



Report to the Ranking Member,  
Committee on the Budget, House of  
Representatives

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July 2016

## MEDICARE PART B

# Data on Coupon Discounts Needed to Evaluate Methodology for Setting Drug Payment Rates

Highlights of GAO-16-643, a report to the Ranking Member, Committee on the Budget, House of Representatives

## Why GAO Did This Study

Use of drug coupons in the private sector has increased in recent years. GAO was asked to study coupon programs for drugs covered by Medicare Part B, including any implications for Part B spending.

This report (1) identifies coupon programs associated with high-expenditure Part B drugs and describes the extent to which privately insured patients use coupons and (2) examines, for drugs with coupon programs, the suitability of the Part B drug payment rate methodology. GAO identified high-expenditure Part B drugs using 2013 Medicare claims data—the latest available at the time of the analysis—and collected information from manufacturers on coupon program characteristics in 2015. GAO also analyzed coupon use and patient costs for drugs using 2013 data from manufacturers and private insurers; estimated how Part B spending could have differed if ASP had accounted for coupon discounts in 2013; reviewed federal laws and regulations; and interviewed CMS officials.

## What GAO Recommends

To determine the suitability of the Part B drug payment rate methodology for drugs with coupon programs, Congress should consider (1) granting CMS authority to collect data from drug manufacturers on coupon discounts for Part B drugs paid based on ASP; and (2) requiring CMS to periodically collect these data and report on the implications of coupon programs for this methodology. The Department of Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.

View GAO-16-643. For more information, contact James Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

July 2016

## MEDICARE PART B

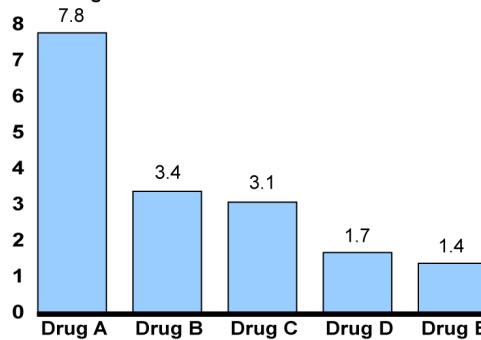
### Data on Coupon Discounts Needed to Evaluate Methodology for Setting Drug Payment Rates

## What GAO Found

In 2015, manufacturers of 29 of the 50 high-expenditure Medicare Part B drugs GAO analyzed offered coupon programs, which reduce the costs patients incur for specific drugs. Part B drugs are typically administered by a physician. Coupon programs are prohibited in the Medicare program but are generally available to privately insured patients. GAO obtained data on coupon discounts for 18 drugs. GAO estimated that 19 percent of privately insured patients who received these drugs used coupons in 2013, but coupon use varied widely depending on the drug—from 1 percent to over 90 percent.

Medicare's methodology for setting Part B payment rates to providers may be less suitable for drugs with coupon programs than for drugs without them. The methodology for most Part B drugs is based on the average sales price (ASP), which is defined by law as the amount physicians and other purchasers pay manufacturers for the drug, net of discounts and rebates to those purchasers. Medicare and its beneficiaries spent \$20 billion on Part B drugs paid based on ASP in 2013. As ASP does not account for coupon discounts to patients, the discounts reduce the effective market price that manufacturers receive for drugs with coupon programs. GAO estimated that, for the 18 drugs for which it obtained coupon discount data, the ASP exceeded the effective market price by an estimated 0.7 percent in 2013. Part B spending for these drugs could have been an estimated \$69 million lower if ASP equaled the effective market price. ASP exceeded the effective market price by more than 1.0 percent for 5 of the 18 drugs, suggesting that the ASP-based methodology may be even less suitable for these drugs.

**Estimated Percentage by which Average Sales Price Exceeded Effective Market Price, Selected Drugs with Coupon Programs, 2013**  
Percentage



Source: GAO analysis of data from drug manufacturers and Truven Health Analytics' MarketScan Commercial Claims and Encounters Database. | GAO-16-643

Notes: The remaining 13 drugs out of the 18 drugs for which GAO obtained coupon discount data had average sales prices that exceeded the effective market price by less than 1.0 percent.

Upward trends in coupon program use and drug prices suggest that these programs could cause the methodology for setting Part B drug payment rates to become less suitable over time for drugs with coupon programs. However, the Centers for Medicare & Medicaid Services (CMS) lacks the authority to collect coupon discount data from manufacturers and thus lacks important information that could inform its ongoing efforts to evaluate alternatives to this methodology.

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**Figure 2: Estimated Percentage by which Average Sales Price Exceeded Effective Market Price, Selected Drugs with Coupon Programs, 2013**

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## Abbreviations

ASP	average sales price
CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
FDA	Food and Drug Administration
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
NDC	national drug code
OIG	Office of Inspector General
OPPS	outpatient prospective payment system

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.  
Washington, DC 20548

July 27, 2016

The Honorable Chris Van Hollen  
Ranking Member  
Committee on the Budget  
House of Representatives

Dear Mr. Van Hollen:

In recent years, the percentage of brand name prescriptions that involved the use of a drug coupon increased substantially from 3 percent in 2011 to 8 percent in 2014.<sup>1</sup> Under coupon programs, drug manufacturers make discounts available to privately insured patients to reduce or eliminate their out-of-pocket costs for specific drugs.<sup>2</sup> The reduction in out-of-pocket costs may improve adherence to drug regimens for patients who use these programs.<sup>3</sup> However, coupon programs may also increase overall drug spending by encouraging patients to use more expensive drugs instead of lower-cost alternatives. In addition, by making drugs more affordable for patients, coupon programs may allow manufacturers

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<sup>1</sup>There were approximately 69 million brand name prescriptions provided to commercially insured patients in 2014. IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014* (Parsippany, N.J.: April 2015).

<sup>2</sup>We use the term "drug coupon program" to refer to programs through which a drug manufacturer provides financial support directly to patients to reduce their out-of-pocket costs for drugs that the manufacturer sells. Coupon programs, which are also referred to as copayment coupons or copay card programs, are typically available to all privately insured patients, regardless of patient income. Manufacturers may also operate patient assistance programs to provide free or discounted drugs to patients of low income; we do not consider these to be coupon programs. Out-of-pocket costs include copayments, coinsurance, and deductibles for drugs covered under a patient's insurance plan, but can also include all costs for drugs that are not covered.

<sup>3</sup>Catherine I. Starner et al., "Specialty Drug Coupons Lower Out-of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums," *Health Affairs*, vol. 33, no. 10 (2014).

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to increase their sales of these drugs and extract higher prices from health care providers and other drug purchasers.<sup>4</sup>

Provision of coupon discounts to induce or reward the use of certain drugs is prohibited in Medicare and other federal health care programs. Used in this way, coupon discounts are considered kickbacks that may induce beneficiaries and their providers to choose certain drugs when lower-cost but equally effective alternatives are available.<sup>5</sup> According to the Department of Health and Human Services (HHS) Office of Inspector General (OIG), kickbacks such as these are unlawful in federal health care programs in part because they could lead to excessive costs to the programs and their beneficiaries.

