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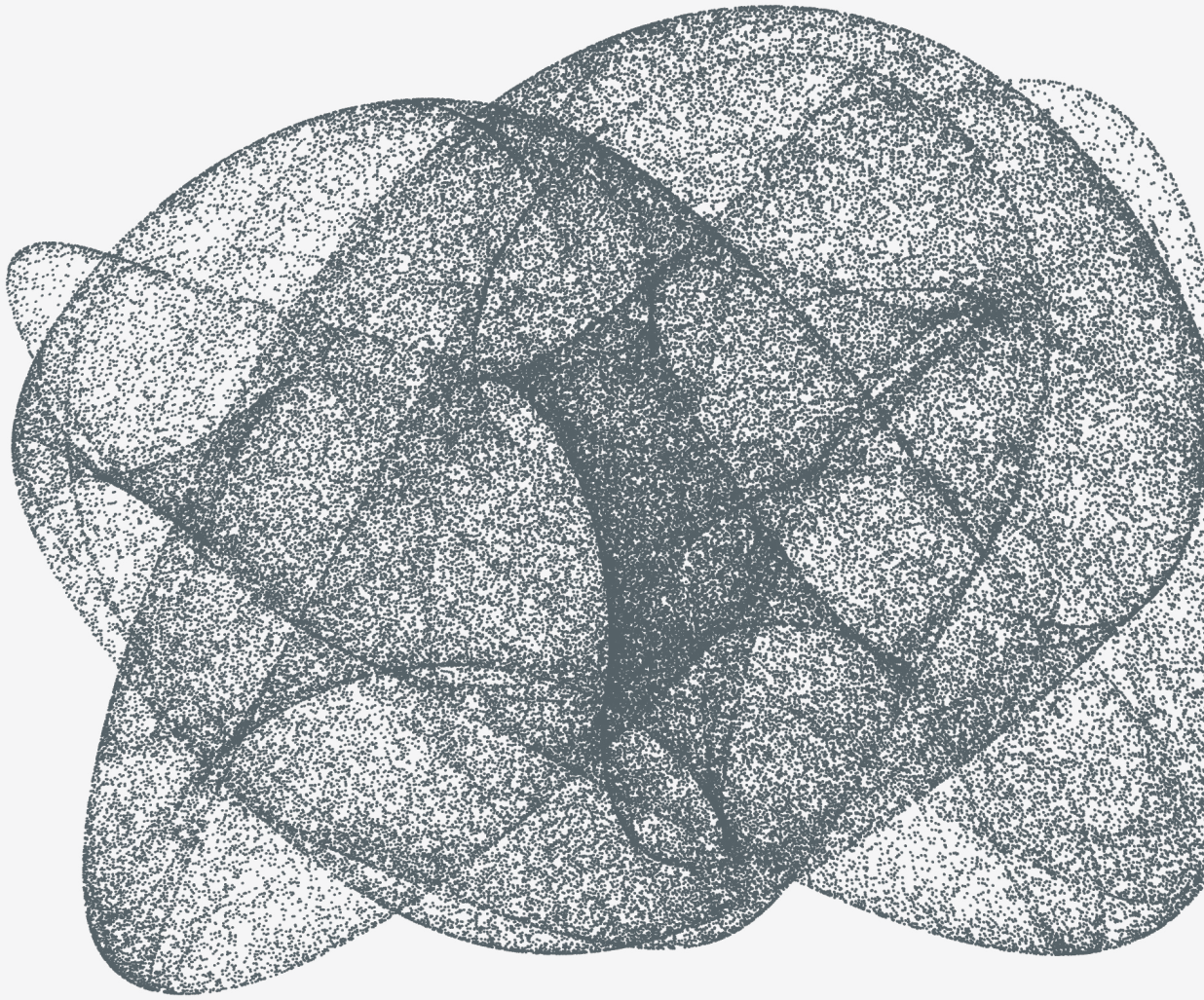
INSTITUTE
FOR HUMAN DATA SCIENCE

Medicine Spending and Affordability in the United States

UNDERSTANDING PATIENTS' COSTS FOR MEDICINES



AUGUST
2020

Introduction

There is a very public conversation about drug prices and costs occurring in the United States presently, but important parts of the discussion are obscured by the complexities and lack of transparency of the current pricing system. Most patients' costs are low, continue to trend downward, and their share of total costs are declining. However, specific patient groups are facing prices that are rising and unaffordable to them, with consequences for their health and their financial wellbeing.

The purpose of this report is to provide context and clarity on the pricing of prescription medicines and the consequences that result for patients. The report includes information on the differing prices paid by stakeholders, and by patients with different kinds of insurance. Uniquely, the report combines prescription cost data with household income data to illustrate how affordability is a distinctly personal issue for patients and their families.

Furthermore, as patients are exposed to higher costs, one consequence is that they abandon necessary prescription medicines with potentially serious impacts on their health. With unprecedented levels of unemployment during the current COVID-19 pandemic, millions of Americans are at risk of losing their health insurance, which will likely impact their personal assessment of affordability and their actions.

The study was produced independently by the IQVIA Institute for Human Data Science as a public service, without industry or government funding. The inclusion of household income data from Experian plc is gratefully acknowledged for the contribution it makes to our understanding of patient cost sensitivity. The contributions to this report of Josh Adler, Kyle Crowell, Bob Doyle, Brian Fallica, Emma Fleuette, Luke Greenwalt, Bryan McDonald and A.J. Pappas, and dozens of others at IQVIA, are gratefully acknowledged.

Find Out More

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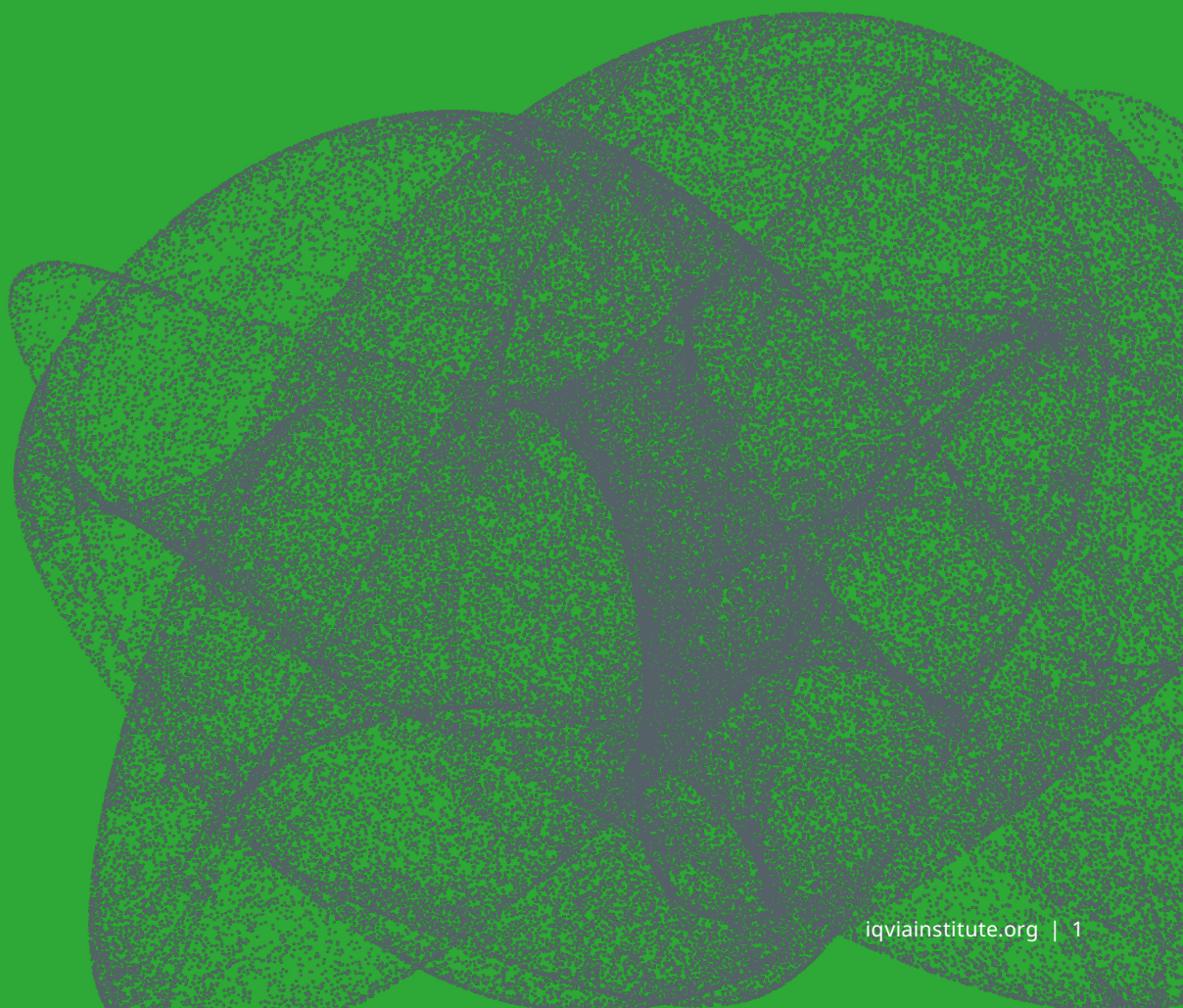


Overview

MEDICINE SPENDING LEVELS AND TRENDS

Understanding the amount spent on medicines in the United States requires looking at a range of measures that apply to different stakeholders. Wholesaler Acquisition Cost (WAC) represents the "list price" set by manufacturers and is the basis for other prices in the value chain, including payer responsibility and some patient out-of-pocket costs. Total sales at WAC prices were $671 billion in 2019, growing at a 7.1% CAGR over the past five years.

Payer net spending is calculated after supply chain discounts, manufacturer rebates, and patient out-of-pocket costs are deducted, and markups and margins by intermediaries are added. Total net payer spending in 2019 was $509 billion and has increased at a CAGR of 4.1% over the past five years.

Manufacturer net sales is calculated after deducting negotiated rebates, discounts, and other forms of price concessions, such as patient coupons or vouchers that offset out-of-pocket costs, and was $235 billion lower than overall payer and patient spending for medicines. Total manufacturer net sales in 2019 were $356 billion and increased at a 4.6% CAGR over the past five years.

Patient financial responsibility for medical services includes costs associated with office visits, diagnostic tests, and hospital outpatient and inpatient services, but exclude out-of-pocket costs for prescription drugs. Such patient non-drug costs reached $260 billion in 2019, having risen at a 4.6% CAGR over the past five years. Patient out-of-pocket costs for prescription drugs include copayment and coinsurance costs associated with medicines dispensed through retail pharmacies, mail-order, or clinics and hospitals. These costs reached $82 billion, with $67 billion related to retail drugs and $15 billion related to non-retail drugs. Growth over the past five years was at a CAGR of 2.1% — with a 1.6% and 4.6% CAGR for retail and non-retail, respectively.

Manufacturer net sales have increased by $56 billion over the past five years with the increase driven by the introduction of new branded medicines, which drove $68 billion of growth and increased use of existing protected brands that drove an additional $40 billion of growth. These amounts were offset by a $70 billion reduction in sales of branded medicines that no longer have patent protection and face generic or biosimilar competition.

Price increases on branded medicines contributed $21 billion to manufacturer net sales growth over the past five years, but have moderated significantly since 2016. Year-over-year invoice price growth has slowed from 9.3% in 2016 to 5.2%, as manufacturers have responded to public calls to moderate price growth and intensifying market-based competition. Net price increases — after adjusting for rebates, discounts, other price concessions, and patient coupons to reduce out-of-pocket costs — have also moderated from 2.9% in 2016 to 1.7% in 2019; the third consecutive year of increases lower than growth seen in the Consumer Price Index.

PATIENT OUT-OF-POCKET COSTS

Patients continued to pay more out of pocket for prescription medicines in total, primarily due to increased usage through retail channels, although more prescriptions are being dispensed with $0 patient payment — 44% of all branded prescriptions in 2019, up from 36% in 2015 — and the final patient cost is dependent on insurance type and design. Patient out-of-pocket costs for prescription medicines reached $82 billion in 2019, up from $74 billion in 2015, with growth primarily driven by increases in the retail channel, which accounts for $67 billion of the total out-of-pocket cost. The average amount paid out of pocket per retail prescription has risen from $10.34 in 2015 to $10.67 in 2019. Average patient costs for the commercially insured and Medicare have declined but costs for cash-paying patients have risen. Depending on plan design, these include prescriptions for the prevention and treatment of chronic disease including routine immunizations, contraception, aspirin for heart

disease (if with a prescription), some cancer medicines, and also prescriptions dispensed after a patient reaches maximum out-of-pocket levels. While 98.9% of prescriptions dispensed carry a patient payment of less than $125, the remaining 1.1% represents some 69.0 million prescription in 2019, up from 60.7 million in 2015, but with the share of prescriptions unchanged.

Medicare patients filling prescriptions under Part D paid $16.1 billion out of pocket, up 27% over the past five years — reflecting an 8.3 million (18.2%) increase in the over-65 population and a 13.7% increase due to greater use of medicines and shifts to drug that may have higher out-of-pocket costs — offset by 5.2% lower per-prescription costs. Lower costs for Part D are driven, at least in part, by the closing of the so-called "donut hole" and patients with standard benefit now have a flat 25% coinsurance after the initial deductible up to catastrophic coverage.

Patients covered by commercial insurance paid $36 billion out of pocket in 2019, down 5% since 2014, reflecting mix and volume changes, as well as greater use of coupons and vouchers provided by manufacturers. By law, coupons are not allowed to be used by patients using government insurance such as Medicare or Medicaid.

Most patients have a fixed and relatively low copay amount per prescription, but for those whose plan design incorporates deductibles or coinsurance, which are generally based on list prices, these now account for 49% of all out-of-pocket costs.

When aggregating costs at a patient level annually, 90% of all patients pay less than $500 in out-of-pocket costs for the full year. In the case of Medicare Part D patients, 20% pay more than this, in part due to the plan design for standard benefit plans, and partly due to their inability to offset costs through manufacturer coupons.

Medicines with high patient cost exposure (>$125) account for a small share of all prescriptions, but bring a high burden to patients and can only be offset by coupons or vouchers in commercial plans. These include diabetes drugs, which account for one-in-five high-cost prescription claims filled in 2019, followed by obesity, asthma, COPD, stroke, and HIV drugs. These six therapy areas account for 42% of total high-cost prescriptions. The high cost of these prescriptions are often offset by coupons among patients in commercial plans, which reduce total cost-exposure by 40% in the case of oncology drugs, by 60% in the case of diabetes drugs, and by over 80% in the case of anticoagulants.

Insulin costs an average of $31 out of pocket per month, however 24% of diabetes prescriptions cost more than the $35 cap to be implemented in 2021 by plans participating in the Medicare Part D "Senior Savings Model." Several states have adopted similar caps, but thus far only three of the ten planning to sign the legislation are at or below the $35 cap. While these caps have the potential to lower patient costs in 2021 and beyond, if all patients nationally had insulin costs capped at $35, annual out-of-pocket savings would be $837 million ($233 million in commercial, $279 million in Medicare, and $326 million for the uninsured paying cash). However, these savings may not result in overall savings to patients if they simply result in per prescription caps but take patients longer to reach their deductible, out-of-pocket maximum, or other plan thresholds.

Without also having caps on other medicine costs or changes in benefit designs, there is little to prevent costs from shifting to later in the year or to other medicines for the same patient. There is also the potential that capping costs for some patients may drive up premiums for others.

PATIENT COST SENSITIVITY

Controlling cost exposure is a critical issue. However, the abandonment of prescriptions at retail pharmacies remains a key public health concern, since this represents patient care that is recommended by a physician but not followed by the patient. In 2019, 9% of all prescriptions were abandoned. Abandonment rates are less than 5% when the prescription carries no out-of-pocket cost, but rise to 45% when the cost is over $125 and 60% when the cost is over $500.

Patient income level has an important impact on abandonment. For example, for prescriptions of diabetes, anticoagulants and cancer medicines costing between $125 and $250, abandonment is 40% for patients with household income of more than $100,000, and nearly 50% for those with household income less than $25,000.

