

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**HIGH-PRICE DRUGS ARE
INCREASING FEDERAL
PAYMENTS FOR MEDICARE
PART D CATASTROPHIC
COVERAGE**



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Why OIG Did This Review

Members of Congress and others have raised concerns about the high prices of certain drugs and the impact these high prices have on Medicare beneficiaries and the health care system.

An important part of the Medicare Part D benefit is catastrophic coverage, which beneficiaries enter when their out-of-pocket costs exceed a certain threshold. In catastrophic coverage, most beneficiaries pay a 5-percent coinsurance for drugs, while the Federal Government pays the vast majority of the remaining costs.

Understanding the effect that high drug prices have on spending in catastrophic coverage is crucial. In catastrophic coverage, beneficiaries' out-of-pocket costs are not capped, and the Federal Government's share of drug spending is the highest.

How OIG Did This Review

We analyzed data from the Centers for Medicare & Medicaid Services to determine the amount that the Federal Government spent for catastrophic coverage through the reinsurance subsidy. We also analyzed the Part D Prescription Drug Event records to identify specific drugs dispensed in catastrophic coverage.

in price. CMS also stated that action is necessary to address rising drug costs and asked the industry to partner with the agency to find solutions that allow for both innovation and affordability. Moving forward, CMS will likely need additional tools to address these issues. Potential tools have been discussed by experts and include restructuring the Part D benefit so that sponsors have more incentives and opportunities to lower costs, creating more transparency about drug pricing, promoting value-based options, and revising the law to allow the Federal Government to negotiate prices for certain drugs. CMS should carefully assess these and other options and should, working with Congress, make any needed changes to the Part D program.

High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage

What OIG Found

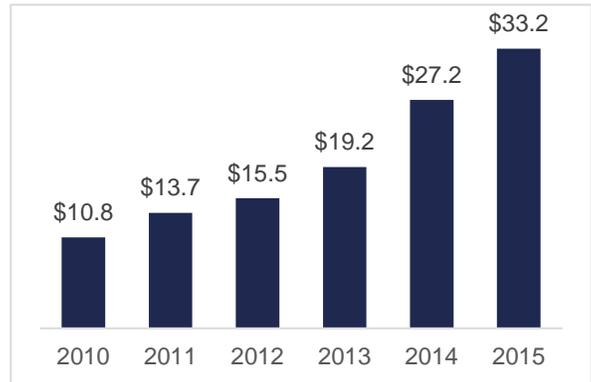
Federal payments for catastrophic coverage exceeded \$33 billion in 2015, which is more than triple the amount paid in 2010. Spending for high-price drugs contributed significantly to this growth. By 2015, high-price drugs were responsible for almost two-thirds of the total drug spending in catastrophic coverage. This is a significant increase from 2010, when high-price drugs were responsible for one-third of the spending.

Moreover, 10 high-price drugs accounted for nearly one-third of all drug spending for catastrophic coverage in 2015. Most of these drugs cost thousands of dollars per month. They treat conditions such as hepatitis C, cancer, and multiple sclerosis. The average prices for each of these drugs ranged from \$1,200 to almost \$34,000 per month, leading to high out-of-pocket costs for some beneficiaries in catastrophic coverage.

What OIG Concludes

Securing the future of the Part D program while ensuring beneficiaries have access to needed drugs is a complex issue that calls for a multifaceted approach. OIG remains committed to examining these issues. Recently, CMS has taken steps in response to rising drug prices. It published information about certain drugs with substantial increases

Federal Payments for Catastrophic Coverage (in Billions)



Source: OIG analysis of CMS Payment Reconciliation System data, 2016.

The dramatic growth in Federal payments for catastrophic coverage and the underlying issue of high drug prices must be analyzed and addressed to secure the future of the Part D program. The issue of high-price drugs is not exclusive to catastrophic coverage; it affects the entire Part D benefit and can lead to higher costs for all beneficiaries.

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OBJECTIVES

1. To describe the growth in Federal payments for Medicare Part D catastrophic coverage.
2. To determine which drugs account for the highest spending in catastrophic coverage.

BACKGROUND

Recently, Members of Congress and others have raised concerns about the high prices of certain drugs, such as the new drugs used to treat hepatitis C, and the impact these high prices have on patients and the health care system.¹ Medicare Part D and its beneficiaries are directly affected by high drug prices. In 2015, more than 41 million beneficiaries were enrolled in Part D.²

An important part of the Part D benefit is catastrophic coverage, which is designed to protect beneficiaries from high out-of-pocket costs. In catastrophic coverage, beneficiaries typically pay a 5-percent coinsurance for drugs, while the Federal Government pays the vast majority of the remaining costs.³ Beneficiaries enter catastrophic coverage when their out-of-pocket costs for the year exceed a certain threshold.