Although prohibited in Medicare, the recent increases in coupon use in the private sector may have implications for the methodology Medicare has used since 2005 to set the rates it pays providers for drugs covered under Part B. Medicare pays for most Part B drugs, which are typically administered by a physician or under a physician's supervision, based on the average amount that purchasers paid to drug manufacturers, net of discounts and rebates—referred to as the average sales price (ASP).<sup>6</sup>

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<sup>4</sup>David H. Howard, "Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?" *New England Journal of Medicine*, vol. 371, no. 2 (2014); Congressional Research Service, *Prescription Drug Discount Coupons: Implications for Public and Commercial Health Care Plans* (Washington, D.C.: Nov. 5, 2015).

<sup>5</sup>Department of Health and Human Services Office of Inspector General Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons (September 2014) (citing the anti-kickback statute, 42 U.S.C. § 1320a-7b(b)). The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any federal health care program.

<sup>6</sup>Critical access hospitals; certain hospitals in Maryland; hospitals located outside the 50 States, the District of Columbia, and Puerto Rico; and hospitals of the Indian Health Service are excluded from the hospital outpatient prospective payment system (OPPS) and therefore not paid on the basis of ASP. 42 C.F.R. § 419.20(b) (2015). Furthermore, several Part B drugs—including certain vaccines, blood products, and drugs infused through durable medical equipment—are paid for on the basis of average wholesale prices and not on the basis of ASP. See 42 U.S.C. § 1395u(o)(1). Part B drugs generally differ from those covered under Medicare Part D in that Part D drugs are usually self-administered.

Part B drug purchasers can include drug wholesalers and distributors, physicians, and hospitals. Discounts are price concessions given by manufacturers that are reflected in the price purchasers pay for a drug at the time of delivery. Rebates are price concessions by manufacturers that are given to purchasers after the drug is delivered.

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Medicare's ASP is a market-based measure of a drug's price. However, this measure, as set forth in section 1847A of the Social Security Act, does not account for coupon discounts that manufacturers provide to patients, the ultimate consumers of these drugs.<sup>7</sup> Although these coupon discounts do not affect the amount that purchasers pay to drug manufacturers, they do lower the net price—here termed the effective market price—that manufacturers ultimately receive for drugs with such coupon discounts. As a result, coupon discounts create a discrepancy between Medicare's ASP and the effective market price of a drug. This discrepancy, coupled with the recent increase in coupon use and Medicare's role as an efficient purchaser of health care items and services, raises questions about how suitable Medicare's Part B payment rate methodology is for drugs with coupon programs.

Given the increasing prevalence of coupon programs in the private sector and that the Medicare program and its beneficiaries spent approximately \$20 billion in 2013 on Part B drugs paid based on ASP, you asked us to examine the use of coupon programs and their potential implications for the Medicare program and its beneficiaries.<sup>8</sup> In this report, we

- identify coupon programs associated with high-expenditure Part B drugs and describe the extent to which privately insured patients use these programs; and
- examine, for drugs with coupon programs, the suitability of Medicare's Part B drug payment rate methodology.

To identify coupon programs associated with high-expenditure Medicare Part B drugs, we developed a list of the 50 highest-expenditure Part B drugs using data on Medicare claims paid based on ASP in 2013—the

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<sup>7</sup>Codified at 42 U.S.C. § 1395w-3a(c)(1). Although ASP includes manufacturer price concessions to purchasers, price concessions to patients, who do not purchase Part B drugs from manufacturers, are not included. Further, ASP expressly excludes sales exempt from the determination of “best price” under Medicaid. 42 U.S.C. § 1395w-3a(c)(2)(A), (3). Manufacturer coupons redeemed by a patient are excluded from consideration in determining best price. 42 C.F.R. § 447.505(d)(8) (2015).

<sup>8</sup>For research on the prevalence of coupon programs, see IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts in 2014*. Estimates of Part B drug spending presented in this report include spending by the Medicare fee-for-service (FFS) program and its beneficiaries. Part B spending estimates in this report do not include spending on drugs for which Medicare's payment is bundled with that of a related service or spending on drugs for which Medicare was not the primary payer and thus did not set the payment rate.

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most recent full year of claims data available at the time of our analysis.<sup>9</sup> In that year, these 50 highest-expenditure drugs accounted for 85 percent of Part B spending for drugs paid based on ASP. (For the complete list of these 50 drugs, see app. I.) We then identified which of the 50 Part B drugs either had coupon programs at the time of our analysis (2015) or in 2013, based on information from manufacturers and their websites, and collected information from these sources on coupon program characteristics.<sup>10</sup> To describe the extent to which privately insured patients used coupon programs, we obtained data for 2013 from (1) drug manufacturers on coupon use—specifically, the number of patients who used these programs and on the average annual discounts provided; and (2) the Truven Health Analytics' MarketScan® Commercial Claims and Encounters Database on the estimated number of privately insured patients nationally who used drugs with coupon programs and the out-of-pocket costs these patients incurred.<sup>11</sup>

To examine the suitability of Medicare's Part B drug payment rate methodology for drugs with coupon programs, we reviewed relevant statutes and regulations and also interviewed officials from the Centers for Medicare & Medicaid Services (CMS), an agency within HHS. To illustrate the potential effect, if any, of coupon programs on the suitability of this methodology for Part B drugs with these programs, we estimated

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<sup>9</sup>We identified drugs based on their Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS is a standard coding system that identifies items and services for payment purposes. Each HCPCS code refers to one or more brand or generic products, which are identified by their national drug codes (NDC). Some drugs that we identified for purposes of our analysis had multiple HCPCS codes because the codes included NDCs for drugs that were pharmaceutically equivalent, as defined by the Food and Drug Administration (FDA). FDA defines pharmaceutically equivalent drugs as those that have the same active ingredient(s), dosage form, route of administration, and strength or concentration.

We excluded from our list two oral cancer drugs and three oral immunosuppressant drugs used to prevent organ rejection after transplant. Claims for these drugs were processed by CMS's contractor that processes durable medical equipment claims, even though these drugs were not administered through durable medical equipment.

<sup>10</sup>If we were unable to identify a coupon program for a drug and did not receive information from its manufacturer, we recorded that the drug did not have a coupon program. We did not collect information on patient assistance programs. These programs are typically available only to uninsured patients and may cover the full costs of a drug.

<sup>11</sup>The MarketScan database contains claims for privately insured individuals for over 44 million enrollees paid by over 160 private insurers across 50 states and the District of Columbia in 2013.

