. Frankly, that claim seems illogical.

OIVIT: "it is claimed to be used to assess the patient's metabolic response to the insulin infusion and to adjust subsequent insulin infusion doses via an explicit or implicit algorithm to achieve an RQ of 0.9 to 1.0. (p.6)

There is no logical way to use the RQ as a means to adjust insulin. If there is, it is the opinion of this group of professionals that such information would be almost useless in adjustments. Perhaps this is why the NCDL was written, as we agree this too is just silly. This does not apply to the Artificial Pancreas Treatment®.

OIVIT: "It is not known how adjustments are made for the confounding ad libitum (in accordance with patient's desire) consumption of glucose." (p.6)

This does not apply. As shown above, the glucose load is given in dextrose and is a very specific 900 to 1,200 kCal of dextrose. It is not "ad lib" as is found in OIVIT.

Again, this shows that the Artificial Pancreas Treatment® is not the Harvard PIVIT treatment.

OIVIT: "Personal glucose monitors do not have the same accuracy as professional laboratory equipment. (p.6) We agree, and again, the Artificial Pancreas Treatment® does not use personal glucose meters. This again is PIVIT.

OIVIT: In Europe RQ was not used, which is contrary to that of OIVIT in the USA. (p.6) This is another statement of the same nature. The Artificial Pancreas Treatment® does not use RQ in any way, shape or form as it is only a ratio and not usable (supra).

OIVIT: "Respiratory quotient measurements are integral." (p.6) This again has nothing to do with the Artificial Pancreas Treatment®.

OIVIT: "Elements of OIVIT: Insulin -> Pump -> Labs -> RQ -> adjustments. p.7 This is not what the Artificial Pancreas Treatment® does. There is no RQ to adjust and the labs are prior to treatment in ordinary and customary care.

OIVIT: "We ask the following questions about the **individual components that comprised OIVIT**. (emphasis added)

1. Incorporate RQ as a guide,
2. Diagnostic Urine urea nitrogen
3. Diagnostic blood glucose or potassium.
4. If affirmative, which outcomes are improved, what are the duration of therapy required, which patient characteristics predict a significant outcome. (p.10-11)

Answer: Once again, the above review of every aspect of the NCDL 40.7 clearly shows the reliance on factors for OIVIT which are brought on by the unnatural way of ever increasing baseline of free insulin, and which are not the components of the Artificial Pancreas Treatment®. **We do not know how more clearly, conclusively or completely this factual reliance on RQ can be demonstrated**. Over and over these same criteria are stated. Over and over they do not apply to the Artificial Pancreas Treatment®. We do not wish to be redundant but this analysis is forced to respond again and again in the same manner… we show non-applicability of 40.7 in every single aspect of the Artificial Pancreas Treatment®, from the backwards approach, to the unnecessary and misguided testing.

14. Conclusion as to NCDL: The writer of the NCDL did not inquire of Bionica, the device manufacturer, Trina Health, nor did anyone seek to learn the Artificial Pancreas Treatment® protocols and safety or efficacy records. The NCDL writer did not seek to learn the differences between the Harvard protocol of PIVIT, and those used with the Bionica ambulatory IV insulin infusion device. The NCDL obviously, by its terms, does not apply to the Artificial Pancreas Treatment®.

Also the NCDL reviewer did not review the Bionica Ambulatory IV Insulin Device Label which provides specifications for the equipment. This would have alerted the writer to the fact that what they were concerned with as to PIVIT does not apply to the Artificial Pancreas Treatment® and the writer could be comfortable with the Bionica Micrdose and its exemplary safety record. Bionica is the only cleared device for IV insulin infusion which uniquely restores normal metabolism (does not use RQ) and does not have adverse reactions.

There is absolutely no showing of any difference in efficiency between in-patient (hospital) treatment and outpatient (clinic) treatment. They are both the same, and the safety is unquestioned. (The Treatment with the Bionica infusion device has 200,000 outpatient treatments without an adverse reaction, which are followed by the FDA). The point made is that if there is a safety issue, that is covered by the FDA on all class II infusion devices. There is no safety issue, leaving no logic to the NCDL or its basis.

15. Any Lack of Evidence to Support Microburst Insulin is Now Superseded by Subsequent Publications. Since the writing of NCDL 40.7 there have been significant improvements in understanding normal microburst insulin and thus the Artificial Pancreas Treatment®:

a. There have been 15 publications and consistent clinical outcomes from the Artificial Pancreas Treatment® (See attached)
b. There are three additional studies of 300, 400 and 1,500 patients, no exclusions, showing excellent outcomes.
c. There have been pivotal breakthroughs in understanding the importance of burst insulin and the mechanisms of action.
d. There continues to be no contradictory evidence that replicating normal burst insulin in miniscule IV bursts does not achieve normal levels of carbohydrate metabolism, which is the core deficiency of both T1DM and T2DM.

Even though the 2009 NCDL does not apply as set forth above, we also respond with the fact, as opined by physicians and endocrinologists, that what is contained in the NCDL is not to be used in opposition to the Artificial Pancreas Treatment®. The skepticism of some of the assertions in the NCDL has now been overcome. Even as to the much less beneficial Harvard Protocol, OIVIT, with its backwards approach, still had some beneficial effect.

As we now know and demonstrate with the attached patient reviews, Artificial Pancreas Treatment® patients experience outcomes which address the most costly and difficult to treat patient population - diabetic patients over the age of 62 with multiple complications from diabetes.

Also, when the writers claimed that there was insufficient evidence, they failed to take notice of the over 50 Administrative Law Judge decisions (all of them fully favorable) applied to the Bionica Microdose, *not OIVIT* (the Bionica device cannot deliver PIVIT or the ever

increasing baseline). The ALJ decisions were ONLY on the Bionica Microdose Artificial Pancreas Treatment® as it is now known, not the Harvard Protocol OIVIT. The treating physicians in each of these was Dr. Eugine Grecu, not Dr. Aoki who was a full time professor at the University of California and who testified that the outcomes were as ruled by the ALJ. In fact, every impartial ALJ has unanimously found medical necessity due to patient benefit, and that the Bionica Inc. protocols was not investigational or experimental. No ALJ has determined the Bionica Artificial Pancreas Treatment® is not Medically Necessary. More importantly, it is clear that prior ALJ decisions were not using PIVIT and the Harvard Protocol as it was physically impossible for them to do so with the Bionica. The same is true of the submitted studies. However, the same is NOT true as to the Dr. Aoki and Dr. Nachlas deemed Studies posted on ClinicalTrials.Gov. In other words, by definition, the ALJ finders of fact were not reviewing any "experimental or investigational" Harvard Protocol of ever-increasing baselines, and were finding good reason for the treatment. To suggest otherwise would require questioning the integrity of the many ALJ's.

Undisputed facts as to Artificial Pancreas Treatment®

a. There are no studies showing that the Artificial Pancreas Treatment® does not seek or achieve normal,
b. There are no studies showing that the Artificial Pancreas Treatment® does not work. (One trial with the Harvard Protocol was using OIVIT which does not apply here).
c. Conversely, there are a multitude of studies and outcomes with the Bionica system which demonstrate the need for burst insulin to achieve normal metabolism and help patients.
d. There are 15 new publications since 2009 on the Artificial Pancreas Treatment® and its rationale.
e. There is a logical preference for any treatment which restores normal function, particularly when that normal function is the basis for all life.

It is well settled that diabetes is a disease of improper metabolism, not improper blood glucose, as that is only one of many symptoms. These multi-center studies also demonstrate that by addressing this core problem of diabetes, improper metabolism, the Artificial Pancreas Treatment® effectively addresses the "poor outcomes" as shown by Clement and colleagues (supra).

16. Double Blinding is Not Feasible. The writer and some others have suggested conducting double blinded clinical trials. However, after consultation with multiple endocrinologists and diabetes experts, it was uniformly determined that it is not possible to design a study where a diabetic patient sits for 4 hours, does not attend to their glucose or meal needs and still remains blinded. It would be also be improper to take over the customary control of glucose and eating, without the patient knowing it. As to non-treated controls, they too would automatically know, and the provider would have to be ready to respond to any hypoglycemia or hyperglycemia (not to mention DKA or other conditions). Since the patient would know, and the provider would have to know, there is no way to design a double blinded study. This avoids the question of whether a helpful treatment can

be withheld in order to conduct a study. Withholding treatment obviously injures the health of many if not most of the patients.

17. Standard Outcomes are Well Documented allowing Historical Controls. Fortunately, diabetes is so well studied that the outcomes and historical progressions are all well documented. Historical progressions are thus proper controls for studies thereby avoiding the need for blind. For example, reversing significant painful neuropathy requires no controls because other treatment do not accomplish the Artificial Pancreas Treatment® outcome. Because double or single blinding is not functionally possible, the next best studies are "all comers" accepting all diabetic patients without any exclusions for any reason. This avoids "cherry picking" and other forms of study abuses. Cross over studies, such as the study on hypertension are only possible where there are no patient risks or ethical issues for those who draw non-treatment.