Understanding the effect that high drug prices have on spending in catastrophic coverage is crucial. Catastrophic coverage is the stage of the benefit in which the Federal Government's share of drug costs is the highest. Also, the beneficiaries who reach this stage may carry a heavy financial burden; they have medical conditions that require high levels of drug spending and their out-of-pocket costs are not capped. Part D does not have an annual or lifetime maximum for beneficiaries' out-of-pocket costs.

Catastrophic Coverage in Part D

Part D is an optional prescription drug benefit for Medicare beneficiaries that is provided by private insurance companies—known as Part D

¹ For example, see United States Senate Committee on Finance. *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, December 2015. Also see, United States House of Representative, Committee on Oversight & Government Reform. *Developments in the Prescription Drug Market*, Feb. 4, 2016. 114th Cong. 2nd sess. United States Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines*, December 9, 2015. 114th Cong. 1st sess.

² The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 186.

³ The Part D sponsor is responsible for 15 percent of the costs.

sponsors—under contract with the Centers for Medicare & Medicaid Services (CMS).⁴ The standard Part D drug benefit is divided into stages, with beneficiaries moving through the stages as their drug costs increase.⁵ The Government’s and the beneficiary’s share of the drug costs differs in each stage. The last stage of the benefit is catastrophic coverage.

Beneficiaries enter this stage when their out-of-pocket costs for the year exceed a certain threshold, which in 2015 was \$4,700. In catastrophic coverage, a beneficiary typically pays a coinsurance that is 5 percent of the price, while the sponsor is responsible for 15 percent of the price and the Federal Government pays the remainder, after it takes rebates and other price concessions into account.⁶ See Appendix A for more detailed information about the stages of the benefit and catastrophic coverage.

Federal Payments for Catastrophic Coverage Through the Reinsurance Subsidy

The Federal Government pays for catastrophic coverage primarily through the reinsurance subsidy. For this subsidy, CMS prospectively pays sponsors based on estimated costs, and then reconciles these payments after the end of the year.

Before the beginning of the plan year, sponsors are required to submit a bid for each plan they intend to offer. The bid contains an estimate of the revenue per beneficiary that the sponsor would need to provide the basic benefit, and the bid includes an estimate of the sponsor’s catastrophic drug costs. CMS uses the bid to set beneficiary premiums. It also uses the bids to determine the monthly prospective payments it pays each sponsor for the reinsurance subsidy.

⁴ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, Social Security Act § 1860D-1(a), 42 U.S.C. § 1395w-101(a). Also see, 42 U.S.C. § 1395w-112(b)(1).

⁵ The stages of the standard benefit include the deductible, initial coverage, coverage gap, and catastrophic coverage. Part D sponsors are required to offer a “basic benefit” that is either the standard benefit or an equivalent alternative. Sponsors may also offer enhanced plans, which cover more than the standard benefit. For example, some enhanced plans do not have a deductible. For more information on the standard benefit, see Appendix A. CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 5, Sections 20.3.1, 20.3.2 and 20.4, September 2011.

⁶ The price represents the amount paid to the pharmacy at the point of sale by all payers. It is negotiated between the sponsors and their network pharmacies for the drug, or is the usual and customary price paid to out-of-network pharmacies. See 42 C.F.R. § 423.100. In catastrophic coverage, the beneficiary is responsible for paying the greater of the 5-percent coinsurance or a set copayment for generic and brand-name drugs. For 2015, the copayment amounts were \$2.65 for generic and \$6.60 for brand-name drugs. See CMS, *Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 7, 2014.

Approximately 9 months after the close of each plan year, CMS reconciles the prospective payments made to sponsors for the reinsurance subsidy with the actual costs incurred by the sponsors for catastrophic coverage. To determine the total reinsurance payment amount for each plan, CMS calculates the total drug costs for the beneficiaries in catastrophic coverage and adjusts this amount to account for manufacturer rebates and other price concessions that the sponsor reports receiving during the year. The total reinsurance amount paid to sponsors is 80 percent of the adjusted amount. In this report, we refer to the total reinsurance amount paid as “Federal payments for catastrophic coverage.”

There are two other subsidies in the Part D program. The direct subsidy covers the basic benefit.⁷ The low-income subsidy covers some or all of the premiums and coinsurance for certain low-income beneficiaries.⁸ These subsidies are not the focus of this report.

Related Public Discussion

Recently, growing public discussion has focused on increases in drug prices. Experts, policy makers, and others have offered various policy options to address concerns. Notably, the Medicare Payment Advisory Commission, Kaiser Family Foundation, and Congressional Budget Office have provided analyses about these different options. These options include restructuring the Part D benefit so that sponsors have more incentives and opportunities to lower costs, creating more transparency about drug pricing, promoting value-based options, and revising the law to allow the Government to negotiate prices for certain drugs.⁹

⁷ The Federal Government shares the risk with sponsors to provide the basic benefit. If at the end of the year, sponsors have overall profits or losses that exceed certain thresholds, they share these profits or losses with the Federal Government. See 42 C.F.R. § 423.336.

