LET'S TALK ABOUT COST

Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance

EXECUTIVE SUMMARY

Out-of-pocket spending for prescription medicines a decade ago consisted almost entirely of fixed copayments, but use of deductibles and coinsurance in commercial health insurance has skyrocketed in recent years.¹ This shift has resulted in many patients with chronic conditions being asked to pay a larger share of the cost of their medicines. Faced with increasing costs each year, a growing share of commercially insured patients rely on cost-sharing assistance programs offered by pharmaceutical manufacturers to help them pay their out-of-pocket costs at the pharmacy counter.

This white paper explores changes in out-of-pocket spending for brand medicines among commercially insured patients between 2015 and 2019. The analysis, conducted by IQVIA, includes patients taking brand medicines across seven therapy areas: anticoagulants, asthma/chronic obstructive pulmonary disease (COPD), depression, diabetes, human immunodeficiency virus (HIV), multiple sclerosis (MS) and oncology. To assess the impact of manufacturer cost-sharing assistance programs on out-of-pocket cost trends, IQVIA analyzed changes in patients' actual out-of-pocket spending as well as changes in their out-of-pocket cost exposure—that is, the amount patients would have paid out of pocket in the absence of any cost-sharing assistance. The findings show that:

- Patients with deductibles and coinsurance face disproportionately high out-of-pocket costs
- The amount of cost sharing required by health plans has been steadily rising
- Manufacturer cost-sharing assistance programs can significantly improve affordability for patients

Deductibles and coinsurance drive high out-of-pocket costs for patients

- Patients pay a substantial share of their out-of-pocket spending for brand medicines in the form of deductibles and
 coinsurance. Combined, deductible and coinsurance spending account for more than two-thirds of patients' total
 out-of-pocket spending for five of the seven therapy areas examined. For two therapy areas, oncology and multiple
 sclerosis, deductibles and coinsurance account for more than 90%.
- Out-of-pocket spending for brand medicines is heavily concentrated among the subset of patients who fill
 prescriptions in the deductible or are required to pay coinsurance. For example, fewer than one-third of patients
 taking brand medicines to treat multiple sclerosis fill prescriptions subject to deductibles or coinsurance, but these
 patients account for 95% of total out-of-pocket spending on brand multiple sclerosis medicines.
- Patients with deductibles and coinsurance for brand medicines have significantly higher annual out-of-pocket costs
 than patients with fixed copays alone. Differences range from patients with deductibles and coinsurance paying more
 than three times as much for anticoagulants to patients with multiple sclerosis paying nearly 32 times as much out
 of pocket.

Health plans require chronically ill patients to pay increasingly high cost sharing for brand medicines

- Health plans expose patients to high cost sharing for brand medicines and expect patients to pay higher costs each
 year. Across all seven therapy areas, average patient cost exposure increased between 2015 and 2019, including a
 32% increase for depression, a 50% increase for HIV, and a 56% increase for anticoagulants.
- The share of prescriptions for which health plans require cost sharing greater than \$125 has also increased. In 2019, patient cost exposure for brand medicines exceeded \$125 for nearly one in every six prescriptions for anticoagulants, as well as for medicines to treat HIV and depression.

Manufacturer cost-sharing assistance helps patients with high out-of-pocket costs start and stay on needed medicines

- Across all seven therapy areas, many patients use cost-sharing assistance programs offered by manufacturers. In 2019, the share of patients using cost-sharing assistance to fill one or more prescriptions ranged from 13% for asthma/ COPD to 70% for multiple sclerosis.
- The portion of patients using manufacturer cost-sharing assistance programs when filling prescriptions for brand medicines increased from 2015 to 2019, including a 54% increase among HIV patients, a 98% increase among patients with depression, and a 129% increase among asthma/COPD patients.
- Without manufacturer cost-sharing assistance programs, patients would likely pay significantly more out of pocket. On average, cost-sharing assistance helped patients taking HIV or oncology medicines with more than \$1,600 toward their out-of-pocket costs in 2019, and helped patients taking multiple sclerosis medicines with more than \$2,200.



