

GAO

Report to the Chairman, Subcommittee
on Health, Committee on Ways and
Means, House of Representatives

January 2010

MEDICARE PART D

Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier



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Highlights of [GAO-10-242](#), a report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

The Centers for Medicare & Medicaid Services (CMS) allows Part D plans to utilize different tiers with different levels of cost sharing as a way of managing drug utilization and spending. One such tier, the specialty tier, is designed for high-cost drugs whose prices exceed a certain threshold set by CMS. Beneficiaries who use these drugs typically face higher out-of-pocket costs than beneficiaries who use only lower-cost drugs.

GAO was asked to provide information about high-cost drugs eligible for a specialty tier. This report provides information on these drugs including spending under Medicare Part D in 2007, the most recent year for which claims data were available; how different cost-sharing structures could be expected to affect beneficiary out-of-pocket costs; how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs; and information Part D plan sponsors reported on their ability to negotiate price concessions and to manage utilization. GAO examined CMS data, including 2007 claims data, negotiated price and out-of-pocket cost data for selected drugs—including the 10 highest-utilization specialty tier-eligible drugs in 2007—and plans from 2006 through 2009, and formulary information provided to CMS by plan sponsors. GAO interviewed officials from CMS and 8 of the 11 largest plan sponsors, based on enrollment in 2008. Seven of the 11 plan sponsors provided data including price concessions for selected drugs for 2006 through 2008.

[View GAO-10-242 or key components.](#)
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MEDICARE PART D

Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier

What GAO Found

High-cost drugs eligible for a specialty tier commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Specialty tier-eligible drugs accounted for 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending under Medicare Part D plans in 2007. Medicare beneficiaries who received a low-income subsidy (LIS) accounted for most of the spending on specialty tier-eligible drugs—\$4.0 billion, or 70 percent of the total. Among all beneficiaries who used at least one specialty tier-eligible drug in 2007, 55 percent reached the catastrophic coverage threshold, after which Medicare pays at least 80 percent of all drug costs. In contrast, only 8 percent of all Part D beneficiaries who did not use a specialty tier-eligible drug reached this threshold in 2007.

Differences in plans' cost-sharing structures—flat copayments or coinsurance rates—can be expected to result in varying out-of-pocket costs for non-LIS beneficiaries only until they reach the catastrophic coverage threshold, which 31 percent of non-LIS beneficiaries did in 2007. After that point, non-LIS beneficiaries' annual out-of-pocket costs for a given drug are likely to be similar regardless of their plans' cost-sharing structures. LIS beneficiaries' out-of-pocket costs are generally not affected by their plans' cost-sharing structures because Medicare sets fixed limits on the cost-sharing amounts for these beneficiaries and pays any difference between these fixed amounts and the amount required under the plans' cost-sharing structures.

Variations in negotiated drug prices—between different drugs, across plans for the same drug, and over time—can affect out-of-pocket costs. For example, the average negotiated price for Gleevec across our sample of plans increased by 46 percent between 2006 and 2009, from about \$31,200 per year to about \$45,500 per year. Correspondingly, the average out-of-pocket cost for a non-LIS beneficiary taking Gleevec for the entire year could have been expected to rise from about \$4,900 in 2006 to more than \$6,300 in 2009.

Plan sponsors reported having little leverage to negotiate price concessions from manufacturers for most specialty tier-eligible drugs, although sponsors were more often able to negotiate price concessions for drugs with more competitors on the market—such as for drugs used to treat rheumatoid arthritis. One factor sponsors cited for this limited leverage was CMS requirements limiting sponsors' ability to exclude drugs from their formularies in favor of competing drugs. Finally, plan sponsors employ practices such as prior authorization to manage beneficiaries' utilization of specialty tier-eligible drugs, and sponsors reported employing those practices somewhat more frequently for these drugs than for lower-cost Part D drugs.

GAO provided a draft of this report to CMS. CMS agreed with portions of GAO's findings and suggested additional information for us to include in our report, which we incorporated as appropriate.

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Abbreviations

AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
HIV	human immunodeficiency virus
HHS	Department of Health and Human Services
LIS	low-income subsidy
MA-PD	Medicare Advantage prescription drug plan
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NDC	national drug code
PBM	pharmacy benefit manager
PDE	Prescription Drug Event
PDP	prescription drug plan

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United States Government Accountability Office
Washington, DC 20548

January 29, 2010

The Honorable Pete Stark
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

Medicare—the federal health insurance program that serves about 45 million elderly and disabled individuals—offers an outpatient prescription drug benefit known as Medicare Part D. According to the 2009 Medicare Trustees’ Report, federal spending on Part D totaled \$49.3 billion in 2008—accounting for nearly 11 percent of total Medicare expenditures.¹ Part D spending depends on several factors, including the number of Part D beneficiaries, their health status and extent of drug utilization, the number of beneficiaries who receive Part D’s low-income subsidy (LIS), and the cost of drugs covered by Part D.² Some drugs covered by Part D have particularly high costs—sometimes exceeding tens of thousands of dollars per year—and may be responsible for a significant share of this spending.

Under Part D, coverage and beneficiary cost sharing can vary. Medicare beneficiaries obtain Part D drug coverage by choosing from multiple competing plans offered by plan sponsors—often private insurers—that contract with the Centers for Medicare & Medicaid Services (CMS) in order to offer the prescription drug benefit.³ Part D plan sponsors can offer a range of plans with either a defined standard benefit or an

¹Includes Part D prescription drug spending and other spending such as subsidies to employer-sponsored retiree prescription drug plans and payments to states for making low-income eligibility determinations. This amount was partially offset by \$7.1 billion in payments from the states with respect to the phased-in federal assumption of Medicaid responsibility for premium and cost-sharing subsidies for dually-eligible individuals and by \$5 billion in beneficiary premium payments.

²The Part D LIS provides assistance with paying premiums and other out-of-pocket costs to beneficiaries meeting certain income and asset requirements.

³Part D plan sponsors offer drug coverage either through stand-alone prescription drug plans (PDP) or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare Advantage, Medicare’s managed care program.

actuarially equivalent alternative, or plans with enhanced benefits. Plans can vary in the coverage provided, monthly premiums, and cost-sharing arrangements such as copayments and coinsurance.⁴ For 2009, the Part D standard benefit included an initial coverage period with 25 percent beneficiary coinsurance, a coverage gap during which beneficiaries paid 100 percent of total drug costs, and a catastrophic coverage phase during which Medicare paid 80 percent of costs.

Part D plan sponsors have several options available to them to manage drug spending and utilization. For example, rather than requiring 25 percent coinsurance for all drugs, plan sponsors can modify the standard benefit by assigning covered drugs to distinct tiers, such as separate tiers for generic and brand-name drugs. These tiers often have increasing levels of cost sharing in order to encourage beneficiaries to utilize less costly drugs such as generics. CMS also allows Part D plans to establish a “specialty tier” for high-cost drugs when the total cost for a drug—as determined through negotiations between the plan and pharmacies—exceeds a certain threshold, set by CMS at \$500 per month for 2007 and \$600 per month for 2008 through 2010.⁵ Drugs eligible to be placed on specialty tiers are among the most expensive drugs on the market at costs that may exceed tens of thousands of dollars per year. Beneficiaries who use these very expensive drugs typically face higher cost sharing and therefore higher annual out-of-pocket costs than beneficiaries who use only lower-cost drugs.

In addition, plans have some flexibility in the drugs they place on their formularies. Plan sponsors may be able to manage drug spending by negotiating price concessions with manufacturers or price discounts with pharmacies when deciding which drugs to place on their formularies.⁶

⁴A copayment is usually a fixed dollar amount paid by the beneficiary, while coinsurance is a percentage of the cost.

⁵Specialty tier-eligible drugs are not synonymous with specialty drugs although there is some overlap between the two groups. Specialty drugs are typically used to treat certain complex chronic or life-threatening conditions for which few other treatment options exist. Specialty drugs may be biologics or drugs that require frequent dosage adjustment, special storage, patient education, or special routes of administration such as injection. In contrast, specialty tier-eligible drugs are drugs that meet the cost threshold and may be placed on a specialty tier by a Part D plan sponsor.

⁶Sponsors must pass price concessions on to the program. See the Social Security Act §§ 1860 D-2(d)(1)(A), -15(b)(2), and -15(e)(1)(B) (as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [MMA]) (codified at 42 U.S.C. §§ 1395w-102(d)(1)(A), -115(b)(2), and -115(e)(1)(B)).

Plan sponsors can also employ various practices—referred to as utilization management—that place restrictions on the usage of certain drugs on a plan’s formulary.

You raised concerns that the costs associated with Part D coverage for these high-cost drugs may lead to significant premium increases and increased government spending. You also expressed interest in obtaining information on Part D plan coverage, spending, and utilization; out-of-pocket costs for Medicare beneficiaries; and cost management approaches related to these drugs in Part D plans. This report provides information on (1) spending under Medicare Part D on specialty tier-eligible drugs covered in 2007, the most recent year for which claims data were available; (2) how the different cost-sharing structures used by Part D plans for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; (3) how prices negotiated with pharmacies for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; and (4) the ability of Part D plans to negotiate price concessions from manufacturers for specialty tier-eligible drugs, and the approaches plans reported using from 2006 through 2009 to manage utilization of these drugs compared to other covered Part D drugs.

To determine spending on specialty tier-eligible drugs covered under Part D in 2007, we examined CMS’s Prescription Drug Event (PDE) claims data from 2007 for Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDP).⁷ We analyzed these claims data to identify drugs eligible to be placed on a Part D plan’s specialty tier. For the purposes of this study, we considered specialty tier-eligible drugs to be all drugs with claims reimbursed under Part D with a median negotiated cost of at least \$500 for a 30-day supply (i.e., where at least half of the claims for these drugs in 2007 met or exceeded the CMS cost threshold of \$500 per month).⁸ We then determined the total amount of

⁷CMS’s PDE data contain a record of each claim reimbursed under Part D, including the plan in which the beneficiary was enrolled; whether the drug was covered by the plan; the quantity of drug supplied; drug price; amounts paid by the beneficiary, the plan, and Medicare; LIS status of the beneficiary; and whether the beneficiary was in the catastrophic coverage phase of the plan when the prescription was filled. At the time we began our study, the 2007 PDE data were the most recent available.

⁸Examples of drugs that are eligible for placement on a specialty tier using our criterion include Enbrel for the treatment of rheumatoid arthritis and Gleevec for treatment of leukemia. Drugs identified as specialty tier-eligible may not have been placed on a specialty tier by any Part D plans.

Part D spending for specialty tier-eligible drugs by Medicare, MA-PD and PDP plans, and beneficiaries in 2007. We also used 2007 PDE data to determine the utilization, in the aggregate, of the specialty tier-eligible drugs we identified—based on the number of 30-day prescriptions and the number of beneficiaries taking the drug. Finally, we determined the number of beneficiaries taking the drug who reached the catastrophic coverage portion of the Part D benefit—the portion where Medicare assumes 80 percent of total drug costs. We also conducted each of these analyses separately for LIS and non-LIS beneficiaries. We performed the same analyses for all Part D covered drugs, regardless of cost, in order to compare spending and utilization for specialty tier-eligible drugs to spending and utilization for all drugs covered under Part D.

