

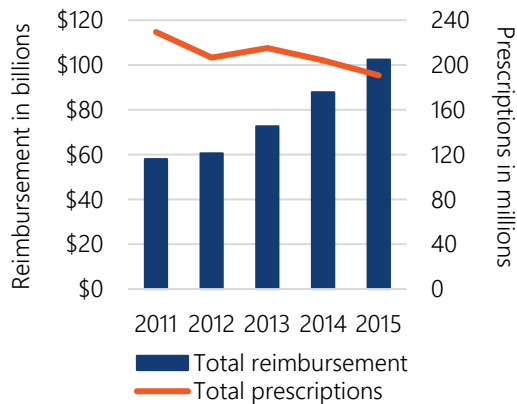


Increases in Reimbursement for Brand-Name Drugs in Part D

What OIG Found

- Total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs.
- After accounting for manufacturer rebates, reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015.
- Part D unit costs for brand-name drugs rose nearly 6 times faster than inflation from 2011 to 2015.
- The percentage of beneficiaries responsible for out-of-pocket costs of at least \$2,000 per year for brand-name drugs nearly doubled across the 5-year span.

Exhibit 1: Total reimbursement for brand-name drugs in Part D increased as utilization for these drugs declined from 2011 to 2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

What OIG Concludes

Our findings show that although there were fewer prescriptions for brand-name drugs in 2015 than in 2011, increases in Part D unit costs for brand-name drugs led to greater overall Medicare Part D spending and higher beneficiary out-of-pocket costs for these drugs. Generally, plan sponsors base their pharmacy reimbursement amounts on the prices that manufacturers set for their drugs. Therefore, increasing manufacturer prices for brand-name drugs may result in increasing costs for Medicare and its beneficiaries, especially those beneficiaries who need access to expensive maintenance drugs.

Full report can be found at oig.hhs.gov/oei/reports/oei-03-15-00080.asp

Why OIG Did This Review

Recent increases in prescription drug prices have drawn the attention of Congress, made headlines in major media outlets, and raised concerns in Government agencies that reimburse for these drugs. Some studies also have shown that certain therapeutic classes of drugs—i.e., groups of drugs that treat specific conditions such as diabetes and heart disease—are becoming more expensive. Drugs in these therapeutic classes are typically maintenance drugs, which means they are usually prescribed for chronic conditions. Therefore, increasing costs for these drugs may have a long-term financial impact on Part D and its beneficiaries.

How OIG Did This Review

This data brief examines how increases in reimbursement for brand-name drugs in Part D may be affecting Medicare and its beneficiaries. We used prescription drug event records, i.e., prescriptions, to provide an analysis of reimbursement amounts and utilization changes for brand-name drugs in Part D from 2011 to 2015. We also examined the impact of manufacturer rebates on total Part D reimbursement across the 5 years. We compared the annual rate of inflation to changes in Part D unit costs for individual drugs with reimbursement in 2 consecutive years. To control for the possibility that (1) increases in utilization or (2) newer, more expensive brand-name drugs may have driven increases in total Part D reimbursement, we analyzed the number of prescriptions and average unit costs for brand-name drugs that were reimbursed by Part D in every year from 2011 to 2015. Finally, we evaluated beneficiary out-of-pocket costs for brand-name drugs in Part D from 2011 to 2015.

BACKGROUND

The Medicare Part D Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide an optional prescription drug benefit for Medicare beneficiaries beginning January 1, 2006. Individuals enrolled in Part D can choose to receive benefits through stand-alone prescription drug plans (PDPs), or through Medicare Advantage prescription drug plans (MA-PDs) that provide integrated medical coverage, including drugs. Part D typically covers a broad range of outpatient drugs, including cardiovascular drugs, insulin, antibacterial drugs, and some vaccines.

The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as plan sponsors, that offer prescription drug plans to their beneficiaries with varying drug coverage and cost-sharing requirements.¹ Plan sponsors must submit a prescription drug event record to CMS for each covered prescription filled for their beneficiaries. Each record contains the national drug code (NDC),² the amount paid to the pharmacy, and utilization data that enable CMS to administer the Part D benefit.

Part D Reimbursement Amounts

Pharmacy reimbursement for Part D drugs is based on negotiations between plan sponsors and pharmacies.³ Benchmark prices, e.g., average wholesale prices (AWPs) or wholesale acquisition costs (WACs), may serve as the bases for drugs' negotiated prices. A plan sponsor (or an entity acting on the plan sponsor's behalf) also may negotiate rebates with drug manufacturers that reduce Part D drug costs to beneficiaries and the Government. Plan sponsors are required to report these rebates to CMS.

Beneficiary cost-sharing. The standard Part D drug benefit is divided into phases, with beneficiaries moving through each phase as their drug costs increase. The phases of the standard benefit are as follows, in chronological order: deductible, initial coverage, coverage gap, and catastrophic coverage.⁴ Cost-sharing amounts for the Government and beneficiaries vary from one phase to another.