BACKGROUND

Commercially insured patients pay cost sharing for prescription medicines through deductibles, copays, and coinsurance. When a patient fills a prescription in the deductible, the patient pays the entire price of the medicine until the amount of the deductible is reached. Patients with copays pay a fixed amount for each prescription (e.g., \$30), while those with coinsurance pay a percentage of the medicine's total price (e.g., 30%).

A decade ago, out-of-pocket spending for prescription medicines consisted almost entirely of copays. But in recent years, use of deductibles and coinsurance in commercial health insurance has skyrocketed.

Consequently, the share of patient out-of-pocket drug spending attributable to coinsurance has more than doubled over the past 10 years, while the share attributable to deductibles has tripled.² Between 2012 and 2017, the share of employer-sponsored health plans requiring patients to meet a deductible for prescription medicines increased from 23% to 52%.³ In the commercial market, average annual deductibles for family coverage range from nearly \$3,000 for health plans offered by employers to more than \$13,000 for bronze plans available on the Health Insurance Exchange.⁴ And after the deductible is met, coinsurance for many brand medicines can be as high as 30% to 50%.⁵

Health plans and pharmacy benefit managers (PBMs) commonly negotiate substantial discounts and rebates on brand medicines, but in most cases, these discounted prices are not made available to patients. Instead, health plans typically require patients with deductibles or coinsurance to pay cost sharing based on a medicine's full undiscounted price. In 2019, pharmaceutical manufacturers paid more than \$175 billion in rebates, discounts, and other price concessions to health plans, the government, and other entities, which lowered the net price of brand medicines by an average of 45%, according to industry analysts.⁶ However, because health plans typically do not factor in these savings when calculating the deductible and coinsurance amounts patients must pay, out-of-pocket costs for these patients can be significantly higher than they otherwise would be if based on the discounted cost of the medicine. Notably, this dynamic is unique to prescription medicines, and to brand medicines in particular. In most cases, health insurers do factor in negotiated savings when calculating patient costs for in-network medical services like physician or hospital visits.

The following analysis examines trends in patient out-of-pocket spending between 2015 and 2019 across the seven therapy areas studied: anticoagulants, asthma/COPD, depression, diabetes, HIV, multiple sclerosis (MS), and oncology. For brevity, some findings are presented for selected therapy areas only. Complete data for all seven therapy areas are included in the appendix.



FINDING ONE: Deductibles and coinsurance drive high out-of-pocket costs for patients

Deductibles and coinsurance account for a substantial share of patients' out-of-pocket costs.

As shown in Figure 1, patients now pay a substantial share of their out-of-pocket spending for brand medicines in the form of deductibles and coinsurance. For six of the seven therapy areas, deductible and coinsurance spending represented more than half of the total amount patients spent out of pocket for brand medicines in 2019. For oncology and MS medicines, deductible and coinsurance spending accounted for 94% and 95% of total out-of-pocket spending, respectively.

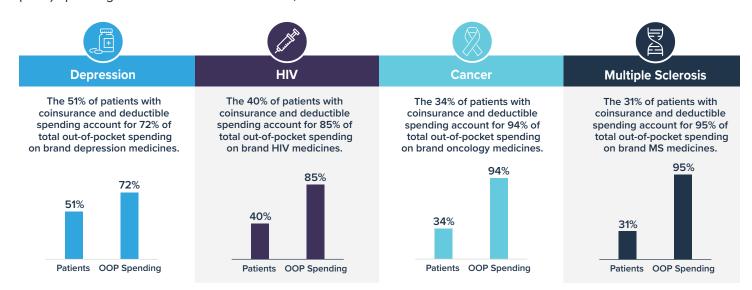
28% Deductible and Coinsurance Spending 95% 94% 85% Copay Spending **72**% 67% 60% 44% Asthma/COPD HIV **Diabetes** Anticoagulants Depression Oncology Multiple Sclerosis

FIGURE 1: Share of Final Patient Out-of-Pocket Spending for Brand Medicines by Type of Cost Sharing, 2019

Out-of-pocket spending for brand medicines is heavily concentrated among patients who fill a prescription in the deductible or who are required to pay coinsurance.