To determine how the different cost-sharing structures used by Part D plans for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs, we examined out-of-pocket costs under a \$50 flat monthly copayment and different coinsurance rates (25 percent and 33 percent) for a hypothetical drug with a monthly negotiated price of \$1,100.⁹ We selected these cost-sharing structures because some plans charge a flat monthly copayment for specialty tier-eligible drugs while others charge a coinsurance rate.¹⁰ We analyzed the effect of each of these typical cost-sharing structures on beneficiary out-of-pocket costs in each phase of the Part D benefit. The results of this analysis can be generalized to Part D beneficiaries taking any specialty tier-eligible drug across most plans.

In order to estimate how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs and the trends in these expected costs from 2006 to 2009, we chose a judgmental sample of 20 specialty tier-eligible drugs and also selected a sample of 36 high-enrollment MA-PD and PDP plans from six counties based on enrollment as of March 2008.¹¹

⁹\$1,100 per month was the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 based on PDE claims data.

¹⁰We selected the 25 percent coinsurance rate to represent the standard benefit design and the 33 percent coinsurance rate because it was the rate required of the median enrollee in plans with specialty tiers in 2009.

¹¹In order to select a sample of Part D plans, we chose six counties across the four census regions (West, Midwest, South, and Northeast), ensuring that the counties exhibited diversity in population density and poverty rates. The six counties were Grand Traverse County, Michigan; Greene County, Georgia; Highlands County, Florida; Kings County, New York; Lincoln County, Wyoming; and Orange County, California.

Our sample of drugs included those used to treat selected chronic conditions as well as the 10 most heavily utilized specialty tier-eligible drugs based on the number of 30-day prescriptions in 2007. (For a list of the 20 drugs included in our sample, see app. I.) We used CMS negotiated price data¹² and CMS estimates of beneficiary out-of-pocket costs for our sample of drugs in 35 of the 36 selected plans¹³ to analyze how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs from 2006 through 2009. The results of this analysis cannot be generalized beyond our judgmental sample of drugs and selected plans.

To determine the ability of Part D plans to negotiate price concessions for specialty tier-eligible drugs and the approaches plans reported using from 2006 through 2009 to manage utilization of these drugs compared to other covered Part D drugs, we conducted interviews with representatives from 8 of the 11 largest MA-PD and PDP plan sponsors based on 2008 enrollment data from CMS. In addition to our interviews, seven of the plan sponsors we interviewed provided price concession data for our sample of 20 specialty tier-eligible drugs for 2006 through 2008. These seven plan sponsors represented 51 percent of all MA-PD enrollment and 67 percent of all PDP enrollment in 2008. In addition, we analyzed data from the Part D Formulary, Pharmacy Network, and Pricing Information files to determine utilization management approaches reported by all Part D plans for 2007.¹⁴ For additional details on our scope and methodology, see appendix II.

¹²Negotiated drug prices are prices negotiated between pharmacies and plan sponsors for drugs dispensed by a pharmacy to plan beneficiaries and are reported by plan sponsors to CMS. CMS negotiated price data, which reflect average prices reported by plans across pharmacies available to beneficiaries, can be used only to estimate average beneficiary out-of-pocket costs, and may not reflect actual out-of-pocket costs paid by beneficiaries. The latter are influenced by factors—such as the extent of price concessions negotiated between plans and pharmacies—that vary by pharmacy and region.

¹³CMS was unable to provide negotiated drug price data and estimated out-of-pocket costs for all four years—2006 through 2009—for one plan in our sample. Therefore, we excluded this plan from our analyses.

¹⁴The Part D Formulary, Pharmacy Network, and Pricing Information files are public-use files provided by CMS that contain information—including formulary placement, tier placement, copayment and coinsurance amounts, and utilization management practices applicable to each drug under each Part D plan—reported by the plans prior to the start of each calendar year. This information is available to beneficiaries through the Medicare Prescription Drug Plan Finder (www.medicare.gov/mpdpf as of December 14, 2009) as a tool for plan selection.

To test the internal consistency and reliability of the data we used in our review, we discussed our data sources with knowledgeable agency officials, performed data reliability checks such as manually and electronically checking the data for missing values and obvious errors, interviewed CMS officials about concerns we uncovered, and reviewed the internal controls that CMS uses to ensure that data are complete and accurate. We checked the negotiated price data for 2006 through 2008 provided by the plan sponsors through the data collection instrument for internal consistency by comparing these data, when possible, to data the plan sponsors had previously provided to CMS. We determined that the data were sufficiently reliable for our purposes. We conducted our work from March 2009 through December 2009 in accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

Background

All 45 million elderly and disabled Medicare beneficiaries, regardless of income, may enroll in the Part D drug benefit. As of February 2009, CMS reported that 26.7 million beneficiaries were enrolled in Part D plans, of which 17.5 million were enrolled in PDPs and 9.0 million were enrolled in MA-PD plans.¹⁵ Of the 26.7 million beneficiaries, about 36 percent, or 9.6 million, received assistance with premiums and cost sharing through Medicare's LIS.

Medicare Part D Plan Structure

Part D plan sponsors offer plans with either a defined standard benefit or an actuarially equivalent alternative, and can also offer plans with enhanced benefits. In 2009, plans offering the defined standard benefit required non-LIS beneficiaries to pay out-of-pocket costs during the initial coverage period of: a deductible equal to the first \$295 in drug costs, followed by 25 percent coinsurance for all drugs—with the plan paying the remaining 75 percent—until total drug costs reached \$2,700, with beneficiary out-of-pocket costs accounting for \$896.25 of that total. (See fig. 1.) This initial coverage period is followed by a coverage gap—the

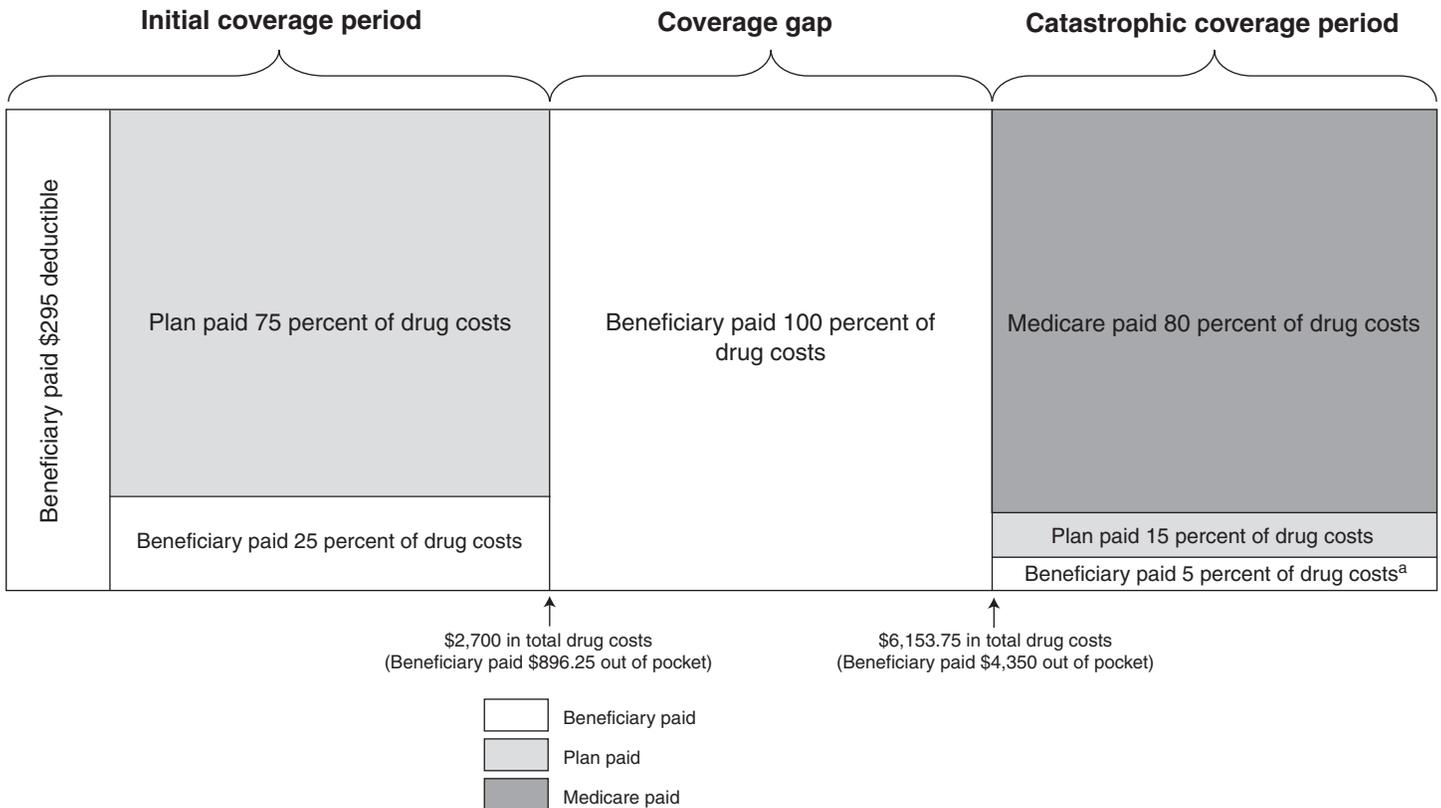
¹⁵An additional 0.2 million beneficiaries were enrolled in other types of Medicare health plans.

so-called doughnut hole—in which beneficiaries pay 100 percent of their drug costs. In 2009, the coverage gap lasted until total drug costs reached \$6,153.75, with beneficiary out-of-pocket costs accounting for \$4,350 of that total. This point is referred to as the catastrophic coverage threshold and is in addition to any monthly premiums required by beneficiaries' Part D plans.¹⁶ After reaching the catastrophic coverage threshold, non-LIS beneficiaries in a defined standard benefit plan taking a specialty tier-eligible drug pay 5 percent of total drug costs for each prescription for the remainder of the year, while the drug plan pays 15 percent and Medicare pays the remaining 80 percent.¹⁷

¹⁶In designing an actuarially equivalent alternative plan, plan sponsors must maintain the catastrophic coverage threshold set by CMS pursuant to law (\$4,350 in 2009). See the Social Security Act §1860D-2(b)(4)(B) (as added by the MMA) (codified at 42 U.S.C. §1395w-102(b)(4)(B)).

¹⁷For 2010, the standard benefit amounts set by CMS are as follows: a \$310 deductible, \$2,830 initial coverage limit, and a catastrophic coverage threshold of \$4,550.

Figure 1: Medicare Part D Cost-Sharing Structure for Specialty Tier–Eligible Drugs under the Defined Standard Benefit, 2009



Source: GAO analysis of CMS data.

^aBecause of the high cost of specialty tier–eligible drugs, the beneficiary will always pay 5 percent of drug costs during the catastrophic coverage period.

In addition to cost sharing for prescription drugs, many Part D plans also charge a monthly premium. In 2009, premiums across all Part D plans averaged about \$31 per month, an increase of 24 percent from 2008.¹⁸ Beneficiaries are responsible for paying these premiums except in the case

¹⁸“A Status Report on Part D for 2009,” *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Medicare Payment Advisory Commission [MedPAC], March 2009), http://www.medpac.gov/document_search.cfm (accessed Aug. 13, 2009).