18. Conclusion as to rationale:

a. Microburst insulin is the normal delivery of insulin, and is missing in both T1DM and T2DM.
b. There is a logical presumption that normal is better. This applies because there is no known rationale for finding fault with "normal" insulin microburst delivery.
c. The Artificial Pancreas Treatment® addresses the core problem of diabetes, rather than just trying to maintain blood glucose control. Tight blood glucose control still leaves a sizable population of people who succumb to the secondary complications.
d. No treating physician using the Artificial Pancreas Treatment® has found that it did not improve patient outcomes.
e. Finally, as of 2012 and 2015 (see publications) it is now conclusively known why normal microburst insulin (like the Artificial Pancreas Treatment®) is so beneficial…it avoids improper lipid metabolism which leads to metabolic inflammatory processes that interfere with healing. (Cytokines including IL-2 IL-6 and TNFα.)
f. No theory has yet been articulated by anyone as to why the treatment should not work.

19. Additional Information Regarding the Artificial Pancreas Treatment®. The Artificial Pancreas Treatment® is a uniquely effective treatment using the US Food and Drug Administration (FDA) cleared Bionica ambulatory (including home) IV microburst insulin infusion device. It has been proven to restore health for many of the most severely impacted people with diabetes. Intravenous insulin has been used in hospital settings, but is now more properly and more economically administered in outpatient clinics, with much better outcomes, with historically demonstrated safety.

Unlike most diabetes treatments, the Artificial Pancreas Treatment® addresses the core problem of diabetes, abnormal carbohydrate metabolism, which then reduces the inflammatory cytokines, and thereby helps to stop and reverse diabetic complications.

This treatment provides a new tool to address exploding diabetes medical costs, by stopping the progression of the disease and avoiding expensive hospital costs. This treatment specifically restores carbohydrate metabolism, and should be distinguished from the NCD. With the Trina Treatment many of the costs of diabetes can be avoided.

20. Ambiguity and Inconsistent Reimbursement Application. Because the above definition of OIVIT does not apply to the Artificial Pancreas Treatment®, this treatment is currently facing ambiguity when some CMS contractors evaluate a National Coverage Determination for Outpatient Intravenous Insulin Treatment (40.7) ("NCD"). The NCD based non-coverage by Medicare of Outpatient Intravenous Insulin Treatment ("OIVIT") aka the Harvard Protocol using RQ, is based upon the premise that all outpatient IV-related treatments had not, as of that time, shown improved health outcomes for Medicare beneficiaries. However, that was not, and still is not true. The Artificial Pancreas Treatment® does not fall within the definition of 40.7. and has been providing very helpful outcomes. (See distinction supra, independent assessments, and treating physicians.

21. A Simple Answer to a Complex Issue is Often Hard to Accept. High blood sugar is just one symptom of diabetes and the diabetic pancreas does not perform its functions correctly. This malfunction is central to the pathophysiology of diabetes. To date, conventional approaches focus on chemical compounds seeking reducing high blood sugar as their goal. However, the best and simple answer to this complex issue is just to mimic a normal pancreas! The success of the Artificial Pancreas Treatment® rests on the simple fact that it "mimics" normal pancreatic stimulation of the liver, as if the pancreas were non-diabetic. When this is done, the core problem of diabetes "Improper Carbohydrate Metabolism" is effectively addressed unlike any other known therapies. Pathways are studies by chemical engineering physicians and scientists who do not have that route of treatment available to them, and they do as best they can. But their complex answers have never met with the type of success routinely found with the Artificial Pancreas Treatment®.

22. Mechanisms of Action when Mimicking Normal Insulin Secretion.

All cells in the body (excluding hemoglobin and other blood products which have no mitochondria) need proper enzymatic pathways to achieve carbohydrate metabolism. It is not controverted that the signal to the liver for the production of these enzymes is one role of pancreatic insulin (the first-in-time role).

a. With Trina Treatment, the entire body of each patient achieves more energy in the form of adenosine triphosphate, (ATP) because these enzymes are available and;
b. They avoid metabolic stress responses such as metabolic inflammation and excessive cytokines, and;
c. When patients are more normal metabolically, that equates to having more normal "life" as we measure it. The most obvious outcome is avoiding emergency rooms and hospitalization as seen with the Artificial Pancreas Treatment®.

23. In-Patient Treatment is No Longer Needed. The NCDL specifically excluded hospital (in-patient) treatment from the determination letter because IV infusion in the hospital is prevalent. **With newly published data is now clear that APT is the best and safest hospital treatment for diabetic ketoacidosis** due to the avoidance of downward pressure on potassium when microburst insulin in delivered by the Artificial Pancreas Treatment®. However, this does not apply to the Harvard Protocol as it has ever-increasing baselines of insulin, often from a bag. One of the more common reasons for IV insulin administration in hospitals is diabetic ketoacidosis (DKA). It is now demonstrated by many clinic treatments that the the Artificial Pancreas Treatment® effectively avoids DKA as given in outpatient clinics, thereby reducing the cost of treatment. As shown by FDA reporting the Trina APT Bionica Microdose system has a flawless safety record both inside and outside the hospital environment. The Bionica pump has been used in both hospital and clinic settings for over 20 years with no adverse reactions.

24. Address the Core Problem, and Health Restoration is Body-wide. Clinicians have asked "Why is APT so broadly effective?" The answer is that no other treatment or drug mimics the pancreas, and in fact, no other drug even tries to mimic the pancreas. The fundamental problem of diabetes from which all the complications originate is defective carbohydrate metabolism. The microburst signal by insulin that the pancreas is supposed to deliver is missing. It was not until 2002 that it was first reported in humans that *all insulin is normally secreted by the pancreas in micro "bursts" of 660% of baseline," which cause oscillations throughout the body.*

25. The Treatment: The Artificial Pancreas Treatment® has been refined to the point of standardization in both hospital and outpatient clinics. A patient no longer must go into a hospital, he or she can be treated in an outpatient clinic and sit in a chair. A peripheral IV allows the Artificial Pancreas Treatment® to provide the two signals (insulin and dextrose) that a non-diabetic pancreas and gut gives to the liver and other tissues (hence the term "Artificial Pancreas Treatment®). Under the observation of a physician or nurse practitioner, patients are treated until they restore their ability to normalize carbohydrate metabolism and obtain the needed outcomes of resolving secondary complications. After that, no further treatment needed.

26. Patient Outcomes. Patient outcomes show almost immediate improvement in their diabetes complications, including customary reversals of neuropathy, kidney, eye, heart and nerve disorders, as well as accelerated wound healing which would otherwise cause amputations. Hospitalization for these diabetes related conditions are eliminated in over 95% of the cases, with substantial costs savings.

27. Logic of Restoring Normal Functionality Through Natural Means. The effectiveness of the Artificial Pancreas Treatment® speaks to the fact of how mimicking a normal pancreas sets in motion many missing mechanisms of action for normalization of metabolism. When normal is delivered, the outcomes are expected and logical:

a. Since the core problem of diabetes occurs in each cell, addressing the basic cellular abnormality in each cell was, and is, the most logical approach.
b. By addressing the core problem of metabolism, all the resulting complications should improve, as they do. This answers the question as to why just one therapy is effective for so many different diabetes complications. This includes neuropathy, kidney disease, cardiovascular disease, retinopathy, and wound healing, just to mention the obvious.
c. Diabetes is actually a form of starvation where the most readily available nutrition, carbohydrates, do not metabolize normally causing the body to revert to lipid, protein and free fatty acid use. With conventional treatment the average diabetic cell has only 70% of normal adenosine triphosphate (energy). Restoring carbohydrates restores that missing energy.
d. By restoring the most effective form of energy from fuel, the body is no longer as metabolically impaired, and the repair sequence encoded into DNA launches the proper response. Repair of diabetic cells are normally blunted by less energy. Restoring that energy is a necessary aspect of healing. Reversal of complications are thus logical and anatomically favored at the cellular level.
e. The most recent studies show the importance of the missing "microburst" signal of a normal pancreas. It is body-wide.
f. With over 200,000 treatments and no adverse reactions, the Artificial Pancreas Treatment® is a safe and necessary treatment for thousands of patients who are the costly to our medical systems. This is because even the most impaired patients are significantly helped by restoration of their metabolic integrity at the cellular level.

28. A Strong Presumption of Microburst Insulin Effectiveness is Due. Reviewing medical treatments should not be conducted in a vacuum. We should start by understanding the physiological goals of the therapy. The goal of the Artificial Pancreas Treatment® is to *restore good metabolic health.* This fundamental goal is thus to restore "normal" by using a physiologically "normal" way.

It is logical that any therapy which restores normal functionality by using a normal pathway, is inherently more safe and should be presumed to be effective (a presumption of benefit from returning normal processes).

"Never does nature say one thing and wisdom another." Decimus Iunius Iuvenalis aka Juvenal 55 AD (quoted thousands of times).