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how a drug's ASP and Part B spending could have changed over a one-year period—from July 2013 through June 2014—if the drug's ASP accounted for coupon discounts. We calculated this estimate based on 2013 data from drug manufacturers on the total coupon discounts provided for each drug in our analysis and data reported by manufacturers to CMS on each drug's total sales and ASP.<sup>12</sup> (For more detail on the data and methods for this study, see app. II.)

We verified the reliability of Medicare claims and other data used in this report through electronic data checks and by speaking with relevant parties knowledgeable about the data, including CMS; drug manufacturers; and Truven Health Analytics. In addition, we verified information on coupon use by conducting checks of internal consistency and by speaking with manufacturers as needed to verify the reliability of the information.<sup>13</sup> We determined that the data used in this report were sufficiently reliable for our purposes.

We conducted this performance audit from August 2015 to July 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>12</sup>There is a two-quarter (6-month) lag between sales for a drug and when the payment rate takes effect due to the time it takes for manufacturers to submit data to CMS, for CMS to review the data and update the payment rates, and the public to review and comment on the revised rates. Thus, our estimates of changes to Part B spending, based on 2013 manufacturer data, pertain to Medicare spending over the 1-year spending period from July 2013 through June 2014.

<sup>13</sup>We did not independently verify that ASP data submitted by manufacturers to CMS accurately represented total national sales for a given drug. Similarly, we did not independently verify that data on coupon use as reported to us by manufacturers were accurate.

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## Background

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### Drug Coupon Programs

Manufacturer drug coupon programs reduce or eliminate out-of-pocket costs for specific drugs and are typically available to privately insured patients regardless of income.<sup>14</sup> Drug manufacturers provide these discounts to patients through several mechanisms. For example, manufacturers may provide patients with debit cards to be activated at the point of sale. Alternatively, manufacturers may pay the patient's coupon discount amount directly to a provider, who would reduce the patient's out-of-pocket cost accordingly. Manufacturers inform patients and providers of coupon programs in a variety of ways, such as distributing promotional materials, operating program websites and patient hotlines, and sending field representatives to communicate program information to providers.

The effect of coupon programs on patients can differ depending on whether programs are associated with single-source or multi-source drugs, and changes in patient behavior may in turn lead to increased drug sales by manufacturers. For single-source drugs, which are only available from one manufacturer and may not have lower-cost, pharmaceutically equivalent alternatives, such programs can help patients afford their medications and have been shown to improve patient adherence to specialty drug regimens.<sup>15</sup> For multi-source drugs, which are available from more than one manufacturer, coupon programs may encourage patients to request, and providers to prescribe, more expensive drugs instead of generics and other lower-cost, pharmaceutically equivalent alternatives. These changes in patient behaviors could benefit drug manufacturers financially while potentially increasing costs for health insurers. Specifically, manufacturers gain revenue from the sale of drugs received by patients who might have quit a drug regimen or chosen a

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<sup>14</sup>Privately insured patients may incur out-of-pocket costs in the form of copayments, coinsurance, or deductibles. While coupon programs are typically designed to reduce or eliminate out-of-pocket costs for insured patients, some programs are available to cash-paying patients without health insurance.

<sup>15</sup>Specialty drugs can be defined in many ways; for example, health insurance companies often consider them to be expensive, treat complex diseases, and require special handling or administration. See EMD Serono, Inc., *EMD Serono Specialty Digest, 10th Edition: Managed Care Strategies for Specialty Pharmaceuticals* (Rockland, Mass.: EMD Serono, Inc., 2014). For research on patient adherence under drug coupon programs, see Starner et al., "Specialty Drug Coupons."

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lower-cost alternative in the absence of a coupon program. Additionally, manufacturers may be able to charge higher prices to purchasers than the market could sustain without these programs.<sup>16</sup>

Although the use of drug coupon programs to induce or reward use of certain drugs is unlawful in federal health care programs such as Medicare, beneficiaries who cannot afford their medications may be eligible to obtain financial assistance from other sources. For example, Medicare beneficiaries may be able to receive medications or assistance with out-of-pocket costs from independent charity patient assistance programs.<sup>17</sup> Medicare beneficiaries with low income may also be eligible to enroll in Medicaid, the joint federal-state program that finances health insurance coverage for certain categories of low-income and medically needy individuals.

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## Medicare Part B Drugs

Medicare Part B covers drugs and biologicals that are generally administered by a physician or under a physician's direct supervision, including drugs administered in a physician's office or hospital outpatient department. Drugs covered under Part B include injectable drugs, oral cancer drugs if the same drug is available in injectable form, and drugs infused or inhaled through durable medical equipment.

Medicare and its beneficiaries make payments for Part B drugs to providers, such as physicians and hospitals, which first purchase the drugs from manufacturers or other sellers. Medicare generally pays 80 percent of a set payment rate for a drug, while beneficiaries are responsible for the remaining 20 percent. For most Part B drugs, Medicare sets payment rates at a drug's ASP plus an additional 6 percent.<sup>18</sup> To set these rates, CMS collects quarterly data from drug

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<sup>16</sup>Howard, "Drug Companies' Patient-Assistance Programs"; Congressional Research Service, *Prescription Drug Discount Coupons*.

<sup>17</sup>See HHS OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

<sup>18</sup>The payment rate for most Part B drugs acquired by a physician's office is set at 106 percent of ASP. 42 U.S.C. § 1395w-3a. CMS is authorized to annually update the payment rate for Part B drugs acquired by hospital outpatient departments, and it has set the payment rate for most drugs at 106 percent of ASP since 2013. See 42 U.S.C. § 1395l(t)(14)(A)(iii). Due to the impact of sequestration, current Part B drug payment rates to both physicians and hospitals are approximately 104 percent of ASP.

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manufacturers on the volume of sales and ASP for each drug.<sup>19</sup> Sales data that manufacturers report must be net of all rebates, discounts, and other price concessions to purchasers, including physicians, hospitals, and wholesalers. Manufacturers are not required to report sales net of coupon discounts or other financial assistance provided by manufacturers directly to patients.<sup>20</sup>

CMS, as part of its ongoing efforts to evaluate Medicare's methodology for setting Part B drug payment rates, recently issued a proposed rule to test alternatives to this payment method.<sup>21</sup> Various studies have pointed out that Medicare's current methodology for setting Part B drug payment rates as a fixed percentage above ASP may give providers a financial incentive to prescribe more expensive drugs.<sup>22</sup> This is among the shortcomings of the current ASP-based payment method that CMS's proposed payment model is designed to address. The first phase of the proposed payment model would change the payment rate for drugs paid based on ASP from ASP plus 6 percent to ASP plus 2.5 percent plus a flat fee. The second phase would implement value-based pricing strategies, such as varying prices based on drugs' clinical effectiveness and decreasing beneficiary coinsurance for drugs deemed high in value.