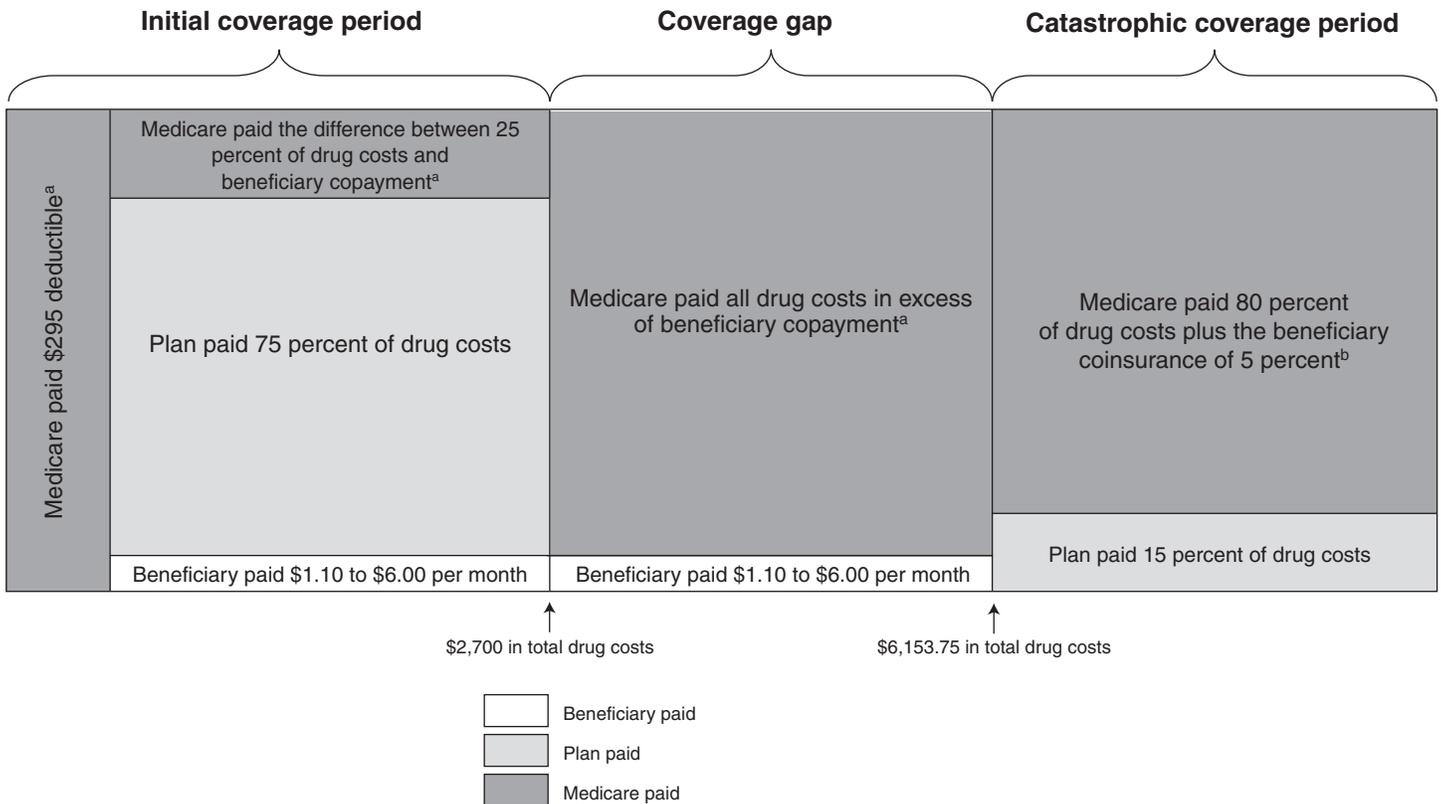
of beneficiaries who receive the LIS, whose premiums are subsidized by Medicare as long as they enroll in an eligible plan.¹⁹

Low-Income Subsidy

When Medicare Part D was established, it replaced Medicaid as the primary source of drug coverage for beneficiaries with coverage under both programs—referred to as dual-eligible beneficiaries. Part D provides substantial premium and cost-sharing assistance through the LIS for dual-eligible beneficiaries and some other low-income beneficiaries. Instead of paying the cost-sharing amounts established by each plan for covered drugs, these beneficiaries—referred to as full subsidy beneficiaries—pay a small copayment (between \$1.10 and \$6.00 in 2009) and Medicare pays the difference between these amounts and the cost sharing required by the plans (see fig. 2).

¹⁹An eligible plan is one with a premium less than or equal to the benchmark premium in the beneficiary's region. The benchmark premium for each region is based on a weighted average of the premiums for basic prescription drug coverage charged by the Part D plans available in the region. A beneficiary also can choose to enroll in a plan with a premium higher than the benchmark premium and pay the difference between the two.

Figure 2: Medicare Part D Cost-Sharing Structure for Specialty Tier–Eligible Drugs under the Defined Standard Benefit for Full Subsidy LIS Beneficiaries, 2009



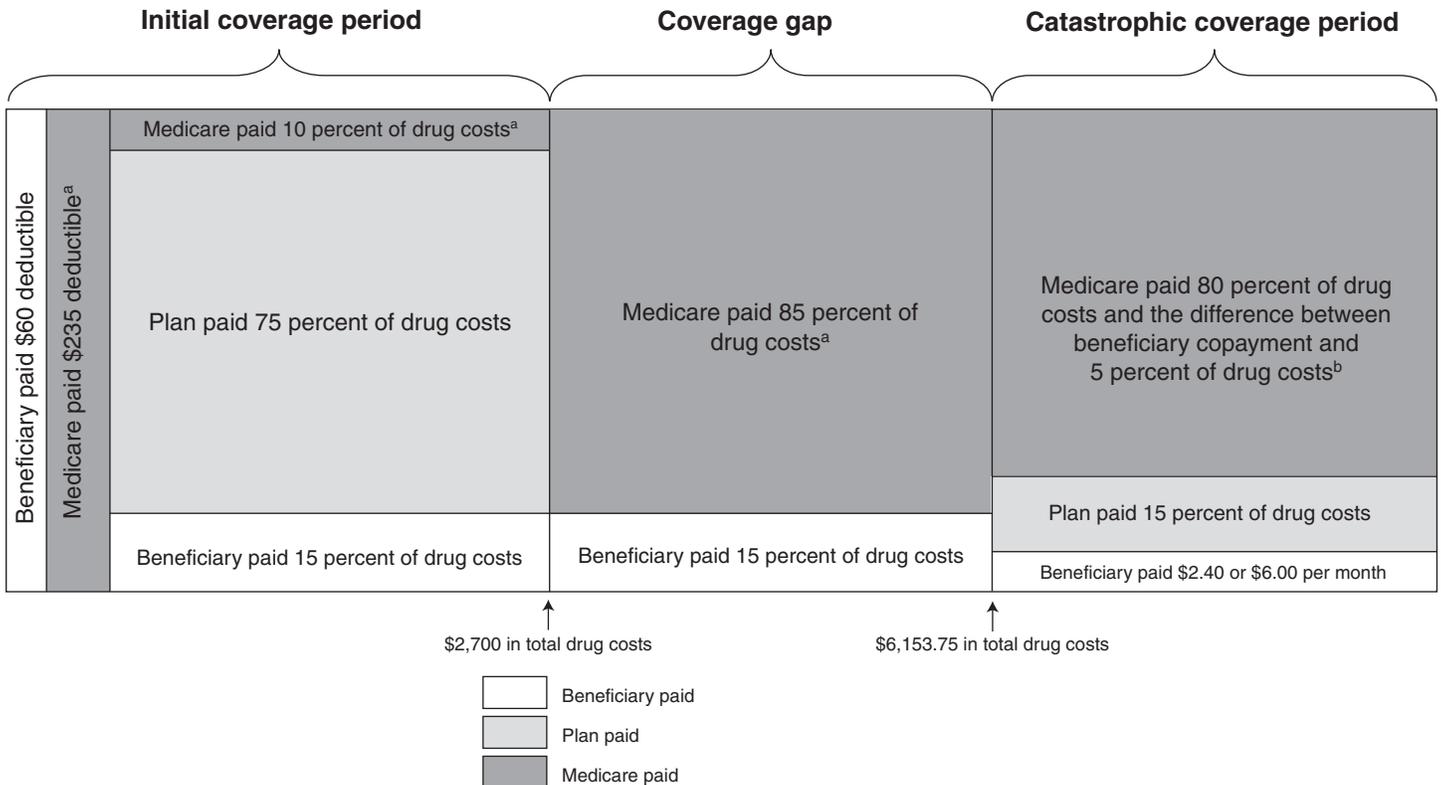
Source: GAO analysis of CMS data.

^aThis is a payment made by Medicare that otherwise would have been paid by the beneficiary, if he or she did not receive the LIS.

^bFor these high-cost drugs, 5 percent of drug costs would otherwise have been paid by the beneficiary, if he or she did not receive the LIS.

Medicare also provides somewhat lower levels of assistance for other beneficiaries who have low incomes and modest assets, making them eligible for the LIS, but who do not meet the eligibility requirements for Medicaid. Instead of paying the cost-sharing amounts established by each plan for covered drugs, these beneficiaries—referred to as partial subsidy beneficiaries—pay 15 percent coinsurance during the initial coverage period and coverage gap. Medicare pays the difference between these amounts and the cost sharing required by the plans (see fig. 3). About 9.6 million Medicare beneficiaries were receiving the LIS as of February 2009; of this total, more than 80 percent were full subsidy beneficiaries.

Figure 3: Medicare Part D Cost-Sharing Structure for Specialty Tier–Eligible Drugs under the Defined Standard Benefit for Partial Subsidy LIS Beneficiaries, 2009



Source: GAO analysis of CMS data.

^aThis is a payment made by Medicare that otherwise would have been paid by the beneficiary, if he or she did not receive the LIS.

^bFor these high-cost drugs, 5 percent of drug costs would otherwise have been paid by the beneficiary, if he or she did not receive the LIS.

Medicare Part D Spending and Utilization Management

In order to manage drug spending and utilization, plans may establish tiers with different levels of beneficiary cost sharing. For example, a plan may establish separate tiers for generic drugs and brand name drugs—with the generic drug tier requiring a lower level of cost sharing than the brand-name drug tier. The Medicare Payment Advisory Commission (MedPAC) has reported that most Part D beneficiaries are in plans that use different drug tiers.²⁰ CMS also allows plans participating in Part D to use a

²⁰MedPAC, “A Status Report on Part D for 2009.”

specialty tier in their formulary for high-cost drugs with negotiated prices exceeding a certain threshold, set at \$500 per month in 2007 and \$600 per month in 2008 through 2010. MedPAC estimated that more than 80 percent of Part D beneficiaries in 2009 were in plans that use a specialty tier for high-cost drugs, with the median beneficiary in such a plan required to pay 33 percent coinsurance for those drugs during the initial coverage period.²¹ Specialty tier-eligible drugs represent a limited number of drugs used by a small proportion of beneficiaries and commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Although Part D beneficiaries using a drug on a nonpreferred brand-name drug tier may seek an exception to obtain the drug at the lower cost-sharing terms applicable to drugs in another tier, plans are not obligated to provide an exception for drugs placed on a plan's specialty tier even if no other drug is available to treat a beneficiary's condition.

In addition to establishing different cost-sharing tiers, Part D plan sponsors have several options available to them to help contain drug spending. For example, plan sponsors can negotiate prices with drug companies and pharmacies. Plan sponsors may use pharmacy benefit managers (PBM)²² to negotiate with drug manufacturers and retail pharmacies for the prices of the drugs that each plan covers.²³ Discounts negotiated with pharmacies are typically reflected in the price that a beneficiary pays at the pharmacy, while price concessions negotiated with drug manufacturers are typically in the form of rebates that are provided to plan sponsors and ultimately passed on to the program.