The corollary for medicine is: "The approach of Medicine should not knowingly deviate from normal physiology unless required."

We request that the analysis of Artificial Pancreas Treatment® be made with this presumption. To disagree, one must have evidence that a biologically proven outcome is somehow not desirable. And, as expected, there is no known evidence that the Artificial

Pancreas Treatment® is not beneficial since it restores normal carbohydrate metabolism.

29. Illogical Thinking. What scientist would ever criticize normal physiology? What scientist would urge taking normal, and replacing it with abnormal? Medicine by its nature should only treat abnormal, always with the same goal, to restore normal. It is supercilious and illogical for anyone to criticize normal without some well proven basis, and as to Trina there is no basis to claim that abnormal delivery of insulin works better than normal. In fact, as proven with various clinical publications, the DCCT, UKPDS, Ohkubo studies all show:

> "while not controlling glucose worsens complications, tight control does not prevent 25% to 40% of diabetic patients from developing overt secondary complications within 10 years." (both Type 1 and Type 2 DM with more rapid complications as to Type 1).

30. The Independent Expert Assessment is Compelling. In order to review the facts, and show how the Artificial Pancreas Treatment® is different from the Harvard OIVIT protocol, Robert C. Cooper, MD, Endocrinologist (CV attached) reviewed the Artificial Pancreas Treatment® and determined that it is not OIVIT and is safe and effective, meeting the definition of medical necessity.

A review of that opinion is telling as Dr. Cooper is, unlike any of the NCDL authors, a board certified practicing Endocrinologist of note.

Also attached is a typical letter (John Elliott, MD) who likewise is a well-known physician with personal knowledge of the benefits and safety of the Artificial Pancreas Treatment®. Dr. Elliott likewise gave the same opinion.

Also attached is the list of supporting physicians who share Dr. Cooper and Dr. Elliott's opinion. In contrast, with all the written documents of the NCDL, there have been no physicians who opine that burst insulin does not and would not be effective as seen in the attached outcomes. This is a case of written claims, without anyone willing to back up the assertions or withstand cross-examination. As such, the refusal to allow payment is a denial of a constitutionally protected right of the practice of a medical trade. But those rights pale in comparison to the loss occasioned if any of the patients who are part of the presented outcomes were to be denied beneficiary status.

The Artificial Pancreas Treatment® is a treatment for those who have failed on conventional therapy, and it is those who respond in a more dramatic and discernable way. Thus, the loss of treatment is all the more life threatening.

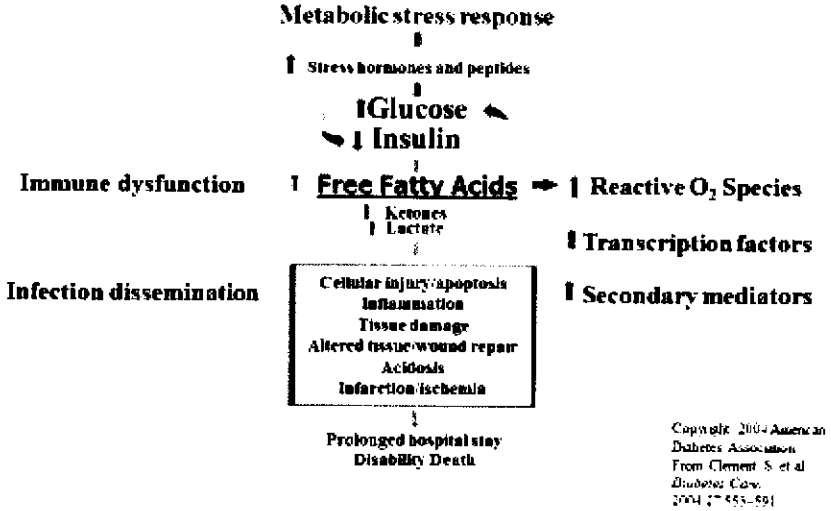
31. Consistent Independent Publications. Provided herewith an exhaustive review of every single publication regarding the "normal" way that insulin is secreted in microbursts and stimulates the liver. Microburst insulin is now proven to be normal.

Normal insulin is secreted in microbursts at approximately 6 minute intervals. To this point there are now over 25 independent studies and publications by others which show that normal secretion is exactly like that provided by the Artificial Pancreas Treatment® microbursts that cause oscillations. (Refer to the Bionica "Microdose" pump). There are absolutely no papers in opposite. Rarely in Medicine is any fact so unambiguously certain. (see Exhibit, Lists of Publications infra.) Our review of medical literature is exhaustive on this issue.

The loss of this signal directly causes a loss of carbohydrate metabolism. Also unassailable is the fact that the restoration of this signal restores proper carbohydrate metabolism.

32. What Causes "Poor Outcomes" is Well Published and Accepted. In order to argue against normal, a scientist would have to further ignore a fundamental compilation of studies showing the direct link between improper carbohydrate metabolism (aka diabetes) and the "poor outcomes" of hospital stays, disability and death as published in Diabetes by Clemens and Colleagues:

Link Between Improper Metabolism and "Poor Outcomes"

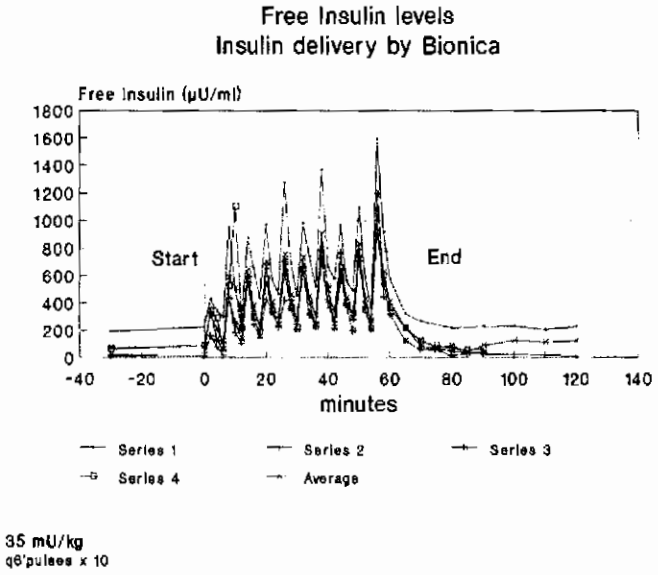


33. Subcutaneous Insulin is Never Burst-like. Subcutaneous delivery, whether with a shot or insulin pump cannot cause the microbursts which are normal. Subcutaneous insulin must be taken up by tissues over a matter of many minutes to hours. And subcutaneous insulin has never been shown to restore metabolism, so it has failed to stop the above "poor outcomes" and progression of diabetes and diabetes complications. While not controlling glucose is harmful, even the most tight control of glucose still does not stop complications

for a significant population. This is totally in contrast to the Artificial Pancreas Treatment® where practitioners are able to achieve proper carbohydrate metabolism.

34. Avoiding Unintended Consequences and Outcomes. Further understanding of the Artificial Pancreas Treatment® is found in the fact that the treatment is not a novel drug, being used to achieve a chemical response which might have other unintended outcomes. When introducing a novel drug, scientists must guard against unintended outcomes (adverse reactions) to make sure that a new drug is safe. The complexity of inducing a man-made chemical into a body necessarily causes uncertainty for many years.

The Artificial Pancreas Treatment® uses no man-made chemicals and has now performed this therapy inside and outside of a hospital with *a perfect safety record* as recorded by the FDA website. There is not one single adverse reaction reported in any of the clinical trials, nor at any clinic. The issue of safety as to this clinical delivery of a formerly hospital treatment is fully proven by the FDA. (see Exhibit "Affidavit of No Adverse Reactions")



This publication (provided) shows that the Bionica Microdose insulin pump achieves both the microburst caused oscillations and an amplitude of normal insulin secretion without an ever increasing base line of insulin. Note also that this is totally unlike the Harvard Protocol - OIVIT where there is an ever-increasing baseline of free insulin is required and is adjusted by RQ. This lack of increasing baseline in the Artificial Pancreas Treatment® is conclusive proof of the difference.

It is easily seen in this publication that the Bionica device does not deliver the Harvard OIVIT protocol, it delivers an absolutely normal delivery of small amounts of insulin. This publication correctly mimics normal, the presumptive goal of all medicine. And, this publication also pre-dates the Butler publication in humans that insulin is secreted in micro

bursts every 4-6 minutes with 660% of baseline. The Artificial Pancreas Treatment® has been doing what is normal, even before normal had even been fully realized.

The publications which are in support of the effectiveness of the Trina Treatment can be downloaded in PDF format upon request.

Independent Publications in PDF form for ease of review are attached. Also attached are the Trina Health Bionica publications.