For six of the seven therapy areas examined, a minority of patients taking brand medicines filled one or more prescription subject to a deductible or coinsurance. However, across all seven therapy areas, patients with deductibles and coinsurance accounted for the vast majority of total out-of-pocket spending. For example, as shown in Figure 2, fewer than one-third of patients taking brand medicines to treat MS filled a prescription in the deductible or were required to pay coinsurance in 2019, but these patients accounted for 95% of all out-of-pocket spending on brand MS medicines.

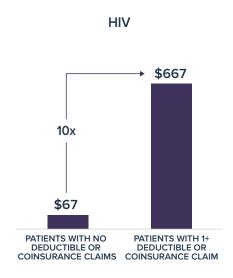
FIGURE 2: Share of Patients with Prescriptions Subject to Deductibles or Coinsurance and Share of Total Out-of-Pocket (OOP) Spending Attributable to These Patients, 2019

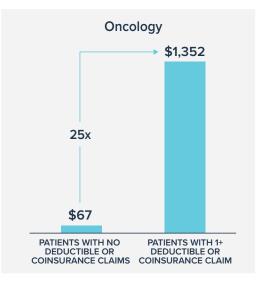


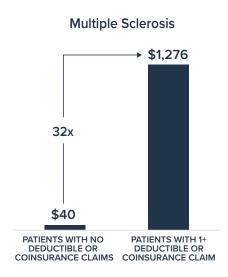
Out-of-pocket costs are significantly higher among patients with deductibles and coinsurance relative to those with fixed copays.

Across all seven therapy areas, patients subject to deductibles and coinsurance paid significantly more out of pocket for their brand medicines than patients whose only form of cost sharing was fixed copays. In 2019, differences ranged from patients with deductibles and coinsurance paying more than three times as much for their anticoagulants (\$96 vs. \$327) to patients with MS paying nearly 32 times as much out of pocket for their medicines (\$40 vs. \$1,276).

FIGURE 3: Average Patient Out-of-Pocket Spending for Brand Medicines by Type of Cost Sharing, 2019







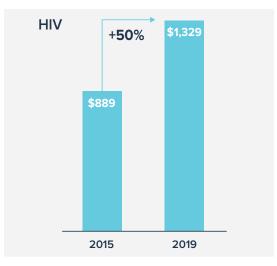
FINDING TWO: Health plans require chronically ill patients to pay increasingly high cost sharing for brand medicines

Health plans expose patients to high cost sharing for brand medicines and expect patients to pay higher costs each year.

Across all seven therapy areas, average patient cost exposure increased between 2015 and 2019. Patient cost exposure does not account for out-of-pocket savings from manufacturer cost-sharing assistance and represents the level of cost sharing patients would have had to pay out of pocket if such assistance had not been available. As shown in Figure 4, between 2015 and 2019 average cost-sharing exposure for brand medicines increased by 32% for depression, 50% for HIV medicines, and 56% for anticoagulants. In contrast to the stark growth in patient cost exposure, net prices for brand medicines over this same period increased by less than 3% per year on average, in line with or below annual inflation.⁷

FIGURE 4: Average Annual Patient Cost Exposure for Brand Medicines in 2015 vs. 2019



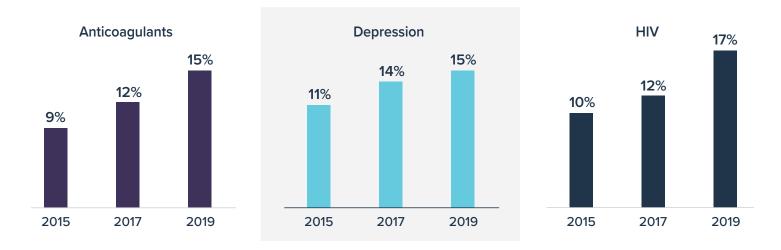




The share of prescriptions for which health plans require high cost sharing has increased.