INSURANCE CHANGES SINCE COVID-19

Related to insurance types and income is the unprecedented unemployment occurring as a result of the COVID-19 pandemic, and the risk that millions of Americans will lose insurance coverage. Analysis of prescription abandonment patterns suggests the potential impact on these patients if they lose coverage. To date, fewer patients have lost commercial coverage in 2020 than in 2019, despite the pandemic-related unemployment, suggesting that employers have retained insurance coverage for furloughed workers through June at least. The extent to which this largesse continues and employees can retain the ability to purchase COBRA coverage if they lose employment, will depend heavily on the provision of unemployment payments from state governments and potentially additional rounds of federal stimulus payments. In the absence of these funds, millions of Americans could lose coverage and be faced with unaffordable medicine costs.

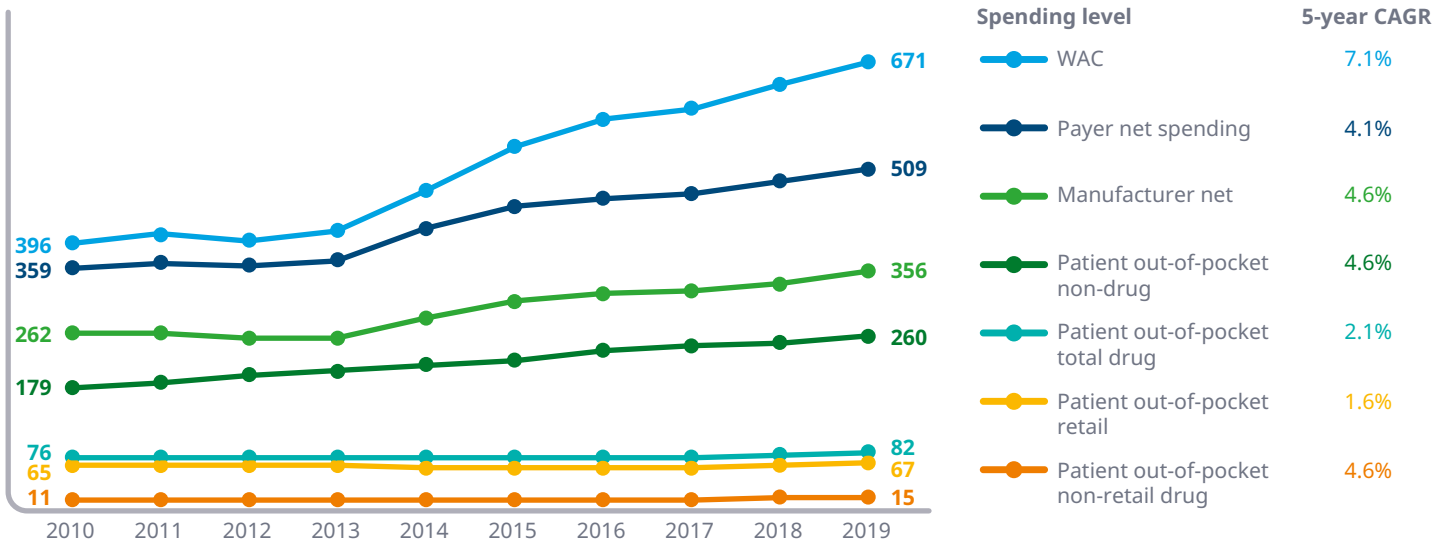
POLICIES IMPACTING MEDICINE PRICING

Beyond these immediate concerns, both federal and state policymakers have been addressing drug costs through a variety of policies, particularly related to affordability dynamics. The Trump administration has announced six policies in recent months, through rule-making authority or via executive orders, relating to Medicare and private insurance, that have potential impact on patient drug costs. The implementation of these rules and orders are intended to take effect in 2021, such as the IRS rule allowing lower costs during the deductible period in participating plans, and the Senior Savings Model, which allows a low-cost diabetes plan design within the Medicare cost-sharing model. Four other policies were announced in late July 2020 with implementation potentially phased in over the following year or longer. These include benchmarking U.S. prices to other developed markets, changing the anti-kickback provisions to force rebates to be given to patients at the point of sale, and allowing reimportation from other lower-priced markets. A rule to ensure that the low purchase prices for insulins and epinephrine be passed to consumers at so-called federally qualified health centers, would see the costs of these life-saving medicines drop to pennies. The details on all of these proposals have not yet been published and face significant hurdles as several are contingent on avoiding increases to other system costs such as premiums, other patient out-of-pocket costs or the federal deficit, which could make them difficult to implement.

At a state level, policies include pushes for greater financial transparency, copay caps — both generally and for insulins specifically — and anti price-gouging policies to prevent sharp increases. In fact, since 2015, 36 states have either enacted or actively advanced legislation to address one or more of these four policy categories. New York has enacted policies in all four categories while Colorado, Illinois, Louisiana, Maryland, Maine, New Jersey, Vermont, Washington, and West Virginia have each addressed policies in three of these. Regardless of the number of policies or their specific characteristics, it is currently unclear if any of them have, or could have, a material impact on prices because existing state and federal regulations limit what state legislators can accomplish. The continuing fragmentation of pricing policy by insurance type, and under federal and state jurisdictions, will perpetuate the dynamic where drug pricing depends considerably on who is paying.

Diverse measures of medicine spending illustrate differing trends depending on the party doing the spending

Exhibit 1: Medicine Spending at Selected Reporting Levels, US$Bn



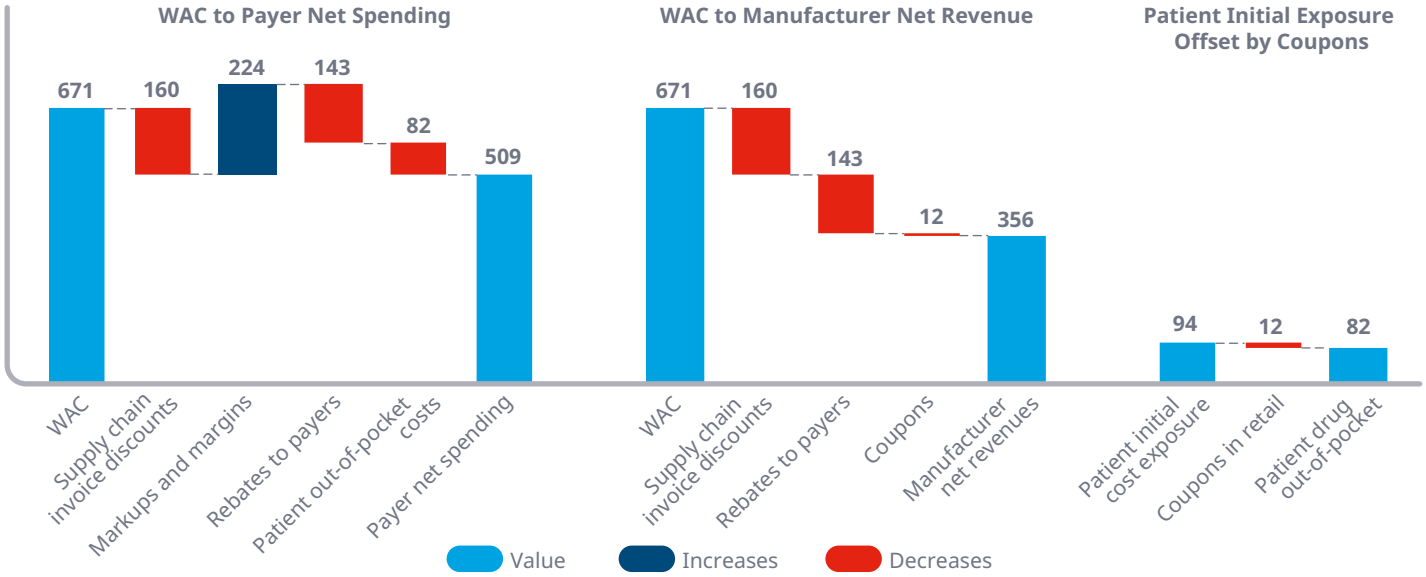
Source: IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- Overall spending trends reflect shifts in the prices of medicines, as well as changes in volume and mix of products used.
- Over the past five years, spending at list prices [Wholesaler Acquisition Cost (WAC)] has increased from $477 billion to $671 billion — an average of 7.1% per year.
- Manufacturer net revenues from these sales, including all products, are estimated to have grown an average of 4.6% over five years and 5.2% from 2018 to 2019.
- Patient out-of-pocket costs for drugs dispensed in a retail setting had been declining up to 2017, but have increased 8% and 3% in the past two years, respectively, resulting in a five-year average growth of 1.6% per year.
- Insurers are responsible to reimburse pharmacies and/or providers to cover the invoice costs of medicines provided to covered patients, less the patient out-of-pocket costs. The rebates payers receive from manufacturers lower their net spending and may limit the need for premium increases or contribute to the profits of pharmacy benefit managers (PBMs) or insurers.
- Manufacturer net revenue is lower than other measures of spending based on a combination of statutory discounts to Medicaid, discounts for 340b eligible institutions, the branded pharmaceutical fee in the ACA, donut-hole subsidies in Medicare Part D, supply chain discounts (often for generic drugs), as well as the value of coupons given to patients.
- Payers benefit from all of these discounts except patient coupons.

Exhibit notes: IQVIA Audits include measures of sales at Wholesaler Acquisition Cost (WAC) or list prices. Additionally, the IQVIA Institute has analyzed company reported net revenues for a sample of companies and products and projected a total market estimate (see Methodology section). Payer net spending reflects the total amount spent by payers for medicines in both retail and non-retail settings, including all insurance types and cash paying patients, offset by the estimates of rebates or payments that reduce payer responsibility. Payer net spending is derived from an analysis of CMS National Health Expenditure (NHE) data, IQVIA audited sales, and IQVIA estimates of manufacturer invoice-level and net revenue. Patient out-of-pocket costs are derived from CMS NHE. Due to lag-times in reporting, CMS-derived measures are projections for 2019 while IQVIA-derived metrics are actual.

There are large differences between list prices and the amounts spent by payers and patients or received by manufacturers

Exhibit 2: Differences Between Various Spending Levels for U.S. Prescription Medicines in 2019, US$Bn



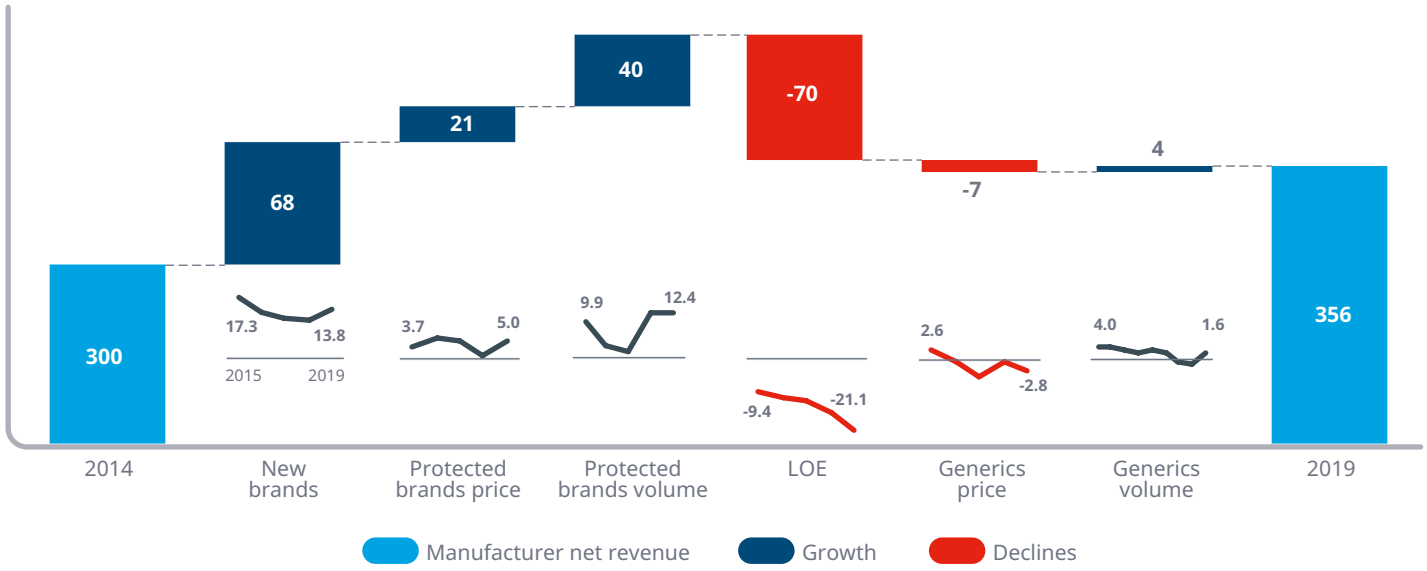
Source: IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- Wholesaler acquisition costs (WAC) are often reported and represent list prices that influence the costs paid by others in the supply chain and some patients. WAC does not reflect elements like discounts and rebates which cause significant differences in the prices experienced by various stakeholders and individuals.
- Payers, in aggregate, paid $509 billion in 2019 for medicines, including those paid through a patient's medical benefit for doctor-administered drugs or drugs used during a hospitalization, which are often excluded from official statistics.
- Manufacturers offer supply chain discounts, rebates to insurers, and coupons to patients resulting in net revenues of $356 billion, $315 billion lower than at WAC prices.
- Patient costs are much lower overall due to insurance coverage but still represent a substantial amount: $82 billion in 2019. This value accounts for $12 billion in savings for patients as a result of manufacturer coupons, but excluding the use of manufacturer-provided pre-paid debit cards.

Exhibit notes: IQVIA Audits include measures of sales at Wholesaler Acquisition Cost (WAC) or list prices. Additionally, the IQVIA Institute has analyzed company reported net revenues for a sample of companies and products and projected a total market estimate (see Methodology section). Payer net spending reflects the total amount spent by payers for medicines in both retail and non-retail settings, including all insurance types and cash paying patients, offset by the estimates of rebates or payments that reduce payer responsibility. Payer net spending is derived from an analysis of CMS National Health Expenditure (NHE) data, IQVIA audited sales, and IQVIA estimates of manufacturer invoice-level and net revenue. Patient out-of-pocket costs are derived from CMS NHE. Due to lag-times in reporting, CMS-derived measures are projections for 2019 while IQVIA-derived metrics are actual.

Manufacturer net revenues increased by $56 billion over the past five years primarily driven by new products and brand volume

Exhibit 3: Net Manufacturer Revenues and Growth 2014–2019, All Channels, US$Bn



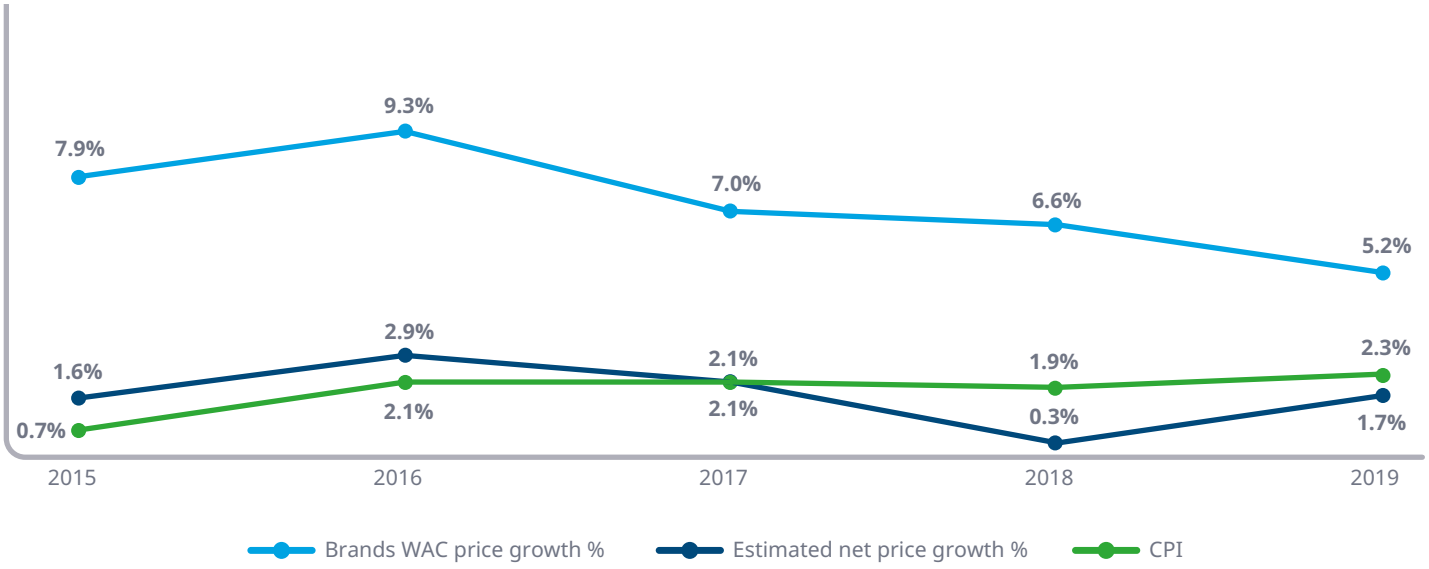
Source: IQVIA Institute Jun 2020

- New products, including 223 new active substances that launched from 2014 through 2019, contributed $68 billion to net manufacturer revenue growth over the past five years.
- Price increases for protected brands, which have slowed substantially in recent years, contributed $21 billion to growth over five years, averaging a 1.3% increase per year.
- Volume growth experienced by protected brands — most often driven by brands in the 3–5 year period since their launch when adoption by HCPs grows — contributed $40 billion to growth over the five year period.
- Losses of Exclusivity (LOE), or patent expiries, typically result in a dramatic shift of volume to generics and also lower brand sales for the originator. These contributed a decline of $70 billion to manufacturer net revenues.
- The impact of LOE has been trending upwards during the past five years. While it had a large impact earlier in the decade, it reached a low point in 2015 with a negative contribution of $9.4 billion, but increased steadily to a contribution of -$21.1 billion in 2019.
- During the past five years, generic prices had some periods of significant increases and periods of decline that have offset those, resulting in overall net negative generic price-driven growth over the past five years.