SUMMARY:

The Medicare Appeals Council decision on the "Harvard Protocol" being an experimental trial on PIVIT demonstrated and ruled that it is the Harvard Protocol with its ever-increasing baseline and critical use of the RQ which was reviewed in the NCDL. It was NOT the Artificial Pancreas Treatment® which has no such insulin delivery, had an entirely different and more normal goal and mechanism to restore carbohydrate metabolism, and does not use RQ.

There is no way to ignore the prior proceedings of CMS;
There is no way to ignore the formal patent filings;
There is no way to ignore or even dispute the legal case filings that find that the Artificial Pancreas Treatment® and the Harvard Protocol (OIVIT) are totally different and distinct.

Searching for similar cases, there apparently has never been a case where so many independent clinical trials show that the subject treatment not only works, but also mimics normal physiology.

a. In this case the non-OIVIT Artificial Pancreas Treatment® restores normalized carbohydrate processing to ill people, in a normal physiological way, and thus allows the patient's body to heal which by definition is medically necessary.
b. In this case there is not one treating physician who has ever said that the Bionica Artificial Pancreas Treatment® is not effective or that it is PIVIT - OIVIT.
c. In this case every physician who has been involved is witness to the remedial aspects of normalizing carbohydrate metabolism.
d. In the entire time that insulin has been delivered, since 1922 when Banting and Best injected a 14-year-old boy, the modality of insulin delivery has been abnormal (non-burst, under the skin) as compared to the way a normal pancreas secretes insulin. Only the Artificial Pancreas Treatment® delivers insulin in the way that a normal pancreas secretes.
e. New clinical trials and new studies all show why mimicking normal is so powerful in restoring health.

For these reasons, and the lack of any credible argument against the Artificial Pancreas Treatment®, we request that the NCDL be deemed to not apply. And, since the NCDL is the

basis for denial of claim, the claims be deemed medically proper and necessary as shown by the treating physicians and the independent Endocrinologist. This is the only factually correct and legally determined logical conclusion.

Very truly yours,

G. Ford Gilbert, PhD, JD

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www.trinahealth.com • www.diabetes.net

TiNA HEALTH

August 16, 2017

(Electronic Delivery)

Re: Follow Up re: Non-applicability of OIVIT to Microburst Insulin
(Artificial Pancreas Treatment)

Dear Colleagues:

On behalf of the many physicians who are currently treating using the Microburst Insulin Infusion of the Artificial Pancreas Treatment, we request that you eliminate confusion which exists in reimbursement. Many CMS payors are, and have been continuously paying for the Artificial Pancreas Treatment ("APT") a.k.a. Microburst Insulin Infusion for over 5 years. A few payors have now asserted that it is Outpatient Intravenous Insulin Treatment ("OIVIT") and disputes are expanding.

In our last meeting, we reported that there is a misconception that Artificial Pancreas Treatment (APT) is synonymous with, and therefore should be billed as, G9147: OIVIT. This incorrect assumption regarding billing should be refuted by CMS as there has already been a Medicare Appeals Council formal finding showing the factual difference between OIVIT and Artificial Pancreas Treatment.

During that meeting, we also reported ongoing studies and we were requested to provide 3 items:

1. *A three-page letter setting forth the request (which this letter constitutes).*
2. *The publication of the ongoing studies (Publication July 14, 2017 attached).*
3. *Patient Outcomes (Patient Outcomes Matrix, attached).*

Our Request: Our request is simple, that your offices provide a letter to us recognizing that APT is not the same as OIVIT. This would be consistent with Medicare Appeals Council.

By coincidence, the week of our meeting, an exhaustive study published by As to further information, on the day after our meeting, we learned that the Mayo Clinic reported an exhaustive study of publications entitled *Glycemic Control for Patients With Type 2 Diabetes Mellitus, Our Evolving Faith in the Face of Evidence*. Dr. Victor Montori stated;

> "Over 90 per cent of experts were saying that controlling blood sugars tightly was associated with a reduction in your risk of going blind or of needing dialysis or having to undergo an amputation," Montori said. "But when we looked at the evidence for that, we could not see any signal that would suggest that is true, despite the question being asked at least since the 1970s." circoutcomes.ahajournals.org/2016/08/23/. (*attached*)

Now, the results of your requested further studies and the ongoing patient outcomes confirm that APT does what OIVIT and blood glucose control cannot, effectively stop or reverse diabetes complications and keep people out of the Hospitals and away from the Emergency Departments. (*Physician Statements - sent under separate cover*). Conversely, there is not one physician who has concluded that APT does not achieve significant beneficial outcomes even in the most impaired and costly patients.

Also attached is the requested Patient Outcomes and matrix of their benefit. (*Patient Outcomes - attached*)

We continue to expand quickly and have many more physicians using this therapy on their most ill patients with unprecedented success. But the confusion exists, and now in places served by one intermediary, patients are now being denied treatment. One hospital in this region is even being denied notwithstanding the fact that OIVIT is specifically "Outpatient." The health of these patients is more than just at risk when the benefits of APT are denied, these people are now being re-hospitalized and losing the gains they had made.

We do not seek to overturn the findings of OIVIT. In fact, we agree that OIVIT "The Harvard Protocol" (*Medicare Appeals Council Case No. 1-392893626*) was not the best treatment. OIVIT, while beneficial to some, was not uniformly beneficial to every diabetic, did not always improve carbohydrate metabolism (as does APT) and OIVIT had a basic flaw which was exposed by the lack of consistent outcomes. Most importantly the Harvard Protocol with the Aoki patented treatment never mimicked a non-diabetic pancreas to restore carbohydrate metabolism as does APT (*Letter to CMS Sept 1, 2016 - attached*). Simply, the Harvard protocol was "backwards" and used "ever increasing baselines of insulin" because it did not look to the physiology of the pancreas for instructions on how normal carbohydrate metabolism is achieved.

At first glance, the two therapies may sound alike, as both OIVIT and Artificial Pancreas Treatment Microburst Insulin Infusion inject insulin intravenously. However, the similarities end there. APT utilizes the Bionica Microdose Infusion Pump to provide Microdoses (microbursts) of insulin to mimic a normal pancreas. APT does not use increasing baselines of insulin, and is not principally designed to normalize the hepatic metabolism of glucose (OIVIT). Rather, APT specifically achieves restoration of body-wide carbohydrate metabolism, and provides missing adenosine triphosphate which is the hallmark of diabetes. "How do we know that is correct?" to which we replied we have an ongoing study to show that is correct. Now that study is finished with even more impressive results than first thought.

Any confusion of the two treatments is eliminated by a reading the attached *September 1, 2016 To Whom It May Concern* letter. However, a short graph can focus on important differences:

The following very basic chart indicates just a few of the differences between APT and OIVIT. It does not point out the basic structural "backwards" aspects of the Harvard Protocol:

Artificial Pancreas Treatment (APT)	Outpatient Intravenous Insulin Treatment (OIVIT)
Delivery	
• Microburst every 4-6 min; mimics normal pancreas • Initial treatments 12 weeks of weekly treatment followed by MD assessment of reversal. • Treatment given until metabolic and complication stabilization or improvement	• Pulsatile or continuous ever increasing doses of insulin (unlike normal insulin secretion). • Scheduled recurring intermittent periods without end. • Continues without durational limits.
Guiding Measurements	
• Treatment is not guided by RQ	• RQ is defining characteristic of OIVIT
Dextrose/Glucose	
• Dextrose given in fixed amount which approximates a "meal" for each hour's treatment. Changes made based on patients' weight. • Insulin given to match "meal" amount.	• Glucose given Ad Lib • Not adjusted based on weight • Glucose given to match Ad Lib insulin • Insulin not given to match a "meal" amount, which is basically physiologically backwards.
Urea Nitrogen	
• Not used	• Urine Urea Nitrogen Periodically used to determine glucose dose
Potassium	
• NO Potassium Concentration used	• Potassium Concentration used
Outcomes	
• Uniform and reproducible	• Patient outcomes are intermittent and not uniform

There is overwhelming evidence that health is improved as a result of APT, and conversely NO evidence that it is not. APT should not be confused with OIVIT.

Promised Studies:

On July 14, 2017, the Journal of Diabetes, Metabolic Disorders & Control published "Microbust Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization." This multi-center, multiple author peer reviewed publication explains how the treatment differs from other methods of therapeutic insulin administration because the Bionica Microdose Insulin Infusion (MII) Pump provides pulsatile administration of insulin in a manner that closely replicates natural pancreatic

insulin secretion from beta cells in the body. No other current therapeutic insulin treatment regimens are uniformly effective. (attached *Publication*)

The Journal report of multiple centers and numerous authors focuses on three major studies:

Carbohydrate metabolism study

An examination of the effects of APT on metabolic rate measures as determined by indirect calorimetry concluded that oxygen consumption and energy expenditure significantly increased over the course of three treatment periods within each complete therapy session. This resulted in promoting a greater carbohydrate oxidation rate and an increased respiratory exchange ratio, while reducing lipolysis and lipid oxidation.