Furthermore, plans may place utilization management requirements on the use of certain drugs on their formulary, such as requiring beneficiaries to obtain prior authorization from their plan before being able to fill a

²¹MedPAC, "A Status Report on Part D for 2009."

²²Health insurance plans typically contract with PBMs to help manage their prescription drug benefits. PBMs negotiate rebates or payments with drug manufacturers, encourage substitution of generic drugs for therapeutically similar brand drugs, and negotiate discounted prices with networks of retail and mail-order pharmacies, passing along a portion of the savings to health plans and beneficiaries. PBMs influence price negotiations with manufacturers through formulary development and management and through the large market share they often represent. In the case of Part D, some plan sponsors are PBMs themselves (e.g., Medco Health Solutions, Inc. and CVS Caremark Corporation).

²³MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between plan sponsors and drug manufacturers and pharmacies. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(i)).

prescription, requiring beneficiaries to first try a preferred drug to treat a medical condition before being able to obtain an alternate drug for that condition, or limiting the quantity of drugs that they cover over a certain period of time. (See table 1.)

Table 1: Utilization Management Practices under Medicare Part D

Prior authorization	Step therapy	Quantity limits
Prior authorization means that a beneficiary will need prior approval from his or her plan before being able to fill a prescription. If a drug has a prior authorization requirement, a beneficiary will need to work with his or her plan and physician to obtain an authorization. Many prior authorization requirements can be resolved at the point of sale and do not require any additional information from the physician.	In some cases, plans require a beneficiary to first try one drug to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe Drug A first. If Drug A does not work for a beneficiary, then the plan will cover Drug B.	For safety and cost reasons, plans may limit the quantity of drugs that they cover over a certain period of time. For example, if a beneficiary currently takes 2 pills per day and the quantity limit is 30 pills per month, he or she would need to work with the plan to get authorization for the higher quantity.

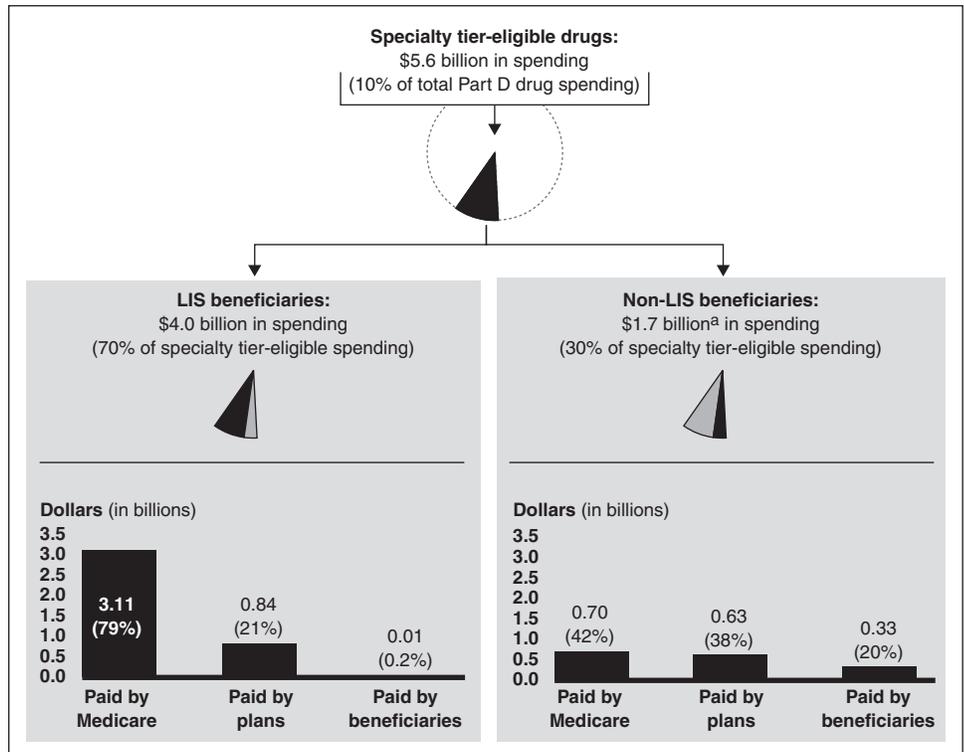
Source: CMS.

In 2007, Specialty Tier-Eligible Drugs Accounted for 10 Percent of Part D Spending and Most of That Spending Was for Prescriptions Filled by LIS Beneficiaries

We found that specialty tier-eligible drugs accounted for about 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending under Part D MA-PD and PDP plans in 2007.²⁴ Additionally, even though only 41 percent of prescriptions for nonspecialty tier-eligible drugs filled under Part D MA-PD and PDP plans in 2007 were for LIS beneficiaries, more than 75 percent of prescriptions for specialty tier-eligible drugs were for LIS beneficiaries. Prescriptions for LIS beneficiaries accounted for about 70 percent, or about \$4.0 billion, of the \$5.6 billion spent on specialty tier-eligible drugs under MA-PD and PDP plans that year. (See fig. 4.)

²⁴These amounts include spending by Medicare, the plans, and beneficiaries.

Figure 4: Spending on Specialty Tier–Eligible Drugs under Part D MA-PD and PDP Plans, 2007



Source: GAO analysis of CMS data.

^aTotals do not add to \$5.6 billion due to rounding.

The fact that spending on specialty tier–eligible drugs in 2007 was largely accounted for by LIS beneficiaries is noteworthy because their cost sharing is largely paid by Medicare. Specifically, of the \$4.0 billion in spending on specialty tier–eligible drugs for LIS beneficiaries, about 79 percent, or \$3.1 billion, was paid by Medicare, 21 percent was paid by plans, and 0.2 percent was paid by beneficiaries. Of the \$3.1 billion paid by Medicare for LIS beneficiaries, \$1.0 billion was for the LIS and \$2.1 billion was for catastrophic coverage. In contrast, of the \$1.7 billion spent on specialty tier–eligible drugs in 2007 for non-LIS beneficiaries, Medicare was responsible for 42 percent, plans were responsible for 38 percent, and beneficiaries were responsible for 20 percent.

While only 8 percent of Part D beneficiaries in MA-PD and PDP plans who did not use specialty tier–eligible drugs reached the catastrophic coverage threshold of the Part D benefit in 2007, 55 percent of beneficiaries who

used at least one specialty tier-eligible drug reached the threshold. Specifically, among those beneficiaries who used at least one specialty tier-eligible drug in 2007, 67 percent of LIS beneficiaries and 31 percent of non-LIS beneficiaries reached the catastrophic coverage threshold. Most (62 percent) of the \$5.6 billion in total Part D spending on specialty tier-eligible drugs under MA-PD and PDP plans occurred after beneficiaries reached the catastrophic coverage phase of the Part D benefit.

Differences in Plans' Cost-Sharing Structures Result in Out-of-Pocket Costs for Non-LIS Beneficiaries That Vary Initially and Then Become Similar, but Different Structures Do Not Significantly Affect Out-of-Pocket Costs for LIS Beneficiaries

Based on our review of typical cost-sharing structures, we found that, for non-LIS beneficiaries who use a given specialty tier-eligible drug, different cost-sharing structures can be expected to result in varying out-of-pocket costs during the benefit's initial coverage period. However, as long as beneficiaries reach the catastrophic coverage threshold in a calendar year, their annual out-of-pocket costs for that drug are likely to be similar regardless of their plans' cost-sharing structures. LIS beneficiaries' out-of-pocket costs for all drugs, including specialty tier-eligible drugs, are not significantly affected by different plans' cost-sharing structures because Medicare has established fixed cost-sharing levels for all LIS beneficiaries, regardless of the plans in which they are enrolled.

For Non-LIS Beneficiaries, Different Cost-Sharing Structures Can Be Expected to Result in Out-of-Pocket Costs That Vary Initially but Become Similar Once Beneficiaries Reach the Catastrophic Coverage Threshold

For non-LIS beneficiaries who use a given specialty tier-eligible drug, different cost-sharing structures can be expected to result in varying out-of-pocket costs during the benefit's initial coverage period. However, as long as beneficiaries reach the catastrophic coverage threshold in a calendar year—as 31 percent of non-LIS beneficiaries using at least one specialty tier-eligible drug did in 2007—their annual out-of-pocket costs for that drug are likely to be similar regardless of their plans' cost-sharing structures.

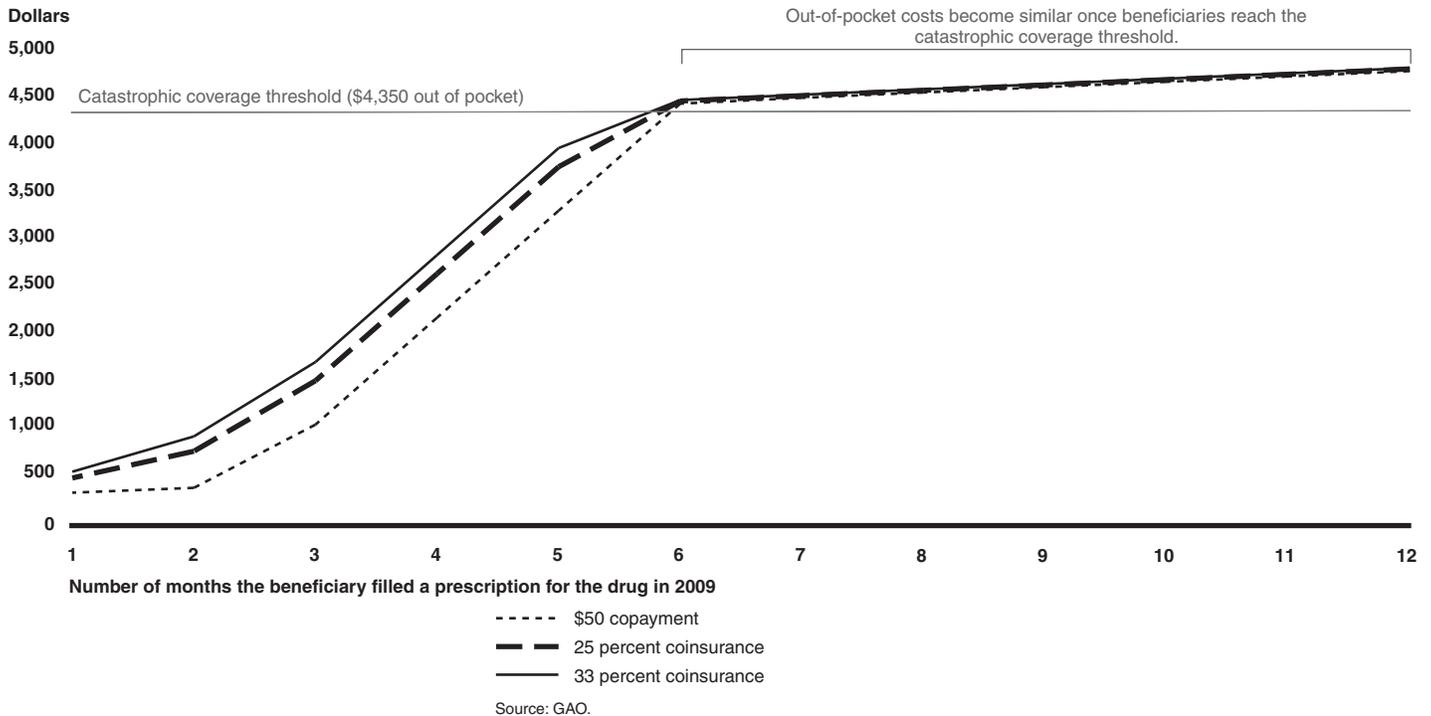
During the initial coverage period, non-LIS beneficiaries' estimated out-of-pocket costs for a given specialty tier-eligible drug are likely to vary because some Part D plans may place the drug on a tier with coinsurance while other plans may require a flat copayment for the drug. For example,

estimated 2009 out-of-pocket costs during the initial coverage period, excluding any deductibles, for a drug with a monthly negotiated price of \$1,100 would range from \$25 per month for a plan with a flat \$25 monthly copayment to \$363 per month for a plan with a 33 percent coinsurance rate.²⁵ Non-LIS beneficiaries' out-of-pocket costs eventually become similar for a given specialty tier-eligible drug regardless of their plans' cost-sharing structure because these beneficiaries are generally responsible for 100 percent of their drug costs during the coverage gap. The coverage gap begins once total drug costs in a calendar year—including the amount paid by the plan and the beneficiary—reach a fixed amount, which, in 2009, was \$2,700 under the standard benefit. Once non-LIS beneficiaries reach the catastrophic coverage threshold, which, in 2009, was \$4,350 in beneficiary out-of-pocket costs for all Part D plans,²⁶ they generally pay only 5 percent of the negotiated drug price for the remainder of the calendar year. (See fig. 5.)