Exhibit notes: IQVIA estimates of net manufacturer revenue and growth are based on comparisons of IQVIA audited data and company reported net revenues (see Methodology section). Products are assigned to segments in each month based on time relative to launch or patent expiry and product type. Growth is calculated annually on a like-for-like product segment basis and then aggregated to five year totals.

List price growth for protected brands was 5.2% in 2019, while net price growth is estimated at 1.7%—the third year at or below the CPI

Exhibit 4: Wholesaler Acquisition Price Growth and Net Price Growth for Protected Brands



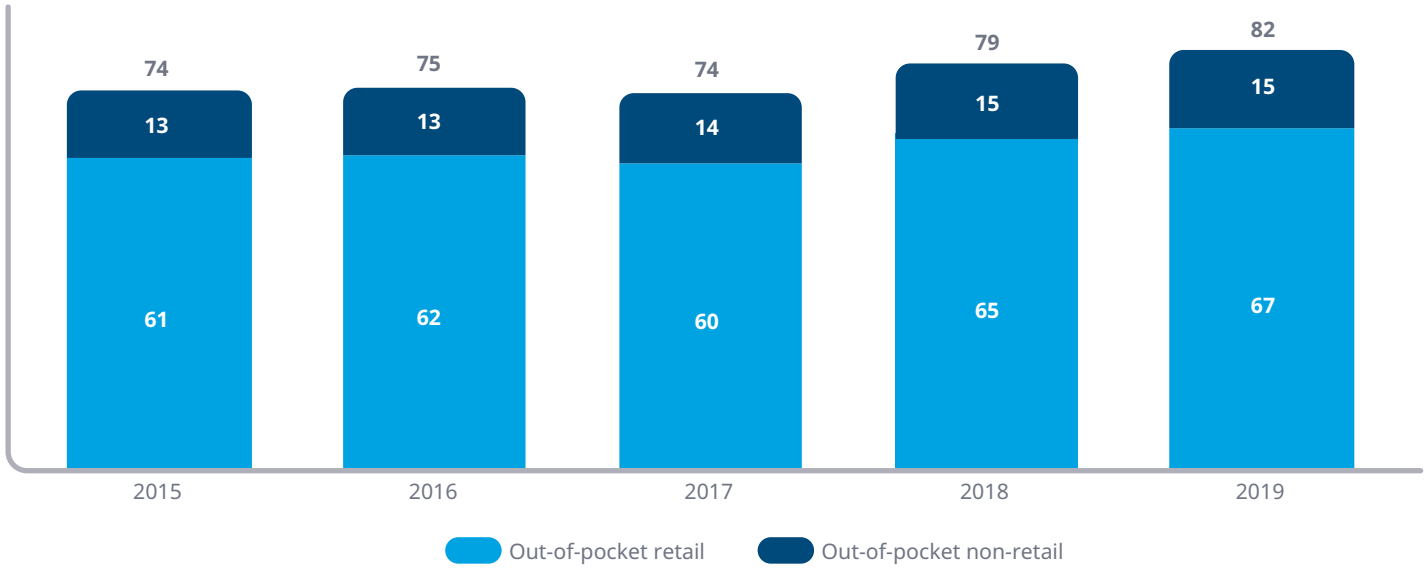
Source: IQVIA Institute, National Sales Perspectives, Dec 2019; Bureau of Labor Statistics, CPI Data, Dec 2014–Dec 2019

- The list prices of protected branded products — those products more than two years after launch having not yet lost patent protection — have been rising over 5% per year for the past five years, but with a slowing rate of growth year by year.
- Net manufacturer prices — the cost of medicines after all discounts and rebates have been paid — have been growing at an average of less than 2% over the past five years and below inflation for the past three years.
- Prices paid by different stakeholders in the U.S. health system are based to varying degrees on list prices and the discounts and rebates they negotiate or receive and do not apply uniformly to all parties.
- Most discounts are offered to wholesalers and pharmacies and do not necessarily result in lower out-of-pocket costs for patients.
- Some of the rebates and other price concessions manufacturers pay (resulting in lower net prices) are statutory payments to government programs like Medicaid. Price concessions also include coupons offered to patients using private insurance, whereas those with government insurance cannot use coupons.
- These complexities mean that the price for each medicine can be unique, reflecting the drug, the insurance type, the other medicines a patient takes during the year, the time of year, the pharmacy, the coupons offered by manufacturers, and whether a patient chooses to use them.

Exhibit notes: CPI = consumer price index

Out-of-pocket costs have been rising, mostly in retail pharmacy

Exhibit 5: Aggregate Patient Out-of-Pocket Cost for Medicines Dispensed in Retail and Non-retail Settings, US$Bn



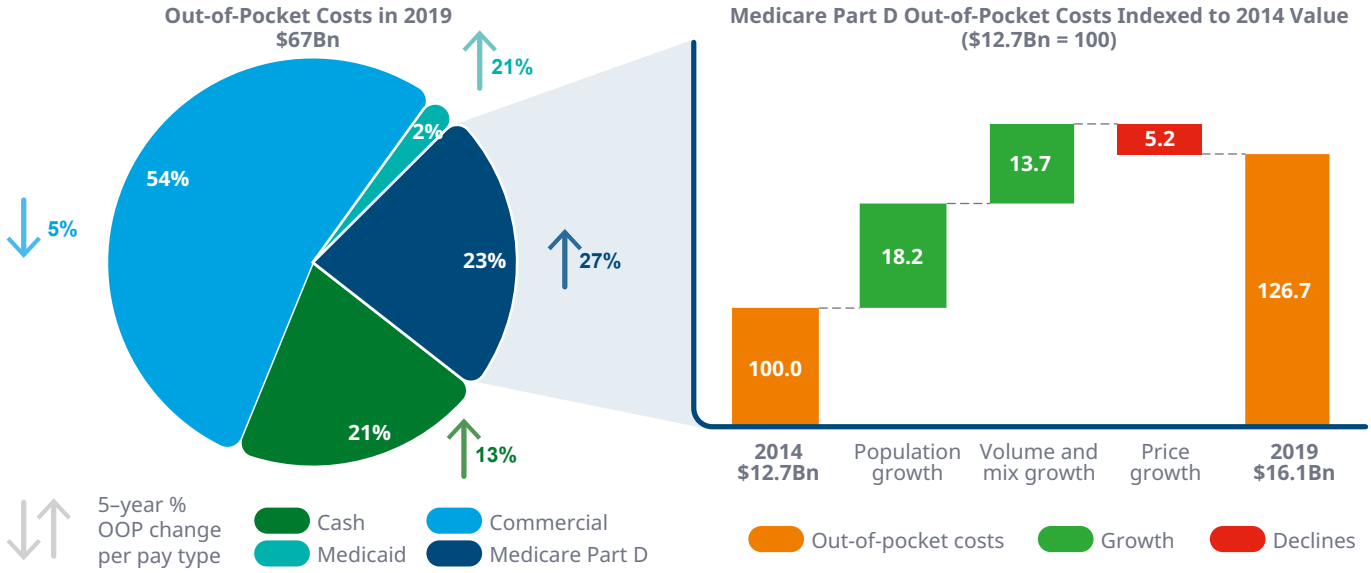
Source: IQVIA Xponent, IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019; IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- Retail pharmacy out-of-pocket costs have risen from $61 billion in 2015 to $67 billion in 2019 though some patients have seen their costs decline during this period (see Exhibit 7).
- Patients with some types of insurance, including Medicare Part D or high-deductible private health plans, have seen their costs rise in line with the rising list prices of drugs, but be offset by the Medicare "donut hole" subsidy program or the use of coupons, respectively.
- As out-of-pocket costs have risen, coupons for commercially insured patients have reached $12 billion in 2019 — up 50% from $8 billion in coupon offsets in 2013 — helping to lower commercially insured patients' out-of-pocket costs over the period.
- Among commercially insured patients on branded medications, 16% of them used coupons to reduce their out-of-pocket costs in 2019.
- Patient out-of-pocket costs for non-retail medicines reached $15 billion in 2019 up from $13 billion in 2015, but these generally represent a smaller share of total costs as more patients reach deductibles or out-of-pocket maximums if they've been hospitalized or received more serious treatments administered by a physician.

Exhibit notes: OOP costs are estimated based on prescription volumes and observed OOP costs. OOP costs are projected from a sample in the IQVIA LAAD sample claims data to a national estimate using national adjusted prescriptions, which were back-projected to estimate the trend prior to a trend break after 2016 due to restatement of NPA volumes (see Methodology).

Medicare costs have increased by 27% over the past five years, driven by an aging population and increased use, offset by declining prices

Exhibit 6: Aggregate Patient Out-of-Pocket Cost for Prescriptions and Value Offset by Coupons



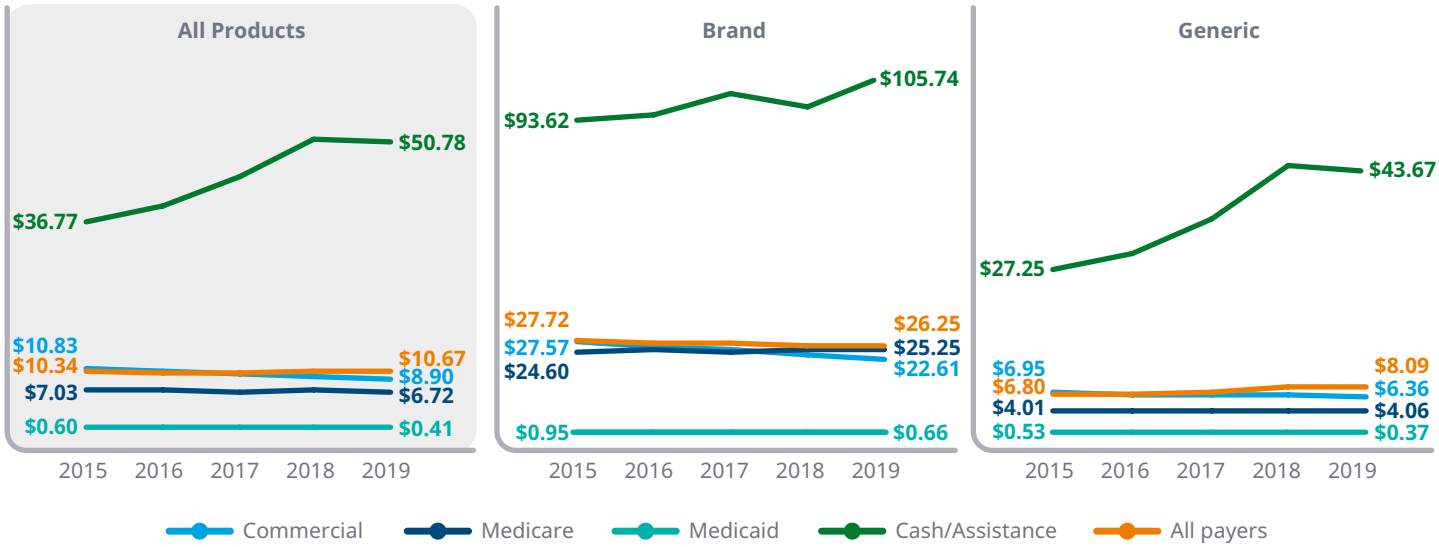
Source: IQVIA Xponent, IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019; US Census Bureau; IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- Medicare out-of-pocket costs grew, in aggregate, from $12.7 billion to $16.1 billion over the past five years, up 27% over five years, with 68% of the growth from population aging as 8.3 million more Americans are now over 65 years old.
- The average out-of-pocket cost per prescription for Medicare beneficiaries declined by 5.2%, from $279 per person to $264 (not shown), excluding the impact of volume and mix changes. This resulted in total savings of $700 million over the same five year period, including the impact of closing the donut-hole.
- Increasing use of medicines overall and/or shifts to those that may have higher out-of-pocket costs added $1.7 billion (not shown), a 13.7% increase in aggregate over five years, and a 51% contribution to the increase in seniors' out of pocket costs.
- The amount of volume and mix growth is likely to be related to the closure of the donut hole, as patient out-of-pocket costs under the policy are now 75% lower, and associated abandonment rates are substantially lower.
- Commercially insured patients or "third party" insured saw their out-of-pocket costs decline 5% over five years, while cash and Medicaid patients saw their aggregate out-of-pocket costs increase by double-digits.
- Patients paying cash account for 21% of overall patient out-of-pocket costs but only for about 5% of prescriptions, while Medicaid patients account for 16% of prescriptions and 2% of patient out-of-pocket costs (see Appendix).

Exhibit notes: OOP = out-of-pocket. OOP costs estimated based on prescription volumes and observed OOP costs. OOP costs were projected from a sample in the IQVIA LAAD sample claims data to a national estimate using national adjusted prescriptions. Note, method of payment is determined based on the most common or mode pay type in recorded claims. Cash method of payment includes those where patients used no insurance, including those who received some assistance from charities, foundations or other programs, or where a mode pay type was impossible to determine. Volume and mix growth is the remainder of all growth minus population and price growth.