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<sup>19</sup>Drug manufacturers who participate in the Medicaid drug rebate program are required to submit data to CMS on all sales of Part B drugs to all U.S. purchasers. 42 U.S.C. § 1396r-8(a)(1), (b)(3)(A). Most drug manufacturers participate in the Medicaid drug rebate program, and those who do not may voluntarily submit sales data to CMS.

<sup>20</sup>42 U.S.C. § 1395(c)(2)(A); 42 C.F.R. § 447.505(d)(8) (2015).

<sup>21</sup>81 Fed. Reg. 13230, 13258 (Mar. 11, 2016) (to be codified at 42 C.F.R. pt. 511).

<sup>22</sup>For example, see David Hutton et al., "Switching to Less Expensive Blindness Drug Could Save Medicare Part B \$18 Billion Over a Ten-Year Period," *Health Affairs*, vol. 33, no. 6 (2014); Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, *Medicare Part B Drugs: Pricing and Incentives* (Washington, D.C.: Mar. 8, 2016); and Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System, Ch. 3 Part B Drug Payment Policy Issues* (Washington, D.C.: June 15, 2015).

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## Most High-Expenditure Part B Drugs Had Coupon Programs in 2015; an Estimated 19 Percent of Privately Insured Patients Taking Such Drugs Used Programs in 2013

In 2015, drug manufacturers offered coupon programs to privately insured patients for 29 of the 50 high-expenditure Medicare Part B drugs in our analysis.<sup>23</sup> Coupon programs were typically open to privately insured patients regardless of income. Programs for 3 of the drugs required patients to have incomes below a certain amount, with maximum annual incomes of approximately \$100,000.

Coupon programs varied in the discount amounts that patients could receive in 2015. Most programs had a maximum annual discount, which ranged across programs from \$400 to \$42,000 per year.<sup>24</sup> Until patients reached that maximum discount, they could pay as low as \$0 to \$50 per coupon use.<sup>25</sup> These amounts could represent a small fraction of patients' full out-of-pocket cost for a prescription. For example, privately insured patients using the drug Yervoy were required to pay an estimated \$571, on average, per prescription without the drug's coupon program, compared to paying \$25 under the coupon program.<sup>26</sup> (See table 1 for examples of drug coupon programs and app. III for more information on out-of-pocket costs for drugs with coupon programs.)

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<sup>23</sup>Some drugs comprised multiple NDCs, which are associated with specific brand or generic products. As a result, some drugs in our analysis had a coupon program for one product but did not have programs for other products, while other drugs had multiple coupon programs.

<sup>24</sup>Coupon programs for all 29 drugs had maximum discounts of a specified dollar amount for at least some groups of patients over some time period or per coupon use; one coupon program had a maximum discount only for patients above a certain income. Some coupon programs had a maximum number of coupon uses in addition to the maximum discount amount in dollars (for example, \$1,000 per year and 42 coupon uses per year).

<sup>25</sup>These fixed amounts applied to each dose, dosing cycle, infusion, monthly supply, or other specified product or period. Patients with deductibles who used these programs may have paid more than the stated amounts because coupon discounts for seven drugs' coupon programs did not apply to patient deductibles.

<sup>26</sup>Estimate of patient out-of-pocket costs is based on 2013 data and has been adjusted for inflation to 2015 dollars using the Consumer Price Index for All Urban Consumers. We calculated this estimate based on the 24 percent of privately insured patients who had at least some out-of-pocket costs for Yervoy.

**Table 1: Examples of Drug Coupon Programs, 2015**

<b>Brand name drug</b>	<b>Examples of conditions treated</b>	<b>Patient out-of-pocket cost per coupon use</b>	<b>Maximum discount</b>
Neulasta	Prevent infection in chemotherapy patients	\$0 for the first dosing cycle and \$25 for subsequent dosing cycles	\$5,000 per 6 months
Recombinate	Hemophilia A	\$0	\$12,000 per year
Remicade	Various autoimmune disorders	\$5 per infusion	\$10,000 per year
Rituxan	Cancer; rheumatoid arthritis	\$25 per prescription for hematology patients <sup>a</sup> \$5 per prescription for rheumatoid arthritis patients	\$25,000 per year for hematology patients \$10,000 per year for rheumatoid arthritis patients
Yervoy	Cancer	\$25 per dose	\$25,000 per year

Source: GAO analysis of information from drug websites and manufacturer interviews. | GAO-16-643

<sup>a</sup>Hematology is a field of medicine that treats blood diseases such as leukemia, a form of cancer.

Factors that can affect privately insured patients' use of coupons include patient out-of-pocket cost requirements and the extent of manufacturer outreach to patients and providers. For example, whether patients are required to pay out-of-pocket costs for a drug can affect whether patients use coupon programs, as patients without such costs do not need these programs. On average, across drugs in our analysis with coupon programs in 2013, we estimated that 50 percent of privately insured patients did not have out-of-pocket costs, and this percentage ranged from 8 to 76 percent, depending on the drug. The amount of patient out-of-pocket costs can also affect the discount amount patients receive, because coupon discounts are directly related to patients' out-of-pocket costs. Other factors, including manufacturer outreach to providers and patients, could also explain variation in coupon program use. For example, some manufacturers told us that they reach out to patients directly regarding coupon programs, while others told us that they communicate directly only with providers.

With respect to patients' use of available drug coupon programs, we determined that 21 of the 50 high-expenditure Part B drugs had coupon programs in 2013, and these drugs accounted for 50 percent of Part B spending paid based on ASP. We were able to obtain data on coupon

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discounts from manufacturers for 18 of these drugs.<sup>27</sup> An estimated 19 percent of the 509,000 privately insured patients who used these 18 drugs in 2013 also used a coupon program. The percentage of these patients who used a coupon program ranged from 1 to over 90 percent, depending on the drug, with coupon programs for all but 2 drugs being used by less than 40 percent of patients.

Coupon discounts reported by manufacturers of the 18 drugs totaled \$205 million in 2013. Individual patients who used coupon programs for these drugs received an average annual discount of \$2,051.<sup>28</sup> This discount ranged from \$1,000 to over \$7,000 per year for 13 of the 18 drugs and was \$800 or less for the remaining 5 drugs.

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<sup>27</sup>For these 18 drugs, we calculated total coupon discounts associated with each drug based on data from manufacturers on the number of patients using coupon programs and average annual patient discounts.

<sup>28</sup>We calculated the average annual discount across drugs weighted on the number of patients using coupon programs for each drug.