²⁵\$1,100 per month was the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 based on PDE claims data.

²⁶Plan sponsors must maintain the catastrophic coverage threshold set by CMS pursuant to law (\$4,350 in 2009).

Figure 5: Cumulative Non-LIS Beneficiary Out-of-Pocket Costs under Different Cost-Sharing Structures for a Drug with a Negotiated Price of \$1,100 per Month



Note: All scenarios include a \$295 annual deductible paid by the beneficiary, \$2,700 initial coverage limit, and \$4,350 catastrophic coverage threshold.

Even if non-LIS beneficiaries pay different out-of-pocket costs during the initial coverage period, their out-of-pocket costs become similar due to the coverage gap and the fixed catastrophic coverage threshold (\$4,350 in 2009). There are several reasons for this. First, beneficiaries taking equally-priced drugs will reach the coverage gap at the same time—even with different cost sharing structures—because entry into the coverage gap is based on total drug costs paid by the beneficiary and the plan, rather than on out-of-pocket costs paid by the beneficiary. Since specialty tier-eligible drugs have high total drug costs, beneficiaries will typically reach the coverage gap within 3 months in the same calendar year. Second, during the coverage gap, beneficiaries typically pay 100 percent of their total drug costs until they reach the catastrophic coverage threshold (a total of \$4,350 in out-of-pocket costs in 2009). This same threshold applies to all non-LIS beneficiaries and includes out-of-pocket costs paid during the initial coverage period. Therefore, non-LIS beneficiaries who paid higher out-of-pocket costs in the initial coverage period had less to

pay in the coverage gap before they reached \$4,350 in out-of-pocket costs. Conversely, non-LIS beneficiaries who paid lower out-of-pocket costs in the initial coverage period had more to pay in the coverage gap before they reached the same threshold of \$4,350 in out-of-pocket costs. Third, after reaching the threshold, beneficiaries' out-of-pocket costs become similar because they typically pay 5 percent of the drug's negotiated price for the remainder of the calendar year.²⁷

For LIS Beneficiaries, Plans' Cost-Sharing Structures Do Not Significantly Affect Out-of-Pocket Costs

LIS beneficiaries' out-of-pocket costs for all drugs, including specialty tier-eligible drugs, are not significantly affected by different plans' cost-sharing structures because Medicare has established fixed limits on the cost-sharing amounts for all LIS beneficiaries, regardless of the plans in which they are enrolled. Medicare pays the difference between the LIS beneficiaries' out-of-pocket costs and the cost-sharing amounts that are required by the plans.

As is the case with non-LIS beneficiaries, LIS beneficiaries reach the catastrophic coverage threshold if they take any specialty tier-eligible drug for the entire calendar year, but actual out-of-pocket costs for specialty tier-eligible drugs can vary greatly depending on the level of assistance an LIS beneficiary receives. In 2009, full subsidy LIS beneficiaries, regardless of the plan in which they were enrolled, paid a copayment between \$1.10 and \$6.00 per drug per month until the total of their low-income subsidy amount paid by Medicare and their out-of-pocket costs reached the catastrophic coverage threshold of \$4,350 for the calendar year. From this point forward, Medicare paid all beneficiary out-of-pocket costs for prescription drugs for the remainder of the calendar year. For a full subsidy LIS beneficiary who took any one specialty tier-eligible drug in 2009, these copayments resulted in a maximum of \$72 in out-of-pocket costs over the course of the calendar year—or \$6.00 per month, and for plans that charged a deductible, the beneficiary's out-of-pocket costs may have been lower.

Partial subsidy LIS beneficiaries in 2009, regardless of the plan in which they were enrolled, paid up to a \$60 deductible followed by up to 15 percent coinsurance until the total of their LIS amount paid by

²⁷While not common, some plan sponsors offer MA-PD plans with lower cost sharing than the usual 100 percent during the coverage gap or the usual 5 percent during the catastrophic coverage period. In these rare cases, non-LIS beneficiaries would have lower out-of-pocket costs for specialty tier-eligible drugs over the course of the calendar year.

Medicare and their out-of-pocket costs reached the catastrophic coverage threshold of \$4,350 in the calendar year. From this point forward, these beneficiaries paid either a \$2.40 or \$6.00 monthly copayment per drug for the remainder of the calendar year. For a partial subsidy LIS beneficiary who took any one specialty tier-eligible drug in 2009, this coinsurance may have resulted in over \$900 in out-of-pocket costs by the time he or she reached the catastrophic coverage threshold and then payments of up to \$6.00 per month for the remainder of the calendar year.

Variations in Negotiated Drug Prices Can Be Expected to Affect Out-of-Pocket Costs for Non-LIS Beneficiaries but Largely Do Not Affect Out-of-Pocket Costs for LIS Beneficiaries

Variations in negotiated drug prices affect non-LIS beneficiaries' out-of-pocket costs during the initial coverage phase if their plans require them to pay coinsurance. Additionally, negotiated drug prices will affect all non-LIS beneficiaries' out-of-pocket costs during the coverage gap and the catastrophic coverage phase. Differences in negotiated drug prices do not affect out-of-pocket costs for full subsidy LIS beneficiaries, and affect out-of-pocket costs for partial subsidy LIS beneficiaries only until they reach the catastrophic coverage threshold.

For Non-LIS Beneficiaries, Variations in Negotiated Drug Prices Affect Out-of-Pocket Costs

Variations in negotiated drug prices affect non-LIS beneficiaries' out-of-pocket costs during the initial coverage phase if their plan requires them to pay coinsurance, which all 35 of our selected plans did in 2009 for at least some of the 20 specialty tier-eligible drugs in our sample. Additionally, negotiated drug prices will affect all non-LIS beneficiaries' out-of-pocket costs during the coverage gap and the catastrophic coverage phase because beneficiaries generally pay the entire negotiated price of a drug during the coverage gap and 5 percent of a drug's negotiated price during the catastrophic coverage phase. Negotiated prices for specialty tier-eligible drugs can vary in three ways that affect out-of-pocket costs for non-LIS beneficiaries. These are variations between drugs, variations across plans for the same drug, and variations from year to year.

First, variations in negotiated drug prices between different drugs have a significant effect on out-of-pocket costs throughout the benefit for non-LIS beneficiaries. For example, in 2009—across our sample of 35 plans—non-LIS beneficiaries who took the cancer drug Gleevec for the entire year

could have been expected to pay about \$6,300 out-of-pocket because Gleevec had an average negotiated price of about \$45,500 per year, while beneficiaries could have been expected to pay about \$10,500 out-of-pocket over the entire year if they took the Gaucher disease drug Zavesca, which had an average negotiated price of about \$130,000 per year.²⁸

Second, negotiated prices across plans for the same drug generally vary less dramatically than prices for different drugs but can still affect non-LIS beneficiary out-of-pocket costs even for plans with the same cost-sharing structure. For example, in 2009, the negotiated price for the human immunodeficiency virus (HIV) drug Truvada varied from about \$10,900 to about \$11,400 per year across different plans with a 33 percent coinsurance rate, resulting in out-of-pocket costs that could be expected to range from about \$4,600 to \$4,850 for non-LIS beneficiaries taking the drug over the entire year.

Third, changes in negotiated drug prices over time also affect non-LIS beneficiaries' annual estimated out-of-pocket costs. Since 2006, average negotiated prices for the specialty tier-eligible drugs in our sample have risen across our sample of plans; the increases averaged 36 percent over the 3-year period.²⁹ These increases, in turn, led to higher estimated beneficiary out-of-pocket costs for these drugs in 2009 compared to 2006. For example, the average negotiated price for a 1-year supply of Gleevec across our sample of plans increased by 46 percent, from about \$31,200 in 2006 to about \$45,500 in 2009. Correspondingly, the average out-of-pocket cost for a non-LIS beneficiary taking Gleevec for an entire year could have been expected to rise from about \$4,900 in 2006 to more than \$6,300 in 2009.

²⁸Values reported are averages in 2009 across the 35 selected plans used in our analysis. Of these 35 plans, 2 applied the standard benefit parameters (\$295 deductible, 25 percent coinsurance during the initial coverage period, and \$2,700 initial coverage limit) to the 20 drugs in our sample, while the other 33 plans used alternate benefit parameters approved by CMS.

²⁹We calculated average negotiated drug prices separately for 2006 and 2009 across all plans that covered a given drug for each year and then compared the two average prices to determine the percent increase. CMS did not provide negotiated prices or estimated out-of-pocket costs for four drugs in our sample—Aranesp, Intron-A, Kaletra, and Letairis—for 2006. Therefore, these drugs are excluded from this calculation.

For Most LIS Beneficiaries, Variations in Negotiated Drug Prices Do Not Affect Out-of-Pocket Costs

In contrast to the situation for non-LIS beneficiaries, differences in negotiated drug prices do not affect out-of-pocket costs for full subsidy LIS beneficiaries, and affect out-of-pocket costs for partial subsidy LIS beneficiaries only until they reach the catastrophic coverage threshold.

Negotiated drug prices do not affect out-of-pocket costs for full subsidy LIS beneficiaries because they pay a flat monthly copayment (between \$1.10 and \$6.00 per drug in 2009) until they reach the catastrophic coverage threshold and pay no out-of-pocket costs for the remainder of the calendar year. On the other hand, partial subsidy LIS beneficiaries are affected by negotiated drug prices until they reach the catastrophic coverage threshold, because they pay 15 percent of a drug's negotiated cost. Therefore, variations in the negotiated price between drugs, across plans for the same drug, and from year to year affect the amount that partial subsidy LIS beneficiaries pay out of pocket. However, once these beneficiaries reach the catastrophic coverage threshold, their out-of-pocket costs are no longer affected by negotiated drug costs because they pay a flat monthly copayment (between \$2.40 and \$6.00 per drug in 2009) for the remainder of the calendar year.