The average amount paid out-of-pocket per retail prescription has risen from $10.34 in 2015 to $10.67 in 2019

Exhibit 7: Average Final Out-of-Pocket Cost per Retail Prescription by Product Type and Method of Payment, 2015–2019



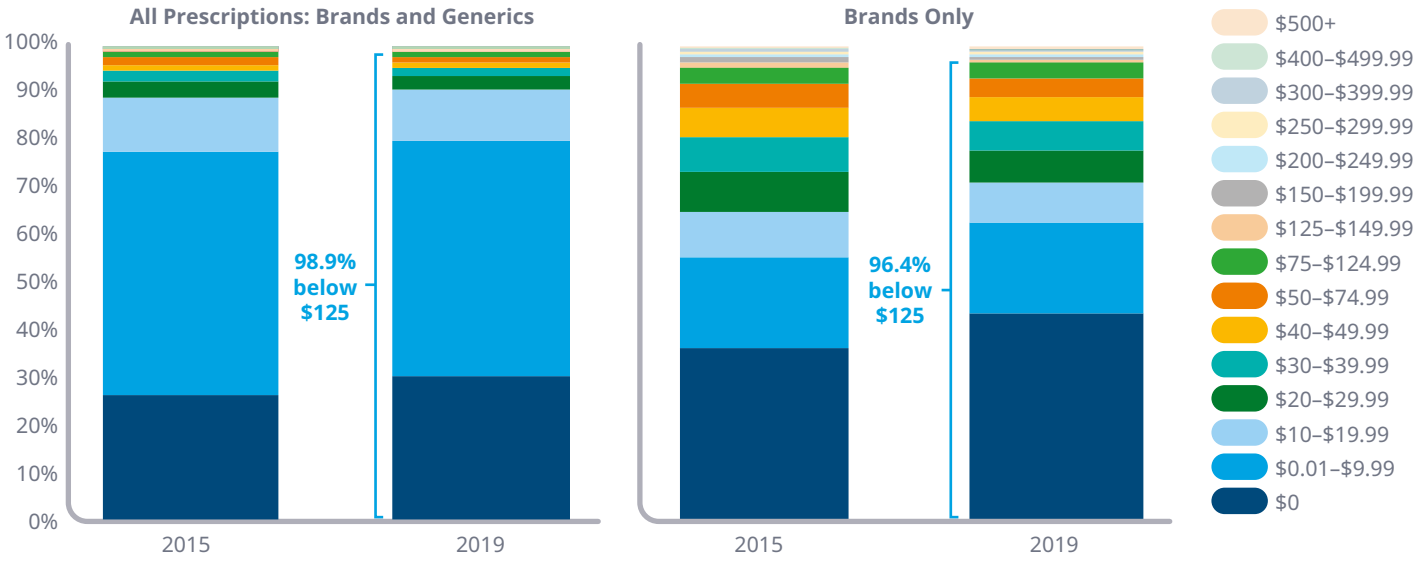
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- Overall, average out-of-pocket costs are not rising rapidly, with an average increase of only $0.33 over five years to $10.67 across all products and all payers.
- Uninsured patients paying with cash have seen costs rise for all types of products from $36.77 to $50.78 per prescription over five years, with brands specifically increasing from an average of $93.62 to $105.74.
- Medicare patients have seen average costs decline from $7.03 to $6.72, while commercially insured patient prescription costs have declined from $10.83 to $8.90.
- Medicare patients have seen brand prescriptions increase from $24.60 to $25.25 average cost. By law, Medicare patients cannot use coupons, which commercial patients used for 16% of brand prescriptions in 2019.
- Some Medicare patients do receive support from charitable foundations, which are reflected in their final out-of-pocket costs here.
- Commercial brand prescriptions averaged $22.61 in 2019 down from $27.57 in 2015.
- For generics, commercial and Medicare patients have seen their costs largely unchanged while cash-paying patients saw costs rise from $27.25 to $43.67 in 2019.

Exhibit notes: Includes paid claims only for patients filling at least one prescription. Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volumecomparison purposes.

Over 90% of branded and generic prescriptions have a final out-of-pocket cost below $20, and only 1.1% have a cost above $125

Exhibit 8: Distribution of Prescriptions by Out-of-Pocket Cost in 2019, All Channels



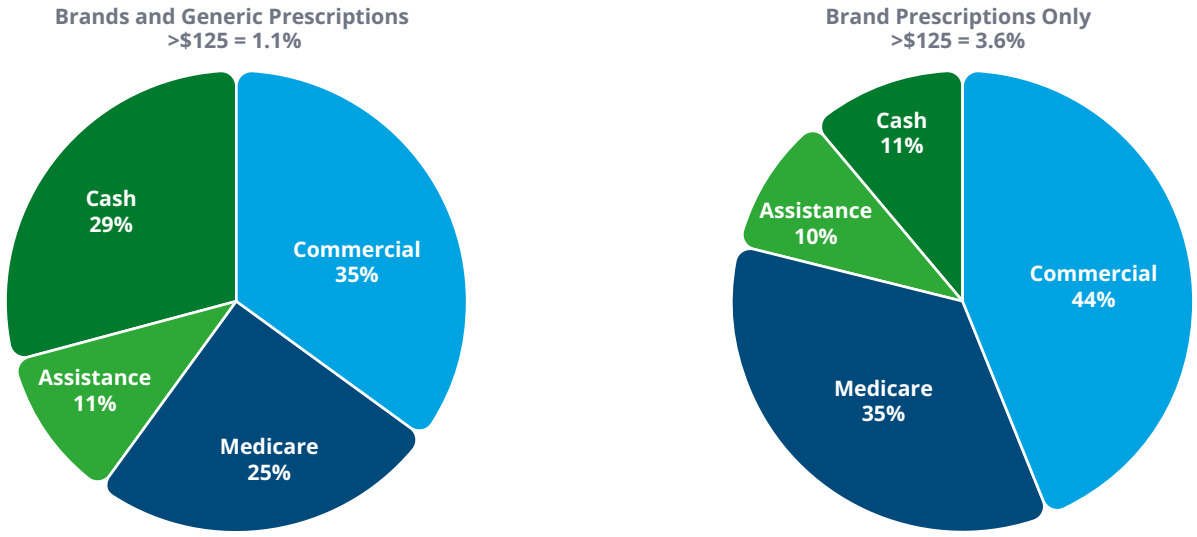
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- Over 90% of all prescriptions have final out-of-pocket costs below $20 (blue bands, left chart), which is up 1.3 percentage points from 2015.
- Branded prescriptions with final out-of-pocket costs below $20 account for 71% of brands filled in 2019, up from 65% in 2015.
- Out-of-pocket costs above $125 for a normalized monthly prescription account for 1.1% or 69.0 million prescriptions, up from 60.7 million in 2015.
- Only 3.6% of branded prescriptions have out-of-pocket costs above $125, down from 3.8% in 2015.
- Many patients have paid lower costs year-over-year due to a variety of shifts in benefit designs, coupon programs, patient assistance programs, rising Medicaid enrollment, and mandated supports, such as the Medicare Part D donut-hole subsidy.
- While few patients fill them, abandonment is higher at higher prescription cost levels, and those prescriptions may be underrepresented as those prescriptions might have been abandoned due to cost (see Exhibit 17).
- A rising number of prescriptions are now dispensed with a $0 payment by the patient, and now amount to 44% of all branded prescriptions in 2019, up from 36% in 2015.

Exhibit notes: Includes paid claims only for patients filling at least one prescription. Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volume comparison purposes.

High-cost prescriptions represent only 1.1% of overall claims and predominantly affect those in commercial and Medicare plans

Exhibit 9: High-Cost Claim Exposure (>$125) by Payment Type, 2019



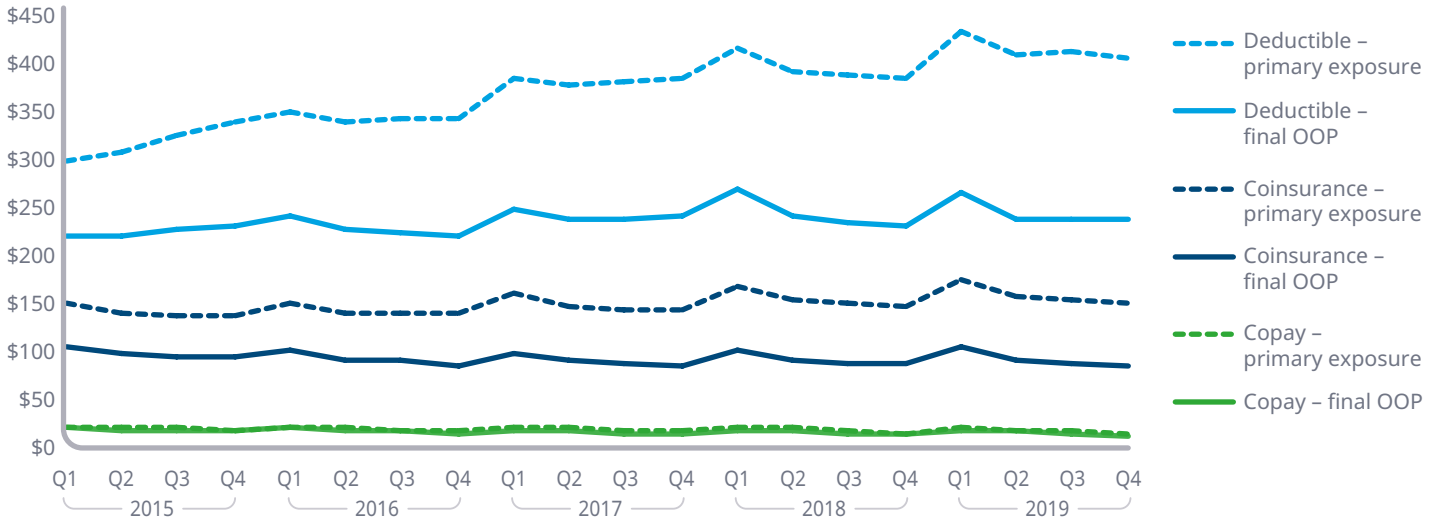
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- High-cost prescription claims are primarily split between Medicare and commercial plans, with commercial having a larger share of high-cost prescriptions in line with its' larger share of overall claims.
- Of all insured patients, Medicare patients are most likely to experience a high-cost claim due to high exposure phases of the Part D benefit design.
- High-cost claims are more common for brands, with 3.6% of brand claims costing more than $125, and 79% of those claims covered by commercial insurance or Medicare.
- In Medicare, high-cost claims for brands represent 9.1% of overall brand Medicare claims, compared to 7.2% of commercial, due to both the benefit design in Part D and potentially to the disease burden many seniors face.
- Commercial insurance and Medicare account for 60% of high-cost claims over $125, while cash payment is made for 29%.
- Cash prescriptions represent only 5% of prescriptions, but for cash-paying patients their lack of insurance contributes to their much higher share of exposure to high costs.

Exhibit notes: Includes approved claims for patients filling at least one prescription. Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volume comparison purposes.

Final out-of-pocket costs for commercial claims in the deductible period increased slightly, while coinsurance and copays declined

Exhibit 10: Primary Cost Exposure and Final Out-of-Pocket Cost by Benefit Design Over Time, Branded Products, Commercial Only



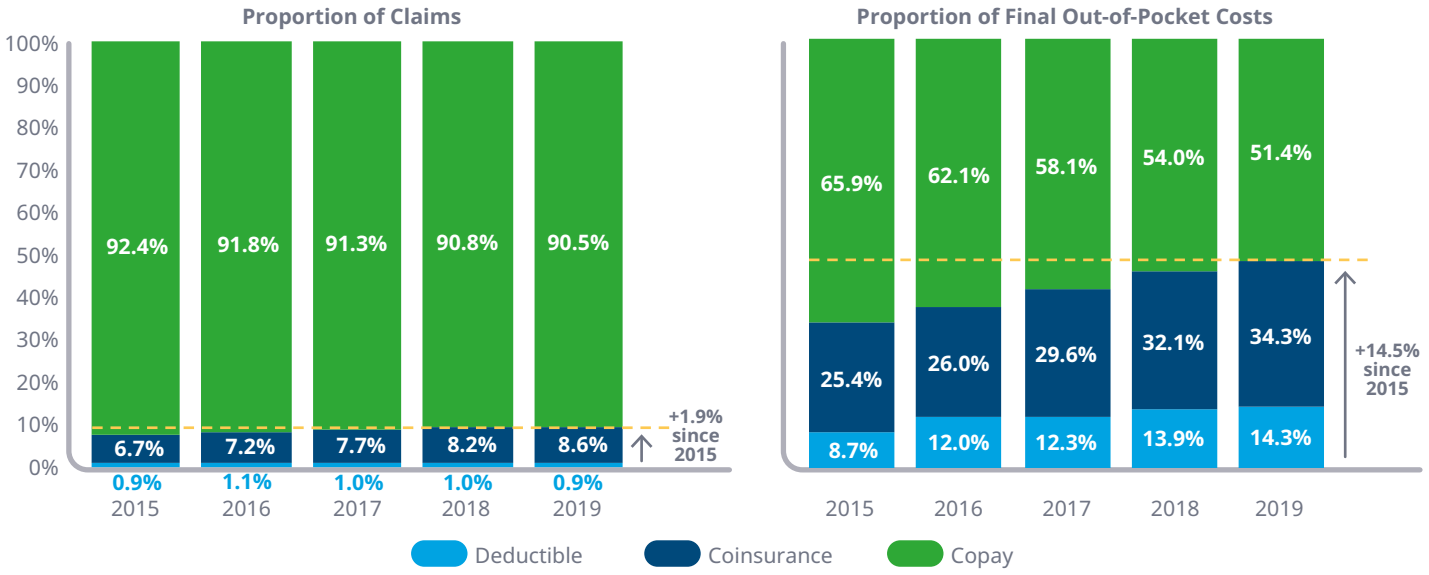
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- As primary cost exposure has risen for patients with deductible or coinsurance benefit designs, final out-of-pocket costs after insurance adjustments have not risen as much.
- For those spending in the deductible period, they are spending on average $200–260 per quarter per brand, with higher amounts at the beginning of the year, while those with coinsurance spend less, averaging $80–100.
- Patients with standard copays, in what is often called traditional insurance, have the lowest cost exposure, which has declined on average from $11 to under $9 per medicine, but notably these patients often pay the highest insurance premiums.
- Coupons and benefit designs combine to influence the final out-of-pocket costs patients pay. Cost exposure is often driven by list price and benefit designs typically include a deductible followed by a period where coinsurance or copays are required, where costs can be potentially offset if a patient receives a manufacturer coupon.
- In recent years, some plans have developed benefit designs where coupons do not contribute or "accumulate" to deductible spending, with the plans called "accumulators", though these impact only a small percentage of overall prescriptions.

Exhibit notes: For the purposes of this analysis, all claims have been assessed by the proportion of patient exposure and patient and payer initial pay amount. Deductible claims are defined as those where the patient would pay more than 50% of the claim, and the primary patient payment is >$250. Coinsurance claims are defined as those where the patient pays 5–25% of the cost with primary payment from $75–250, or where patient share is 5–50% and primary patient payment is >$75. Copay claims have been determined based on a primary patient copay less than $75.

Most patients have fixed copays, but for those with deductibles and coinsurance, these make up 48.6% of all out-of-pocket costs

Exhibit 11: Share of Branded Commercial Claims and Out-of-Pocket Costs by Benefit Design Cohort



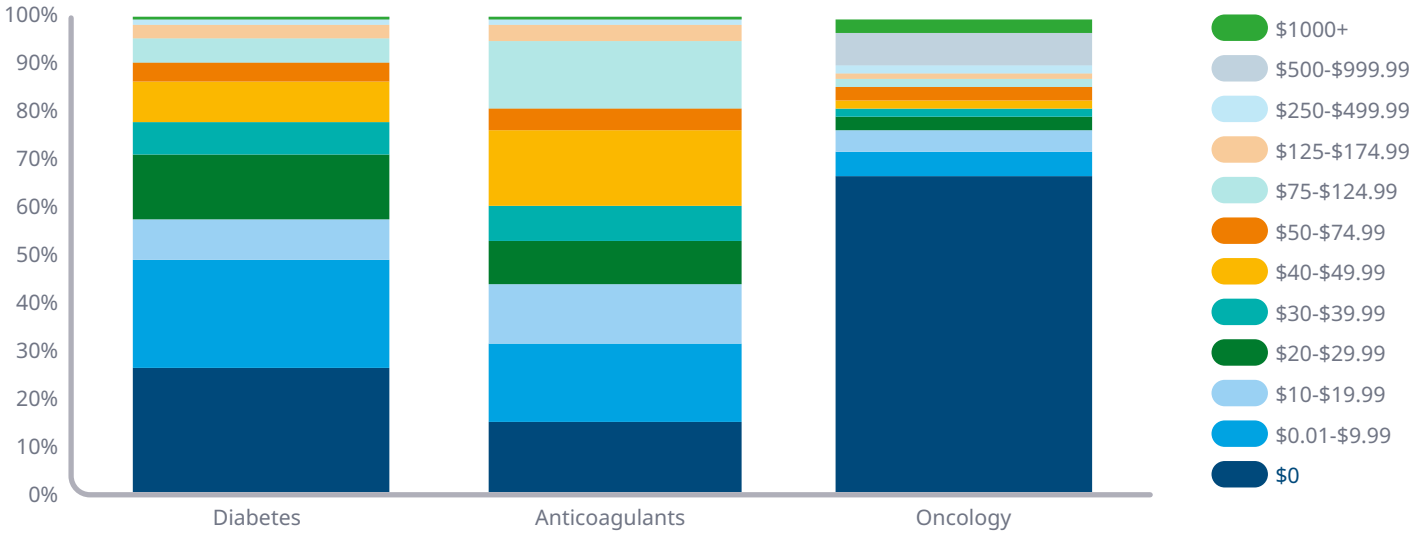
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- Though claims with a copay benefit design make up the highest proportion of claim volume, deductible and coinsurance claims make up almost half of out-of-pocket spending in 2019, and this proportion is increasing.
- Plan designs vary considerably, and while there are three main types of payment (i.e., copay, coinsurance and deductible), some plans include more than one of them.
- Some standard copay plans have deductibles as part of the plan design, though these are typically lower than those in so-called high-deductible plans.
- A high-deductible plan (HDHP) may have a much lower plan premium and larger deductible, typically includes a coinsurance phase after the deductible spend is reached, and often includes an out-of-pocket maximum amount for the year.
- Plans of all types may include a coinsurance payment for some higher-cost medicines, often called a specialty tier.
- List prices for drugs, which are used as the basis for calculating coinsurance or deductible claims, cause more patients to pay higher costs out-of-pocket through these various insurance mechanisms.
- Nearly all high-cost prescriptions are paid as part of coinsurance or deductible components of insurance plans.