⁸ For more information about these subsidies, see 42 C.F.R. § 423.315.

⁹ For more information about proposals related to restructuring the Part D benefit, see MedPAC, *June 2016 Report to the Congress: Medicare and the Health Care Delivery System, Chapter 6: “Improving Medicare Part D,”* June 2016. For information about drug price transparency, see *Fair Accountability and Innovative Research Drug Pricing Act of 2016*, H.R. 6043 114th Congress, 2016. Also see, United States Senate Committee on Finance, *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, December 2015. For more information about value-based purchasing, see HHS Pharmaceutical Forum: Innovation, Access, Affordability and Better Health, November 20, 2015. Accessed online at <http://www.hhs.gov/hhs-pharmaceutical-forum/#> on September 20, 2016. Also see, MedPAC, *June 2015 Report to the Congress: Medicare and the Health Care Delivery System, Chapter 4: “Value-based Incentives for Managing Part B Drug Use,”* June 2015. For information about Government price negotiation, see Douglas Holtz-Eakin, Director, CBO, Letter to Senator Ron Wyden, March 3, 2004. Also see, Richard G. Frank, *Issue Brief: Prescription Drug Procurement and the Federal Budget*, Kaiser Family Foundation, May 2012.

METHODOLOGY

Analysis of Federal Payments for Catastrophic Coverage

We analyzed data from CMS’s Payment Reconciliation System (PRS) to determine the actual amount that the Federal Government paid each sponsor for catastrophic coverage through the reinsurance subsidy. We analyzed the data by plan from 2006 to 2015 but focused our analysis on the 6 most recent years. As stated earlier in this report, we refer to the total reinsurance subsidy payments as the Federal payments for catastrophic coverage. These payments represent the actual amount the Federal Government paid for catastrophic coverage after rebates and other price concessions are taken into account.

Analysis of Total Drug Spending for Catastrophic Coverage

To better understand the growth in Federal payments for catastrophic coverage and which drugs contributed to this growth, we analyzed the Part D prescription drug event (PDE) records from 2010 to 2015. We used the PDE records because they contain information on the specific drugs that were dispensed in catastrophic coverage. Drug-level data are not available in the PRS data.

The PDE records contain the total amount paid to the pharmacy by all payers—including the beneficiary, Government, and sponsor—for each drug. We refer to the total amount paid for all drugs in catastrophic coverage as “total drug spending”; it is different from the payment data in the PRS which contain information on the Federal Government’s share of drug spending in catastrophic coverage, after rebates and other price concessions are taken into account.

We analyzed the PDE records to identify trends in total drug spending for catastrophic coverage. To determine this amount, we summed four fields on the PDE records—ingredient cost, dispensing fee, sale tax, and vaccine administration fee. This amount is the point-of-sale price that is negotiated between the sponsors and their network pharmacies or is the usual and customary price paid to out-of-network pharmacies. It is not adjusted for manufacturer rebates or other price concessions that the sponsors may receive.

Using the same fields in the PDE records, we then determined the average price per month for each drug, by drug name. We identified the drugs that had an average price of more than \$1,000 per month. For the purposes of

this report, we refer to these drugs as “high-price drugs.”¹⁰ Next, we analyzed trends in spending for high-price drugs. We identified the high-price drugs that had the highest total spending in catastrophic coverage. See Appendix B for more detailed information about the methodology.

Limitations

This study focuses on Federal payments made for catastrophic coverage through the reinsurance subsidy. It does not include the additional amounts the Federal Government contributes toward catastrophic coverage through the direct or low-income subsidies. In addition, we did not assess whether Part D drug spending affected spending in other parts of Medicare.

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.

¹⁰ CMS considers drugs that exceed \$600 per month to be eligible to be placed on a specialty tier of a sponsor’s formulary. Sponsors often have different tiers on their formulary, and each tier has a different copayment or coinsurance. Specialty tiers typically have the highest copayments or coinsurance.