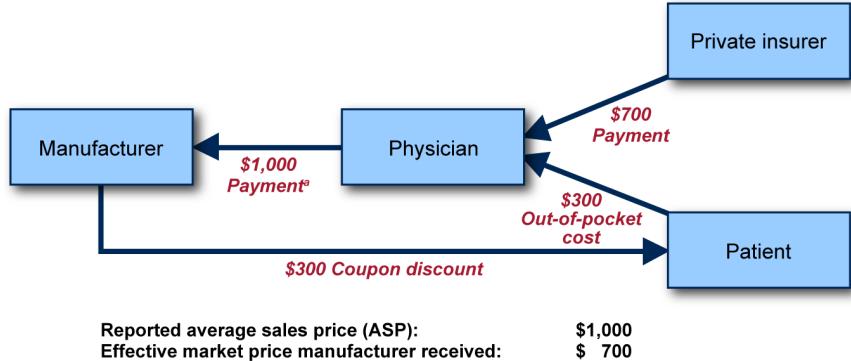
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## Methodology for Setting Part B Drug Payment Rates May Be Less Suitable for Drugs with Coupon Programs, but CMS Lacks Data to Evaluate Methodology

### Payment Rate Methodology for Part B Drugs May Be Less Suitable for Drugs with Coupon Programs because Medicare's Average Sales Price Exceeds Effective Market Price

Medicare's market-based methodology for setting Part B drug payment rates may be less suitable for drugs with coupon programs than for other Part B drugs that are paid based on ASP. Because ASP does not account for coupon discounts between manufacturers and patients, the ultimate consumers of these drugs, the ASP for drugs with coupons exceeds the effective market price a manufacturer receives for a drug purchase. For example, in figure 1, the ASP reported by the manufacturer was \$1,000; however, the effective market price the manufacturer received for the drug—net of the coupon discount the manufacturer provided to the patient—was actually \$300 less, or \$700.

**Figure 1: Example of Financial Transactions for Drug with Coupon Program**



*For simplicity, payments to the physician in this illustrative example do not cover the physician's administrative and overhead costs.*

Source: GAO. | GAO-16-643

<sup>a</sup>Payment is net of discounts and rebates provided by the manufacturer to the physician.

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We estimated that, for the 18 drugs for which we obtained coupon discount data in 2013, ASP exceeded the effective market price by an average of 0.7 percent.<sup>29</sup> Medicare spending for these 18 drugs could have been \$69 million lower if ASP had been equal to the effective market price manufacturers received.<sup>30</sup> ASP exceeded the effective market price for some drugs by much more than the 0.7 percent average, which suggests that the ASP-based payment method may be even less suitable for these drugs. For example, for 5 of the 18 drugs, ASP exceeded the effective market price by an estimated 2.7 percent, on average, and ranged from 1.4 to 7.8 percent depending on the drug (see fig. 2).<sup>31</sup> Part B spending for these 5 drugs combined could have been an estimated \$50 million lower if ASP equaled the effective market price. The drugs for which ASP exceeded the effective market price by the highest percentage either had high rates of coupon use relative to other drugs, a high average annual discount, or both. For example, the drug in figure 2 with the highest percentage (Drug A) had the highest average annual discount per patient (\$7,100) and the second highest percentage of patients who used a coupon (53 percent). (For more detail on the data and methodology for these estimates, see app. II.)

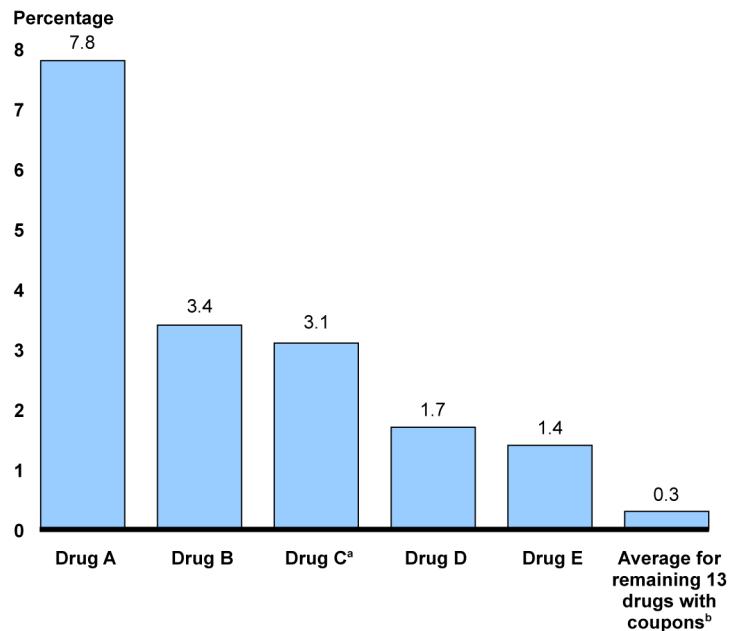
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<sup>29</sup>We calculated this average percentage by weighting each drug by its total Medicare expenditures over the 1-year spending period used in our analysis—July 2013 through June 2014.

<sup>30</sup>This reduction applied to Part B spending from July 2013 through June 2014. During this time period, Medicare spent \$9.5 billion on these 18 drugs. The \$69 million reduction in Medicare spending we present is an underestimate given that we were unable to obtain coupon discount data from manufacturers for 3 of the 21 drugs with coupon programs in 2013 that we identified. These 3 drugs accounted for 5 percent of Medicare spending on the 21 drugs with coupon programs.

<sup>31</sup>We calculated the average percentage by weighting each drug by its total Medicare expenditures over the 1-year spending period used in our analysis—July 2013 through June 2014.

**Figure 2: Estimated Percentage by which Average Sales Price Exceeded Effective Market Price, Selected Drugs with Coupon Programs, 2013**



Source: GAO analysis of data from drug manufacturers and Truven Health Analytics' MarketScan Commercial Claims and Encounters Database. | GAO-16-643

Notes: These percentages were calculated based on 2013 data reported by manufacturers to the Centers for Medicare & Medicaid Services on each drug's sales and average sales price (ASP) and data from drug manufacturers on the total coupon discounts provided for each drug in the analysis. We estimated the effective market price for each drug by recalculating the drug's ASP after reducing the drug's total sales by the total coupon discounts provided. (See app. II for more detail on the data and methodology.)

<sup>a</sup>For Drug C, the manufacturer was unable to provide information on total coupon discounts in 2013 but was able to provide other information for this coupon program in 2013 that we used to estimate this amount. We estimated total coupon discounts for this drug by multiplying the average discount provided to patients who received a coupon discount, as reported by the manufacturer, by our estimate of the number of patients who received a discount. To estimate the number of these patients, we multiplied the total number of patients enrolled in the program, as reported by the manufacturer, by the median percentage among other coupon programs in our analysis of program enrollees who received a discount.

<sup>b</sup>For each of these drugs, the ASP exceeded the effective market price by less than an estimated 1.0 percent.