Exhibit notes: For the purposes of this analysis, all claims have been assessed by the proportion of patient exposure and patient and payer initial pay amount. Deductible claims are defined as those where the patient would pay more than 50% of the claim, and the primary patient payment is >$250. Coinsurance claims are defined as those where the patient pays 5–25% of the cost with primary payment from $75–250, or where patient share is 5–50% and primary patient payment is >$75. Copay claims have been determined based on a primary patient copay less than $75.

Two-thirds of oral oncology prescriptions are zero cost to patients — a much higher proportion than in diabetes or for anticoagulants

Exhibit 12: Final Out-of-Pocket Cost Distribution for Brands in 2019 Across All Pay Types in Select Therapeutic Classes



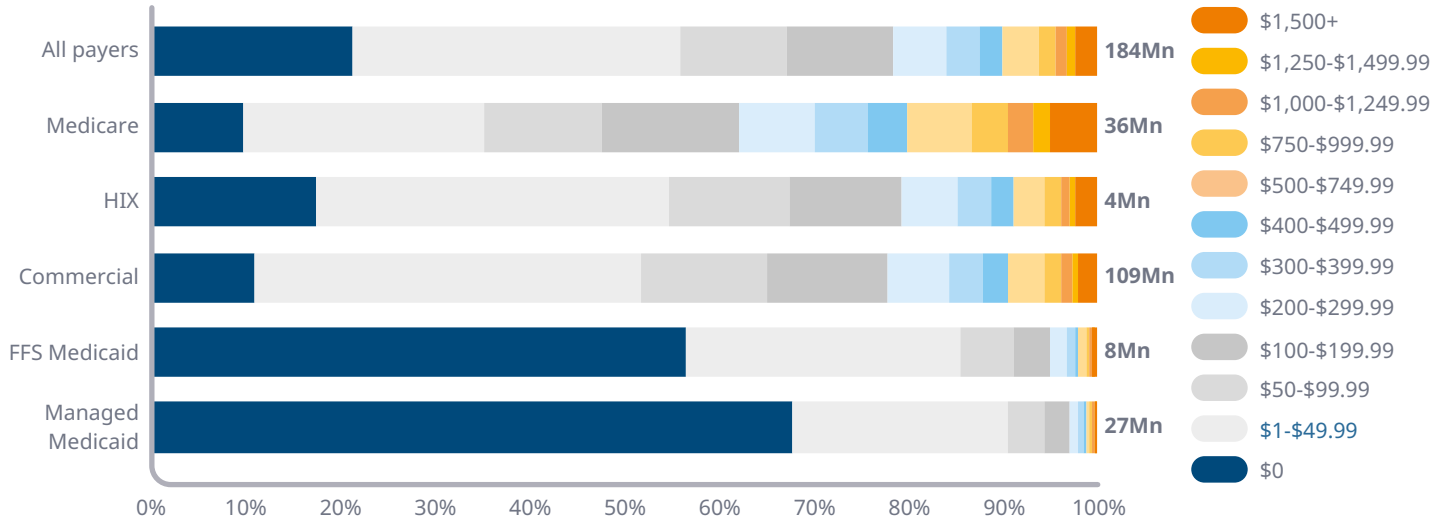
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- Diabetes, anticoagulants, and oral oncology medicines represent three therapeutic classes with quite different costs per drug, as well as varying dynamics per patient during the year.
- Oral oncology drugs include older medications taken over long-time periods, such as those taken to prevent recurrence of breast cancer, as well as more novel therapeutics, which are sometimes associated with substantial costs.
- The older therapies can qualify for zero-dollar copays under the ACA, while higher-cost medications often contribute to a patient reaching out-of-pocket maximums in a commercial plan and having zero out-of-pocket costs for that prescription.
- The range of costs in these classes suggest that some patients may have zero cost while others pay over $1000 for the same medicine, though this could happen to the same patient at different times of the year.
- All three of these therapeutic classes would result in significant worsening of clinical outcomes if patients were to forego treatment due to costs.

Exhibit notes: ACA = Affordable Care Act

Overall, 10% of patients reach annual out-of-pocket costs above $500 compared to 20% in Medicare in large part due to benefit design

Exhibit 13: Patients by Annual Prescription Out-of-Pocket Cost in 2019



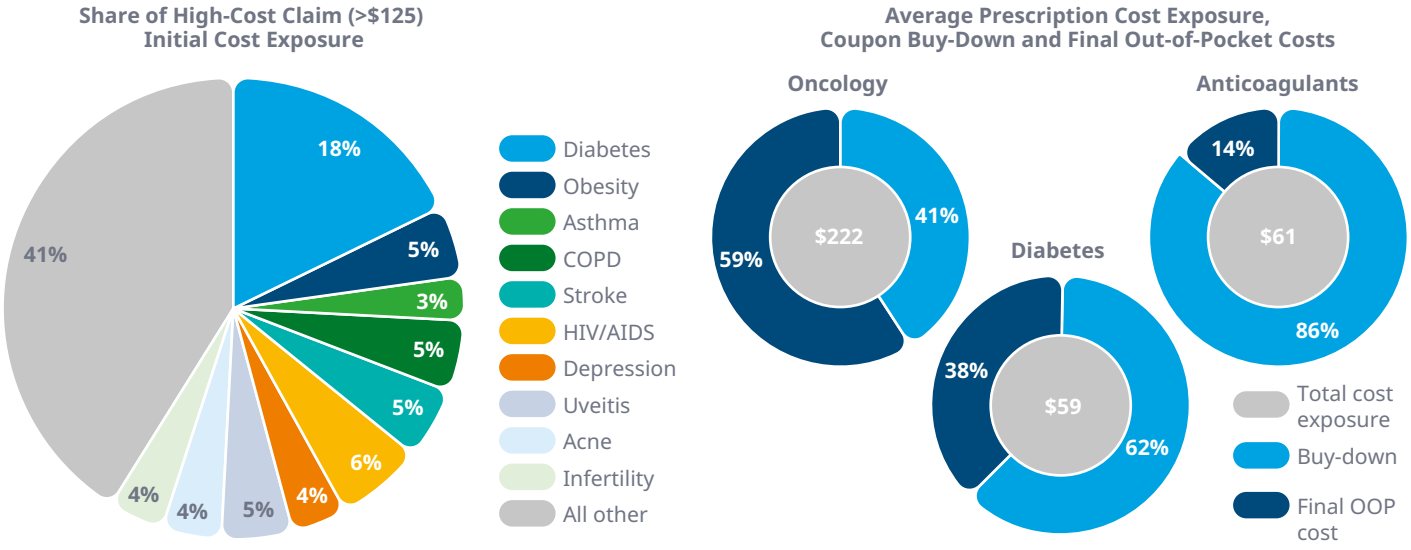
Source: IQVIA LAAD Sample Claims Data, Jan 2015–Dec 2019

- Across all pay types, 9.9% of patients pay more than $500 and 2.3% pay more than $1,500 out-of-pocket for prescriptions.
- In Medicaid, only 1.3% of patients pay more than $500 out-of-pocket for prescriptions, and only 0.3% pay more than $1500, and these most likely relate to patients on a different kind of insurance for part of the year.
- In Medicare, 20% of patients pay more than $500 out-of-pocket — the amount where cost-sharing starts for patients with standard coverage under Medicare Part D, and patients become responsible for 25% of costs. Five percent (5.0%) also pay more than $1,500.
- As a result, seniors have higher cost exposures than the commercially insured population.
- In commercial coverage, 9.4% of patients pay more than $500 and 2.0% pay more than $1,500.
- With the average deductible in commercial near $1,000 per year for an individual and Medicare Part D deductible at $185 per year, the cost exposure of Medicare Part D patients represents a potentially significant cost barrier to adherence.

Exhibit notes: Patients who filled at least one prescription in our sample were included. Patients were grouped into cohorts by mode pay type and costs aggregated in the year.

There are significant differences across therapy areas in the costs patients are exposed to and their final costs

Exhibit 14: High-Cost Claim Exposure and Elements of Cost Exposure by Therapeutic Class for Brands in Commercial Insurance in 2019



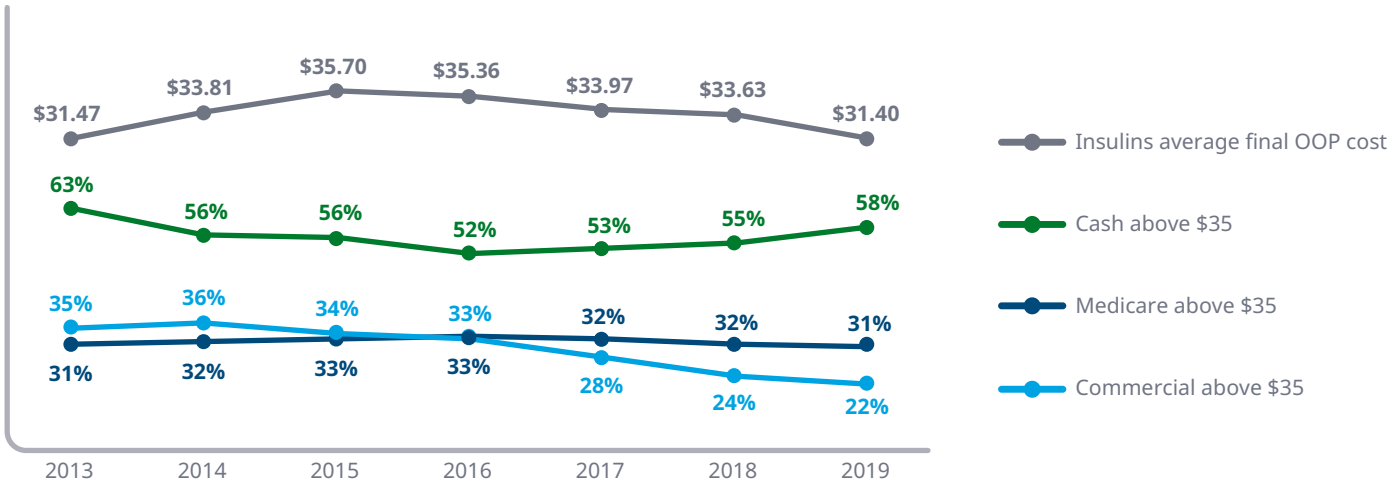
Source: IQVIA LAAD Sample Claims Data, 2019

- The therapeutic areas with the largest proportion of high cost claims include both specialty therapy areas, which may be covered with coinsurance in so-called "specialty tiers", and lifestyle products, which may not be covered by plans.
- Final out-of-pocket costs are reduced in several of these therapy areas through the use of coupons or if patients reach deductibles or out-of-pocket maximums.
- Patients with diabetes make up 18% of high-cost claims initial cost exposure, but only 5% of final out-of-pocket for high-cost claims. Average cost exposure is $59, also including a mix of benefit designs, with some patients exposed to the full cost of brands costing over $500 per month, and others exposed to fixed copays often less than $30. Coupons reduce patient costs to an average $23.
- Oral branded therapies in oncology — often newer therapies with significant overall prices — have an average cost exposure of $222, as some patients reach their deductibles and are exposed to lower costs afterwards.
- Final out-of-pocket costs for a month of oral oncology therapies — often life-extending medicines — average $130, with coupons off-setting an average of $92.
- In the anticoagulant market, several newer medicines in direct competition with each other offer coupons resulting in zero patient cost and average final out-of-pocket costs of just $9 in this market.
- The variations in patients' specific insurance plans, formularies, and the coupons offered for specific medicines make it exceedingly difficult for a patient to determine if they are getting the best possible price for their circumstance.

Exhibit notes: Includes paid claims only. Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volume comparison purposes.

Although insulin costs $31 on average, a significant percentage of these prescriptions cost more than the $35 cap proposed in new rules

Exhibit 15: Average Insulin Final Out-of-Pocket Costs Across All Payers in US$ and Percentage of Prescriptions by Pay Type with Final Out-of-Pocket Cost Above $35



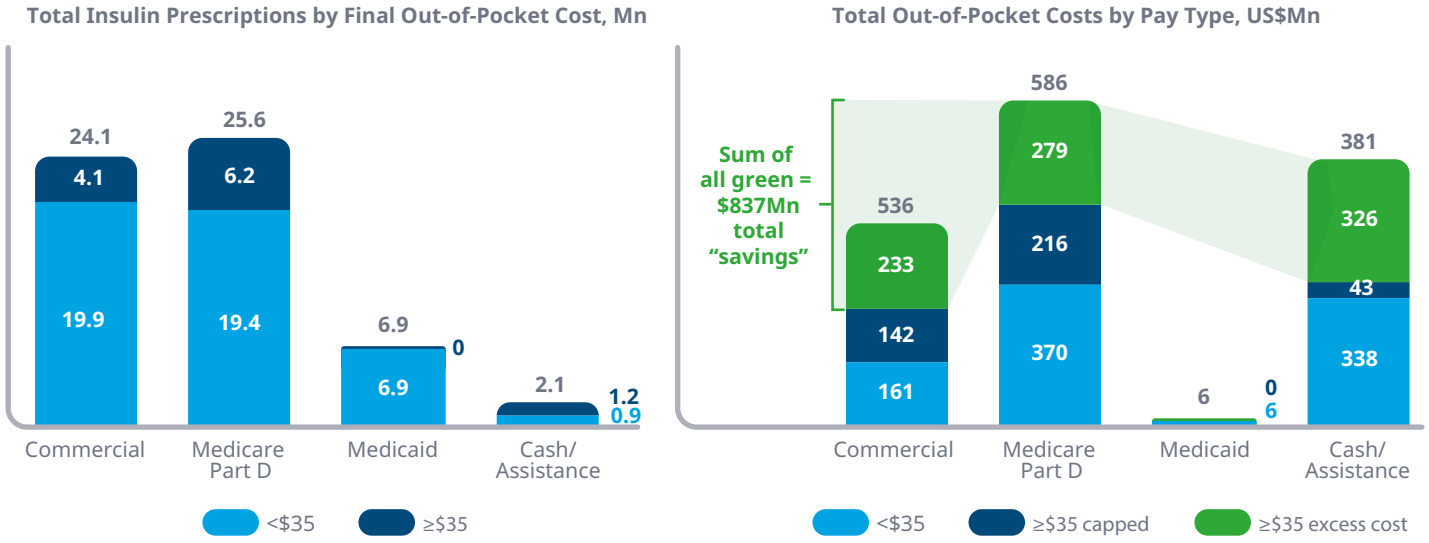
Source: IQVIA LAAD Sample Claims Data, Jan 2013–Dec 2019

- The average cost of insulin prescriptions in 2019 was $31.40, down from a peak of $35.70, but with significant differences across insurance types and individual patients.
- In total, 24% of prescriptions cost patients more than $35, and those higher-cost prescriptions averaged $106.78 in final out-of-pocket costs.
- Of prescriptions costing more than $35, 22% were in commercial plans, 31% in Medicare, and 58% in cash.
- This $35 per month threshold has been proposed for Medicare plans that offer the "Senior Savings Model" for their 2021 plan year, or some newly enacted state policy copay cap policies that would benefit Medicare and commercially insured patients in those states, but stop short of assisting the uninsured or cash-paying patients (see Exhibits 21 and 22).
- Only a subset of Medicare patients have higher out-of-pocket costs, as others are dual-eligible with Medicaid and receive Low income subsidies (LIS) or enroll in Medicare Advantage plans with lower copays or have Employer Group Waiver plans (EGWP), where they receive generous benefits in Part D after retirement.
- Because of issues and fragmentation affecting both commercial insurance and Medicare, some patients may have the cost of each insulin prescription capped but others may not save money having already reached their deductible or already having a lower out-of-pocket cost.