Painful diabetic neuropathy (PDN) study

Utilization of the Microburst insulin infusion (APT) "showed a complete elimination or significant reduction of pain in 93% of PDN patients after 3 months of treatment – with complete resolution of pain in 47% of PDN patients."

Hospital and emergency room utilizations study

This two-year study was conducted at 14 centers, nationwide, and involved 1,524 Type 1 and Type 2 diabetic patients with two or more secondary complications of diabetes (no exclusions), including neuropathy, cardiomyopathy, retinopathy, hypertension, fibromyalgia, and hyperlipidemia, and histories of multiple hospitalizations and emergency department visits. The study concluded:

APT reduced hospitalizations to 1.65/1,000/year-as opposed to 46.7 patients per 1,000 over a one year period (National Hospital Discharge Survey (NHDS));

APT reduced emergency department visits to 2.3/1,000/year versus 58.4 (U.S. Agency for Healthcare Statistics (USAHS))

In other words, hospitalizations for diabetic patients are reduced for those undergoing APT by 95.63% and emergency department visits are 94.66% fewer for those patients.

The article points out: "This represents a significant reduction in hospital admissions and emergency department visits compared to normal rates-presumably generating substantial savings for the health care system."

The article and the studies it highlights show that APT is having uniformly positive significant health benefits for patients suffering from the most devastating co-morbidities of diabetes (list of co-morbidities in article). Their personal histories show that without APT, they now face a daily and genuine fear that they are returning to unhealthy states and face hospitalization, and, ultimately, death. These patients who have been treated are now painfully aware of the terrifying reality: that they may not survive to once again undergo the treatment that restored their health and provided a truly full and healthy life.

We request a personal meeting as previously suggested, and are available at your convenience.

We suggest any date in September, or as your calendar allows.

Sincerely,

G. Ford Gilbert, JD PhD

BlueCross BlueShield of Montana

October 6, 2017

Ms. Erin MacLean
Freeman & MacLean, P.C.
P.O. Box 884
Helena, MT 59624

RE: Trina Health of Montana
BCBSMT Response Dated August 28, 2017
Artificial Pancreas Treatment for BCBSMT Clients

Dear Ms. MacLean:

This will acknowledge receipt of your September 13, 2017, letter in the above matter. Thank you for granting me a one week extension to respond to your letter. As I understand your September 13 letter, you requested that we provide you with an objective analysis as to why we believe Artificial Pancreas Treatment (APT) and Chronic Intermittent Intravenous Insulin Therapy (CIIIT) are the same or substantially the same treatment, and that we provide coverage for APT. I believe we addressed both matters in our August 28, 2017, response, but will re-address those issues here. We have conducted a reasonable review and analysis, and decline to cover APT for the reasons described below and in my prior correspondence.

I.

To conduct an objective analysis of APT on a medical basis requires us to review materials other that just what Trina Health provided. Therefore, we conducted an extensive search for any such other literature which reviewed, compared or contrasted APT and CIIIT (or any of the other names by which the procedure or service is known). We were unable to locate any other such materials. We do not believe it possible to conduct the objective analysis of APT on a medical basis that you demanded by solely relying on the self-serving materials you provided with your last letter.

We remain unconvinced that APT is a distinctly different service or procedure than CIIIT, based on the way in which Trina Health itself and its affiliates characterize APT. In the 29-page enclosure you sent in conjunction with your September 13, 2017, letter, Trina Health attempts to distance itself from OIVIT (which we both agree is a synonym for CIIIT, PIVIT, et al.) by engaging in a lengthy discussion as to how APT does not use a respiratory quotient (RQ) as a component of its treatment protocol, stating variously that "*We also agree that there is no therapeutic need to use the RQ*"; "*The Artificial Pancreas Treatment is absolutely <u>not</u> guided by the results of the*

EXHIBIT 10

Respiratory Quotient" [emphasis in the original]; "*The Trina Health Treatment does not use the 'Respiratory Quotient' in the 'integration of insulin by any means.' Nor is Treatment 'guided by the results of measurement of' any of those factors*"; and finally, "*This provides the undeniable conclusion that the RQ does not guide the Trina Artificial Pancreas Treatment*". Explanation of Non-Applicability of OIVIT to Artificial Pancreas Treatment with Medical Necessity Information Not Contained in OIVIT NCDL 40.7, at p. 11 (September 1, 2016).

Materials posted by Trina Health of Arizona and by Trina Health of Alabama, characterize APT as incorporating measurements of carbon dioxide expiration for insulin dosing purposes, thus squarely contradicting the assertions in Trina's September 1, 2016 letter. Trina Health of Arizona states in its FAQs:

> **How do you know the cells are properly metabolizing carbohydrates?**
>
> In the clinic, we use a metabolic measurement system that was originally designed for sports medicine and cardiology departments. This machine (on a wheeled cart fitted with separate tubes for multiple patients) measures the volume of carbon dioxide breathed out (expired) while the patient is at rest and is used to monitor the treatment and provide information for dosing.

[Emphasis added.] http://www.trinahealthaz.com/faqs/ (accessed October 3, 2017). A copy of the FAQs is enclosed with this letter.

Trina Health of Alabama is even more detailed in its characterization of APT declaring the method of APT's therapy in relevant part as:

> Artificial Pancreas Treatment (APT) is a process which promotes the normalization of carbohydrate metabolism in diabetic patients. [The] process is monitored by frequent glucose levels and metabolic measurements. Metabolic measurements are taken by a metabolic cart which determines the ratio of VCO2/VO2. This ratio is specific for the fuel used and any one time by the body. The glucose levels are monitored to keep glucose levels appropriate, and the metabolic measurement determines the need to readjust the infusion.

[Emphasis added.] http://aldiabetescoverage.com/ (accessed October 3, 2017). A copy of the Alabama Diabetes Coverage Petition in which the foregoing language is contained is enclosed with this letter.

In its August 28, 2017, response to you, BCBSMT pointed out numerous instances where Trina Health and its affiliates have ***themselves*** equated or linked APT with CIIIT, et al. To those numerous examples, I would add the following:

Trina Health of Arizona provides a compendium of references to various articles in support of its statement that "*Below are links to articles and cases that provide proof that Artificial Pancreas Treatment works.*" A non-exhaustive search of the articles includes those that specifically discuss the characteristics of PIVIT (item nos. 5 and 15) and CIIIT (item nos. 11 and 17). http://www.trinahealthaz.com/references/ (accessed October 3, 2017). A copy of the reference section of Trina Health's website is enclosed with this letter. Sterile Medical

Technology, which describes itself as a partner of Trina Health, describes the treatment history of APT in relevant part as follows: "*Artificial Pancreas System and Artificial Pancreas Treatment are based on many clinical trials and human treatments, using several names including PIVIT, Metabolic Treatment, CIIIT, etc. They are all part of the evolution of APT.*" http://sterilemedicaltech.com/?page_id=362 (accessed September 21, 2017). A copy of Sterile Health's Introduction to Artificial Pancreas Treatment is enclosed with this letter.

Contrary to your dismissal of those materials, their existence substantively supports our assertion that APT and CIIIT et al. are the same or substantively the same treatment. Trina Health and its affiliates have themselves closely associated them.

II.

Trina Health further demands BCBSMT cover APT until such time as it has "independently evaluated the APT treatment under reasonable objective standards". We have conducted a review and decline to cover APT as you have demanded. Part of the research BCBSMT conducted involved a search of literature validating the treatment outcomes Trina Health claims APT makes possible. We could find no independent validation or other authority, outside of the claims of Trina Health and its affiliates alone, establishing APT to be medically efficacious. Additionally, we conducted a search of various international diabetes authorities[1] but found no reference to intermittent IV insulin therapy or microburst IV insulin therapy, much less any inclusion of APT, as a medically accepted standard for the treatment of diabetes.

Finally, please note that we analyzed the July 2017 article you provided us ('*Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization* Journal of Diabetes, Metabolic Disorders & Control (2017)), in consultation with medical staff. We found the studies referenced to be observational, retrospective studies which are not as rigorous as randomized controlled trials or cohort studies. Observational studies draw inferences as independent variables are not controlled. Since these are not randomized studies, they are subject to bias. In the background portion of the article, pulsed therapy is noted to have mixed results in lowering blood glucose levels compared to both continuous and standard therapy. The "most encouraging study on the

[1] World Health Organization (WHO): Global report on diabetes (2016); **Canada** CDA Clinical Practice Guidelines Expert Committee: Clinical practice guidelines for prevention and management of diabetes in Canada (2013); **United States** ADA: Standards of medical care in diabetes (2017) and Endocrine Society: Clinical practice guideline on diabetes technology – Continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults(2016); **European** European Society of Cardiology (ESC): Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the European Association for the Study of Diabetes (EASD) (2013); **United Kingdom** National Institute for Health and Care Excellence (NICE): Guideline on type 1 diabetes in adults – Diagnosis and management (2015, updated 2016) and Scottish Intercollegiate Guidelines Network (SIGN): National clinical guideline on management of diabetes (2010); **Australia** Australasian Paediatric Endocrine Group (APEG) and ADS: National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults(2011); **Japan** Japanese Diabetes Society (JDS): Evidence-based practice guideline for the treatment for diabetes in Japan (2013).

effects of pulsed therapy" showed statistically significant preservation of renal function but no effect on diabetic retinopathy. The study involved only 65 patients in 7 centers. These results would suggest further studies are needed to validate these results.