FINDINGS

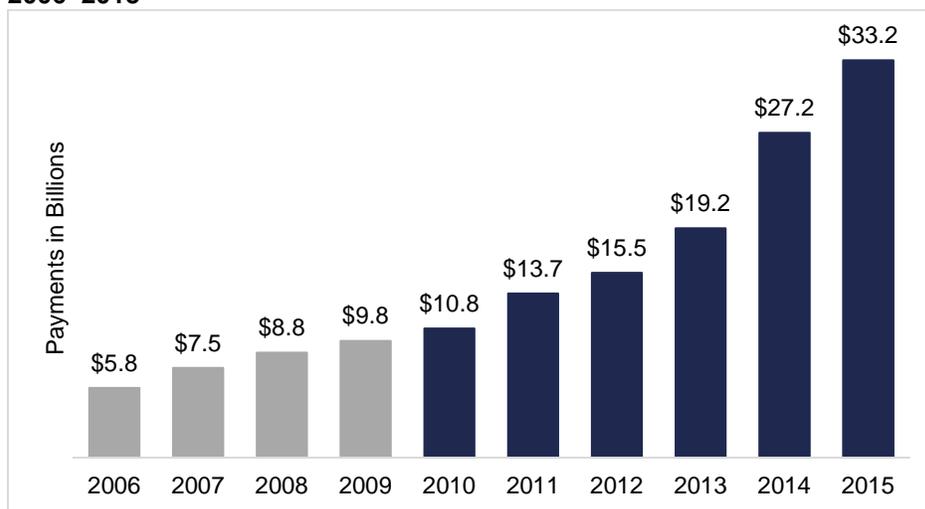
Federal payments for Part D catastrophic coverage exceeded \$33 billion in 2015, which is more than three times the amount paid in 2010

Federal payments for Part D catastrophic coverage have grown substantially in recent years. From 2010 to 2015, Federal payments for catastrophic coverage more than tripled, growing from \$10.8 billion to \$33.2 billion.¹¹ These payments represent 80 percent of total drug spending in catastrophic coverage after rebates and other price concessions are taken into account.

The substantial increase in these payments in recent years—208 percent, or \$22.4 billion—is significantly higher than the growth in earlier years of the program.¹² From 2006 to 2010, Federal payments for catastrophic coverage grew 85 percent, or \$5 billion.

The largest annual increases occurred in 2014 and 2015, first jumping \$8 billion and then another \$6.1 billion (see Figure 1).

Figure 1: Federal Payments for Medicare Part D Catastrophic Coverage, 2006–2015



Source: OIG analysis of CMS Payment Reconciliation System data, 2016.

¹¹ For the purposes of this report, we refer to the reinsurance subsidy as the Federal payments for catastrophic coverage. Most of the Federal Government’s contributions toward catastrophic coverage is through the reinsurance subsidy. In 2015, the Federal Government paid about \$1.6 billion in coinsurance for low-income beneficiaries in catastrophic coverage. We did not calculate the amount the direct subsidy contributed to catastrophic coverage.

¹² Note that these numbers and others presented in this report are rounded. Because our calculations are based on unrounded numbers, they cannot always be recreated from the numbers presented in the report.

Federal payments for catastrophic coverage became the most expensive part of the Part D program in 2014. By 2015, Federal payments for catastrophic coverage accounted for 42 percent of Federal payments for Part D.¹³ Prior to 2014, the most expensive part of the Part D program was either the direct or low-income subsidy.

Spending for high-price drugs contributed significantly to the growth in Federal payments for Part D catastrophic coverage

Federal payments for Part D catastrophic coverage are 80 percent of total drug spending after rebates and other price concessions are taken into account. Drug spending is the amount paid for a drug to the pharmacy by all payers—including the beneficiary, Government, and sponsor.¹⁴ Drug spending for high-price drugs has grown considerably and has contributed to the increase in Federal payments for catastrophic coverage. High-price drugs are defined as those with an average price of more than \$1,000 per month.

Drug spending for high-price drugs in catastrophic coverage increased almost sevenfold from 2010 to 2015. It rose from \$5 billion to \$33.4 billion, with the biggest increase occurring in 2015.

By 2015, high-price drugs were responsible for almost two-thirds of the total drug spending in catastrophic coverage. This is a significant increase from 2010, when high-price drugs were responsible for one-third of the spending. Specifically, total drug spending in catastrophic coverage amounted to \$51.4 billion in 2015. High-price drugs accounted for 65 percent of it (\$33.4 billion of \$51.4 billion). In 2010, high-price drugs accounted for 32 percent of total drug spending in catastrophic coverage.

At the same time, the proportion of beneficiaries receiving these drugs increased. By 2015, 28 percent of all beneficiaries in catastrophic coverage received high-price drugs, up from 14 percent in 2010.

Another factor that contributed to the growth in the Federal payments was an increase in the overall number of beneficiaries in catastrophic coverage. From 2010 to 2015, the number of beneficiaries who reached

¹³ In 2015, Medicare paid a total of \$21.4 billion for the direct subsidy and \$26.3 billion for the low-income subsidy for all stages of the Part D benefit.