Exhibit notes: Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volume comparison purposes. Final out-of-pocket cost reflects the final patient responsibility after insurance and the use of coupons or other assistance for cash or commercial patients. Savings calculated as out-of-pocket cost minus $35 per prescription for prescriptions costing above $35. Savings could be offset in future if lower-cost prescriptions have higher costs.

Capping insulin costs at $35 per month could save Americans $837 million in prescription costs

Exhibit 16: Number of Insulin Prescriptions with Final Out-of-Pocket Cost Above and Below $35 in 2019 and Potential Savings if Costs Were Capped at $35 per Month, US$Mn



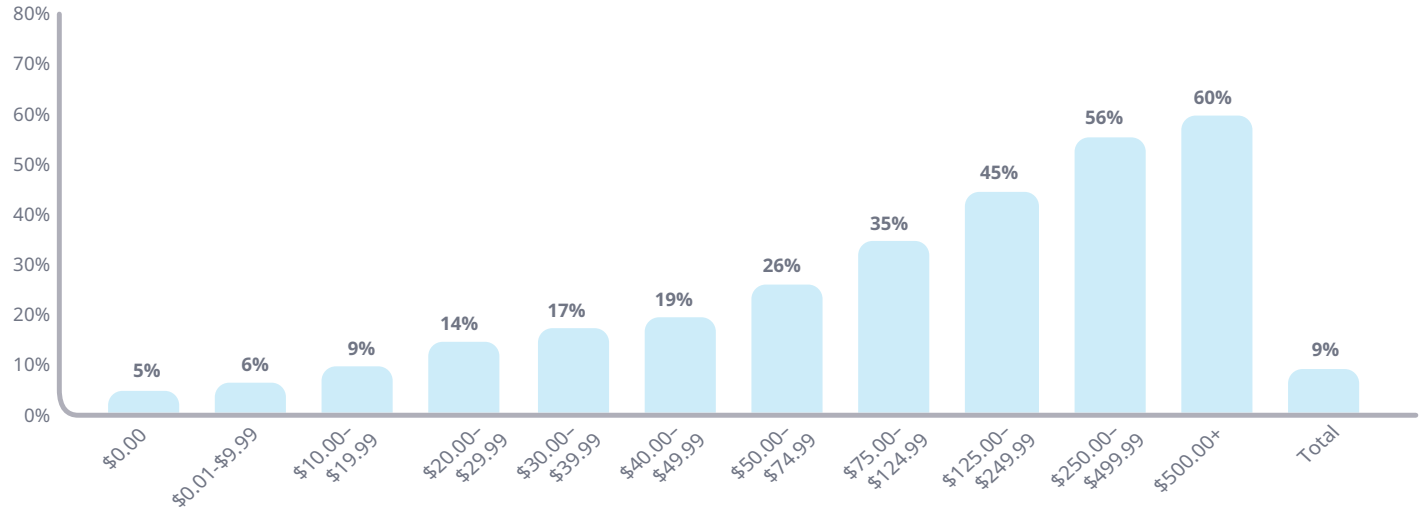
Source: IQVIA LAAD Sample Claims Data, Jan 2013–Dec 2019

- Total out-of-pocket costs paid by patients with insulin prescriptions amounted to $1.5 billion in 2019, and 82% of those costs are linked to the 24% of prescriptions that cost patients more than $35.
- Patients spent $532 million in commercial plans, $586 million in Medicare, and $381 million when paying cash for the respective 18.7 million, 20.2 million, and 2.1 million insulin prescriptions filled in 2019.
- For just those prescriptions above $35 in cost, patients paid $374 million dollars in commercial plans, $495 million in Medicare, and $369 million with cash.
- If those costs were reduced to $35 for all of those patients, they would save $837 million: $232 million in commercial plans, $279 million in Medicare, and $326 million for cash-paying patients (typically the uninsured). Per prescription savings would average $56 in commercial, $45 in Medicare, and $264 for cash.
- These savings do not reflect potential changes in the costs of lower-cost prescriptions or additional volume due to better adherence related to lower costs.
- Some lower-cost prescriptions are currently supported by manufacturer coupons, which would likely no longer be required. Notably, patients may not reach their deductibles as quickly if these lower costs are counted, and some may fail to realize savings on an annual basis as a result.

Exhibit notes: Values may not sum due to rounding. Prescriptions in retail pharmacies were adjusted to consistent 30-day prescription lengths for cost and volume comparison purposes. Final out-of-pocket cost reflects the final patient responsibility after insurance and the use of coupons or other assistance for cash or commercial patients. Savings calculated as out-of-pocket cost minus $35 per month for prescriptions costing above $35. Savings could be offset in future if lower-cost prescriptions have higher costs.

Patients starting new therapy abandon prescriptions at pharmacies with increasing frequency as prescription costs rise

Exhibit 17: 14-day Abandonment Share of New-to-Product Prescriptions by Final Out-of-Pocket Cost in 2019, All Payers, All Products



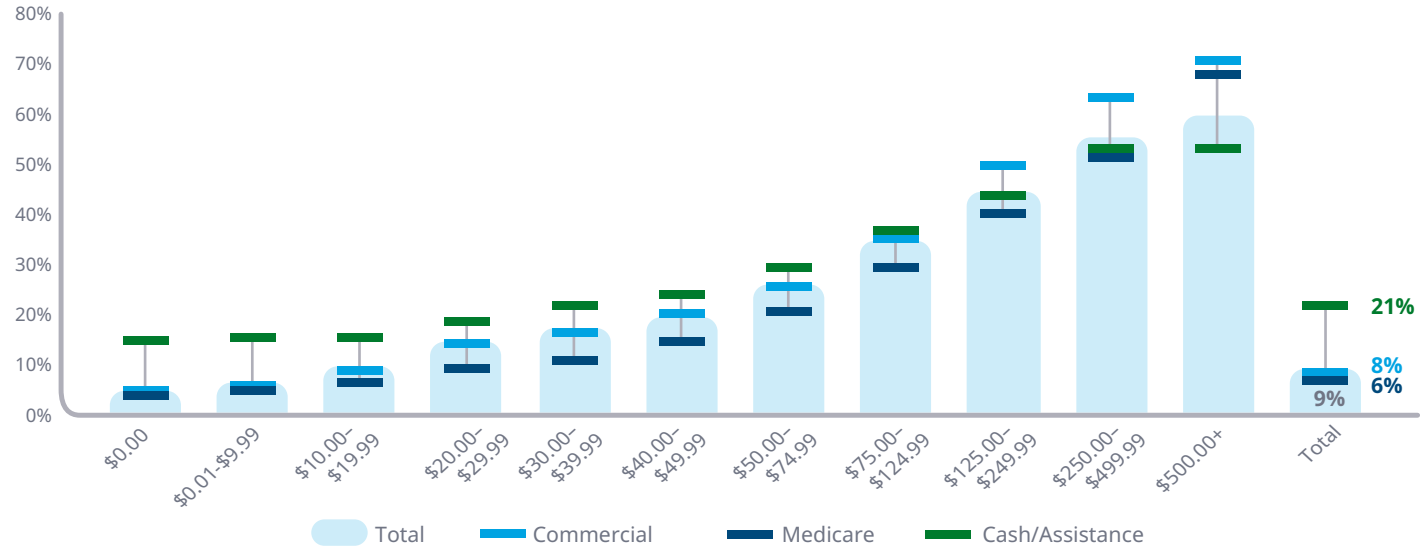
Source: IQVIA LAAD Sample Claims Data, Dec 2019

- The number of prescriptions written and transmitted to pharmacies by doctors, either by traditional paper, by phone or electronically, exceeds the number patients actually fill for a variety of reasons.
- Some patients choose not to fill a prescription if they don't agree with the doctor's advice or found it inconvenient to do so, but the more common reason is the cost of the prescription.
- Of prescriptions with a final cost above $500, 60% are not picked up by patients, as compared with 5% of patients who do not fill even when there is zero cost.
- The overall abandonment rate for all prescriptions across all pay types is 9%, primarily because over 90% of prescriptions are generic, and the costs are more typically less than $20 for those medicines.
- Many traditional insurance plans with a fixed copay design include brand copays of less than $30 for preferred products, with abandonment of 14% or less. This can be compared to a non-preferred brand copay of $75 with an abandonment of 26% or higher.
- Benefit designs that inherently expose patients to costs use this patient behavior relating to costs to encourage the use of lower-cost medicines, but can equally result in patients not taking necessary medicines.

Exhibit notes: New to product prescriptions are those where patients have not had a prescription for the specific brand or generic drug within the prior year. Pharmacies in the sample provide information on prescriptions which were prepared for dispensing and whether they were dispensed, with abandonment defined as the prescription in question not being dispensed to the patient within 14 days of the initial fill.

Abandonment rates for the commercially insured are generally higher than Medicare with some variability by prescription cost

Exhibit 18: 14-day Abandonment of New-to-Product Prescriptions By Pay Type and Final Out-of-pocket Cost in 2019, All Products



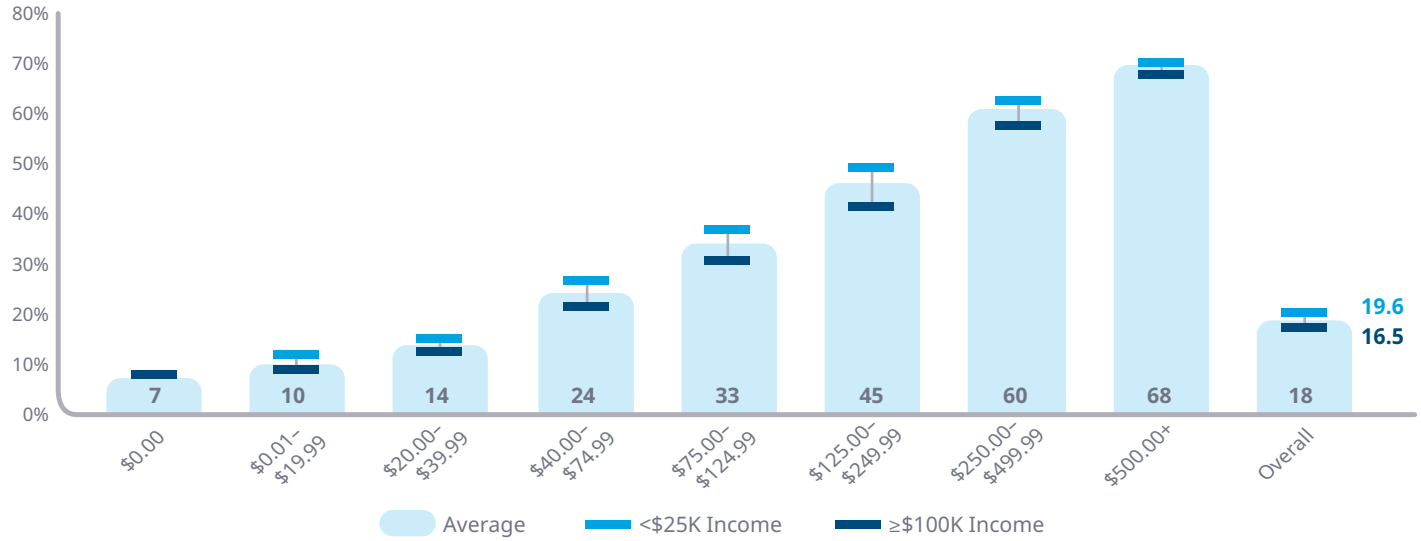
Source: IQVIA LAAD Sample Claims Data, Jan–Dec 2019

- The impact of rising costs on abandonment rates has differing levels of impact depending on the type of insurance or cost-sharing model employed.
- Medicare patients typically have the lowest abandonment, up to prescriptions costing $500. Though this insurance includes the standard Medicare benefit model with 25% coinsurance after a deductible up to a catastrophic coverage level with 5% coinsurance, it also includes low-income subsidies, Medicare Advantage and employer retiree coverage — all with lower copays.
- Cash patients generally receive no support with their costs and have the highest abandonment up to $125, at which point the number of prescriptions they receive diminishes and the rate they abandon them also becomes less than other insurance types.
- Although, across all pay types, abandonment occurs with 9% of prescriptions, cash patients abandon 21% of their prescriptions, while commercial insurance abandon 8%, and Medicare 6%.
- Commercial insurance includes several benefit types, including the traditional fixed-copay model, which rarely includes costs above $70. Increasingly, plans have higher coinsurance tiers for specialty medicines, and most plans have some form of deductible, exposing patients to costs based on list prices for some of their prescriptions.
- Commercially insured patients can legally use coupons to offset their costs, and do so for 16% of their brand prescriptions. However, they are not offered for all products, and many have eligibility rules that limit the amount of value per prescription or annually for a patient.
- High deductible health plans (HDHP) offered by employers, along with health insurance exchanges (HIX), are based on exposure to list prices. Notably, these plans result in greater abandonment than other insurance types once costs reach $125 — presumably once patients could not use a coupon.

Exhibit notes: New to product prescriptions are those where patients have not had a prescription for the specific brand or generic drug within the prior year. Pharmacies in the sample provide information on prescriptions which were prepared for dispensing and whether they were dispensed, with abandonment defined as the prescription in question not being dispensed to the patient within 14 days of the initial fill.

Abandonment rates average 18% across three common therapeutic classes and slightly higher for people with incomes below $25k/year

Exhibit 19: 14-day Abandonment of New-to-Product Branded Prescriptions for Diabetes, Anticoagulants, and Oral Oncology by Household Income and Prescription Cost, 2019



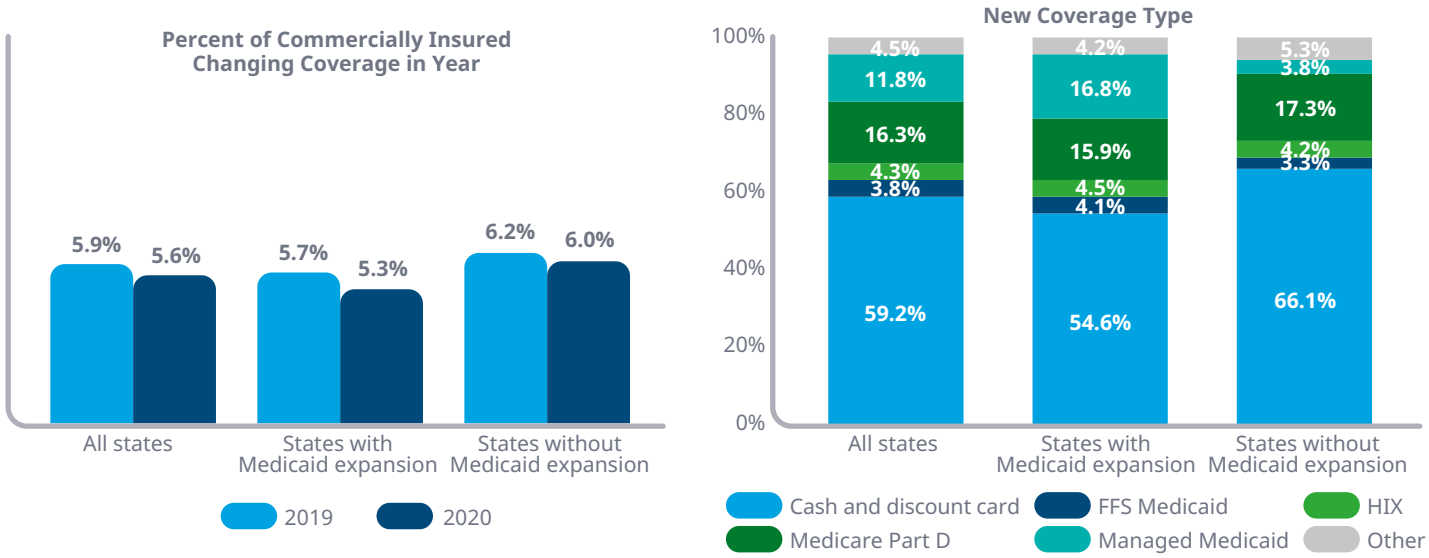
Source: IQVIA LAAD Sample Claims Data, and Experian Patient-level Wealth Data, Jan–Dec 2019, limited to brands in the anticoagulant, diabetes, and oral oncology markets

- Affordability of medicines inherently varies based on the financial resources of a patient. However, it is noteworthy that the abandonment rates for higher-income patients are only slightly lower than for the lowest income patients.
- Across three common therapeutic classes —diabetes, anticoagulants and oral oncology — abandonment is often quite similar overall and does not vary substantially by income.
- At 18.0%, abandonment across these three therapeutic classes is twice as high as the overall market, with low income patients abandoning 19.6% of new prescriptions and higher income patients abandoning 16.5%.
- While these three therapeutic classes are clearly medically necessary, and patients are likely motivated to seek and take treatment, financial considerations are much less a driver of behavior for individuals than the general behavior all patients have to react to higher cost medications.
- Notably, patients of all income levels have relatively similar abandonment of around 7% across these three therapeutic classes when prescriptions have no cost, which is slightly higher than the 5% on the overall market (see Exhibit 17).
- One important limitation of abandonment rates as a proxy for the impact of costs on patients, is that they do not reflect patients who do not go to the doctor and thus do not first receive a prescription. Therefore, it is likely that further patients are not receiving the prescriptions they need.