Upward trends in the use of coupon programs suggest that drug coupons could have an even greater effect in the future on the suitability of Medicare's methodology for setting Part B drug payment rates. A recent study found that coupon use more than doubled between 2011 and

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2014.<sup>32</sup> Several manufacturers we interviewed told us that the number of patients using coupon programs and the discount amounts that patients receive have increased over time. In addition, to the extent that drug prices continue to increase and translate into higher out-of-pocket costs for privately insured patients, this could increase patients' use of drug coupons and the discount amounts they receive.<sup>33</sup>

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### CMS Lacks Data to Evaluate Implications of Coupon Programs for Medicare's Part B Drug Payment Rate Methodology

CMS currently lacks data on coupon discounts, which are necessary for evaluating the implications of coupon programs for Medicare's Part B payment rate methodology. CMS lacks the authority to collect data from drug manufacturers on coupon discounts to patients because the authority to collect information relating to ASP is based on manufacturer sales to purchasers. In addition, these data are proprietary and are not readily available from other sources. Standards for internal control in the federal government require agencies to have access to quality information to achieve their objectives, which for CMS entails having the information necessary to evaluate the implications coupon programs may have for Medicare's methodology for setting Part B drug payment rates.<sup>34</sup> Without data on coupon discounts, CMS lacks information that could inform its ongoing efforts to evaluate alternatives to this payment rate methodology.

---

<sup>32</sup>A study by IMS Health reported that the percentage of prescriptions for brand name drugs that involved the use of coupon programs increased from 3 percent in 2011 to 8 percent in 2014. See IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts in 2014*.

<sup>33</sup>Increases in spending and prices for prescription drugs, particularly for specialty drugs, have been well documented. For example, see Congressional Research Service, *Specialty Drugs: Background and Policy Concerns* (Washington, D.C.: Aug. 3, 2015); IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020* (Parsippany, N.J.: April 2016); and The Express Scripts Lab, *Express Scripts 2015 Drug Trend Report* (St. Louis, Mo.: March 2016).

For research on patient out-of-pocket expenditures, see IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.*; and Gary Claxton, Larry Levitt, and Michelle Long, *Payments for Cost Sharing Increasing Rapidly Over Time* (Kaiser Family Foundation Peterson-Kaiser Health System Tracker, April 2016), accessed May 3, 2016, <http://www.healthsystemtracker.org/insight/payments-for-cost-sharing-increasing-rapidly-over-time/>.

<sup>34</sup>GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

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## Conclusions

The high spending on Part B drugs based on ASP—approximately \$20 billion in 2013—underscores the need to ensure that Medicare pays appropriately for these drugs. Various studies have noted previously that payments to providers under the current ASP-based payment methodology could lead providers to prescribe more costly drugs. Our findings in this report indicate that the shortcomings of this payment system go beyond problems with the incentives associated with payments to providers. In particular, even if Medicare Part B drug payments accurately reimburse providers' costs and do not introduce inappropriate incentives, Medicare still may be paying more than necessary for drugs with coupon programs because the ASP for these drugs exceeds the effective market price that manufacturers ultimately received. Furthermore, upward trends in coupon program use and drug prices suggest that Medicare's Part B drug payment rate methodology could become less suitable over time for drugs with coupon programs. These trends emphasize the need for regular monitoring of the implications that coupon programs may have for this methodology as CMS works to propose an alternative payment system. However, the agency lacks the authority to collect data on coupon discounts and therefore lacks important information that could inform its ongoing efforts to design and evaluate alternative approaches.

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## Matter for Congressional Consideration

To determine the suitability of Medicare's Part B drug payment rate methodology for drugs with coupon programs, Congress should consider

- granting CMS the authority to collect data from drug manufacturers on coupon discounts for Part B drugs paid based on ASP and
- requiring the agency to periodically collect these data and report on the implications that coupon programs may have for this methodology.

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## Agency Comments

We provided a draft of this product to HHS. HHS provided us with 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 until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, and the Administrator of the Centers for Medicare & Medicaid Services. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James Cosgrove".

James Cosgrove  
Director, Health Care

# Appendix I: Highest-Expenditure Medicare Part B Drugs Paid based on Average Sales Price (ASP), 2013

Rank by total 2013 Medicare expenditures paid based on ASP	Brand name(s)	Drug description(s) <sup>a</sup>	Healthcare Common Procedure Coding System (HCPCS) code(s) <sup>b</sup>	Condition(s) treated	Medicare expenditures paid based on ASP, 2013 (dollars in millions) <sup>c</sup>
1	Rituxan	Rituximab injection	J9310	Cancer; rheumatoid arthritis	\$1,515
2	Lucentis	Ranibizumab injection	J2778	Wet age-related macular degeneration	1,368
3	Remicade	Infliximab injection	J1745	Various autoimmune disorders	1,106
4	Neulasta	Injection, pegfilgrastim 6mg	J2505	Prevent infection in chemotherapy patients	1,105
5	Eylea	Aflibercept injection (ophthalmic)	J0178	Wet age-related macular degeneration	1,090
6	Avastin	Bevacizumab injection	C9257, J9035	Cancer	1,047
7	Prolia, Xgeva	Denosumab injection	J0897	Osteoporosis; prevent skeletal-related events in cancer patients	636
8	Alimta	Pemetrexed injection	J9305	Cancer	552
9	Herceptin	Trastuzumab injection	J9355	Cancer	505
10	Velcade	Bortezomib injection	J9041	Cancer	453
11	Flebogamma, Gammaked, Gammplex, and various other brands <sup>d</sup>	Injection, IVIG Bivigam (C9130) Gammplex injection (J1557) Gamunex-C/Gammaked (J1561) Octagam injection (J1568) Flebogamma injection (J1572)	C9130, J1557, J1561, J1568, J1572	Primary immunodeficiency; chronic immune thrombocytopenic purpura	373
12	Reclast, Zometa	Zoledronic acid (J3487) Reclast injection (J3488) Zoledronic acid 1mg (Q2051)	J3487, J3488, Q2051	Prevent and treat osteoporosis; treat Paget's disease of bone; high calcium levels and bone disease in cancer patients	367
13	Treanda	Bendamustine injection	J9033	Cancer	319