¹⁴ This amount represents the price that is negotiated between the sponsors and their network pharmacies for the drug, or is the usual and customary price paid to out-of-network pharmacies. It is calculated from the PDE record. Unlike the Federal payments for catastrophic coverage, PDE data on total drug spending are not adjusted for rebates and other price concessions. We used these data to gain a better understanding of the growth in Federal payments because the PDE records contain information about specific drugs.

catastrophic coverage rose 53 percent, from 2.4 million to 3.6 million.¹⁵ Most of that increase occurred in 2014, when the number of beneficiaries entering catastrophic coverage grew by more than half a million.

Ten high-price drugs accounted for nearly one-third of all drug spending for catastrophic coverage in 2015

Ten high-price drugs were responsible for 30 percent of all drug spending in catastrophic coverage in 2015. Together, they accounted for \$15.6 billion of drug spending in catastrophic coverage for the year. Most of these drugs had an average price of several thousand dollars per month. The total spending for each ranged from \$635.5 million to \$6.3 billion.¹⁶ The 10 drugs treated conditions such as hepatitis C, cancer, and multiple sclerosis (see Table 1).

Table 1: Ten Drugs Accounted for Nearly One-third of Spending in Catastrophic Coverage, 2015

Drug Name	Company*	Key Indications	FDA Approval Year	Average Price per Month**	Total Spending in Catastrophic Coverage
Harvoni	Gilead Sciences	Hepatitis C	2014	\$33,811	\$6,284,357,265
Revlimid	Celgene	Cancers of the blood	2005	\$11,516	\$1,718,263,750
Sovaldi	Gilead Sciences	Hepatitis C	2013	\$30,217	\$1,209,329,646
Humira	AbbVie, Inc.	Inflammatory conditions	2002	\$3,930	\$1,205,270,252
Copaxone	Teva Pharms USA	Multiple Sclerosis	1996	\$5,642	\$1,143,986,768
Gleevec	Novartis	Various cancers	2001	\$9,299	\$1,021,721,929
Enbrel	Amgen	Inflammatory conditions	1998	\$3,540	\$938,254,647
Tecfidera	Biogen Idec, Inc.	Multiple Sclerosis	2013	\$5,595	\$735,215,799
Renvela	Sanofi	Chronic kidney disease	2007	\$1,158	\$675,261,441
Xtandi	Astellas	Prostate cancer	2012	\$8,673	\$635,500,941
Total					\$15,567,162,441

Source: OIG analysis of Prescription Drug Event records, 2016.

* The term "company" refers to the New Drug Application (NDA) holder or Biologics License Application (BLA) holder.

**Note: The price is the amount paid to the pharmacy by all payers. It is negotiated between the sponsors and their network pharmacies for the drug, or is the usual and customary price paid to out-of-network pharmacies. It is not adjusted for rebates or other price concessions.

Two hepatitis C treatments—Harvoni and Sovaldi—accounted for \$7.5 billion of drug spending in catastrophic coverage in 2015. The average price per month for each of them exceeded \$30,000, which means that any beneficiary receiving one of these drugs would enter catastrophic coverage almost immediately. Both of these drugs are new to the market, having received Food and Drug Administration (FDA) approval in 2013 and 2014.

¹⁵ The number of Part D beneficiaries overall increased by 41 percent from 2010 to 2015.

¹⁶ We did not assess whether Part D drug spending affected spending in other parts of Medicare.

Three of the drugs—Revlimid, Gleevec, and Xtandi—are indicated for the treatment of cancer. The average price for each of these drugs exceeded \$8,600 per month. Together, they accounted for \$3.4 billion of drug spending in catastrophic coverage in 2015. Xtandi is the newest of the three. It was approved by FDA in 2012.

Humira and Enbrel are both biologics that treat inflammatory conditions, such as rheumatoid arthritis. Together, they accounted for \$2.1 billion of drug spending in catastrophic coverage.¹⁷

Two multiple sclerosis drugs—Copaxone and Tecfidera—accounted for \$1.9 billion in catastrophic coverage in 2015. The average monthly price of each was approximately \$5,600 in 2015.

Lastly, Renvela accounted for \$675 million in drug spending in catastrophic coverage in 2015. It is prescribed to individuals with chronic kidney disease. Its average monthly price was nearly \$1,200.

Four of the drugs were new to the market; the remaining six had been on the market and had sharp price increases since 2010

Of the 10 drugs that accounted for 30 percent of total drug spending in catastrophic coverage, four entered the market after 2010. The remaining six—Renvela, Gleevec, Humira, Enbrel, Copaxone, and Revlimid—were on the market in 2010. Since 2010, all six have had steep increases in their average price per month.

From 2010 to 2015, the average price per month of each of the six drugs rose by more than \$600. Gleevec, a cancer drug approved in 2001, saw the highest increase during this period. Its average price per month rose \$4,900, an increase of 112 percent (see Table 2).