Prior research shows that 62% of patients required to pay cost sharing higher than \$125 abandon their prescription rather than initiating therapy.⁸ The share of prescriptions for which patients were exposed to cost sharing greater than \$125 increased across all seven therapy areas during the 2015 to 2019 period. Figure 5 shows that by 2019, health plans required cost sharing of greater than \$125 for nearly one in six prescriptions for brand medicines to treat HIV and depression, as well as for brand anticoagulants.

FIGURE 5: Share of Prescriptions for Brand Medicines with Cost Exposure Greater than \$125, 2015 to 2019

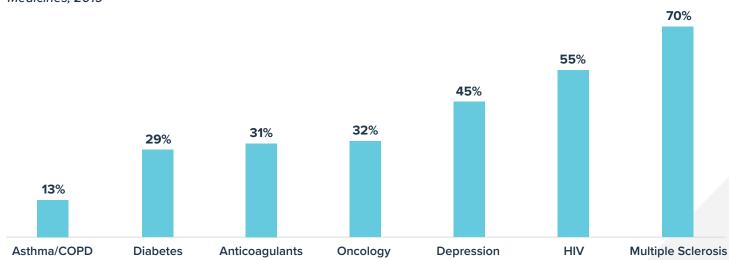


FINDING THREE: Manufacturer cost-sharing assistance programs help patients with high out-of-pocket costs start and stay on needed medicines

Many chronically ill patients use cost-sharing assistance programs offered by pharmaceutical manufacturers.

Across the seven therapy areas included in this analysis, the share of patients who used manufacturer cost-sharing assistance when filling a prescription for one or more brand medicines in 2019 ranged from 13% for asthma/COPD to 70% for MS in 2019. See Figure 6.

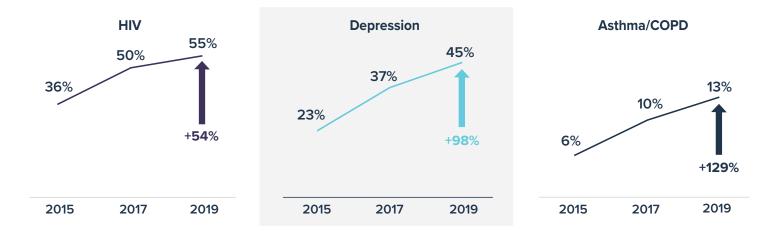
FIGURE 6: Share of Patients Using Manufacturer Cost-Sharing Assistance to Fill One or More Prescriptions for Brand Medicines, 2019



An increasing share of patients use manufacturer cost-sharing assistance programs each year

Between 2015 and 2019, the share of patients using manufacturer cost-sharing assistance to fill one or more prescriptions for brand medicines increased across all seven therapy areas. As shown in Figure 7, the share increased by 54% among HIV patients, 98% among patients with depression, and 129% among asthma/COPD patients.

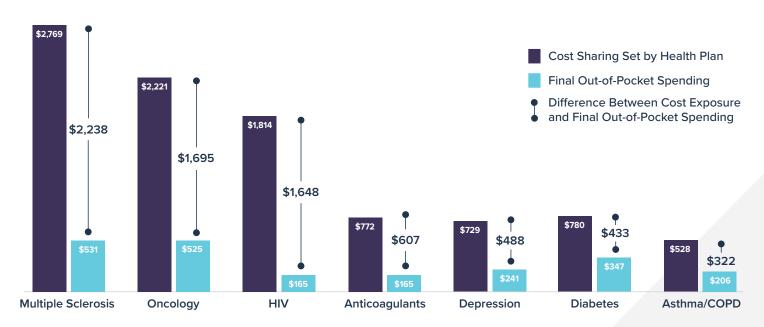
FIGURE 7: Increase in Share of Patients Using Manufacturer Cost-Sharing Assistance to Fill One or More Prescriptions for Brand Medicines, 2015 vs. 2019



Without manufacturer cost-sharing assistance programs, patients would likely pay significantly more out of pocket.