**Appendix I: Highest-Expenditure Medicare Part  
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<b>Rank by total 2013 Medicare expenditures paid based on ASP</b>	<b>Brand name(s)</b>	<b>Drug description(s)<sup>a</sup></b>	<b>Healthcare Common Procedure Coding System (HCPCS) code(s)<sup>b</sup></b>	<b>Condition(s) treated</b>	<b>Medicare expenditures paid based on ASP, 2013 (dollars in millions)<sup>c</sup></b>
14	Epogen, Procrit	Epoetin alfa, non-ESRD (J0885)  Epoetin alfa 1000 units ESRD (J0886)  Epoetin alfa, 100 units ESRD (Q4081)	J0885, J0886, Q4081	Anemia in end-stage renal disease (ESRD), chemotherapy, and human immunodeficiency virus patients; prevent blood loss in surgical patients	312
15	Sandostatin LAR Depot	Octreotide injection, depot	J2353	Acromegaly; diarrhea and flushing caused by carcinoid tumors and vasoactive intestinal peptide secreting adenomas	305
16	Orencia	Abatacept injection	J0129	Rheumatoid arthritis	293
17	Aranesp	Darbepoetin alfa, non-ESRD (J0881)  Darbepoetin alfa, ESRD use (J0882)	J0881, J0882	Anemia in ESRD and chemotherapy patients	292
18	Erbitux	Cetuximab injection	J9055	Cancer	263
19	Eligard, Lupron Depot, Lupron Depot-PED	Leuprolide acetate /3.75 MG (J1950)  Leuprolide acetate suspension (J9217)	J1950, J9217	Cancer; various other conditions	256
20	Lexiscan	Regadenoson injection	J2785	Stress agent for myocardial perfusion imaging	241
21	Pulmicort Respules	Budesonide non-comp unit	J7626	Maintenance treatment of asthma and as prophylactic therapy	235
22	Tysabri	Natalizumab injection	J2323	Multiple sclerosis; Crohn's disease	231
23	Vidaza	Azacitidine injection	J9025	Myelodysplastic syndrome	228
24	Advate, Helixate FS, Kogenate FS, and various other brands <sup>e</sup>	Xyntha inj (J7185)  Factor vii recombinant (J7192)	J7185, J7192	Hemophilia A	221
25	Yervoy	Ipilimumab injection	J9228	Cancer	217
26	Abraxane	Paclitaxel protein bound	J9264	Cancer	215

**Appendix I: Highest-Expenditure Medicare Part  
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27	Gammagard Liquid	Gammagard liquid injection	J1569	Primary humoral immunodeficiency; multifocal motor neuropathy	203
28	Botox, Botox Cosmetic	Injection, onabotulinumtoxinA	J0585	Various conditions, such as urinary incontinence	191
29	Aloxi	Palonosetron hcl	J2469	Prevent nausea and vomiting in chemotherapy and surgical patients	187
30	Provenge	Sipuleucel-T auto CD54+	Q2043	Cancer	180
31	Xolair	Omalizumab injection	J2357	Asthma	178
32	Tyvaso	Treprostинil, non-comp unit	J7686	Hypertension	175
33	Privigen	Inj IVIG privigen 500 mg	J1459	Primary humoral immunodeficiency; chronic immune thrombocytopenic purpura	166
34	Faslodex	Injection, Fulvestrant	J9395	Cancer	165
35	Synvisc, Synvisc-One	Synvisc or Synvisc-One	J7325	Osteoarthritis of the knee	151
36	Dacogen	Decitabine injection	J0894	Myelodysplastic syndrome	143
37	Soliris	Eculizumab injection	J1300	Paroxysmal nocturnal hemoglobinuria	142
38	Hyalgan	Hyalgan/supartz inj per dose (J7321) Euflexxa inj per dose (J7323)	J7321, J7323	Osteoarthritis of the knee	132
39	Brovana	Arformoterol non-comp unit	J7605	Symptoms of chronic obstructive pulmonary disease	123
40	Actemra	Tocilizumab injection	J3262	Rheumatoid arthritis	122
41	NovoSeven, NovoSeven RT	Factor viia	J7189	Hemophilia; prevent surgical bleeding	118
42	Nplate	Romiplostim injection	J2796	Chronic immune thrombocytopenia	115

**Appendix I: Highest-Expenditure Medicare Part  
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(ASP), 2013**

<b>Rank by total 2013 Medicare expenditures paid based on ASP</b>	<b>Brand name(s)</b>	<b>Drug description(s)<sup>a</sup></b>	<b>Healthcare Common Procedure Coding System (HCPCS) code(s)<sup>b</sup></b>	<b>Condition(s) treated</b>	<b>Medicare expenditures paid based on ASP, 2013 (dollars in millions)<sup>c</sup></b>
43	Adriamycin, Doxil	Doxorubicin hcl injection (J9000)  Doxil injection (J9002)  Imported Lipodox inj (Q2049)  Doxorubicin inj 10mg (Q2050)	J9000, J9002, Q2049, Q2050	Cancer	111
44	Dermagraft	Apligraf skin sub (Q4101)  Dermagraft skin sub (Q4106)  Graftjacket skin sub (Q4107)	Q4101, Q4106, Q4107	Diabetic foot ulcers	110
45	Neupogen	Filgrastim 480 mcg injection	J1441	Prevent infection in cancer, bone marrow transplant, and chronic neutropenia patients; prepare blood for leukapheresis in chemotherapy patients	110
46	Docefrez, Taxotere	Docetaxel injection	J9171	Cancer	88
47	Eloxatin	Oxaliplatin	J9263	Cancer	85
48	Cubicin	Daptomycin injection	J0878	Skin and bloodstream infections	80
49	Angiomax	Bivalirudin	J0583	Anticoagulant in patients with unstable angina	78
50	Cimzia	Certolizumab pegol inj	J0718	Crohn's disease	69

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and RED BOOK. | GAO-16-643

Notes: We developed this list of the 50 highest-expenditure Medicare Part B drugs using data on Medicare claims paid based on ASP in 2013. We identified drugs based on their HCPCS codes. Some drugs that we identified for purposes of our analysis had multiple HCPCS codes because these codes included national drug codes (NDC) for drugs that were pharmaceutically equivalent, as defined by FDA. FDA defines pharmaceutically equivalent drugs as those that have the same active ingredient(s), dosage form, route of administration, and strength or concentration. We excluded from our list 2 oral cancer drugs and 3 oral immunosuppressant drugs used to prevent organ rejection after transplant. Claims for these drugs were processed by CMS's contractor that processes durable medical equipment claims even though these drugs were not administered through durable medical equipment. (See app. II for more detail on our data sources and methodology.)

<sup>a</sup>When a drug with multiple HCPCS codes also had multiple descriptions, each description is listed along with the associated HCPCS code.

<sup>b</sup>HCPCS is a standard coding system that identifies items and services for payment purposes.

<sup>c</sup>Expenditure amounts are for all brand and generic products associated with the HCPCS code(s) in a given row in this table.

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**Appendix I: Highest-Expenditure Medicare Part  
B Drugs Paid based on Average Sales Price  
(ASP), 2013**

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<sup>d</sup>Also includes Flebogamma 10% DIF, Flebogamma 5% DIF, Gamunex, Gamunex-C, and Octagam.

<sup>e</sup>Also includes Kogenate FS BIO-SET, Recombinate, ReFacto, and Xyntha.

# Appendix II: Data and Methods

This appendix describes the data and methods we used in our study.