¹⁷ Biologics differ from most drugs. Instead of being chemically synthesized, they are derived from living organisms. See FDA, *What are “Biologics” Questions and Answers*. Accessed at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077> on May 17, 2016.

Table 2: Six High-Price Drugs with Large Increases in Their Average Price Per Month, 2010–2015

Brand Name	Average Price Per Month		Increase in Average Price Per Month*	Percent Increase
	2010	2015	2010–2015	2010–2015
Gleevec	\$4,391	\$9,299	\$4,907	112%
Humira	\$2,005	\$3,930	\$1,924	96%
Copaxone	\$3,061	\$5,642	\$2,581	84%
Enbrel	\$1,886	\$3,540	\$1,654	88%
Revlimid	\$8,911	\$11,516	\$2,605	29%
Renvela	\$472	\$1,158	\$686	145%

Source: OIG analysis of Prescription Drug Event records, 2016.

*Note: The price represents the amount paid to the pharmacy by all payers. It is negotiated between the sponsors and their network pharmacies for the drug, or is the usual and customary price paid to out-of-network pharmacies. It is not adjusted for rebates or other price concessions.

Some beneficiaries in catastrophic coverage face high out-of-pocket costs

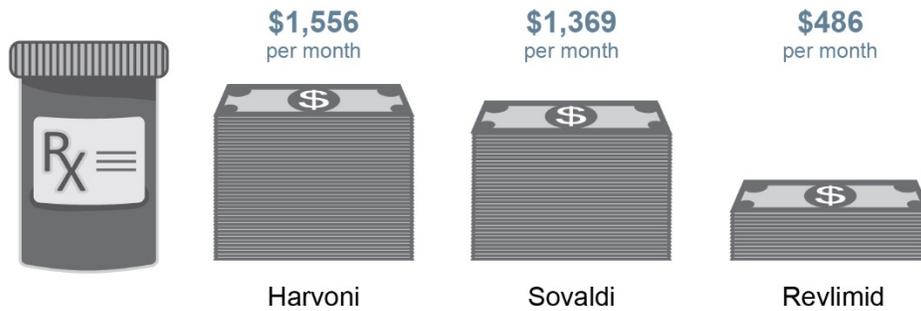
High-price drugs mean high out-of-pocket costs for some beneficiaries. In catastrophic coverage, beneficiaries who do not receive the low-income subsidy typically pay 5 percent of each drug’s price. These costs are on top of the out-of-pocket costs they face before entering catastrophic coverage.

From 2010 to 2015, beneficiaries’ out-of-pocket costs for high-price drugs in catastrophic coverage increased 47 percent.¹⁸ In 2015, beneficiaries paid an average of \$257 a month for each high-price drug in catastrophic coverage, up from \$175 in 2010.

Some beneficiaries faced even higher out-of-pockets costs, especially if they were taking hepatitis C drugs. For two hepatitis C drugs, beneficiaries paid more than \$1,300 a month. For example, beneficiaries in catastrophic coverage paid an average of \$1,556 a month for Harvoni. This means that, on average, beneficiaries paid \$4,669 for a typical 3-month course of treatment (see Figure 2).

¹⁸ This analysis only includes beneficiaries who did not receive the low-income subsidy because beneficiaries who receive this subsidy pay little or no coinsurance. Specifically, 28 percent or 1 million beneficiaries in catastrophic coverage did not receive the low-income subsidy in 2015.

Figure 2: Average Beneficiary Out-of-Pocket Costs in Catastrophic Coverage for Select Drugs, 2015



*Note: Averages are for beneficiaries who do not receive the low-income subsidy.
Source: OIG analysis of Prescription Drug Event records, 2016.

Beneficiary out-of-pocket costs are not capped in Part D, so there is no annual or lifetime limit to the amount that beneficiaries may pay in coinsurance. Beneficiaries receiving more than one high-price drug could have out-of-pocket costs amounting to many thousands of dollars. As mentioned earlier, these payments are in addition to the amount that the beneficiary pays before entering catastrophic coverage, which in 2015 was \$4,700.

CONCLUSION

Federal payments for Part D catastrophic coverage exceeded \$33 billion in 2015, which is more than three times the amount paid in 2010. Spending for high-price drugs contributed significantly to this growth.

Moreover, in 2015, 10 high-price drugs accounted for nearly one-third of all drug spending in catastrophic coverage. Four of the drugs were new to the market; the remaining six had been on the market and had sharp price increases since 2010. The prices for each of these 10 drugs are thousands of dollars per month, leading to high out-of-pocket costs for some beneficiaries in catastrophic coverage.

The dramatic growth in Federal payments for catastrophic coverage and the underlying issue of high-price drugs must be analyzed and addressed to secure the future of the Part D program. Continued growth at this pace may pose a risk to the sustainability of the program. In addition, the issue of high-price drugs is not exclusive to catastrophic coverage; it affects Federal payments for the entire Part D benefit and can lead to higher premiums and drug costs for all.