In Part D, beneficiary cost-sharing obligations are collectively known as "out-of-pocket costs," and may include deductibles, copayments (fixed payment amounts), and coinsurance amounts (payments based on a percentage of the drug's cost). In some cases, beneficiaries may receive financial support for these costs from various sources, such as

¹ Part D sponsors can offer prescription drug coverage under PDP and/or MA-PD contracts.

² An NDC is an 11-digit identifier that provides information about the drug's manufacturer, product, and package size.

³ Section 1860D-11(i) of the Social Security Act prohibits the Government from interfering with negotiations between drug manufacturers, pharmacies, and plan sponsors.

⁴ Beginning in January 2011, beneficiaries' drug costs during the coverage gap phase were reduced by manufacturer discounts and cost-sharing from the Part D plans. In 2015, beneficiaries were responsible for 45 percent of brand-name drug costs during the coverage gap phase.

additional insurance or charity care. Plan sponsors often use tiered cost-sharing, which may cause a beneficiary's cost to vary depending on the drug's tier. For example, plan sponsors may place generic drugs, which are generally less expensive, on the first tier and brand-name drugs, which tend to be more expensive, on higher tiers. As a result, beneficiaries may pay higher cost-sharing amounts for brand-name drugs than generics.

For some brand-name drugs, such as those used to treat certain cancers and hepatitis C, beneficiary cost-sharing amounts can be thousands of dollars per month. For expensive drugs on the highest tier, CMS allows plan sponsors to charge coinsurance of up to 33 percent instead of a set copayment amount. In 2016, nearly all beneficiaries were enrolled in Part D plans that included high-cost tiers for the most expensive drugs.⁵

Related Work

A 2017 MedPAC study of drug prices in Part D found that newer, more expensive drugs significantly affected overall Part D reimbursement.⁶ Because beneficiaries who take these expensive drugs are more likely to reach the catastrophic-coverage phase of their benefits, the Government pays for a greater share of their drug costs. A 2017 Office of Inspector General (OIG) report analyzed Federal payments for catastrophic coverage in Part D, and the drugs dispensed in this benefit phase.⁷ OIG found that Federal payments for catastrophic coverage tripled from \$10.8 billion in 2010 to \$33.2 billion in 2015. In addition, OIG found that 10 high-price drugs—which cost up to \$34,000 per month—accounted for nearly one-third of all drug spending for catastrophic coverage in 2015.

The Part D trends that the MedPAC and OIG reports identified are consistent with a 2016 issue brief by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) that analyzed overall prescription drug spending from 2009 to 2015.⁸ ASPE reported that increases in total prescription drug spending outpaced increases in the number of prescriptions over the time period it reviewed. ASPE suggested that increases in drug prices contributed more to the growth in spending than increases in the volume of prescriptions.

Methodology

Total Part D reimbursement. We collected prescription drug event records to calculate changes in reimbursement and utilization for all brand-name drugs in Part D from 2011 to 2015. We considered each 11-digit NDC to be an individual drug⁹ and each prescription drug event record to be one prescription.

⁵ The Henry J. Kaiser Family Foundation, *Medicare Part D in 2016 and Trends over Time*. Accessed at <http://www.kff.org/medicare/report/medicare-part-d-in-2016-and-trends-over-time/> on August 29, 2017.

⁶ MedPAC, *Status Report on the Medicare Prescription Drug Program (Part D)*, ch. 14, March 2017.

⁷ OIG, *High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage* (OEI-02-16-00270), January 2017.

⁸ ASPE, *Issue Brief: Observations on Trends in Prescription Drug Spending*, March 2016. Accessed at <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf> on February 1, 2018.

⁹ A particular drug compound may have multiple 11-digit NDCs. For example, our analysis included 13 NDCs for the drug Abilify.

[Part D rebates.](#) We collected rebate data for all brand-name drugs in Part D and subtracted each drug's total rebates from its total reimbursement each year. We then compared changes in this rebate-adjusted reimbursement for all brand-name drugs in Part D across the 5 years.

[Part D unit costs.](#) We calculated Part D unit costs by dividing total Part D reimbursement by the number of units that Part D dispensed for each brand-name drug under review. Drug units may include individual tablets, capsules, or milliliters of the drug being dispensed. To control for the possibility that newer, more expensive brand-name drugs may have driven increases in total Part D reimbursement, we limited our analysis of average unit costs to the 3,578 brand-name drugs that were reimbursed in every year from 2011 to 2015. We calculated changes in average unit costs and utilization for these brand-name drugs that were reimbursed by Part D in all 5 years under review.

[Inflation rate.](#) In our comparison of Part D unit costs to the rate of inflation, we determined the year-to-year changes in Part D unit costs by selecting all brand-name drugs that were reimbursed by Part D in 2 consecutive years under review. For example, to determine the percentage change in unit costs between 2011 and 2012, we used brand-name drugs that were reimbursed by Part D in both years and calculated the median percentage change in unit costs for these drugs. We did this year-by-year analysis across the 5-year span and compared changes in Part D unit costs to the rate of inflation from 2011 to 2015.

