



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](#). For more information, contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov.

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.