OIG remains committed to examining these issues, as these trends demand further analysis. For instance, we are reviewing the increases in prices for brand-name drugs in Part D.¹⁹ However, the gravity and complexity of these issues—that is, securing the future of the program while ensuring beneficiaries have access to needed drugs—calls for a multifaceted approach.

CMS has taken some steps in response to rising drug prices. Recently, it published information about certain drugs with substantial increases in price.²⁰ CMS also stated that action is necessary to address rising drug costs and asked the industry to partner to find solutions that allow for both innovation and affordability.²¹ Further, the Department held a forum with stakeholders that focused on topics such as strengthening incentives and promoting competition.

¹⁹ For more information, see OIG, *Work Plan Fiscal Year 2017*. Accessed at <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/hhs%20oig%20work%20plan%202017.pdf> on December 1, 2016.

²⁰ CMS recently published information about these drugs in an effort to address both the affordability of prescription drugs and to increase transparency. See CMS's Medicare Drug Spending Dashboard available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/>.

²¹ CMS Blog, *Remarks by Andy Slavitt: The Need to Partner on Drug Innovation, Access and Cost*, November 4, 2016. Accessed at <https://blog.cms.gov/2016/11/04/remarks-by-andy-slavitt-the-need-to-partner-on-drug-innovation-access-and-cost/> on December 1, 2016.

Moving forward, CMS will likely need additional tools to address these issues. As mentioned in the background of this report, potential tools have been discussed by experts and include restructuring the Part D benefit so that sponsors have more incentives and opportunities to lower costs, creating more transparency about drug pricing, promoting value-based options, and revising the law to allow the Federal Government to negotiate prices for certain drugs. CMS should carefully assess these and other options, taking into account beneficiary costs and access to needed drugs, and should, working with Congress, make any needed changes to the Part D program.

APPENDIX A

The Standard Part D Benefit, 2015^a

DEDUCTIBLE <i>Total drug spending is \$320 or less</i>	INITIAL COVERAGE <i>Total drug spending is more than \$320 but less than or equal to \$2,960</i>	COVERAGE GAP <i>Total drug spending is more than \$2,960, but the beneficiary's out-of-pocket costs are \$4,700 or less^b</i>	CATASTROPHIC COVERAGE <i>Beneficiary's out-of-pocket costs are over \$4,700</i>
Beneficiary Pays 100%	Sponsor Pays 75%	FOR BRAND-NAME DRUGS: Manufacturer Discount 50% Beneficiary Pays 45% Sponsor Pays 5%^c	Federal Government Pays 80% through Reinsurance Subsidy
		FOR GENERIC DRUGS: Beneficiary Pays 65% Sponsor Pays 35%	
	Beneficiary Pays 25%		
			Beneficiary Pays 5%^d

^a This represents the standard benefit for beneficiaries who are not enrolled in the low-income subsidy. The Federal Government shares the risk with sponsors to provide the basic benefit. The amount the Federal Government prospectively pays each sponsor is based on estimated costs. These payments are reconciled at the end of the year with actual benefit costs that the sponsor paid. If the sponsors have overall profits or losses that exceed certain thresholds, the Federal Government shares these profits or losses with the sponsor.

^b When calculating beneficiaries' out-of-pocket costs, CMS includes some payments by third-party payers, such as State pharmacy assistance plans. It also includes manufacturer discounts received through the Coverage Gap Discount Program.

^c For applicable brand-name drugs, the manufacturer provides a 50-percent discount in the coverage gap, while the sponsor pays 5 percent of the ingredient cost and sales tax and 55 percent of the dispensing and vaccine administration fees.

^d Beneficiary coinsurance is the greater of 5 percent of the total drug cost or \$2.65 for generic or \$6.60 for brand-name drugs.

Source: OEI analysis of CMS guidance, 2016.

APPENDIX B: DETAILED METHODOLOGY

Data Sources and Analysis

Analysis of Federal Payments for Catastrophic Coverage

We analyzed data from CMS's Payment Reconciliation System (PRS) to determine the total amount the Federal Government paid for catastrophic coverage through the reinsurance subsidy.²² We analyzed the data by plan for 2006 through 2015.²³ For each plan, we determined the amount that the Federal Government paid for catastrophic coverage through the reinsurance subsidy for each year. We then summed all payments for the reinsurance subsidy for each year to determine the amount the Federal Government paid for catastrophic coverage.²⁴ In total, we analyzed the data for between 3,431 and 5,080 plans each year. These are actual amounts the Government paid for catastrophic coverage after rebates and other price concessions are taken into account.