[Benchmark prices.](#) We obtained WACs from two national drug compendia: Red Book and First Databank and we obtained AWP from the Red Book compendium. We calculated the median percentage changes in AWP and WACs for brand-name drugs that were reimbursed by Part D in 2 consecutive years from 2011 to 2015. We then compared these year-to-year changes in benchmark prices to Part D unit costs and the rate of inflation across the 5 years.

[Beneficiary out-of-pocket costs.](#) Out-of-pocket costs represent beneficiary cost-sharing obligations and, in some cases, may not represent payments made directly by beneficiaries. To better approximate what beneficiaries may have paid, we removed from our analysis any beneficiaries who received third-party assistance—e.g., low-income cost-sharing subsidies, group health plans, or State Pharmaceutical Assistance Programs—to cover their cost-sharing obligations. For the remaining beneficiaries, we calculated total annual out-of-pocket costs (based on the patient pay amount) for beneficiaries who had at least one prescription for any brand-name drug from 2011 to 2015.

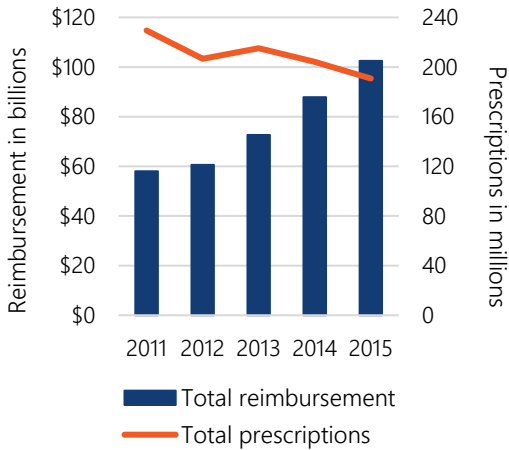
For brand-name drugs that were reimbursed in all 5 years we reviewed, we determined the average out-of-pocket costs for each drug and calculated changes in these amounts from 2011 to 2015. Finally, we grouped brand-name drugs into therapeutic classes to determine which therapeutic classes had the highest total beneficiary out-of-pocket costs from 2011 to 2015.

Appendix A provides a detailed methodology for the evaluation.

RESULTS

From 2011 to 2015, total reimbursement for brand-name drugs in Part D increased 77 percent, despite a decrease in utilization for these drugs

Exhibit 2: Reimbursement for brand-name drugs in Part D increased as utilization for these drugs declined



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

Total reimbursement for all brand-name drugs in Part D increased 77 percent over the 5 years, from \$58 billion in 2011 to \$102 billion in 2015 (see Exhibit 2).¹⁰ Overall, Part D paid \$382 billion for all brand-name drugs from 2011 to 2015. Appendix B provides total reimbursement for brand-name drugs categorized by the number of years that each drug had Part D reimbursement from 2011 to 2015.

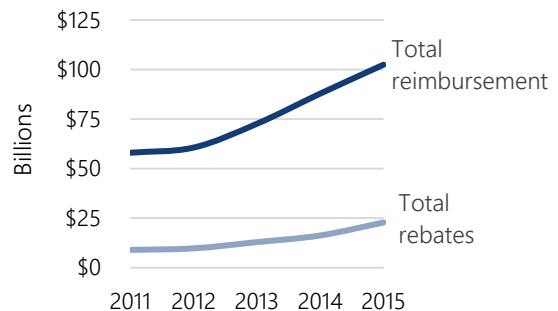
Although total reimbursement increased substantially from 2011 to 2015, the total number of prescriptions for brand-name drugs decreased 17 percent, from 229 million in 2011 to 191 million in 2015.

After accounting for rebates, Part D reimbursement still increased 62 percent from 2011 to 2015

Part D relies on plan sponsors to negotiate drug manufacturer rebates that reduce the cost of the program to beneficiaries and the Government. Total rebate dollars for all brand-name drugs in Part D more than doubled (a 155 percent increase) across the 5 years, from \$9 billion in 2011 to \$23 billion in 2015.

Despite the substantial growth in rebates, the gap between total reimbursement and total rebates increased from 2011 to 2015, as shown in Exhibit 3. Therefore, total rebate-adjusted reimbursement under Part D still increased 62 percent, from \$49 billion in 2011 to \$80 billion in 2015. In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased. Specifically, manufacturers paid rebates for 72 percent of brand-name drugs

Exhibit 3: From 2011 to 2015, the gap between total reimbursement and total rebates increased each year for brand-name drugs in Part D



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

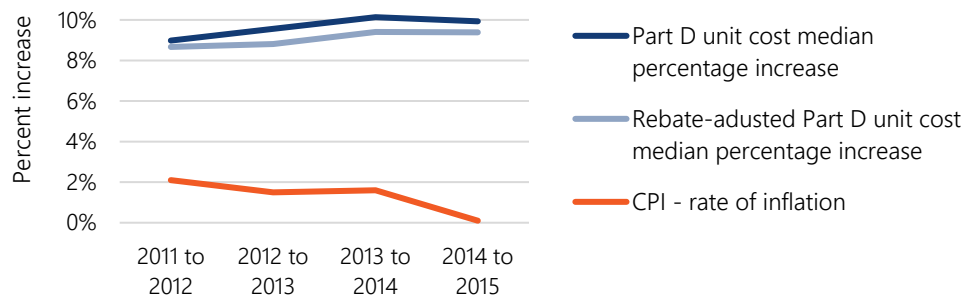
¹⁰ These reimbursement totals do not include rebates. We also did not include dispensing fees, sales tax, or vaccine administration fees in our calculation of Part D reimbursement.