The study in regards to diabetic neuropathy demonstrates a reduction in pain after pulsed insulin infusion. However, there were no controls or direct comparisons made to standardized treatment. The studies own conclusion is again more studies "are warranted".

The final study in this article reportedly shows decreased hospital and emergency room utilization when compared to National Hospital Discharge Survey (NHDS) and U.S. Agency for Healthcare Statistics (UAHS). Although homologous groups were used for comparison, it is unclear if these findings were also true across other age groups. There is no accounting for socioeconomic backgrounds, geographic location or types of hospitals. The study included Type I and II diabetics but did not appear to separate the results for each group. Finally, there is no reference to what type of ER visits these cases represented; in other words, were the visits due to diabetic complications or did the visits represent cases in which diabetes is listed as simply a diagnosis.

Accordingly, and based on the foregoing objective standards and review, BCBSMT declines Trina Health's invitation to immediately begin providing coverage for APT.

III.

Finally, I wanted to address your contentions concerning the billing matters discussed in our August 28, 2017, correspondence. Contrary to your assertion, it was not the intention to lead anyone, least of all a provider, into a so-called 'billing trap'. My intention in addressing the billing codes was merely to confirm that even if APT (CIIIT, OIVIT, etc.) was not itself a covered procedure or service, our Medical Policy envisions that providers could nevertheless bill certain subsidiary services or supplies (e.g. 94681, 96365, 96366, etc.) rendered in conjunction with APT, that may themselves otherwise be covered services/supplies, and which your clients were already billing prior to the April 2017 cease and desist letters. If your clients choose not to bill for what may otherwise be covered related services and supplies, that is at their discretion.

BCBSMT has engaged in discussions with you, conducted the review and investigation as you have demanded, and reached its conclusions in good faith. Following its investigation, the opinions expressed by BCBSMT in the April 2017 cease and desist letters and in my subsequent letters with you remain unchanged. Should you have additional concerns, please do not hesitate to contact me.

Very truly yours,

Christopher M. Herriges
Assistant General Counsel

Enclosures (4)

cc: Dr. Monica Berner, Divisional Vice President, Chief Medical Officer
Mary Belcher, Vice President and General Counsel
Therese Anderson, Manager, Special Investigations Dept.

Trina Health of Arizona

Giving Hope to Diabetics

FAQ's

Call 480-306-8195 or Contact Us

Why do they call it "Artificial Pancreas" Treatment®?

During our treatment, the uniquely-designed and programmed pump is mimicking the pancreas of a healthy person when they eat carbohydrates (e.g. sugar) – sending pulses of insulin to the liver. These pulses trigger the liver to produce at least 33 different enzymes which are necessary for the cells in the body to metabolize carbohydrates.

When these cells metabolize carbohydrates, they produce adenosine triphosphate (ATP) which is the chemical energy a cell requires to perform its function in the body.

For most people with diabetes (both type 1 and type 2), their liver is not properly receiving the oscillations of insulin from the pancreas and

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therefore, is not producing and secreting the enzymes required for proper metabolism. The core problem of diabetes is improper cellular metabolism – high blood sugar is a symptom of this core problem.

Using a standard insulin pump that many people with diabetes use today, even if it is programmed to deliver insulin in pulses, will not achieve the results described above. This is because, with these pumps, the insulin is delivered under the skin, and by the time the insulin is received by the liver, any pulse is sufficiently blunted. The required insulin concentration and oscillation threshold is not achieved. Many of the required metabolic enzymes are therefore not produced.

With the APT therapy, the pulses are delivered intravenously and within 4 seconds, the liver will experience the appropriate oscillations. Thus, the liver will be activated to produce and excrete the required metabolic enzymes. The cells throughout the body will be fed and begin to function properly.

How do you know the cells are properly metabolizing carbohydrates?

In the clinic, we use a metabolic measurement system that was originally designed for sports medicine and cardiology departments. This machine (on a wheeled cart fitted with separate tubes for multiple patients) measures the volume of carbon dioxide breathed out (expired) while the patient is at rest and is used to monitor the treatment and provide information for dosing.

PET EXHIBIT 10-516

When a person with diabetes is first measured before starting the treatment, their carbon dioxide output is low relative to a healthy person. This is because they are not metabolizing carbohydrates.

When they finish each session of Artificial Pancreas Treatment, the carbon dioxide expiration numbers will be almost three times higher, indicating that they are achieving complete carbohydrate metabolism. The higher the carbon dioxide numbers, the better the cells are metabolizing sugar and the more energy is being created in each cells.

Why is it so important to metabolize carbohydrates?

When the cells are able to metabolize carbohydrates, the mitochondria in the cells are able to create at least ten times more ATP (adenosine triphosphate) than they do when the cells are metabolizing lipids (fat). ATP is the main energy source for the majority of cellular functions. When the cells have more ATP, they are able to begin to perform the functions for which they were designed. Also, when the cells are metabolizing carbohydrates, they do not need the extra oxygen that fat metabolism requires, and this need for extra oxygen is counter-productive.

When the cells are not able to metabolize carbohydrates (even though the glucose is in the blood and tissue right next to the cells), they are often unable to effectively perform their functions. Thus, depending on genetic predisposition and which cells are more susceptible, the associated complications of diabetes result (nerve, kidney, heart, vision, blood pressure, etc.)

How long is an APT Office visit?

Typically, in one clinic visit, the patient receives three one-hour sessions with a break between sessions. At the end of the last session, the patient rests for 10-15 minutes before leaving the clinic to be sure all blood sugar levels are stabilized. Therefore, the total time in the clinic will be approximately 4 hours depending on the patient.

How long do I go between treatments?

When the patient first starts the treatment, we recommend two treatments on two consecutive days in order to more quickly reawaken the liver to produce the enzymes needed for proper metabolism and to be able to maintain better storage of glycogen. Then, the patient will typically return from 1 to 4 times a month based on the body's ability to maintain its carbon dioxide output levels. This is an indication of the liver's ability to "maintain its charge" between sessions.

At a minimum, the patient should continue the therapy until all of the serious complications of diabetes have stopped and, when possible, have reversed. At that point, you may be able to reduce the frequency of your visits or stop for blocks of time until and unless the side-effects return.

Every patient's body responds a little differently and the time before the side-effects return will vary.

Ultimately, we hope that someday there will be a way to prevent diabetes from ever developing. In the meantime, the goal of the APT therapy is to maintain as healthy a body as possible.

How should I expect to feel?

During the Therapy

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During the therapy, you should expect to feel normal with an increased feeling of well-being. In some cases, it may take several sessions for this feeling of well-being. Patients often feel a resurgence of blood flow throughout the body where it has been lacking before. Some patients sleep during the treatment, some remain even more active than normal, it depends upon how ill the patient is before beginning treatments.

After the Therapy Session

Because the body may also be producing its own insulin, some patients may feel hunger. If they do, they should eat a snack and check their blood sugar level.

After On-Going Therapy

Patients report feeling progressively better with each therapy session. Most patients report a very sound night's sleep as APT reestablishes the circadian rhythm of sleep and wake states. They will very often begin to feel their extremities, even if they have not been able to for several years. If a patient has had a vision problem in the past, their eyesight may become more clear and colors more vivid. Their skin color will improve due to proper metabolism and they will even see wounds beginning to heal.

Patients report a general sense of well-being after 3-5 treatments.

Patients will continue to feel better with more energy in all areas of their body. They report having less daily fatigue, will usually regain any lost sexual function, and reduce their diabetes related depression. If they had any wounds, these wounds will all be well on their way to healing or totally healed.

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Do I continue to see my current doctor?

The Artificial Pancreas Treatment does not cure diabetes. APT only stops or retards the complications of diabetes from getting worse and, in most cases, reverses these complications. Individuals receiving the APT treatment should continue to see their current doctor and follow his/her recommendations between therapy sessions. When not at the clinic, the patient should continue to take their medications. If the patient is on insulin, they should continue their doctor's prescribed regimen to control their blood sugar. Our experience is that the amount of medication required, or the amount of insulin administered, will be reduced the longer that the patient is on the APT therapy.

Does insurance cover this treatment?

Most insurance carriers are providing coverage, including Medicare.

Our goal is to help as many patients as possible to improve their health. We have developed several programs to assist patients to financially afford APT therapy including: either using medical credit cards or making cash payments. We are willing to work on a patient-by-patient basis.

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SIGN THE ALABAMA DIABETES COVERAGE PETITION

SIGN THE PETITION

BLUE CROSS BLUE SHIELD OF ALABAMA and ALABAMA MEDICARE:

The Artificial Pancreas Treatment is changing the lives of Diabetic Patients! The people of Alabama need coverage!