Had manufacturer assistance not been available, average patient out-of-pocket costs for brand medicines would have been 225% to 1,096% higher in 2019. As shown in Figure 8, cost-sharing assistance, on average, helped patients taking brand HIV and oncology medicines with more than \$1,600 and helped patients taking brand MS medicines with more than \$2,200 toward their out-of-pocket costs in 2019. Research shows that as out-of-pocket costs increase, patients are more likely to abandon prescriptions at the pharmacy counter or become non-adherent to therapy, leading to worse health outcomes and higher overall costs down the road.⁹

FIGURE 8: Average Cost Exposure and Final Out-of-Pocket Spending for Patients Using Manufacturer Cost-Sharing Assistance to Fill One or More Brand Medicine Prescriptions, 2019



DISCUSSION

The growing use of deductibles and coinsurance in the commercial market has substantially altered patient cost sharing for brand medicines. For all seven therapy classes in this analysis, prescriptions filled in the deductible or with coinsurance represented a disproportionately large share of patients' total out-of-pocket spending, in some instances upwards of 90%. Although health plans and PBMs often negotiate large rebates that significantly reduce the prices of brand medicines, patients with deductibles and coinsurance typically do not benefit from these savings and must pay cost sharing based on the full undiscounted prices. Not sharing rebate savings directly with patients effectively shifts more of the cost of care to patients, a particularly unfair and arguably discriminatory penalty for individuals with chronic conditions best managed with brand medicines.

Over the 2015 to 2019 period, health plans exposed chronically ill patients to increasingly high cost sharing for brand medicines. This was true for all seven therapy areas examined. In contrast to the stark growth in patients' out-of-pocket cost exposure, average net prices for brand medicines grew by less than 3% annually, less than or in line with inflation, over this same period. Today, health plans require cost sharing of \$125 or greater for nearly one in every six prescriptions filled for brand anticoagulants, as well as brand medicines to treat depression and HIV. In prior research, 62% of commercially insured patients who were asked to pay cost sharing higher than \$125 abandoned their prescription rather than initiating therapy. An extensive body of literature shows that patients facing high cost sharing are also less likely to take medicines as prescribed and more likely to delay or forgo treatment, putting them at higher risk for expensive emergency room visits, avoidable hospitalizations, and poorer health outcomes.

Across all seven therapy areas, manufacturer cost-sharing assistance helped patients pay their out-of-pocket costs for brand medicines at the pharmacy counter. In 2019, cost-sharing assistance helped patients with asthma/COPD, diabetes and depression with an average of \$300 and \$500 towards their out-of-pocket costs and helped patients with HIV, cancer and MS with \$1,600 to \$2,200 on average. By helping patients pay their out-of-pocket costs, manufacturer cost-sharing assistance can help improve adherence to treatment and reduce the risk that patients will abandon their prescriptions at the pharmacy counter.¹⁴

The findings of this analysis cast doubt on the wisdom and fairness of typical health plan and PBM practices and recent federal policy changes that could jeopardize cost-sharing assistance for commercially insured patients. Commercial health plans have increasingly adopted accumulator adjustment programs (AAPs), which prevent manufacturer cost-sharing assistance from accumulating toward patient deductibles and annual out-of-pocket limits. Much like the surprise billings that distress many insured patients in the medical setting, AAPs can surprise patients with thousands of dollars in unexpected and unaffordable costs at the pharmacy. In many cases, patients leave the pharmacy empty-handed as a result. One recent study found that the implementation of AAPs for specialty autoimmune medicines was correlated with reductions in medication adherence among high deductible health plan enrollees.¹⁵ There is no explicit federal requirement that health plans notify patients when putting an AAP in place for the first time, nor are they explicitly instructed to disclose the use of an AAP in summaries of benefits and coverage. In some cases, affected patients may have been stable on a medicine with cost-sharing assistance for years and only learn of the AAP when they arrive at the pharmacy. Recognizing the clear risk to patient affordability and adherence, four states have already implemented bans on AAPs and a legislative ban approved by a fifth state is currently awaiting the governor's signature. Legislation to ban the use of AAPs was pending in five additional states as of July 2020.