(2,612 of 3,637 drugs) in 2011, but paid rebates for 61 percent of brand-name drugs (3,328 of 5,492 drugs) in 2015.

Part D unit costs for brand-name drugs rose nearly 6 times faster than inflation from 2011 to 2015

From 2011 to 2015, the average unit cost for brand-name drugs with Part D reimbursement in all 5 years increased 29 percent; this is nearly 6 times greater than the 5-percent increase in the consumer price index (CPI) measure of inflation.¹¹ Part D unit costs outpaced inflation for 85 percent of the brand-name drugs we reviewed.

Exhibit 4: The rate of inflation slowed as Part D unit costs for brand-name drugs increased from 2011 to 2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

As Exhibit 4 shows, the median rate of increase in Part D unit costs grew from 2011 to 2015, while the rate of increase in the CPI declined across the 5-year period. Specifically, the CPI increased between 0.1 percent and 2.1 percent each year from 2011 to 2015. At the same time, Part D unit costs had median increases of 9 to 10 percent for brand-name drugs with Part D reimbursement across 2 consecutive years. When we adjusted Part D unit costs to take rebates into account, rebate-adjusted unit costs increased at almost the same rate as non-rebate-adjusted unit costs from 2011 to 2015.¹²

Benchmark prices for brand-name drugs in Part D also increased faster than inflation from 2011 to 2015

Benchmark prices—i.e., AWP and WAC—reflect manufacturer prices, and plan sponsors generally use benchmark prices as a basis to negotiate Part D reimbursement amounts.

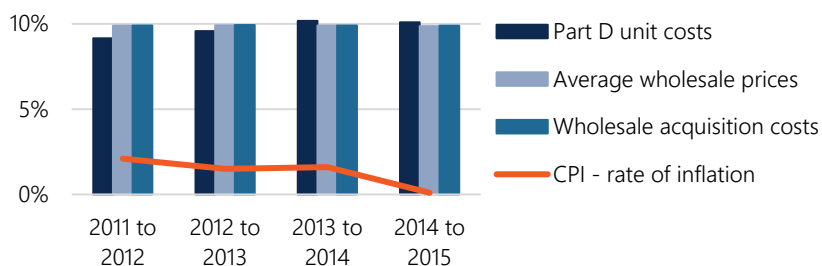
We found that while the rate of inflation slowed from 2011 to 2015, benchmark prices actually increased approximately 10 percent for brand-name drugs reimbursed by Part D in

¹¹ The CPI is the measure of inflation used to set rebates for drugs in the Medicaid program.

¹² Not all brand-name drugs that we reviewed were included in the rebate data (between one and seven drugs were missing from these files in each year). We did not include these missing drugs in our analysis of rebate-adjusted reimbursement amounts.

2 consecutive years, as shown in Exhibit 5. Part D unit costs more closely followed the increasing trend of benchmark prices than the declining trend in inflation rates.

Exhibit 5: Benchmark prices for brand-name drugs in Part D increased at a greater rate than inflation from 2011 to 2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

For almost half of brand-name drugs reviewed, Part D unit costs increased at least 50 percent from 2011 to 2015

Of the 3,578 brand-name drugs that were reimbursed by Part D in every year from 2011 to 2015, 89 percent had unit cost increases across the 5-year span. The average unit cost for these brand-name drugs increased 29 percent, from \$115 in 2011 to \$148 in 2015.

For nearly half of brand-name drugs reimbursed by Part D from 2011 to 2015, unit costs increased at least 50 percent; Part D spent \$12 billion more for these same drugs in 2015 than in 2011. As shown in Exhibit 6, unit costs at least doubled for 12 percent of these brand-name drugs we reviewed. For 15 percent of these drugs, unit costs were at least

Exhibit 6: Part D unit costs at least doubled for 12 percent of brand-name drugs from 2011 to 2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

6 times higher in 2015 than in 2011. The unit cost for one drug, Cuprimine (250 milligram oral capsule), which can be used to treat rheumatoid arthritis, increased 2,143 percent, from \$6 in 2011 to \$135 in 2015.

In some cases, drugs with higher unit costs had increases that were smaller in terms of percentages but significant in terms of dollar amounts. The unit cost for Stelara (a solution of 45 milligrams per half milliliter), a drug used to treat psoriasis, increased \$5,523 over the 5 years, from \$10,669 in 2011 to \$16,191 in 2015—a 52-percent increase. Appendix C provides the top 20 brand-name drugs by percentage increases in Part D unit costs from 2011 to 2015.