Exhibit notes: Household income data has been anonymized and then linked to patients' anonymized prescription data, see Methodology for details.

Few commercially insured patients have lost coverage to date, and fewer than in 2019, but more could be at risk as COVID-19 continues

Exhibit 20: Percentage of Patients that Changed from Commercial (non-HIX) Insurance to New Coverage and New Coverage Type



Source: IQVIA MAAS COVID-19 Coverage Change Tracker, June 12, 2020

- While coverage changes have been expected due to the unprecedented increase in unemployment since March, the fullest impact of COVID-19-driven unemployment has not yet been felt in changes to patients' coverage.
- Only 5.6% of commercially insured patients had a change in the way they paid for medicines to date — less than the 5.9% in the same period in 2019.
- Of those who have changed coverage, the most common change has affected use of cash discount cards, typically provided by an independent company, a pharmacy or a drug manufacturer.
- This shift to use cash or discount cards is even more pronounced in states that did not expand Medicaid eligibility through the ACA, and conversely, those that did expand eligibility have seen 16.8% of the patients that changed coverage move into Medicaid.
- As states manage the budget impacts of COVID-19, and the eventual recovery, states that expanded Medicaid can expect a greater degree of Medicaid enrollment if job losses continue for a sustained period.
- Some employers have publicly indicated their intention to maintain coverage for several months. But should this come to an end, larger portions of those with commercial insurance can be expected to shift to HIX or Medicaid, and some who choose to retire may switch to Medicare.
- As cash payments typically have higher out-of-pocket costs, patient affordability will be challenged and their dependence on coupons and discount cards will be a critical element over the coming months.

Exhibit notes: Pre-COVID-19 timeframe was 1/1/2020–3/15/2020 compared to 3/16/2020–6/12/2020 to identify changes in coverage. Only patients with at least one filled prescription in the pre- and post- periods were included.

A number of recent Federal policies target patient affordability, particularly in diabetes

Exhibit 21: Federal Policies Expected to Impact Affordability and Prices in 2020 and Beyond

IRS rule

Allowing copay reductions in high deductible plans

Senior Savings Model

Med D 2021 Plan designs with a $35 monthly copay cap for insulins

International price index

Price reductions in Medicare based on prices in other countries

Rebate passthrough

Rules governing PBM-received rebates aimed to reduce patient out-of-pocket costs

Lifesaving medicines

Penny pricing for insulins and injectable epinephrine to be passed through from purchasing entities to patients, including uninsured and those facing affordability challenges

Drug importation

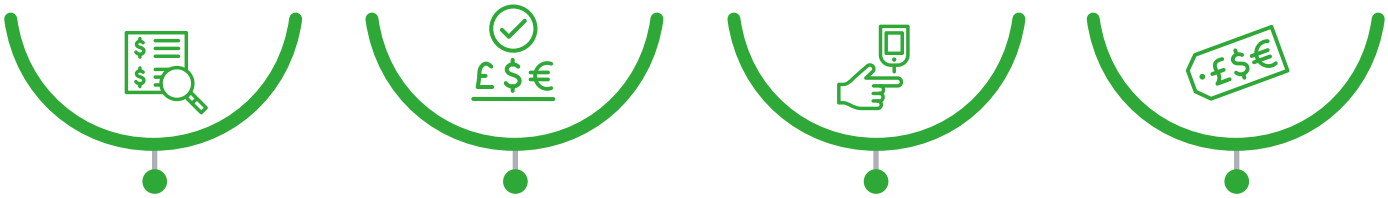
Allowing drug reimportation from other countries where prices may be lower

Source: IQVIA Institute, Jul 2020

- The changed IRS rule governing high-deductible plans with Health Savings Accounts (HDHP/HSA) expands the range of therapies that are considered preventive (adding diabetes and hypertension among others) and allows lower out-of-pocket costs during deductibles for beneficiaries of those plans in 2021 and beyond.
- The new CMS Senior Savings Model announced in March 2020 would cap insulin copays at $35 per month supply for participating Medicare Part D plans in 2021.
- In executive orders announced July 24th, the administration laid out policies with wide-ranging impacts on drug pricing, while the specific provisions and impacts of the policies remain unclear.
- One order laid out an international price index that benchmarks U.S. prices to those in other developed markets, with implementation and details pending negotiation with drug makers.
- The order eliminating the safe harbor for drug rebates requires that rebates be passed to consumers at the point-of-sale rather than being used at the discretion of pharmacy benefit managers (PBMs), but can only take effect if deemed not to increase Medicare premiums, the deficit, or patients' total out-of-pocket costs. It therefore may be difficult to implement as prior versions of this proposal were deemed to have those effects.
- Lifesaving medicines such as insulin and epinephrine are often purchased at 'penny-pricing' by federally qualified health centers (FQHC) through the 340b program, which would be required to offer patients access to these drugs at acquisition costs and open up eligibility to the uninsured and those patients facing an unaffordable deductible — potentially millions of Americans.
- Drug reimportation programs to obtain drug from other countries via city, state, native-American tribe or individual actions, would enable access to lower cost medicines, though it remains unclear if there are sufficient supplies in source countries to satisfy demand.

Thirty-six states have passed or are actively advancing legislation on four areas relating to drug pricing

Exhibit 22: State Policies Expected to Impact Affordability and Prices in 2020 and Beyond



Financial Transparency

17 states enacted

- Require advance notice and/or justification of price increases
- Report information on development and manufacturing costs and prices
- Require PBMs to disclose manufacturer rebates

Copay Caps

18 states enacted

- Limits on monthly out-of-pocket costs
- Limit patient cost obligation to retail price if less than plan defined-copay/coinsurance

Insulin Copay Caps

10 states enacted
(11 progressing)

- Limits on monthly insulin copays with states ranging from $25 to $100 per month
- All enacted policies except in Minnesota cover commercial plans regulated by states, some go beyond
- Minnesota covers uninsured and underinsured at max $50 for 90 day supply

Anti-Price Gouging

2 states passed
(10 progressing)

- Legislation providing jurisdiction for states to sue manufacturers for "unconscionable" price increases, ones that are not justified by the costs of making or distributing the drug

Source: IQVIA Institute, Jul 2020

- Federal drug pricing reforms in the past two years have broadly focused on rule changes to Medicare via executive authority, which are possible without new legislation. However, the most high-profile proposals from early 2019 have largely failed to be finalized, and states have been pursuing policies independently.
- Since 2015, 36 states have either enacted, or are actively advancing, legislation to address one or more of four key pricing policy areas: transparency, copay caps — both generally and for insulins specifically — and anti price-gouging policies to prevent sharp increases.
- New York has enacted policies in all four categories while Colorado, Illinois, Louisiana, Maryland, Maine, New Jersey, Vermont, Washington, and West Virginia have each enacted or are currently advancing policies in three of the areas.
- Regardless of the characteristics of the various state policies, it is unclear if any of them could have a material impact on prices because existing state and federal regulations limit the powers of states.
- Additionally, transparency and anti-price gouging laws are often narrowly focused on generics or essential medicines that have the most obvious excess price levels or increases.
- Furthermore, narrowly-focused regulations affecting one type of drug or therapy area do not account for plan designs with deductibles that manage patient cost exposure for the entire year. As a result, some patients may see no impact of the policies, while others not directly impacted by the regulations may see their premiums rise.
- A September 2019 Gallup Poll revealed that more than 20% of patients reported not having enough money to pay for needed medicine — more than double the 9% overall average abandonment rate — and this suggests that lack of affordability may be driving underlying cost pressures and may not be solely related to high-cost medicines.

Exhibit notes: Gallup-West Health National Healthcare Study, Sept 16-30, 2019, N=1,099.

Appendix

Exhibit 23: Top Therapeutic Classes by Descriptions

	DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Total U.S. Market		**4,237**	**4,213**	**4,218**
1	Antihypertensives	680	674	663
2	Mental health	381	387	395
3	Pain	424	400	388
4	Nervous system disorders	371	367	365
5	Antibacterials	258	247	248
6	Lipid regulators	250	249	246
7	Antidiabetics	214	214	216
8	Respiratory agents	170	172	176
9	Anti-ulcerants	163	160	159
10	Thyroid preparations	130	128	126
11	Dermatologics	101	105	110
12	ADHD	90	91	94
13	Anticoagulants	79	80	80
14	Hormonal contraception	86	81	77
15	Corticosteroids	72	72	76
16	Vitamins & minerals	72	70	69
17	GI products	61	63	57
18	Vaccines	34	46	54
19	Other cardiovasculars	45	45	46
20	Benign prostatic hypertrophy	43	44	45

Source: IQVIA National Prescription Audit, Jul 2020

Notes: Therapeutic classes are based on proprietary IQVIA definitions. Includes prescription-bound products including insulins dispensed through chain and independent pharmacies, food store pharmacies, mail service pharmacies, and long-term care facilities. Excludes OTC products. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates. Prescriptions are not adjusted for length of therapy; 90-day and 30-day prescriptions are both counted as one prescription.

APPENDIX

Exhibit 24: Top Therapeutic Classes by Non-Discounted Spending

	NON-DISCOUNTED SPENDING US$BN	2015	2016	2017	2018	2019
Total U.S. Market		**426.7**	**446.4**	**455.0**	**483.8**	**511.4**
1	Oncologics	39.1	45.1	50.2	58.5	67.5
2	Antidiabetics	43.6	49.7	54.2	60.7	66.7
3	Immunology	31.2	38.9	46.6	55.1	66.3
4	Respiratory agents	23.7	25.6	27.0	29.3	29.7
5	HIV antivirals	16.1	18.7	20.6	22.6	24.4
6	Anticoagulants	9.9	12.1	14.2	17.1	20.5
7	CNS & others	16.8	18.9	20.5	22.2	20.1
8	Multiple sclerosis	17.5	17.7	18.8	18.8	18.7
9	Mental health	19.7	17.0	15.9	16.6	16.9
10	Pain	20.3	19.7	17.4	16.2	16.0
11	Vaccines (pure, comb, other)	10.2	10.6	10.5	11.8	13.8
12	Other cardiovasculars	7.4	8.3	9.4	10.7	10.1
13	ADHD	11.2	11.0	9.9	9.3	8.9
14	GI products	7.1	8.0	8.4	8.7	8.8
15	Dermatologics	10.7	11.1	9.5	8.7	7.8
16	Antihypertensives, plain & combo	10.3	9.5	7.5	7.1	7.8
17	Viral hepatitis	18.8	14.9	10.8	7.5	6.1
18	Ophthalmology, general	4.9	5.0	5.4	5.4	5.7
19	Hormonal contraception, systemic and topical	5.4	5.4	5.6	5.5	5.5
20	Sex hormones (androgens, oestrogens, progestogens)	6.4	6.4	6.3	6.2	5.4

Source: IQVIA National Sales Perspectives, Jul 2020

Notes: Therapeutic classes are based on proprietary IQVIA definitions. Includes prescription and insulin products sold into chain and independent pharmacies, food store pharmacies, mail service pharmacies, long-term care facilities, hospitals, clinics, and other institutional settings. Excludes OTC. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates.

APPENDIX

Exhibit 25: Top Medicines by Prescription

	DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Total U.S. Market		**4,237**	**4,213**	**4,218**
1	atorvastatin	109	114	118
2	levothyroxine	117	115	113
3	lisinopril	101	98	96
4	amlodipine	85	87	89
5	metoprolol	86	87	85
6	metformin	83	81	80
7	gabapentin	65	67	69
8	albuterol	65	66	67
9	omeprazole	69	66	64
10	acetaminophen/hydrocodone	79	68	61
11	losartan	49	54	57
12	amoxicillin	56	55	55
13	sertraline	48	49	51
14	prednisone	44	44	47
15	hydrochlorothiazide	46	45	46
16	fluticasone	43	44	45
17	furosemide	44	43	42
18	ibuprofen	41	42	42
19	pantoprazole	37	39	41
20	montelukast	38	40	41

Source: IQVIA National Prescription Audit, Jul 2020

Notes: Includes prescriptions and insulins dispensed through chain and independent pharmacies, food store pharmacies, mail service pharmacies, and long-term care facilities. Excludes OTC. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates. Prescriptions are not adjusted for length of therapy; 90-day and 30-day prescriptions are both counted as one prescription. Table shows leading active-ingredients or fixed combinations of ingredients and includes both branded and generic products.

APPENDIX

Exhibit 26: Top Medicines by Non-Discounted Spending

	NON-DISCOUNTED SPENDING US$BN	2015	2016	2017	2018	2019
Total U.S. Market		**426.7**	**446.4**	**455.0**	**483.8**	**511.4**
1	Humira	10.1	13.5	16.3	18.4	21.4
2	Eliquis	1.6	3.0	4.6	7.1	9.9
3	Enbrel	7.2	7.6	7.9	8.0	8.1
4	Stelara	2.0	2.6	3.7	5.0	6.6
5	Keytruda	0.4	0.7	2.2	4.3	6.5
6	Trulicity	0.3	1.2	2.7	4.5	6.5
7	Januvia	4.1	4.7	5.0	5.7	6.0
8	Xarelto	2.8	3.5	4.3	5.2	6.0
9	Biktarvy	–	–	–	1.3	5.1
10	Remicade	5.0	5.3	5.5	5.3	4.7
11	Opdivo	0.8	2.7	3.1	4.2	4.4
12	Rituxan	3.7	3.9	4.0	4.3	4.3
13	Lantus Solostar	5.8	5.5	4.8	4.3	4.3
14	Symbicort	2.7	3.0	3.1	3.5	3.9
15	Jardiance	0.3	0.6	1.4	2.2	3.9
16	Genvoya	0.0	1.6	3.6	4.5	3.8
17	Tecfidera	3.5	3.4	3.6	3.5	3.8
18	Vyvanse	2.6	3.0	3.3	3.6	3.7
19	Victoza 3-Pak	2.0	2.4	2.9	3.5	3.6
20	Ibrance	0.7	2.1	2.9	3.2	3.6

Source: IQVIA National Sales Perspectives, Jul 2020

Notes: Spending is based on IQVIA National Sales Perspectives and is not adjusted for estimates of off-invoice discounts and rebates. Includes prescription and insulin products sold into chain and independent pharmacies, food store pharmacies, mail service pharmacies, long-term care facilities, hospitals, clinics, and other institutional settings. Excludes OTC. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates. Copaxone includes both 20mg and 40mg strengths.

Exhibit 27: Dispensing Location by Non-Discounted Spending

NON-DISCOUNTED SPENDING US$BN	2015	2016	2017	2018	2019
Total U.S. Market	**426.7**	**446.4**	**455.0**	**483.8**	**511.4**
Retail and mail	306.7	322.0	322.9	337.6	354.4
Chain stores	131.1	138.4	135.4	140.0	144.1
Mail service	98.6	105.8	111.6	121.4	132.5
Independent	48.2	49.8	49.6	50.2	50.3
Food stores	28.9	28.0	26.3	25.9	27.5
Non-retail	118.8	123.2	130.8	145.0	155.6
Clinics	57.2	64.1	71.3	81.2	91.0
Non-federal hospitals	33.5	34.3	34.2	36.6	37.2
Long-term care	16.6	16.5	16.6	16.7	15.8
HMO	4.9	1.7	1.9	2.0	2.2
Home health care	3.9	3.8	4.2	5.7	6.6
Federal facilities	2.7	2.8	2.7	2.8	2.9
Miscellaneous	1.2	1.3	1.4	1.3	1.3

Source: IQVIA National Sales Perspectives, Jul 2020
Notes: Spending is based on IQVIA National Sales Perspectives and is not adjusted for estimates of off-invoice discounts and rebates. Includes prescription-bound products including insulin products and excluding other products such as OTC. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates.