Recent federal rulemaking, however, seems to double down on health plans' use of AAPs in the commercial market. The 2021 Notice of Benefits and Payment Parameters (NBPP) final rule allows health plans to adopt AAPs without limitation starting in 2021, despite a final rule that required the exact opposite just last year. In addition, a recently proposed Medicaid rule would modify price reporting rules to account for the value of manufacturer cost-sharing assistance in a medicine's "best price" if its manufacturer is unable to "ensure" the full value of assistance goes to benefit patients and no other entity. The proliferation of AAPs and the lack of explicit health plan disclosure requirements make it virtually impossible for manufacturers to control whether cost-sharing assistance given to patients is later taken away from patients by PBMs or health plans. Accordingly, these two regulatory proposals combine to render the future of manufacturer assistance uncertain at best, leaving patients at risk of financial hardship due to the high and rising out-of-pocket costs health plans continue to demand.



METHODOLOGY

PhRMA engaged IQVIA's U.S. Market Access Strategy and Consulting team to analyze trends in out-of-pocket costs between 2015 and 2019 for commercially insured patients across multiple therapy areas, including anticoagulants, asthma/COPD, depression, diabetes, HIV, MS and oncology. For each therapy area, patient inclusion criteria included a minimum of two medical claims with a diagnosis for the condition(s) of interest, as well as a subsequent prescription for at least one brand medicine to treat the condition(s) in the year of analysis. Patient cost exposure and final out-of-pocket spending for each therapy area was limited to spending for brand medicines used to treat the condition(s) of interest. Analyses included paid prescription claims only; claims that were adjudicated and later reversed were excluded. Patients were classified as being subject to deductibles or coinsurance if they filled one or more prescriptions with cost sharing equal to the total reimbursement amount, or a percentage thereof, regardless of therapy area. Differences between cost exposure and final patient out-of-pocket spending reflect reimbursement amounts from secondary payers, which are most commonly manufacturer cost-sharing assistance programs but can include any additional support outside of traditional commercial insurance, including the AIDS Drug Assistance Program, charitable foundation support, and supplemental commercial coverage. Manufacturer cost-sharing assistance programs that are administered via debit cards are not captured in IQVIA's data, and therefore are not reflected in patients' final out-of-pocket spending.

APPENDIX

TABLE 1: Share of Final Patient Out-of-Pocket Spending for Brand Medicines by Type of Cost Sharing, 2015 and 2019

	2015			2019		
Therapy Area	Deductible	Copay	Coinsurance	Deductible	Copay	Coinsurance
Anticoagulants	29.3%	45.5%	25.2%	28.1%	33.2%	38.7%
Asthma/COPD	21.3%	63.5%	15.2%	23.8%	56.4%	19.8%
Depression	50.0%	31.6%	18.4%	45.3%	28.3%	26.4%
Diabetes	28.4%	41.3%	30.2%	30.8%	40.2%	29.0%
HIV	45.8%	29.3%	24.9%	64.4%	14.8%	20.8%
Multiple Sclerosis	56.7%	14.3%	29.0%	68.1%	5.3%	26.6%
Oncology	67.2%	9.9%	22.9%	75.4%	5.7%	18.9%

TABLE 2: Share of Patients with Brand Prescriptions Subject to Deductibles or Coinsurance and Share of Total Out-of-Pocket Spending for Brand Medicines Attributable to These Patients, 2019