BACKGROUND

Diabetes is among the fastest growing diseases in the United States today. According to the Centers for Disease Control an Prevention (CDC), nearly 30 million Americans have diabetes and face its devastating consequences. What's true nationwide is also true in Alabama.

Approximately **579,084 people in Alabama** have been diagnosed with diabetes and an estimated **127,000 have diabetes but don't know it!**

Every year, an estimated **29,000 people in Alabama are diagnosed with diabetes.**

In the midst of this growing epidemic, **Blue Cross Blue Shield of Alabama, the largest health insurance provider in Alabama, and Alabama Medicare have chosen not to cover an important treatment that has proven successful in correcting the core problems of diabetes.**

In a decision that has disrupted life-changing treatment options for thousands of Alabamians, Blue Cross Blue Shield of Alabama issued a denial of coverage in May 2015 for the Artificial Pancreas Treatment offered at Trina Health of Foley and in August 2015 for the treatment at Trina Health of Fairhope. In late March 2016, Alabama Medicare followed suit and issued a denial of coverage for the state as well.

That's why we're circulating this petition asking that **Blue Cross Blue Shield of Alabama and Alabama Medicare approve coverage of the Artificial Pancreas Treatment and help improve lives and ease the burden of Diabetes in the state.**

Sign the petition. Tell Blue Cross Blue Shield of Alabama and Alabama Medicare: Blue Cross Blue Shield companies and Medicare in other states have accepted the Artificial Pancreas Treatment and have included it in their coverage. **In Alabama where the challenge of diabetes is so great, the people deserve nothing less!**

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Important Information

Artificial Pancreas Treatment

Method of Therapy

Testimonials

Artificial Pancreas Treatment (APT) is a process which promotes the normalization of carbohydrate metabolism in diabetic patients. APT affects multiple organs, especially muscle, retina, liver, kidney, and nerve endings. The process involves the administration of insulin pulses similar to those found in the portal circulation of normal humans using the Bionica Microdose infusion device which is FDA labeled for this treatment. The process is monitored by frequent glucose levels and metabolic measurements. Metabolic measurements are taken by a metabolic cart which determines the ratio of VCO2/ VO2. This ratio is specific for the fuel used at any one time by the body. The glucose levels are monitored to keep glucose levels appropriate, and the metabolic measurement determines the need to readjust the infusion. APT is done over 1-hour periods with a ¾ to 1-hour rest period between each session for three courses each day of treatment. Typically, APT is performed on a weekly or bi-weekly basis following the first week of two back-to-back daily sessions.

Trina Health of Arizona

Giving Hope to Diabetics

References

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Below are links to articles and cases that provide the proof that Artificial Pancreas Treatment® works. Please click on the link and read the related article.

Trina Health of Arizona welcomes referrals. If you have a diabetic patient that has complications and they are not responding to treatment, please call us and talk to our Medical Director, Dr. John Elliott, to see how Trina Health could assist you in helping your patient.

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Exciting new publication! Please READ!!

****Microburst Insulin Infusion: Results of Observational Studies – Carbohydrate Metabolism, Painful Diabetic Neuropathy, and Hospital/Emergency Department Utilization****

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Introduction to Artificial Pancreas Treatment® (APT)

Artificial Pancreas Treatment® using the Bionica Artificial Pancreas System® is the only US FDA cleared safe and effective way to stop the progression of diabetes and in most ways reverse the chronic complications of diabetes. It is uniformly effective for both Type 1 and Type 2 diabetic patients. APT has been shown to be effective in even the most impaired patients. It has been steadily developing with confirming published clinical trials (See Publications and reports).

Correcting the Core Problem: Diabetes is not a disease of improper blood sugars, they are just a symptom. Diabetes is "a disease of improper metabolism" according to every medical writing, yet treatments have focused on blood sugar. The Artificial Pancreas Treatment® is the only treatment which addresses this core problem, and does so by mimicking the natural way that a pancreas signals a liver to cause proper metabolism.

Diabetes is technically caused by a lack of carbohydrate processing enzymes made by the liver. This is the result of insufficient stimulation of the liver by the pancreas. Fortunately, when the body metabolizes carbohydrates it stops converting high levels of lipids and free fatty acids, which directly cause all of the complications of

diabetes through improper levels of inflammatory cytokines (IL-6, IL-2, TNFα, NF which exist when a patient cannot process carbohydrates properly (a person with diabetes).

The ***first*** important role of insulin is ***to signal the liver to produce the enzymes that are necessary for proper carbohydrate metabolism.*** These are the pathways necessary to induce the Krebs (citric acid cycle) metabolism. APT uniquely addresses and restores proper enzymes, which is treating the core problem. Mimicking the natural stimulation of a pancreas using a sophisticated two-signal delivery process, APT effectively makes proper metabolism a reality for people who, other than with this treatment, cannot ever achieve anything near to normal metabolism.

With proper carbohydrate metabolism, two things occur. First, normal levels of cellular energy are restored (a diabetic person has approximately 70% of the intra-cellular energy of a non- diabetic person). And secondly, the destructive high lipid metabolism with elevated free fatty acids are reduced. Because lipid metabolism is the "back-up" system of providing nutrients to the cells, it was never meant to be the primary source of energy, as it is with the diseases of diabetes (both type 1 and type 2). The reason both types of diabetes have the same complications and disease outcomes is simple, they both fail to provide proper resting carbohydrate metabolism, and that leads to elevated lipid and free fatty acids, reactive oxidative species, inflammatory responses (especially with the endothelium) ischemia, reproduction errors (transcription), remarkably less intra-cellular energy (ATP) and a host of other inflammatory cytokine related body wide dysfunction.

There are many published clinical trial studies which demonstrate that it is simply a very diverse number of factors from improper metabolism which cause all the complications of diabetes. They include kidney failure, blindness, amputations, heart disease, stroke, neuropathy, progressing wounds, fatigue, sexual dysfunction, diabetes dementia and depression, just to name the more obvious. There are other disease states which have, at their core, improper metabolism, such as Alzheimer's Disease and age dementia, dementia from Parkinson's, fatty liver disease, and autoimmune diseases causing improper metabolism.

The complexity of hormone metabolism has caused many to look at chemically induced changes for an answer, when in fact a resolution of the core problem was always available through replicating proper organ stimulation. Krebs received the Nobel Prize for just understanding a small part of metabolism, and the function of the endocrine system is so monstrously complicated that it has baffled science...but the Artificial Pancreas Treatment® is strikingly obvious, it mimics the pancreas to

provide a bi-signal to the liver using insulin and carbohydrates, and by doing so, achieves what compounds have never been able to accomplish, normal ATP and a reduction of lipid metabolism.

Noticing the difference between normal and diabetic insulin response to a simple glucose load, which causes a monstrous first phase release of insulin, caused Ford Gilbert to design an additive wave using many small bursts, which unexpectedly, and very surprisingly turned out to be the way man was designed. ***This exposed the reality that one need only achieve proper liver stimulation to stop the complications of diabetes, and provide individual cells the energy necessary to perform the function defined by their DNA.***

No other treatment achieves these outcomes, no other technology mimics the normal pancreas signals to the liver, and no other technology is even close to doing so. Certainly chemical actions on an organ which is incapable of reproducing what it was originally doing is better than nothing, but still allows the complications and is grossly inferior to the Artificial Pancreas Treatment®.

The Treatment History: Artificial Pancreas System® and Artificial Pancreas Treatment® are based on many clinical trials and human treatments, using several names including PIVIT, Metabolic Treatment, CIIIT, etc. They are all part of the evolution of APT, and all were developed using the Bionica infusion device, a US FDA, and CE (European) cleared medical infusion device (pump) with special abilities and software. APT achieves normalized carbohydrate processing by providing the two (2) signals needed for the liver to perform its job of producing the enzymes which are deficient in diabetic people and keep their whole bodies from properly metabolizing carbohydrates of all kinds. The patient's improvement in body-wide metabolism is documented by standard metabolism measurement equipment.

Both Types of Diabetes: Since Artificial Pancreas Treatment® using the Artificial Pancreas System® addresses the core problem of diabetes, it is effective for both Type 1 and Type 2 diabetes. It was first used in 1984 with Type 1 patients, where the progression of the disease was significantly slowed or stopped in the most severely ill. In 1992 studies of Type 2 patients began,

and the same effectiveness has been proven for Type 2 diabetes. After an estimated 200,000 treatments, there is no doubt that the therapy works on both Type 1 and Type 2 patients.

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Developed in University Settings: APT was developed and then tested in a number of university and centers of excellence including Harvard (Joselin), University of California Davis, University of Arizona, Scripps, Temple University, and the Mayo Clinic, just to name a few (see publications). APT is main-stream medicine, seeking only to provide the body with proper stimulation, and thus allowing the body to achieve its own repair. All of the clinical trials addressing outcomes have used the generally accepted standard tests for assessing the patient's diabetic conditions.