APPENDIX

Exhibit 28: Prescriptions by Location Unadjusted Prescription Length

DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Total U.S. Market	**4,236.7**	**4,213.3**	**4,217.8**
Retail and mail	3,848.1	3,818.1	3,813.4
Chain stores	2,397.2	2,370.3	2,340.3
Mail service	211.6	213.7	205.6
Independent	706.8	702.8	705.9
Food stores	532.5	531.4	561.6
Non-retail	388.6	395.1	404.5
Long-term care	388.6	395.1	404.5

Source: IQVIA National Prescription Audit, IQVIA Institute, Jul 2020

Exhibit 29: Prescriptions by Location Adjusted for Prescription Length

DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Total U.S. Market	**6,023.3**	**6,201.9**	**6,414.3**
Retail and mail	5,470.8	5,620.3	5,800.1
Chain stores	3,408.1	3,489.1	3,559.5
Mail service	300.8	314.6	312.7
Independent	1,004.8	1,034.5	1,073.7
Food stores	757.0	782.2	854.2
Non-retail	552.5	581.6	615.2
Long-term care	552.5	581.6	615.2

Source: IQVIA National Prescription Audit, National Sales Perspectives, Jul 2020
Notes: Prescription counts are adjusted for length of prescriptions and re-aggregated. Prescriptions referred to as 90-day are calculated based on transactions with 84 days supply or more to include medicines with up to one week fewer treatment days. Prescriptions for 84 days supply or more or factored by three, and those under 84 days unchanged.

APPENDIX

Exhibit 30: Dispensing by Payment Type for Retail Prescriptions

DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Retail prescriptions	3,848.1	3,818.1	3,813.4
Commercial third party	50.8%	50.9%	51.6%
Medicare Part D	27.5%	27.6%	27.4%
Medicaid	16.4%	16.4%	16.1%
Cash	5.4%	5.1%	4.9%

Source: IQVIA National Prescription Audit, US SMART, Managed Care, Apr 2020
Notes: Report reflects prescription-bound products including insulins and excluding other products such as OTC. Medicaid includes both Fee for Service and Managed Medicaid.

Exhibit 31: Non-Discounted Spending and Dispensing by Product Type

NON-DISCOUNTED SPENDING US$BN	2015	2016	2017	2018	2019
Total U.S. Market	**426.7**	**446.4**	**455.0**	**483.8**	**511.4**
Branded	73.7%	74.6%	76.7%	78.6%	80.0%
Unbranded generic	16.2%	15.1%	13.2%	11.7%	11.2%
Branded generic	10.2%	10.3%	10.1%	9.7%	8.8%

DISPENSED PRESCRIPTIONS MN	2017	2018	2019
Total U.S. Market	**4,236.7**	**4,213.3**	**4,217.8**
Branded	10.0%	10.1%	9.8%
Unbranded generic	85.2%	85.4%	86.2%
Branded generic	4.7%	4.4%	3.8%

Source: IQVIA National Prescription Audit, National Sales Perspectives, Jul 2020
Notes: Includes prescriptions and insulins dispensed by chain and independent pharmacies, food store pharmacies, mail service pharmacies, and long-term care facilities. Spending figures also include sales into hospitals, clinics, and other institutional settings. IQVIA routinely updates its national audits, which may result in changes to previously reported market size and growth rates

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW

The trends presented reflect U.S. activities only.

NATIONAL SALES PERSPECTIVES (NSP)™
measures revenue within the U.S. pharmaceutical market by pharmacies, clinics, hospitals, and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. The prices do not reflect off-invoice price concessions that reduce the net amount received by manufacturers.

IQVIA'S NATIONAL PRESCRIPTION AUDIT (NPA
NPA is the industry standard source of national prescription activity for all pharmaceutical products. It measures demand for prescription drugs, including dispensed pharmaceuticals to consumers across three unique channels: retail, mail service, and long-term care pharmacies. From sample pharmacies, IQVIA collects new and refilled prescription data daily. NPA represents and captures over 92% of all outpatient prescription activity in the United States and covers all products, classes, and manufacturers.

IQVIA'S NATIONAL PRESCRIPTION AUDIT: NEW TO BRAND (NPA NTB)
NPA New to Brand provides enhanced visibility into the volume of a patient's true, first-time use of a brand versus continued therapies. IQVIA's longitudinal data allows users to analyze new therapy starts, switched to/add-on products, as well as continued therapies. In addition to reporting the new or refill information from a prescription, the therapy history for the patient is taken into account in order to categorize that prescription. New to Brand Rx (NBRx) = New Therapy Start Rx + Switch/Add-On Rx.

IQVIA'S LONGITUDINAL PRESCRIPTION DATA
IQVIA receives nearly four billion prescription claims per year with history from January 2006, and covers over 90% of the retail channel, 60–85% of mail service, and 75– 80% of long-term care. Longitudinal data derives from electronic data received from pharmacies, payers, software providers and transactional clearinghouses. This information represents activities that take place during the prescription transaction and contains information regarding the product, provider, payer, and geography. Rx data is longitudinally linked back to an anonymous patient token and is linkable to events within the data set itself and across other patient data assets.

Definitions

Cost exposure is the price a patient faces when presenting a prescription to be filled, prior to the application of benefit design or coupons which can contribute to lower final out-of-pocket costs.

Final out-of-pocket costs are the observed patient costs for their prescriptions after applying benefit design rules at the point of sale and applying coupons presented by the patient, and are normalized to 30-day prescription lengths.

Gross sales are defined as sales volumes reported at wholesaler acquisition cost (WAC).

Invoice sales are defined as sales volumes reported at the invoice prices between wholesalers and their customers as reported in IQVIA National Sales Perspectives.

Manufacturer Net Revenues are defined as the net amount of revenue received by a manufacturer after deducting off-invoice discounts, rebates or coupons paid to other market participants including payers, pharmacies, wholesalers or patients.

Methodology

HOUSEHOLD INCOME
Household income along with other metrics are sourced from Experian, a credit reporting agency, which anonymizes individuals' data using an IQVIA proprietary token methodology that then allows IQVIA's anonymous patient prescription claim records to be linked to household income data.

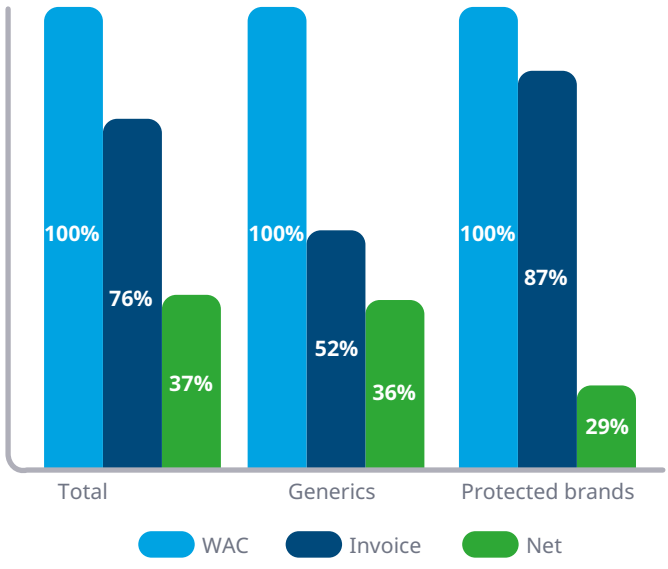
DIAGNOSIS ELIGIBILITY FOR AFFORDABILITY ANALYSES
Eligibility is granted on a year-by-year basis so patients can fall in and out of cohorts based on their activity and prescription history. Patients must have at least two diagnoses of interest during the five year study period to be considered for inclusion, and at least one related prescription per year to be included in each yearly cohort.

DISPENSED PRESCRIPTIONS ADJUSTED FOR 90-DAY PRESCRIPTIONS (METHOD USED IN APPENDIX TABLES)
Prescriptions with >84 days supply to the patient are assumed to represent a three-month prescription, and all other prescriptions are assumed to represent a one-month prescription. Three-month prescriptions are factored by three to normalize prescriptions to one-month durations.

ESTIMATES OF NET MANUFACTURER REVENUE AND PRICES
IQVIA audits reflect invoice-based pricing derived from proprietary information gathered from wholesalers and company direct sales. While IQVIA invoice prices reflect supply-chain price concessions, they do not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants. Estimated net prices and revenue are projected from a sample of large and mid-sized companies analyzed from 2011–2019. Branded products are included in the sample if their net sales amount is disclosed in financial filings with the Securities and Exchange Commission (SEC) and if the volume of sales captured in IQVIA audits is consistent with information provided directly by manufacturers in support of IQVIA proprietary datasets. Net prices are calculated by dividing publicly reported net sales values by volumes for the same products reported to IQVIA. Estimated brand net price growth for the total market is projected from the analysis sample to the total market. Net prices represent an estimate of the average manufacturer realized price, reflecting any reductions in net revenues due to off-invoice discounts, rebates, copay assistance or other price concessions, and do not necessarily reflect the net costs paid by insurers, the federal government, or patients, which all vary significantly and independently. For generic companies, a sample of five large generic companies' generic portfolios were analyzed in aggregate consistent with their SEC filings, as specific generic product analyses are not possible. See Medicine Use and Spending in the United States, April 2019 for more details.

The IQVIA "net sales adjustment" analysis is based on ex-manufacturer invoice sale prices, which are lower than wholesaler acquisition cost (WAC). In Diabetes, invoice is 48–49% below WAC, and net manufacturer revenues in diabetes are 67% lower for protected brands, 30% for generics, and 51% overall. In the market overall, invoice prices are 24% below WAC, with net prices 63% below that list price (see Exhibit 32).

Exhibit 32: WAC, Invoice and Net Prices, 2019



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Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decisionmakers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

Michael Kleinrock serves as research director for the IQVIA Institute for Human Data Science, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of human data science in healthcare in the United States and globally. Kleinrock leads the research development included in Institute reports published throughout the year. The research is focused on advancing the understanding of healthcare and the complex systems and markets around the world that deliver it. Throughout his tenure at IMS Health, which began in 1999, he has held roles in customer service, marketing, product management, and in 2006 joined the Market Insights team, which is now the IQVIA Institute for Human Data Science. He holds a B.A. degree in History and Political Science from the University of Essex, Colchester, UK, and an M.A. in Journalism and Radio Production from Goldsmiths College, University of London, UK.

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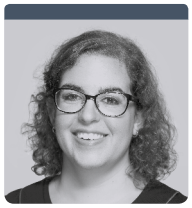
Gina Campanelli is an Associate Consultant with the U.S. Market Access Strategy Consulting division of IQVIA, driving analytical capabilities and strategic insights on client engagements. Using her expertise in longitudinal claims data and patient analytics, Gina has investigated health policy changes in both Medicare Parts B and D with a focus on patient access and manufacturer margin. She has extensive experience in analyzing and optimizing patient savings programs that bridge patient access with affordability. Prior to her time at IQVIA, Gina worked in clinical research and patient care in the rheumatology space. Gina holds a B.A. in Art History from Dartmouth College.



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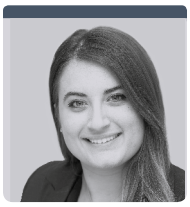
Marcella Vokey leads thought leadership initiatives for IQVIA's U.S. Market Access Strategy Consulting team with a focus on trends and strategy for biopharmaceutical manufacturers. Marcella joined IQVIA in 2013 as a consultant, developing evidence-based insights for payer contracting, salesforce, and patient assistance strategy. She has more than nine years of experience in patient longitudinal data, payer managed markets, health policy and stakeholder incentives. Marcella holds a B.S. in Political Science from the Massachusetts Institute of Technology.



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Claudia Tawil serves as an Associate Consultant for the U.S. Market Access Strategy Consulting division of IQVIA, leading analytics for an array of client engagements around patient access to pharmaceuticals. She has conducted in-depth assessments of patient savings programs, including commercial copay card optimizations, voucher and denial conversion program evaluations, and copay accumulator and maximizer impact assessments. Prior to her time at IQVIA, Claudia interacted with various stakeholders in the healthcare sector and pharmaceutical supply chain through health policy research, ranging from the global impact of intellectual property law on pharmaceutical trade to the domestic impact of opioid dependence and abuse. Claudia holds a Bachelor of Science in Global Health from Georgetown University.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

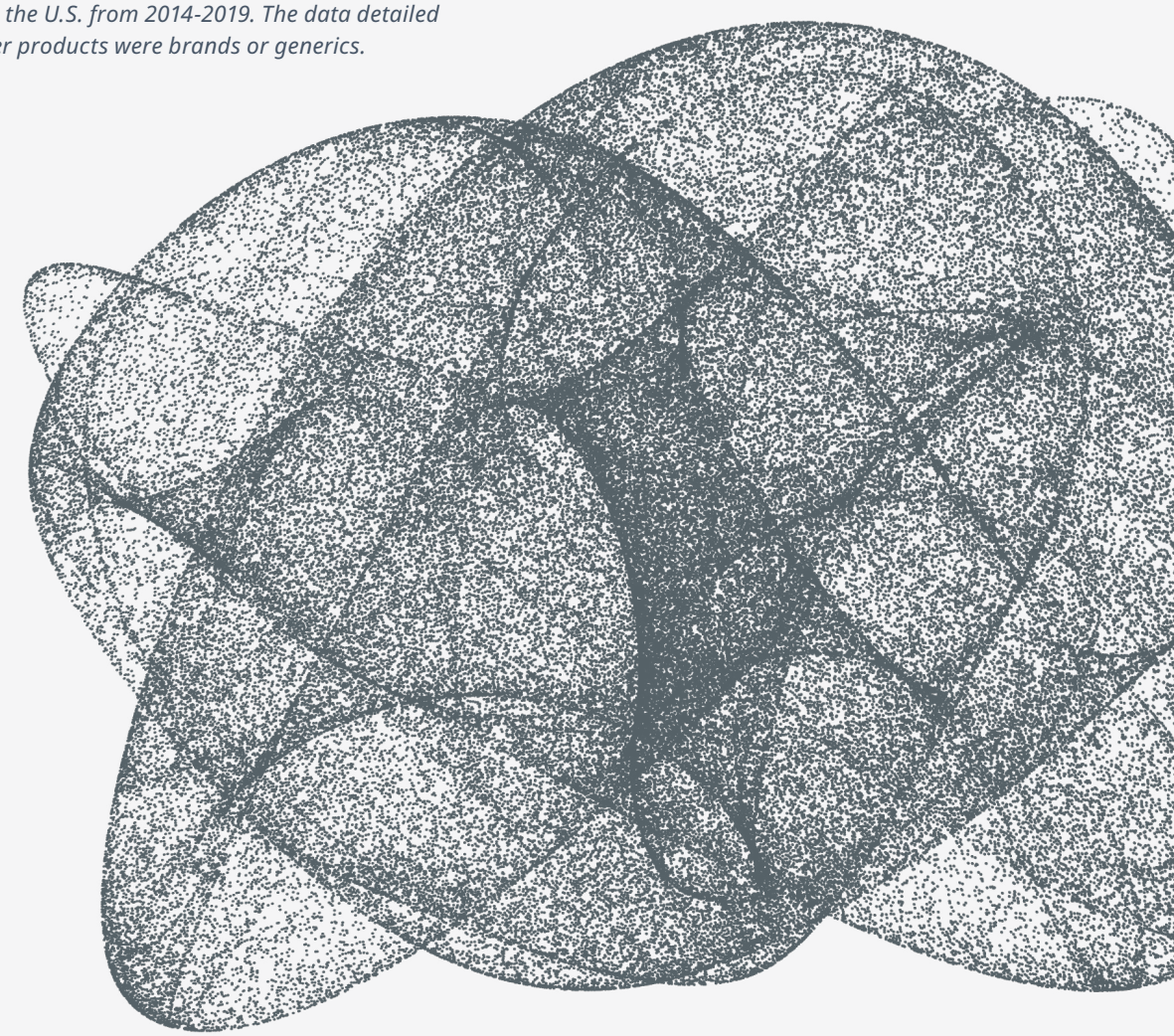
Guiding Principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

The artwork on this report cover in based on data pertaining to patient cost exposure, payer payments, and patient final out-of-pocket costs for retail prescription drugs in the U.S. from 2014-2019. The data detailed insurance type and whether products were brands or generics.



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