Therapy Area	Patients with 1+ Deductible or Coinsurance Prescription	Patients with no Deductible or Coinsurance Prescriptions	Share of Spending from Deductibles and Coinsurance	Share of Spending from Copayments
Anticoagulants	47.8%	52.2%	66.8%	33.2%
Asthma/COPD	29.1%	70.9%	43.6%	56.4%
Depression	50.9%	49.1%	71.7%	28.3%
Diabetes	42.4%	57.6%	59.8%	40.2%
HIV	40.1%	59.9%	85.2%	14.8%
Multiple Sclerosis	30.7%	69.3%	94.7%	5.3%
Oncology	34.4%	65.6%	94.3%	5.7%

TABLE 3: Average Patient Out-of-Pocket Spending for Brand Medicines by Benefit Design, 2019

Therapy Area	No deductible or coinsurance claim	1+ deductible or coinsurance claim	No deductible claims	1+ deductible claim	No coinsurance claims	1+ coinsurance claim
Anticoagulants	\$95.83	\$327.08	\$157.47	\$418.53	\$150.54	\$301.64
Asthma/COPD	\$77.46	\$281.45	\$102.97	\$332.77	\$106.36	\$270.41
Depression	\$96.92	\$352.50	\$133.26	\$528.49	\$189.45	\$290.83
Diabetes	\$134.71	\$478.76	\$197.61	\$663.98	\$200.92	\$446.17
HIV	\$66.92	\$676.60	\$112.29	\$1,065.07	\$259.29	\$438.20
Multiple Sclerosis	\$40.29	\$1,275.58	\$119.24	\$2,158.30	\$303.08	\$833.01
Oncology	\$53.60	\$1,352.05	\$127.70	\$2,123.63	\$438.29	\$728.98

TABLE 4: Average Annual Patient Cost Exposure for Brand Medicines, 2015 to 2019

Therapy Area	2015	2016	2017	2018	2019
Anticoagulants	\$253.30	\$293.37	\$334.08	\$374.33	\$386.53
Asthma/COPD	\$169.14	\$176.50	\$187.07	\$198.70	\$208.54
Depression	\$408.29	\$409.11	\$445.45	\$497.44	\$501.99
Diabetes	\$402.77	\$420.25	\$428.37	\$456.62	\$430.32
HIV	\$901.41	\$1,012.73	\$1,159.58	\$1,285.35	\$1,342.26
Multiple Sclerosis	\$898.58	\$919.44	\$813.68	\$917.62	\$960.88
Oncology	\$896.81	\$848.64	\$847.75	\$921.39	\$973.41

TABLE 5: Share of Prescriptions for Brand Medicines with Cost Exposure Greater than \$125, 2015 to 2019

Therapy Area	2015	2016	2017	2018	2019
Anticoagulants	8.7%	10.3%	11.5%	13.7%	15.2%
Asthma/COPD	4.4%	4.8%	5.1%	5.5%	6.5%
Depression	11.4%	11.4%	13.9%	14.0%	15.0%
Diabetes	8.6%	8.6%	8.5%	8.9%	8.3%
HIV	10.4%	11.2%	12.3%	14.8%	17.3%
Multiple Sclerosis	12.3%	12.7%	12.0%	11.7%	13.4%
Oncology	14.1%	16.1%	14.4%	14.8%	13.9%

TABLE 6: Share of Patients Using Manufacturer Cost-Sharing Assistance to Fill One or More Prescriptions for Brand Medicines, 2015 to 2019

Therapy Area	2015	2016	2017	2018	2019
Anticoagulants	20.7%	24.4%	28.2%	29.4%	31.1%
Asthma/COPD	5.6%	7.6%	10.0%	11.7%	12.8%
Depression	22.7%	31.1%	36.8%	41.2%	44.9%
Diabetes	22.8%	24.5%	26.6%	29.0%	28.9%
HIV	36.0%	45.2%	50.0%	54.5%	55.4%
Multiple Sclerosis	62.2%	64.4%	61.7%	70.1%	70.0%
Oncology	27.8%	27.8%	29.8%	31.1%	32.0%

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