Plan Sponsors Report Having a Limited Ability to Negotiate Price Concessions for Specialty Tier-Eligible Drugs but Frequently Use Practices to Manage Utilization

All of the Part D plan sponsors we interviewed, including the seven that provided price concession data for our sample of specialty tier-eligible drugs, reported having a limited ability to negotiate price concessions with manufacturers of specialty tier-eligible drugs. The reasons they gave included a lack of competitors for many of these drugs, CMS formulary requirements that may limit plan sponsors' ability to exclude drugs from their formularies in favor of competing drugs, and low utilization for some drugs, which limits incentives for manufacturers to provide price concessions. However, plan sponsors are able to employ practices, such as prior authorization, to manage beneficiaries' utilization of specialty tier-eligible drugs, and they employ these practices somewhat more often for specialty tier-eligible drugs than for other drugs.

**Part D Plan Sponsors
Report Three Main
Reasons Why They Have a
Limited Ability to
Negotiate Price
Concessions with
Manufacturers for Many
Specialty Tier-Eligible
Drugs**

The eight Part D plan sponsors we interviewed told us that they have little leverage in negotiating price concessions for most specialty tier-eligible drugs. All seven of the plan sponsors we surveyed reported that they were unable to obtain price concessions from manufacturers on 8 of the 20 specialty tier-eligible drugs in our sample between 2006 and 2008.³⁰ For most of the remaining 12 drugs in our sample, plan sponsors who were able to negotiate price concessions reported that they were only able to obtain price concessions that averaged 10 percent or less, when weighted by utilization, between 2006 and 2008. (See app. III for a drug-by-drug comparison of the average price concessions negotiated by the plan sponsors we surveyed, for our sample of 20 drugs, from 2006 to 2008.)

The plan sponsors we interviewed often cited three main reasons why they have typically had a limited ability to negotiate price concessions for specialty tier-eligible drugs. First, they stated that pharmaceutical manufacturers have little incentive to offer price concessions when a given drug has few competitors on the market, as is the case for drugs used to treat cancer. For Gleevec and Tarceva, two drugs in our sample that are used to treat certain types of cancer, plan sponsors reported that they were not able to negotiate any price concessions between 2006 and 2008. In contrast, plan sponsors told us that they were more often able to negotiate price concessions for drugs in classes where there are more competing drugs on the market—such as for drugs used to treat rheumatoid arthritis, multiple sclerosis, and anemia. The anemia drug Procrit was the only drug in our sample for which all of the plan sponsors we surveyed reported that they were able to obtain price concessions each year between 2006 and 2008.

Second, plan sponsors told us that even when there are competing drugs, CMS may require plans to include all or most drugs in a therapeutic class on their formularies, and such requirements limit the leverage a plan sponsor has when negotiating price concessions. When negotiating price concessions with pharmaceutical manufacturers, the ability to exclude a drug from a plan's formulary in favor of a therapeutic alternative is often a significant source of leverage available to a plan sponsor. However, many specialty tier-eligible drugs belong to one of the six classes of clinical concern for which CMS requires Part D plan sponsors to include all or substantially all drugs on their formularies, eliminating formulary

³⁰One of the plan sponsors we interviewed declined to provide price concession data through our survey.

exclusion as a source of negotiating leverage.³¹ We found that specialty tier-eligible drugs were more than twice as likely to be in one of the six classes of clinical concern compared with lower-cost drugs in 2009.³² Additionally, among the 8 drugs in our sample of 20 specialty tier-eligible drugs for which the plan sponsors we surveyed reported they were unable to obtain price concessions between 2006 and 2008, 4 drugs were in one of the six classes of clinical concern. Plan sponsors are also required to include at least two therapeutic alternatives from each of the other therapeutic classes on their formularies.

Third, plan sponsors told us that they have limited ability to negotiate price concessions for certain specialty tier-eligible drugs because they account for a relatively limited share of total prescription drug utilization among Part D beneficiaries. For some drugs in our sample, such as Zavesca, a drug used to treat a rare enzyme disorder called Gaucher disease, the plan sponsors we surveyed had very few beneficiary claims between 2006 and 2008. None of the plan sponsors we surveyed reported price concessions for this drug during this period. Plan sponsors told us that utilization volume is usually a source of leverage when negotiating price concessions with manufacturers for Part D drugs. For some specialty tier-eligible drugs like Zavesca, however, the total number of individuals using the drug may be so limited that plans are not able to enroll a significant enough share of the total users to entice the manufacturer to offer a price concession.

³¹A therapeutic class or category of drugs is generally based on a Food and Drug Administration-approved indication. Part D sponsor formularies must include all or substantially all drugs in the following six classes of clinical concern as identified by CMS: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. Examples of other therapeutic classes include analgesics, blood glucose regulators, cardiovascular agents, dermatological agents, respiratory tract agents, and sedatives.

³²This analysis was conducted by comparing specialty tier-eligible and nonspecialty tier-eligible drugs at the drug (ingredient) level with a list of drugs in the six classes of clinical concern provided by CMS.

Part D Plans Employ Utilization Management Practices Somewhat More Frequently for Specialty Tier-Eligible Drugs Than for Other Covered Drugs

Plan sponsors employ various practices to manage beneficiaries' utilization of Part D drugs. According to plan sponsors that we interviewed and our analysis of CMS data, these practices are somewhat more common for specialty tier-eligible drugs than for lower-cost drugs. For example, based on our analysis of certain drugs and plans,³³ one or more plans placed at least one utilization management requirement on 99 percent of specialty tier-eligible drugs in 2007, while they placed at least one utilization management requirement on a smaller percentage—89 percent—of nonspecialty tier-eligible Part D drugs. According to the plan sponsors we interviewed, prior authorization is the most common of the various utilization management practices employed for specialty tier-eligible drugs. Based on our analysis, one or more plans placed a prior authorization requirement on 95 percent of specialty tier-eligible drugs in 2007. Quantity limits and step therapy were used less often, with one or more plans placing quantity limits on 58 percent of specialty tier-eligible drugs and a step therapy requirement on 14 percent of specialty tier-eligible drugs.

Most of the plan sponsors we interviewed described utilization management as a strategy for promoting patient safety and limiting inappropriate use of Part D drugs, including specialty tier-eligible drugs. One plan sponsor explained that specialty tier-eligible drugs often have a more serious side-effect profile than other drugs covered under Part D and, as a result, plans may employ prior authorization to minimize the potential for adverse effects among beneficiaries who are prescribed these drugs. Plan sponsors also told us that they often use prior authorization to ensure that beneficiaries who have been prescribed specialty tier-eligible drugs are using them for a medically-accepted indication.

Some plan sponsors explained that it is more difficult to employ certain utilization management practices, like quantity limits and step therapy, with specialty tier-eligible drugs than with other Part D drugs, which is why these practices are used less often than prior authorization. For example, plan sponsors said that because there are often few, if any,

³³This analysis of utilization management practices for 2007 was limited to certain drugs identified by proxy national drug codes (NDC) assigned by CMS, and those PDP and MA-PD plans that used these proxy NDCs in their formularies. A unique proxy NDC is assigned by CMS to each drug at the brand name, generic name, dosage form, and strength level. CMS recommends that this same proxy NDC be used for all therapeutically equivalent versions of a drug. Our analysis was limited to a total of 611 proxy NDCs identified for specialty tier-eligible drugs and 6,652 proxy NDCs identified for lower-cost drugs.

therapeutic equivalents or alternatives for specialty tier-eligible drugs, plans do not have many opportunities to promote the use of less costly drugs through a step therapy protocol. Plan sponsors also told us that they are less likely to employ quantity limits for specialty tier-eligible drugs.

Agency Comments and Our Evaluation

The Department of Health and Human Services (HHS) provided us with CMS's written comments on a draft version of this report. These comments are reprinted in appendix IV. CMS agreed with portions of our findings, took issue with the amount of a deductible we present in one of our figures, and suggested additional information for us to include in our report.

In its written comments, CMS agreed with our finding that specialty tier-eligible drugs accounted for about 10 percent of total prescription drug spending under Part D in 2007. Also, consistent with our finding that different cost-sharing structures used by plans can initially affect beneficiary out-of-pocket costs, CMS noted that a plan requiring 25 percent coinsurance plus a \$295 deductible would initially result in higher beneficiary out-of-pocket costs than a plan requiring 33 percent coinsurance with no deductible. CMS did not agree with the \$295 deductible we included in figure 5 of our draft report to illustrate certain cost-sharing scenarios. In its comments, CMS pointed out that a \$295 deductible does not apply in scenarios in which plans charge 33 percent coinsurance, because CMS has a requirement that plans cannot charge such a deductible when using 33 percent coinsurance for specialty tier drugs. Although CMS does have such a requirement, we included the \$295 deductible in our scenario because plans may also place specialty tier-eligible drugs on nonspecialty tiers that include both a \$295 deductible and a coinsurance rate above 25 percent (e.g., 33 percent or 42 percent). Our analysis identified a number of plans requiring such cost-sharing combinations for the 20 specialty tier-eligible drugs in our sample. We included the \$295 deductible for illustrative purposes to clearly demonstrate how differences in the coinsurance percentage or copayment amount would affect beneficiary out-of-pocket costs. However, using different deductible amount—for example, \$0—for one or more scenarios would not change our overall finding: different cost-sharing structures can be expected to result in out-of-pocket costs that vary initially but become similar once beneficiaries reach the catastrophic coverage threshold.

In its written comments, CMS suggested that we report changes in negotiated drug prices over time in the context of changes to the drug's average wholesale price (AWP). However, we chose to report changes to

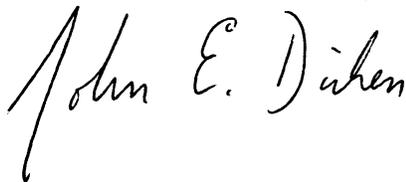
actual negotiated prices as reported to CMS by plan sponsors because they are a better reflection of prices paid by beneficiaries, who may pay a percentage of the negotiated price during the initial coverage period and often pay the entire negotiated price during the coverage gap. Additionally, CMS questioned our statement comparing the proportion of specialty tier-eligible drugs and lower-cost drugs that belong to one of the six classes of clinical concern and requested more information about our methodology. We modified our report to include an expanded discussion of the methodology for this analysis. Finally, CMS clarified that it permits plan sponsors to cover drugs for any medically-accepted indication, which in some cases can include off-label uses not approved by the Food and Drug Administration.

We also provided excerpts of the draft report to the eight plan sponsors who were interviewed for this study. The plan sponsors provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Health and Human Services and interested congressional committees. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix V.

Sincerely yours,



John E. Dicken
Director, Health Care

Appendix I: Sample of 20 Specialty Tier-Eligible Drugs

Indication and drug	Utilization rank (2007) ^a
Multiple sclerosis	
1. Glatiramer acetate (Copaxone)	
2. Interferon beta-1a (Avonex)	
Rheumatoid arthritis, psoriasis, Crohn's disease^b	
3. Adalimumab (Humira)	8
4. Anakinra (Kineret)	
5. Etanercept (Enbrel)	3
Human immunodeficiency virus (HIV)	
6. Atazanavir sulfate (Reyataz)	5
7. Emtricitabine and tenofovir disoproxil fumarate (Truvada)	4
8. Lamivudine and zidovudine (Combivir)	10
9. Lopinavir and ritonavir (Kaletra)	6
Cancer	
10. Erlotinib (Tarceva)	
11. Imatinib mesylate (Gleevec)	
Hepatitis C	
12. Interferon alfa-2b (Intron-A)	
13. Peginterferon alfa 2a (Pegasys)	
Anemia	
14. Darbepoetin alfa (Aranesp)	
15. Epoetin alfa (Procrit)	1
Enzyme disorders	
16. Miglustat (Zavesca)—Gaucher disease drug	
Pulmonary arterial hypertension	
17. Ambrisentan (Letairis)	
18. Bosentan (Tracleer)	
Other (selected based on high utilization)	
19. Mycophenolate mofetil (CellCept)—immune suppressant	9
20. Teriparatide (Forteo)—osteoporosis	2

Source: GAO analysis of CMS data.