Safe, Effective and Necessary: Following the necessary years of clinical studies proving the effectiveness of APT, Medicare Administrative Law Judges and other judges have ruled that the treatment is no longer experimental, is not investigational, and is medically necessary for the patients treated. A landmark lawsuit against CalPers achieved the same result, as have cases against Blue Cross. While reimbursement is not uniform, it can be obtained from insurance through the dispute resolution systems. These decisions are provided in a separate document and contradict any claims by insurance that there is something left to be done or that the patients do not get well from APT.

Long Development Cycles has Caused Delay: In chronic diseases, it takes many more years of studies to show that a treatment is effective, and then stays effective instead of losing effect or causing harm. Most drugs take approximately 20 to 30 years from discovery to approval.

Artificial Pancreas Treatment® has been in development for years because of these realities. Seemingly slow progress is actually relatively quick for this type of broad application and outcomes Development time was also increased due to the cost of setting up clinics and paying physicians for research. Finally, the task of making the treatment into a protocol which every practitioner with every co-morbidity could treat in multiple locations was a huge task which is now achieved.

Treatment. Patients treat for 4-5 hours in the clinic once a week for a few weeks, then a most treat once every two to even three weeks. Patients understand the devastating physical and mental impact of diabetes, and 5 hours twice a month in exchange for getting their lives back is a small price to pay. Patients enjoy coming to the clinic because of their new quality of life, new energy, new hope and the stopping of complications, the "Second Bite of the Apple." Many times family members realize and reports all the benefits of treatment as the diabetic person often does not know how their mental acuity has been compromised by not processing carbohydrates. This is because the primary food of the brain, nerves and eyes is carbohydrates.

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During a treatment day, three infusions are given with the patient sitting in a recliner or chair but still able to walk around etc. During the treatments, carbohydrates and intravenous insulin are administered using the Bionica programmed infusion device. The patient stays in the treatment area, and continues to read, watch TV, type, compute, telephone or engage in any other passive activity. Clinics normally have an open area without dividers at the request of patients. Many

patients enjoy coming into the clinic early in the morning, and being finished by shortly after lunch time.

Dramatic Outcomes: APT is not a subtle treatment of marginal improvement. It is effective even for the severely ill. The more ill the patient, the more dramatic the outcomes. This is extremely gratifying for diabetes practitioners who have, in the past, only been able to watch the disease progress.

Objective of APT Treatment: The treatment works by returning patients to a more normal resting metabolism, thereby addressing the core problem of diabetes. Once cells have the ATP (energy) to achieve repair, the DNA of the cells know what to do, and do it. No physician who has worked with APT during the clinical trials has reported any negative outcomes. They uniformly understand the logic of providing the natural stimulation needed to metabolize properly.

Treatment Outcomes: The treatment is independently clinically proven safe and effective for the major complications of diabetes including kidney disease, cardiovascular disease, wound healing, retinopathy, hypertension, neuropathy, and the general maladies of diabetes including lack of wellbeing, energy, sleep, sexual functions and the likes. With deficient metabolism it is not surprising that widespread basic biochemical abnormalities exist. The fundamental body-wide defect is the reduced ability of glucose to be used as a fuel for body tissues, and a corresponding increase in lipid use. Diabetic people fail to metabolize (burn) the carbohydrates (sugars or glucose) and instead metabolize lipids (fats) and free fatty acids at a much higher rate than normal, ("butter burners"). Unlike conventional treatment where the patient is starved of appropriate carbohydrates, patients on the Artificial Pancreas Treatment® metabolize carbohydrates and can eat more normal and healthy foods as their bodies can burn carbohydrates.

When the core problem is addressed, it is reasonable that widespread and diverse outcomes would occur, and they do! All of the long-term studies have shown a significant improvement and ***stopping, retarding and then reversing all major complications of diabetes***. No study has been a failure. Because the therapy works

at a body-wide cellular level restoring metabolic integrity and energy production in all cells, the DNA undertake repair and the treatment causes reversal, in cardiomyopathy, nephropathy, retinopathy, neuropathy, erectile dysfunction, wound healing and dementia.

One uniform benefit is the greatly improved sense of well-being and energy. Feeling normal and physically well is unique to ATP. Most people with diabetes have forgotten what it feels like to feel well as they have slowly deteriorated over time. With APT they often say that they just did not realize how sickly they had become until they felt normal again.

Another benefit of the treatment is the elimination of diabetic loss of consciousness due to low blood sugar, called hypoglycemic coma. Not only is low blood sugar a condition which can cause a diabetic to have traffic and other accidents, it is a condition which has been shown to cause brain impact. With blood glucose of only 53 mg/dl (normal is 80 to 120), neurological symptoms appear. Conventionally treated diabetics regularly fall below this number. Hypoglycemic reactions are

more common to diabetics trying to achieve tight control of their blood sugars, and of course are common to those diabetics who are brittle. Hypoglycemia is recognized and avoided by APT treated patients.

Another surprising benefit of APT is that it reduces hypertension (high blood pressure) in patients. Hypertension is linked to several complications. The randomized cross-over studies with APT have clearly demonstrated highly significant improvement in blood pressure in 3 months without any other changes. High blood pressure is associated with heart disease and kidney loss, always resulting in early death.

Fatty Liver Disease: The power of reestablishing the Krebs Cycle includes remedial stimulation of the liver. With or without diabetes, fatty liver disease is reversed, and normal liver enzyme levels can be achieved after treatment of 3 to 6 months.

Safe and Effective: Both the treatment and the unique Bionica infusion pump have flawless safety records, with no adverse reactions, no claims, no recalls, malpractice suits or anything negative stemming from the treatment. Every person with diabetes complications will benefit from the APT treatment. APT is fully developed, rolled out in a "turn key" manner, and is ready to treat millions of critically ill people. No further research or development is needed.

Operations: The cost of setting up a clinic with all equipment including the APS is relatively inexpensive, and the returns are very attractive. This is because:

1. **There are no special requirements for the facilities**, and both installing and moving the equipment is easily
2. **The clinics are scalable**, and a clinic can start with 6 to 8 chairs and grow to any size without any loss of economies of
3. **The market is huge**, just for the severely ill patients. And there is an ever increasing number of new patients each
4. **Each clinic chair can be used for two shifts**, and thus one chair can treat two people each day. This means that the demand for each chair is
5. **The reimbursement rates are very attractive**. Medicare publishes the rates that are used for APT, and insurance companies typically pay significantly more than the Medicare rate. Even at Medicare rates, the business is highly profitable. A rough cost of business per day per patient is $200 per day depending upon personnel and
6. **Mid-level medical personnel deliver the treatment.** The treatment is best given by med techs who are overseen by a nurse practitioner or physician's assistant. There is no need for the physician to be there when the treatment is being given. The physician can consult the patients for other things while making a good wage just on initial and daily interviews.
7. **Payment is Electronic**. Medicare and insurance companies now require electronic submissions. They use the same AMA codes for diagnosis and treatment. APT uses standard codes and will not seek a bundled code for the treatment

8. **Advertisement costs will only be significant at the beginning.** Each clinic will advertise its opening until there are sufficient patients to fill the clinic. After that, word- of-mouth appears to be effective, and the advertising expenses will
9. **No other or competing technologies.** There are no other technologies that normalize carbohydrate metabolism or address the core problem of diabetes. Stem cells do not do this, and no other technologies imitate how man was made to have the body heal
10. **Insurance costs are extremely low.** Because the therapy has a proven perfect safety record, there are no additional requirements for use of medical personnel or a clinic. The clinic itself does not provide treatment under a license, and thus is not liable for medical malpractice. Individual nurse practitioners and physician assistants have inexpensive insurance policies. In addition bionic a, the manufacturer has product liability insurance which is also low because of the lack of any claims to

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11. **Home therapy will also provide benefits.** After the patient has normalized his or her metabolism, they different and stable. After 4 months, the treatment regimen usually becomes predictable, and the same doses are used over and over. This allows the patient and one other significant person to be trained for home therapy which will be needed as there are too many people with diabetes to treat them in clinics after they are stable. Home patients come to the clinic and take the pump

Conclusion: The result of all the prior work is that the Artificial Pancreas Treatment® is one of the most important medical advancements of this decade. All that is needed is funding for clinics where medical professionals will help many needful people and be properly paid for delivering Artificial Pancreas System® treatments.

Other Indications: The anecdotal outcomes on concurrent conditions such as Alzheimer's Disease, Parkinson's Disease, Fatty Liver Disease (above), low energy, and diseases of degeneration suggest that the frontier of metabolic normalization has just now been reached. The benefit is that there may be no additional regulatory approval, or approval may be immediate for these wellness conditions.

frequently asked questions (http://trinahealthntx.com/frequently-asked-questions)

You can find more information at www.diabetes.net (http://www.diabetes.net/) or www.trinahealth.com (http://www.trinahealth.com/) .

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