Brand-name drugs with utilization decreases had greater increases in average unit costs from 2011 to 2015

A majority of the drugs with Part D reimbursement for all 5 years we reviewed had lower utilization in 2015 than in 2011.¹³ On average, unit costs increased 38 percent for brand-name drugs with fewer prescriptions in 2015 than in 2011. For the remaining

¹³ Of the brand-name drugs reimbursed in every year from 2011 to 2015, 65 percent of these brand-name drugs had fewer prescriptions in 2015 than in 2011, and 63 percent had fewer units dispensed in 2015 than in 2011.

brand-name drugs, unit costs increased at a lower rate (23 percent, on average) from 2011 to 2015.¹⁴ In other words, the brand-name drugs with utilization decreases were associated with greater increases in unit costs.

Part D unit costs for brand-name drugs with the most utilization increased at a significantly greater rate than all brand-name drugs in Part D from 2011 to 2015

Average unit costs for the 200 brand-name drugs with the most prescriptions in 2015 increased at nearly double the rate of increase for all the brand-name drugs we reviewed (57 percent vs. 29 percent). The 200 most-utilized brand-name drugs in 2015 accounted for 85 percent of prescriptions and 71 percent of total Part D reimbursement for the brand-name drugs we reviewed. Part D reimbursement for these same 200 brand-name drugs was \$26 billion higher in 2015 than in 2011. Therefore, manufacturers may have raised prices for brand-name drugs taken by a substantial number of beneficiaries in 2015.

Beneficiaries' average out-of-pocket costs for brand-name drugs increased 40 percent from 2011 to 2015

Between 2011 and 2015, Part D beneficiaries who did not receive third-party assistance had \$29 billion in out-of-pocket costs (which include copayments and coinsurance amounts) for all brand-name drugs in Part D.¹⁵ For brand-name drugs with reimbursement in all 5 years we reviewed, beneficiaries had an average of \$161 in out-of-pocket costs per brand-name drug in 2011, but spent an average of \$225 for these same drugs in 2015—an increase of 40 percent.¹⁶

In addition, the percentage of beneficiaries who had at least \$2,000 per year in out-of-pocket costs for brand-name drugs nearly doubled from 3.7 percent in 2011 to 7.3 percent in 2015. These trends are consistent with those described in the 2017 OIG report, which found an increase in the number of beneficiaries who reached the catastrophic-coverage phase from 2010 to 2015.¹⁷

Beneficiaries' total out-of-pocket costs were highest for three therapeutic classes of maintenance drugs

For brand-name drugs with Part D reimbursement in all 5 years we reviewed, total beneficiary out-of-pocket costs were highest for brand-name insulins, cholesterol

¹⁴ Brand-name drugs with fewer units dispensed also were associated with greater increases in average unit costs (42 percent vs. 21 percent) from 2011 to 2015.

¹⁵ For this analysis, we did not include beneficiaries who received third-party assistance—e.g., low-income cost-sharing subsidies, group health plans, or State Pharmaceutical Assistance Programs—to cover their cost-sharing obligations. The percentage of beneficiaries that we removed from our analysis ranged from 44 percent to 56 percent per year.

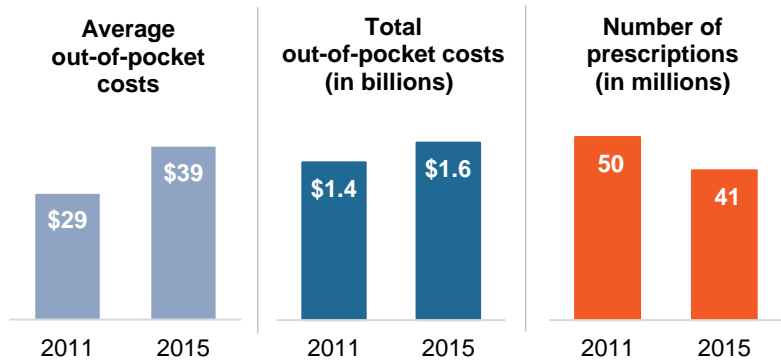
¹⁶ At the median, beneficiary out-of-pocket costs per brand-name drug increased from an average of \$77 in 2011 to \$97 in 2015 for drugs with reimbursement in all 5 years.

¹⁷ OIG, [High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage](#) (OEI-02-16-00270), January 2017.

reducers,¹⁸ and respiratory tract corticosteroids, e.g., inhalers. Beneficiaries paid \$7.2 billion in out-of-pocket costs for brand-name drugs in these therapeutic classes across the 5 years.

Although insulins, cholesterol reducers, and respiratory tract corticosteroids were not among the most expensive therapeutic classes (out-of-pocket costs averaged between \$23 and \$45 per prescription), millions of beneficiaries used these drugs each year between 2011 and 2015. Part D total reimbursement for brand-name drugs in these therapeutic classes was \$6.5 billion higher in 2015 than in 2011. For brand-name drugs in these three therapeutic classes, Exhibit 7 provides the total and average out-of-pocket costs, and the number of prescriptions from 2011 to 2015.