^aThe drug with 7th highest utilization in 2007 did not meet the cost threshold for specialty tier placement in 2009 and has therefore been excluded from our sample.

^bThese three distinct diseases (rheumatoid arthritis, psoriasis, and Crohn's disease) may be treated using some of the same drugs. We selected three of those drugs for our sample.

Appendix II: Scope and Methodology

To determine spending on specialty tier-eligible drugs covered under Part D in 2007, we examined 2007 Prescription Drug Event (PDE) claims data from the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDP).¹ At the time our study began, the 2007 PDE data were the most recent available. Specifically, we analyzed 2007 PDE data at the nine-digit national drug code (NDC) level to identify all drugs having at least one claim with a cost equal to or exceeding \$500 for a 30-day supply.² We then aggregated all claims—regardless of cost—for the relevant NDCs to determine the median cost of a 30-day supply of each drug. For the purposes of this study, we considered specialty tier-eligible drugs to be all drugs with claims reimbursed under Part D in 2007 with a median negotiated cost of at least \$500 per 30-day supply (i.e., where at least half of the claims for these drugs in 2007 met or exceeded the CMS cost threshold of \$500 per month).³ For the resulting list of specialty tier-eligible drugs, we determined the total amount of Part D spending for specialty tier-eligible drugs by Medicare, MA-PD and PDP plans, and beneficiaries through MA-PD and PDP plans in 2007 for these specialty tier-eligible drugs. We also used 2007 PDE data to determine the utilization, in the aggregate, of the specialty tier-eligible drugs we identified—based on the number of 30-day prescriptions and the number of beneficiaries taking the drug. Finally, we determined the number of beneficiaries taking the drug who reached the catastrophic coverage threshold of the Part D benefit—after which Medicare assumes at least 80 percent of total drug costs. We also conducted each of these analyses

¹CMS's PDE data contain a record of each claim reimbursed under Part D, including the plan in which the beneficiary was enrolled; whether the drug was covered by the plan; the quantity of drug supplied; drug price; amounts paid by the beneficiary, the plan, and Medicare; low-income subsidy (LIS) status of the beneficiary; and whether the beneficiary was in the catastrophic coverage phase of the plan when the prescription was filled.

²NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration assigns the first segment of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular firm; and the third segment identifies package size. A single drug can have multiple NDCs associated with it. For example, a drug made by one manufacturer, in one form or strength, but in three package sizes would have three NDCs. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size.

³Examples of drugs that are eligible for placement on a specialty tier using our criterion include Enbrel for the treatment of rheumatoid arthritis and Gleevec for treatment of leukemia. Drugs identified as specialty tier-eligible may not have been placed on a specialty tier by any Part D plans, and some drugs that did not meet our definition of specialty tier-eligible may have been placed on a specialty tier by one or more Part D plans.

separately for low-income subsidy (LIS) and non-LIS beneficiaries.⁴ We performed the same analyses for all Part D covered drugs, regardless of cost, in order to compare spending and utilization for specialty tier-eligible drugs to spending and utilization for all Part D covered drugs.

To determine how the different cost-sharing structures used by Part D plans for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs, we examined out-of-pocket costs under a \$50 flat monthly copayment and different coinsurance rates (25 percent and 33 percent) for a hypothetical drug with a monthly negotiated cost of \$1,100.⁵ We selected these cost-sharing structures because some plans charge a flat monthly copayment for specialty tier-eligible drugs while others charge a coinsurance rate. We selected the 25 percent coinsurance rate to represent the standard benefit design and the 33 percent coinsurance rate because it was the rate required of the median enrollee in plans with specialty tiers in 2009.⁶ We analyzed the effect of each of these typical cost-sharing structures on beneficiary out-of-pocket costs in each phase of the Part D benefit. The results of this analysis can be generalized to Part D beneficiaries taking any specialty tier-eligible drug across most plans.

In order to estimate how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs and the trends in these expected costs from 2006 to 2009, we chose a judgmental sample of 20 specialty tier-eligible drugs and also selected a sample of 36 high-enrollment MA-PD and PDP plans from six counties.⁷ To select our sample of specialty tier-eligible drugs, we reviewed formularies for Part D plans and identified 10 chronic conditions having drugs commonly placed on specialty tiers. We selected two specialty tier drugs for each condition except in cases where only one such drug was available. In doing so, we excluded drugs

⁴Part D includes substantial premium and cost-sharing assistance through the LIS for beneficiaries who have limited assets and income.

⁵\$1,100 per month was the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 based on PDE claims data.

⁶"A Status Report on Part D for 2009," *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Medicare Payment Advisory Commission [MedPAC], March 2009), http://www.medpac.gov/document_search.cfm (accessed Aug. 13, 2009).

⁷The six counties were Grand Traverse County, Michigan; Greene County, Georgia; Highlands County, Florida; Kings County, New York; Lincoln County, Wyoming; and Orange County, California.

that are administered through intravenous infusion and therefore generally reimbursed through Medicare Part B. We ensured that each of the selected drugs was covered by Part D in 2007 and that the median cost of claims filed for each drug in 2007 exceeded \$500 per 30-day prescription. Additionally, we identified the 10 most heavily utilized specialty tier-eligible drugs in 2007, which we determined using PDE claims data by examining total prescription volume aggregated at the drug level. We added any of these drugs not already included in our sample, with the exception of one drug that no longer qualified as a specialty tier-eligible drug in 2009 based on cost. (For a list of the 20 drugs included in our sample, see app. I.) In order to select the sample of 36 Part D plans, we chose six counties across the four census regions (West, Midwest, South, and Northeast), ensuring that the counties exhibited diversity in population density and poverty rates. We selected the three MA-PD plans with the highest enrollment and the three PDP plans with the highest enrollment in each county as of March 1, 2008, and confirmed that the plans had nonzero enrollment in the relevant county in each year from 2006 through 2009. In selecting MA-PD plans, we excluded employer-sponsored and special needs plans because they were not available to the general public. For two of our selected counties, we were only able to identify one MA-PD plan that met the selection criteria. In selecting the PDP plans, we ensured that at least one of the three selected plans was eligible for automatic enrollment of LIS beneficiaries; if none of the three plans met this criterion, we added the highest enrollment PDP plan in each county that did meet the criterion. This selection process resulted in a sample containing 14 MA-PD plans and 22 PDP plans. We used CMS data on negotiated drug prices⁸ and CMS estimates of beneficiary out-of-pocket costs for our sample of drugs in 35 of the 36 selected plans⁹ to analyze how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs from 2006 to 2009. The results of our analysis cannot be generalized beyond our judgmental sample of drugs and selected plans.

⁸Negotiated drug prices are prices negotiated between pharmacies and plan sponsors for drugs dispensed by a pharmacy to plan beneficiaries, including dispensing fees, and are reported by plan sponsors to CMS. CMS negotiated price data, which reflect average prices reported by plans across pharmacies available to beneficiaries, can be used only to estimate beneficiary out-of-pocket costs, and may not reflect actual out-of-pocket costs paid by beneficiaries. The latter are influenced by factors—such as the extent of price concessions negotiated between plans and pharmacies—that vary by pharmacy and region.

⁹CMS was unable to provide negotiated drug price data and estimated out-of-pocket costs for all four years—2006 through 2009—for one plan in our sample. Therefore, we excluded this plan from our analyses.

To determine the ability of Part D plans to negotiate price concessions for specialty tier-eligible drugs and the approaches plans reported using from 2006 through 2009 to manage utilization of these drugs compared to other covered Part D drugs, we conducted interviews with representatives from eight of the largest PDP and MA-PD plan sponsors. To determine the largest MA-PD and PDP plan sponsors, we examined 2008 Part D enrollment data and selected all MA-PD plan sponsors with at least 200,000 beneficiaries (7 plan sponsors) and all PDP plan sponsors with at least 500,000 beneficiaries (8 plan sponsors). As a result of overlap between the two lists, there were 11 plan sponsors in total, of which 8 were interviewed and 7 provided specific price concession data for our sample of 20 specialty tier-eligible drugs for 2006 through 2008.¹⁰ The 7 plan sponsors that provided price concession data represented 51 percent of all MA-PD enrollment and 67 percent of all PDP enrollment in 2008. The results of our interviews and data-collection instrument cannot be generalized beyond the selected plan sponsors or drugs. In addition, we analyzed Medicare Part D Formulary, Pharmacy Network, and Pricing Information files to determine utilization management approaches reported by all Part D plans in 2007 and the number of Part D drugs in one of the six classes of clinical concern for 2007 through 2009.¹¹

To test the internal consistency and reliability of the data we used in our review, we discussed our data sources with knowledgeable officials, performed data reliability checks such as manually and electronically checking the data for missing values and obvious errors, interviewed CMS officials about concerns we uncovered, and reviewed the internal controls CMS uses to ensure that data are complete and accurate. We checked the negotiated price data provided by the plan sponsors through the data-collection instrument for internal consistency by comparing these data, when possible, to data the plan sponsors had previously provided to CMS. We determined that the data were sufficiently reliable for our purposes. We conducted our work from March 2009 through December 2009 in

¹⁰We invited the remaining three plan sponsors to participate in our study but received no response.

¹¹The Part D Formulary, Pharmacy Network, and Pricing Information files are public-use files provided by CMS that contain information—including formulary placement, tier placement, copayment and coinsurance amounts, and utilization management practices applicable to each drug under each Part D plan—reported by the plans prior to the start of each calendar year. This information is available to beneficiaries through the Medicare Prescription Drug Plan Finder (www.medicare.gov/mpdpf as of December 14, 2009) as a tool for plan selection.

accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

Appendix III: Comparison of Price Concessions Negotiated by Seven Plan Sponsors for a Sample of 20 Drugs

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions			Average negotiated cost per 30-day supply, before price concessions, weighted by utilization (dollars)			Average price per 30-day supply, after price concessions, weighted by utilization (dollars)		
	2006	2007	2008	2006	2007	2008	2006	2007	2008
Multiple sclerosis									
Glatiramer acetate (Copaxone) 20 mg/ml injection	6	6	7	1,460	1,654	1,867	1,370	1,522	1,732
Interferon beta-1a (Avonex) 30 mcg intramuscular injection	3	4	5	1,412	1,578	1,935	1,397	1,544	1,884
Inflammatory conditions (e.g., rheumatoid arthritis, psoriasis, Crohn's disease^a)									
Adalimumab (Humira) 40 mg/0.8 ml injection	6	7	7	1,430	1,517	1,600	1,343	1,408	1,469
Anakinra (Kineret) 100 mg injection	— ^b	— ^b	— ^b	1,299	1,364	1,424	1,299	1,363	1,423
Etanercept (Enbrel) 50 mg/ml injection	6	7	6	1,400	1,461	1,527	1,372	1,421	1,470
Human immunodeficiency virus (HIV)									
Atazanavir sulfate (Reyataz) 150 mg tablet	5	6	6	779	809	853	758	782	810
Emtricitabine and tenofovir disoproxil fumarate (Truvada) 200 mg/300 mg tablet	0	0	0	765	815	881	765	815	881
Lamivudine and zidovudine (Combivir) 150 mg/300 mg tablet	7	7	6	666	709	741	644	685	714
Lopinavir and ritonavir (Kaletra) 200 mg/50 mg tablet	0	0	0	697	720	745	697	720	745
Cancer									
Erlotinib (Tarceva) ^c 150 mg tablet	0	0	0	2,746	3,103	3,393	2,746	3,103	3,393
Imatinib mesylate (Gleevec) 400 mg tablet	0	0	0	2,994	3,153	3,389	2,994	3,153	3,389
Hepatitis C									
Interferon alfa-2b (Intron-A) 3 million IU injection	0	0	0	476	655	580	476	655	580
Peginterferon alfa 2a (Pegasys) ^c 180 mg/0.5 ml injection	5	5	6	1,589	1,648	1,817	1,457	1,461	1,561