We followed a similar process to determine the total amount the Federal Government paid for the direct subsidy and the low-income subsidy for each year. We also calculated the total amount the Federal Government paid for all three subsidies each year.²⁵

Analysis of Total Drug Spending in Catastrophic Coverage

To better understand the growth in Federal payments, we analyzed the PDE records from 2010 to 2015. Part D sponsors submit a PDE record to

²² In addition, to estimate the amount the Federal Government contributed to catastrophic coverage through the low-income subsidy, we summed the amount of low-income cost-sharing reported on each PDE record for the drugs dispensed entirely in catastrophic coverage. We did not include PDE for drugs that straddled the coverage gap and catastrophic coverage.

²³ We based this analysis on the final reconciled data, including any revisions that occurred during a reopening, that was available as of October 5, 2016. Years 2006 and 2008 were each reopened twice, and years 2007, 2009, and 2010 were each reopened once. Not all plans participated in each reopening. We analyzed the most updated information for each plan. For example, if plan A participated in both reopenings for 2008, we used the data from the second reopening. However, if plan B participated in only the first reopening for 2008, we used data from the first reopening.

²⁴ These payments do not include the amount that the Federal Government pays for the low-income cost-sharing subsidy for beneficiaries in catastrophic coverage and the amount that the Federal Government contributes to the 15 percent that the sponsor pays for catastrophic coverage.

²⁵ This analysis includes payments made through the Limited Income Newly Eligible Transition (LINet) program, which provides temporary Part D coverage for low-income beneficiaries under certain circumstances. This analysis does not include Federal payments for the Retiree Drug Subsidy Program—under which the Government reimburses certain qualified retiree prescription drug plans for a portion of their drug costs for individuals who would otherwise have been covered by Part D. For more information, see 42 C.F.R. § 423.884.

CMS each time a drug is dispensed to a beneficiary enrolled in their plans. We used the PDE records because they contain information on the specific drugs that were dispensed in catastrophic coverage.

We analyzed the PDE records to identify trends in total drug spending for catastrophic coverage. We identified all PDE records that had dates of service in these years, which amounted to between 1.1 billion and 1.4 billion records per year. We first calculated total drug spending for catastrophic coverage from 2010 to 2015. To do this, we calculated the amount spent on all drugs dispensed in catastrophic coverage. To determine this amount, we summed four fields on the PDE records—ingredient cost, dispensing fee, sale tax, and vaccine administration fee.²⁶ This amount represents what is paid to the pharmacy at the point of sale by all payers. It is the price negotiated between the sponsors and their network pharmacies, or is the usual and customary price paid to out-of-network pharmacies. It is not adjusted for manufacturer rebates or other price concessions that the sponsors may receive. We summed this amount for all drugs dispensed in catastrophic coverage to determine total drug spending.

We then determined the average price per month for each drug, by drug name. To do this, we matched the National Drug Code (NDC) on each PDE record to First DataBank to identify each drug's name.²⁷ For each differently named drug, we determined the average price per month.²⁸ We considered drugs with an average price per month of more than \$1,000 to be high price.²⁹ We determined the total amount of spending for these high-price drugs each year.

In addition, we calculated the number of beneficiaries who entered catastrophic coverage and the number of beneficiaries who received high-price drugs in catastrophic coverage for 2010 and 2015.

²⁶ When a drug was covered partially in the coverage gap and partially in catastrophic coverage, we included only the portion of the price covered in catastrophic coverage in our analysis.

²⁷ We based this analysis on a field in First Databank that identifies the drug name. We analyzed brand-name and generic versions of the same drug separately; we did not differentiate between different strengths and forms of the same drug.

²⁸ We determined the average price of each drug based on a 30-day supply. If the drug was dispensed for a different number of days, we adjusted the price. We use the term “month” to refer to a 30-day supply.

²⁹ We considered a drug to be high price if its average price per month was more than \$1,000 and its annual total spending per beneficiary was more than \$1,000. We developed these criteria by looking at the distribution of all drugs in catastrophic coverage.

Finally, we conducted in-depth analysis of specific high-price drugs in 2015. We calculated the spending for each drug—by drug name—that was dispensed in catastrophic coverage. We then identified the high-price drugs that had the highest total spending in catastrophic coverage. For each of these drugs, we reviewed FDA-approved drug labels to determine the key indications and the year they received FDA approval. We also calculated the average beneficiary out-of-pocket costs in catastrophic coverage for high-price drugs in 2010 and 2015 and the average out-of-pocket costs for selected high-price drugs in 2015.³⁰

³⁰ For this analysis, we included only PDE records that were covered entirely in catastrophic coverage. We excluded PDE records for beneficiaries receiving the low-income subsidy. We also excluded payments made on behalf of beneficiaries by third-party payers, such as State pharmacy assistance plans.

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