Exhibit 7: Beneficiary out-of-pocket costs for brand-name drugs in three therapeutic classes of maintenance drugs increased from 2011 to 2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

Because this analysis of brand-name drugs by therapeutic classes included only drugs reimbursed in all 5 years we reviewed, increased out-of-pocket costs cannot be attributed to beneficiaries' paying for newer, more expensive drugs. Furthermore, the brand-name drugs in these therapeutic classes are typically maintenance drugs, which means that they may be prescribed for chronic, long-term conditions and are taken on a regular, recurring basis. Therefore, to the extent that unit costs continue to increase, Part D beneficiaries are likely to continue to be affected for years to come.

CONCLUSION

We found that, over a 5-year period, increases in Part D reimbursement for brand-name drugs outpaced inflation. Despite a decrease in utilization of brand-name drugs, these substantial increases in reimbursement led to greater Medicare spending and higher beneficiary out-of-pocket costs for these drugs. Specifically, total Part D reimbursement for all brand-name drugs increased 77 percent, from \$58 billion in 2011 to \$102 billion in 2015. To control for the possibilities that (1) increases in utilization or (2) newer, more expensive brand-name drugs may have affected total Part D reimbursement, we analyzed the number of prescriptions and unit costs for brand-name drugs that were reimbursed in every year from 2011 to 2015. Overall, we found that utilization decreased for the majority of these

¹⁸ This therapeutic class refers to brand-name drugs in a specific type of cholesterol-lowering medications called HMG-CoA reductase inhibitors.

brand-name drugs, while the average Part D unit cost increased 29 percent from 2011 to 2015.

Increases in Part D unit costs significantly outpaced inflation; in fact, the average unit cost for brand-name drugs in Part D rose nearly 6 times faster than inflation from 2011 to 2015. We also found that Part D unit costs closely followed the upward trend in benchmark prices, which are typically reflective of manufacturer prices. Therefore—like the 2016 ASPE report, which suggested that increases in drug prices contributed to the growth in total prescription drug spending—we conclude that increases in unit prices for brand-name drugs resulted in Medicare and its beneficiaries' paying more for these drugs.

We also found that the percentage of beneficiaries who were responsible for out-of-pocket costs of at least \$2,000 per year for brand-name drugs nearly doubled across the 5 years. These trends are consistent with those described in the previous OIG report, which found increases in the number of beneficiaries who reached the catastrophic-coverage phase of their Part D benefits. In addition, we found that total beneficiary out-of-pocket costs were highest for brand-name drugs in three therapeutic classes of maintenance drugs. Because maintenance drugs are typically used to treat chronic, long-term conditions, increasing reimbursement for these drugs will continue to affect Part D and its beneficiaries for years to come. OIG remains committed to examining these issues and working with CMS to ensure the integrity of the Part D program.

APPENDIX A: Detailed Methodology

Part D Reimbursement Analysis

We used prescription drug event records, i.e., prescriptions, for calendar year 2015 as our basis to select brand-name drugs covered by Part D for our analysis. We defined brand-name drugs as NDCs that were classified as (1) innovator products by the First Databank compendium and (2) brand-name products in the Red Book compendium.¹⁹

Total Part D reimbursement. To calculate the total amount Part D reimbursed for brand-name drugs, we aggregated the total ingredient costs for all brand-name drugs paid through Part D for each year from 2011 to 2015. We did not include additional drug costs included on prescription drug event records, e.g., dispensing fees or sales tax, which may vary by locality.

Average unit costs. In our calculation of average Part D unit costs, we kept only the 3,578 brand-name drugs that had at least 1 prescription in each of the 5 years under review. To determine the Part D unit costs for a brand-name drug, we summed the total ingredient costs for each drug and divided by the total units of the drug dispensed each year. We then compared changes in these amounts from 2011 to 2015.

We also determined changes in average Part D unit costs for brand-name drugs with utilization decreases and those without utilization decreases from 2011 to 2015. We calculated utilization based on (1) the number of prescriptions per drug and (2) the number of units dispensed for each drug. In addition, we selected the 200 brand-name drugs with the highest number of prescriptions in 2015. We determined average unit costs for these 200 brand-name drugs with the highest utilization, and we compared changes in reimbursement amounts for these drugs from 2011 to 2015.

Rebates. We obtained Direct and Indirect Remuneration (DIR) data from CMS and summed the total rebates for all brand-name drugs that were reimbursed by Part D from 2011 to 2015. Not all brand-name drugs under review were included in the DIR data (for each of the 5 years, between one and seven drugs were missing from these files). We did not include the drugs without DIR data in our analysis of rebate-adjusted reimbursement amounts.

We subtracted the total rebates from total Part D reimbursement to calculate total rebate-adjusted reimbursement for all brand-name drugs from 2011 to 2015. We also determined the number and percentage of brand-name drugs that had rebates in each of the 5 years.