Appendix III: Comparison of Price Concessions Negotiated by Seven Plan Sponsors for a Sample of 20 Drugs

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions			Average negotiated cost per 30-day supply, before price concessions, weighted by utilization (dollars)			Average price per 30-day supply, after price concessions, weighted by utilization (dollars)		
	2006	2007	2008	2006	2007	2008	2006	2007	2008
Anemia									
Darbepoetin alfa (Aranesp) 100 mcg/0.5 ml injection	3	5	4	1,019	999	1,128	1,017	913	994
Epoetin alfa (Procrit) 40,000 units/ml injection	7	7	7	1,432	1,465	1,593	1,269	1,311	1,420
Enzyme disorders (e.g., Gaucher disease)									
Miglustat (Zavesca) ^d 100 mg capsule	0	0	0	— ^d	8,848	8,344	— ^d	8,848	8,344
Pulmonary arterial hypertension									
Ambrisentan (Letairis) ^e 10 mg tablet	0	0	0	— ^e	4,100	4,416	— ^e	4,100	4,416
Bosentan (Tracleer) 125 mg tablet	0	0	0	3,483	4,065	4,423	3,483	4,065	4,423
Other (selected based on high utilization)									
Mycophenolate mofetil (CellCept)— immune suppressant 500 mg tablet	5	7	7	576	614	681	554	590	652
Teriparatide (Forteo) ^c —osteoporosis 250 mcg/ml injection	3	5	4	638	689	748	600	634	641

Source: GAO analysis of price concessions data provided by seven plan sponsors GAO surveyed.

^aThese three distinct diseases (rheumatoid arthritis, psoriasis, and Crohn's disease) may be treated using some of the same drugs. We selected three of those drugs for our sample.

^bThe total number of plan sponsors who reported receiving price concessions for this drug across the 3-year period was too small to allow us to report values while maintaining confidentiality.

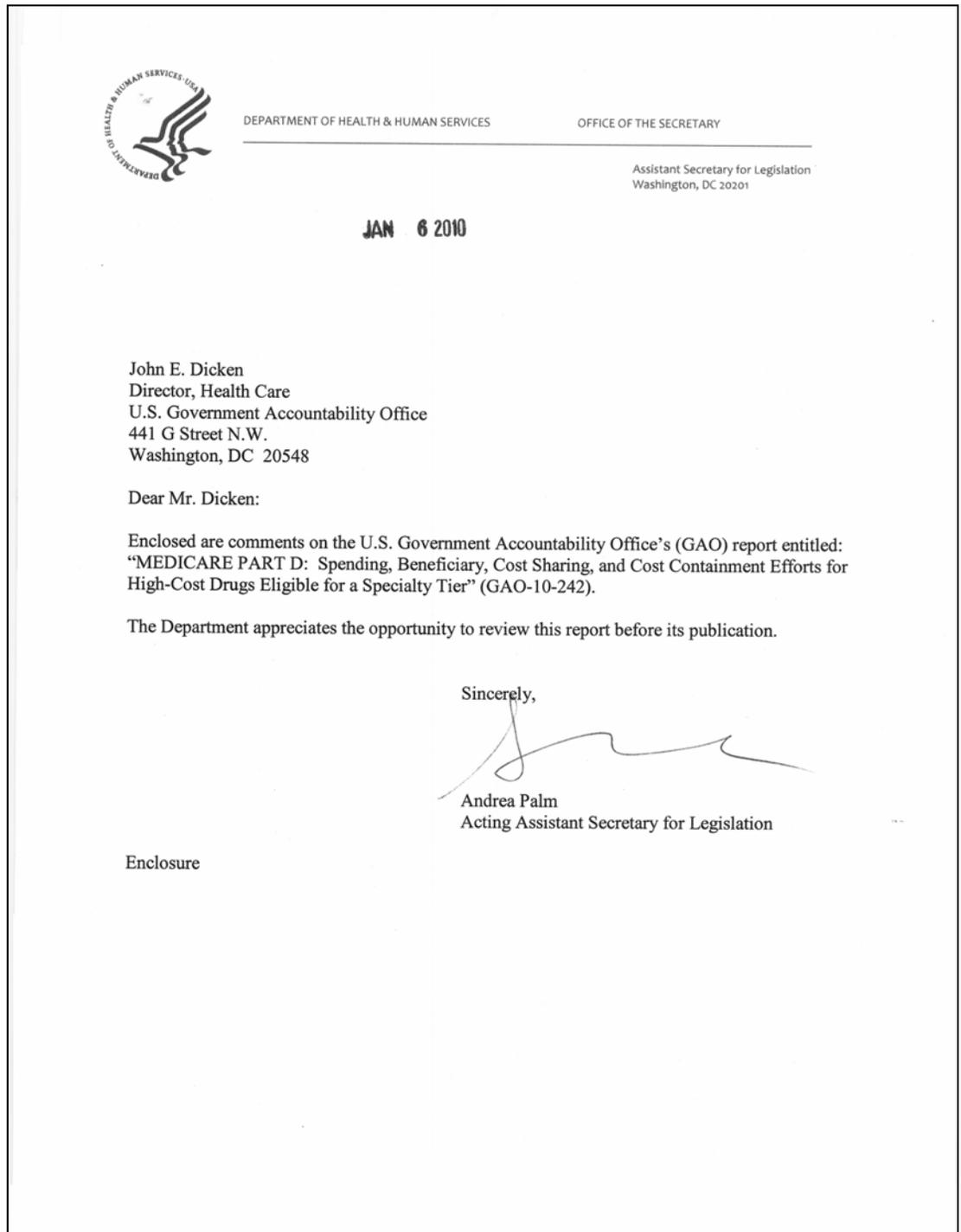
^cOne of the seven plan sponsors we surveyed did not submit any data for this drug. Therefore, values listed for this drug are based on data submitted by six plan sponsors, rather than seven plan sponsors.

^dNone of the seven plan sponsors we surveyed reported utilization of Zavesca in 2006.

^eLetairis was approved by the FDA on June 15, 2007. Therefore, none of the plan sponsors we surveyed reported utilization of Letairis in 2006.

Appendix IV: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.



GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "MEDICARE PART D: SPENDING, BENEFICIARY COST SHARING, AND COST CONTAINMENT EFFORTS FOR HIGH-COST DRUGS ELIGIBLE FOR A SPECIALTY TIER" (GAO-10-242)

Thank you for the opportunity to comment on the Government Accountability Office's (GAO) Draft Report: "MEDICARE PART D: Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier" (GAO-10-242). The Centers for Medicare & Medicaid Services (CMS) appreciates the importance of analyzing specialty tier utilization and costs, given the proportion of Medicare Part D spending that is attributed to specialty tier drugs.

The GAO evaluated contract year CY 2007 spending on specialty tier drugs by identifying, through prescription drug event (PDE) data, drugs that could be eligible for specialty tier placement. The report estimates that 10 percent of total prescription Part D drug spending was for specialty tier eligible drugs. Although a different methodology was utilized, this estimate is not inconsistent with CMS' internal estimate of 9.5 percent.

In the report, the out-of-pocket spending for a hypothetical drug with a negotiated cost of \$1,100 per month was analyzed at the following beneficiary cost share levels: \$50 monthly co-pay, 25 percent coinsurance, and 33 percent coinsurance. We would like to note that the overwhelming majority of Part D plans utilize a coinsurance structure for specialty tier cost-sharing, with coinsurances as low as 10 percent and a maximum of 33 percent. The use of additional coinsurance levels would provide for a broader range of example beneficiary out-of-pocket costs. We understand that the methodology for evaluating cost-sharing ignores the impact of deductibles. However, plans are required to have a \$0 deductible in order to have a 33 percent specialty-tier cost-sharing, which is fairly common for Part D plans, particularly with those that have higher specialty drug cost-sharing than the standard 25 percent coinsurance. Since Figure 5 ignores the impact of deductibles, it incorrectly presents that cost-sharing for those using specialty-tier drugs with a 33 percent coinsurance would pay more than those paying the standard 25 percent coinsurance. In actuality, beneficiaries with no deductible and paying the 33 percent specialty-tier coinsurance would start out paying less than those with a standard deductible and coinsurance up to the initial coverage limit, at which point both would have paid about the same cost-sharing and would continue to do so for the balance of the benefit.

Negotiated prices were analyzed for a sample of specialty tier eligible drugs to estimate beneficiary out-of-pocket costs. Based on analyses of these sample drugs, GAO reports that out-of-pocket costs vary between different drugs. This result is expected given the substantial differences in manufacturers' prices across all different drugs. We would also expect to see some variation in negotiated prices for the same drug across plans, given the various factors affecting Part D sponsors' ability to negotiate with pharmaceutical manufacturers. GAO reports that, on average, negotiated prices of the sample specialty tier drugs increased by 36 percent between CY 2006 and CY 2009. We would like to note that price increases are not unique to specialty tier drugs. An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier drugs) between January 2006 and October 2009. Negotiated prices are generally based on a discount to Average

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "MEDICARE PART D: SPENDING, BENEFICIARY COST SHARING, AND COST CONTAINMENT EFFORTS FOR HIGH-COST DRUGS ELIGIBLE FOR A SPECIALTY TIER" (GAO-10-242)

Wholesale Price (AWP). Therefore, we recommend that any specific examples addressed in the report, such as Gleevec, be reported in the context of changes to the drug's AWP.

The GAO interviewed a sample of Part D sponsors to identify factors affecting their ability to negotiate prices with manufacturers. One reason cited as a barrier to negotiations related to formulary requirement of all or substantially all drugs from the protected classes (immunosuppressives for transplant rejection prophylaxis, antidepressants, antiretrovirals, antipsychotics, antineoplastics, and anticonvulsants). On page 21-22, GAO notes that "...specialty tier-eligible drugs were more than twice as likely to be in one of the six classes of clinical concern compared with lower-cost drugs in 2009." We do not believe this statement to be true and respectfully request that the methodology to support this conclusion be provided to us. On page 23 of the draft report, a comment was provided by a Part D sponsor that suggests CMS does not permit sponsors to cover indications that are not approved by the Food and Drug Administration (FDA). However, the definition of a Part D drug does provide for coverage for any "medically accepted indication," which can include off-label uses so long as they are supported by one or more citations in specified compendia. We request that this clarification be included in the final report.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, major contributors to this report were Will Simerl, Assistant Director; Karen Howard; Alexis MacDonald; Cleo Samuel; and Michael Zose. Martha Kelly and Suzanne Worth provided technical support in design, methodology, and data analysis; George Bogart provided legal support; and Krister Friday assisted in the message and report development.

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