Inflation Rate Analysis

We used the CPI as calculated by the Bureau of Labor Statistics to examine price trends for consumer goods. According to the Bureau of Labor Statistics, the CPI measures the

¹⁹ The drug classifications from the compendia were obtained in July 2016. We did not include drugs that were categorized as “branded-generics” in Red Book.

average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.

To determine the year-to-year changes in Part D reimbursement for brand-name drugs, we selected drugs that were reimbursed by Part D in 2 consecutive years under review. For example, to determine the percentage change in reimbursement between 2011 and 2012, we kept brand-name drugs that were reimbursed by Part D in both years and compared unit costs for these drugs. The number of drugs that were included in our comparison of consecutive years increased as new drugs were approved and covered by Part D. As a result, we were able to include year-to-year changes for newer brand-name drugs that may not have been available during all 5 years under review.

We calculated the median percentage change in Part D unit costs and rebate-adjusted unit costs between each year from 2011 to 2015. We then compared these rates of change to the rate of change in the CPI from year to year.

Benchmark Prices

We obtained WACs from two national drug compendia: Red Book and First Databank and we obtained AWP from the Red Book compendium. We used the WACs and AWPs from the fourth quarter of each year from 2011 to 2015 to track the changes in unit prices for each benchmark price.²⁰ For this analysis, we included brand-name drugs that (1) had unit prices for each benchmark and (2) were also reimbursed by Part D in 2 consecutive years reviewed. We calculated the median percentage changes in benchmark prices for these drugs from year to year, and we compared them to Part D unit costs and the rate of inflation from 2011 to 2015.

Beneficiary Out-of-Pocket Costs

Beneficiary out-of-pocket costs include the cost-sharing amounts, e.g., deductibles, copayments, and coinsurance amounts, the beneficiary is obligated to pay for a drug. Prescription drug event records have a “patient pay amount” field that includes the cost-sharing amounts that were not reimbursed by a third party. In our calculation of beneficiaries’ total out-of-pocket costs, we did not include beneficiaries who may have received third-party assistance—e.g., low-income cost-sharing subsidies, group health plans, or State Pharmaceutical Assistance Programs—to cover their cost-sharing requirements at the point of sale.²¹

We summed the patient pay amounts for brand-name drugs in each year to determine the total amounts that all beneficiaries spent in out-of-pocket costs for these drugs from 2011

²⁰ First Databank files are available monthly. We downloaded these files from October, November, and December to calculate the average fourth-quarter WACs from 2011 to 2015, with the exception of the October 2013 First Databank file, which was not available; we calculated average fourth-quarter 2013 WACs using the November and December 2013 files. We used these data to substitute WACs for brand-name drugs that did not have WACs in Red Book.

²¹ The percentage of beneficiaries that we removed from our analysis ranged from 44 percent to 56 percent per year.

to 2015. We then calculated changes in beneficiary average out-of-pocket costs for only the brand-name drugs that were reimbursed in all 5 years we reviewed.

[Therapeutic classes](#). We used the American Hospital Formulary Service codes available in First Databank to group brand-name drugs into therapeutic classes.²² Although some drugs may be used to treat more than one condition, each drug we reviewed was assigned to one therapeutic class in First Databank. We matched each brand-name drug with its corresponding therapeutic classification code according to the First Databank files. There were 195 therapeutic classes with at least 1 brand-name drug in 2015.

We identified the three therapeutic classes with the highest total out-of-pocket costs. We calculated the average out-of-pocket costs, total out-of-pocket costs, and number of prescriptions for these three therapeutic classes and compared the changes in these amounts from 2011 to 2015. For this analysis, we kept only brand-name drugs that were reimbursed by Part D in all 5 years we reviewed.

Limitations

We did not independently verify the completeness or accuracy of data from CMS, Red Book, First Databank, or the Bureau of Labor Statistics.

Standards

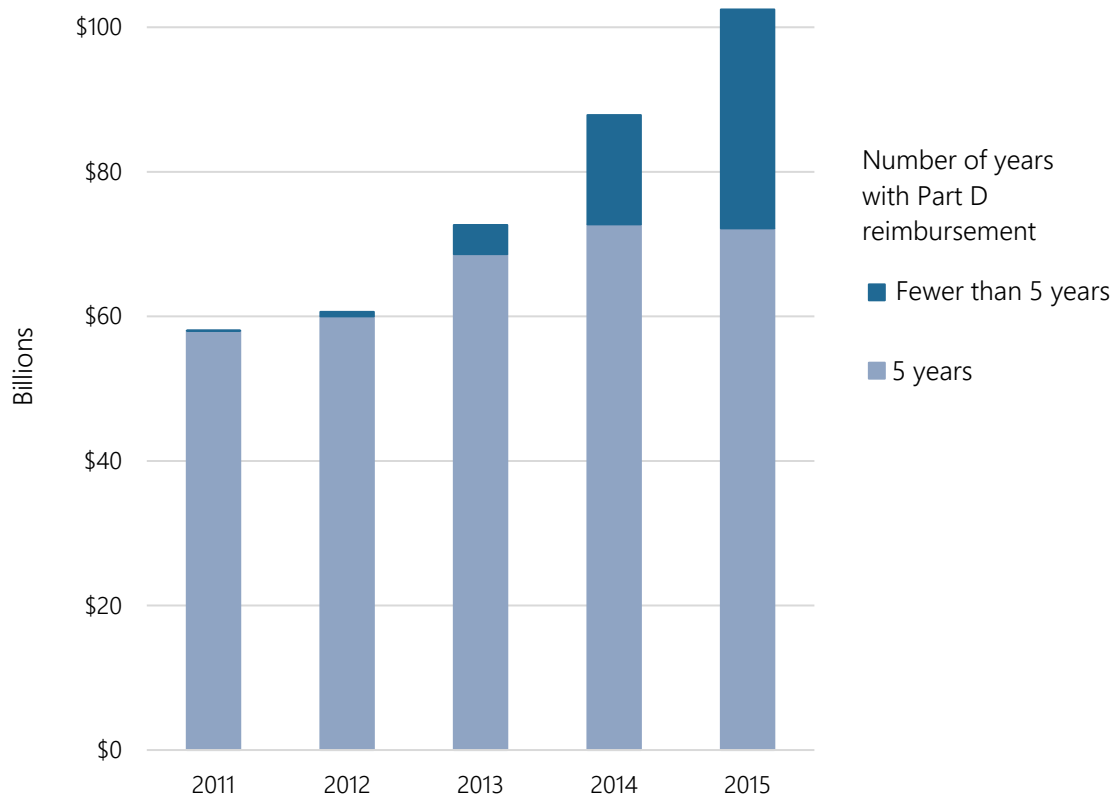
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

²² We used the First Databank file from January 2016 to select American Hospital Formulary Service codes.

APPENDIX B: Total reimbursement for brand-name drugs categorized by the number of years that Part D reimbursed these drugs from 2011 to 2015

This appendix provides information about the amount of total Part D reimbursement associated with brand-name drugs that were reimbursed by Part D in every year from 2011 to 2015. We calculated total Part D reimbursement for brand-name drugs that were reimbursed in all 5 years, and we compared these amounts to total reimbursement for all brand-name drugs in Part D from 2011 to 2015.

We found that total Part D reimbursement for brand-name drugs with reimbursement in all 5 years increased 24 percent, from \$58 billion in 2011 to \$72 billion in 2015. In addition, 70 percent of total Part D reimbursement in 2015 was for brand-name drugs that were reimbursed every year from 2011 to 2015. The remaining 30 percent of total Part D reimbursement in 2015 was associated with drugs that had Part D reimbursement in fewer than 5 years.



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

APPENDIX C: Top 20 brand-name drugs by percentage increases in unit costs from 2011 to 2015

Drug Name	NDC	Selected Treatment(s)	Percentage Increase in Unit Costs 2011 to 2015	Percentage Change in Prescriptions 2011 to 2015	Total Reimbursement, 2011 to 2015
Dianeal low calcium with dextrose	00941-0409-06	Renal failure	209,248%	-37%	\$177,755
Isordil Titradoso	64455-0152-01	Angina (chest pain)	6,112%	100%	\$3,759
Timentin	00029-6579-21	Infections	4,661%	-77%	\$43,159
Doribax	50458-0402-01	Infections	4,219%	-99%	\$67,781
Levsin	68220-0111-05	Irritable bowel syndrome	4,212%	200%	\$3,801
Salex	13548-0010-17	Skin disorders, lesions	4,202%	-62%	\$69,218
Miacalcin	00078-0149-23	Osteoporosis	2,771%	-63%	\$11,180,866
Thiola	00178-0900-01	Kidney stone prevention	2,465%	1,388%	\$10,884,884
Cuprimine	25010-0705-15	Rheumatoid arthritis, Wilson's disease	2,143%	-32%	\$48,216,331
Travasol	00338-0644-03	Nitrogen loss	2,046%	-84%	\$151,531
Tygacil	00008-4990-01	Infections, pneumonia	1,924%	-98%	\$271,305
Syprine	25010-0710-15	Wilson's disease	1,898%	-62%	\$21,921,906
Tygacil	00008-4990-02	Infections, pneumonia	1,588%	-100%	\$2,764,697
Aldara	99207-0260-12	Skin conditions	1,474%	2,200%	\$953,855
Dibenzyliline	65197-0001-01	Certain tumors	1,431%	-47%	\$23,041,204
Zyvox	00009-5137-01	Infections	1,328%	100%	\$40,397
Android	00187-0902-01	Breast cancer, testosterone deficiency	1,070%	-92%	\$4,998,554
Ala-Scalp HP	00316-0140-01	Skin inflammation	1,051%	10%	\$66,809
Rocephin	00004-1964-01	Infections	1,013%	-2%	\$145,334
Depen	00037-4401-01	Rheumatoid arthritis, Wilson's disease	987%	-25%	\$5,757,734

Source: OIG analysis of Medicare Part D data, 2011 to 2015.

Note: Because of different package sizes or formulations, a drug name may appear multiple times.

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