## Identifying Coupon Programs Associated with High-Expenditure Medicare Part B Drugs and Describing Use among the Privately Insured

To identify coupon programs associated with high-expenditure Medicare Part B drugs, we used 2013 Medicare claims data—the most recent full year of data available at the time we began our analysis (2015)—to develop a list of the 50 highest-expenditure Part B drugs paid based on the average sales price (ASP) methodology. We identified drugs based on their Healthcare Common Procedure Coding System (HCPCS) codes.<sup>1</sup> Each HCPCS code refers to one or more brand or generic products, which are identified by their national drug codes (NDC). The drugs we identified for our analysis had multiple HCPCS codes if the codes shared one or more NDCs for products that were pharmaceutically equivalent, defined by the Food and Drug Administration as those with the same active ingredient(s), dosage form, route of administration, and strength or concentration. Our final list of the 50 highest-expenditure drugs accounted for 85 percent of Part B spending in 2013 for drugs paid based on ASP.<sup>2</sup> (For the complete list of these 50 drugs, see app. I.)

We identified which of the 50 high-expenditure Part B drugs had coupon programs, either at the time of our analysis (2015) or in 2013, based on information from manufacturers and their websites.<sup>3</sup> If we were unable to identify a coupon program for a drug and did not receive information from its manufacturer, we recorded that the drug did not have a coupon program. Some drugs in our analysis comprised multiple NDCs. As a result, some drugs we analyzed had a coupon program for one product but did not have programs for other products, while other drugs had multiple coupon programs.

To describe the extent to which privately insured patients used coupon programs, we obtained data from Truven Health Analytics' MarketScan®

<sup>1</sup>HCPCS is a standard coding system that identifies items and services for payment purposes.

<sup>2</sup>We excluded from our list two oral cancer drugs and three oral immunosuppressant drugs used to prevent organ rejection after transplant. Claims for these drugs were processed by CMS's contractor that processes durable medical equipment claims even though these drugs were not administered through durable medical equipment.

<sup>3</sup>We did not collect information on patient assistance programs. These programs are typically available only to uninsured patients and may cover the full costs of a drug.

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Commercial Claims and Encounters Database on the estimated number of privately insured patients nationally who used drugs with coupon programs in 2013 (to correspond with the year of available Medicare claims data) and the out-of-pocket costs these patients incurred. We also obtained data for 2013 from drug manufacturers on coupon use—specifically, the number of patients who used each program and the average annual coupon discount provided. We calculated the percentage of patients taking a drug who used a coupon program by dividing the number of patients who used a coupon program by the estimated total number of patients who used the drug. To calculate the average of this percentage across all drugs in our analysis for which we obtained data on coupon use, we weighted each drug's percentage by the total number of patients who used the drug. We calculated the total amount of coupon discounts provided in 2013 for each drug by multiplying the number of patients who used the program by the average discount provided. To calculate the average annual coupon discount across all drugs for which we obtained data on coupon use, we weighted the average annual discount for each drug by the number of patients who used the coupon program. In addition to data on coupon use, we collected information from manufacturers on the mechanisms through which manufacturers provide coupon discounts to patients and on the ways in which manufacturers inform patients and providers about drug coupon programs.

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**Examining the Suitability  
of Medicare's Part B Drug  
Payment Rate  
Methodology**

To examine the suitability of Medicare's Part B drug payment rate methodology for drugs with coupon programs, we reviewed relevant statutes and regulations and interviewed officials from the Centers for Medicare & Medicaid Services (CMS). To illustrate the potential effect, if any, of coupon programs on the suitability of this methodology for Part B drugs with these programs, we estimated how a drug's ASP and Part B spending may have changed if the drug's ASP accounted for coupon discounts. For each drug for which we had manufacturer data on coupon discounts, we calculated the drug's ASP in 2013 and our estimate of the effective market price as follows:

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$$\text{Average Sales Price (ASP) in 2013}^a = \frac{\text{Total sales in } 2013^b}{\text{Total units sold in } 2013}$$

$$\begin{aligned}\text{Effective market price in 2013} \\ = \frac{\text{Total sales in } 2013^b - \text{Total coupon discounts in } 2013}{\text{Total units sold in } 2013}\end{aligned}$$

<sup>a</sup>The ASP for a drug in 2013, as calculated above, is equal to the average of the quarterly ASPs in 2013 reported to CMS by drug manufacturers, weighted by the units of the drug sold in a given quarter.

<sup>b</sup>Total sales net of manufacturer price concessions to purchasers, as defined by ASP.

We then calculated the percentage by which ASP exceeded the effective market price in 2013 for each drug and across all drugs with coupon discount data in our analysis. To calculate this percentage across all drugs in the analysis, we weighted the percentage for each drug based on the drug's Medicare spending from July 2013 through June 2014, which is the time period during which changes in ASP in 2013 would take effect.<sup>4</sup> Finally, to estimate what Medicare spending from July 2013 through June 2014 could have been if a drug's ASP accounted for coupon discounts, we multiplied the drug's actual Medicare spending during this time by the percentage by which ASP in 2013 could have decreased if it had equaled the effective market price. We then calculated the difference between this spending estimate and actual Medicare spending for the same time period for each drug and across all drugs in our analysis with coupon discount data.

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<sup>4</sup>This two-quarter (6-month) lag between the sales of a drug and when these sales are reflected in ASP is due to the time it takes for manufacturers to submit data to CMS, for CMS to review the data and update the payment rates, and the public to review and comment on the revised rates.

# Appendix III: Estimated Out-of-Pocket Costs of Privately Insured Patients for Drugs with Coupon Programs in 2015

<b>Brand name(s) for drugs with coupon programs</b>	<b>Percentage of patients with out-of-pocket costs<sup>a</sup></b>	<b>Average annual out-of-pocket cost among patients with out-of-pocket costs (in 2015 dollars)<sup>b</sup></b>
Abraxane	24	\$1,046
Actemra	60	1,154
Advate, Helixate FS, Kogenate FS, and various other brands <sup>c</sup>	71	1,599
Alimta	23	1,386
Avastin	39	390
Botox, Botox Cosmetic	52	357
Cimzia	92	677
Cubicin	34	617
Eligard, Lupron Depot, Lupron Depot-PED	63	353
Erbxitux	24	1,142
Eylea	50	999
Faslodex	40	909
Flebogamma, Gammaked, Gammaplex, and various other brands <sup>d</sup>	47	1,356
Gammagard Liquid	48	1,371
Herceptin	33	1,214
Lucentis	43	781
Neulasta	28	630
Neupogen	34	274
NovoSeven, NovoSeven RT	59	1,251
Nplate	50	1,454
Orencia	76	943
Prolia, Xgeva	54	399
Provenge	25	1,180
Remicade	56	1,309
Rituxan	35	1,262
Sandostatin LAR Depot	51	1,219
Tysabri	61	1,714
Xolair	75	567
Yervoy	24	1,965

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services (CMS), Truven Health Analytics, and drug manufacturers. | GAO-16-643

Notes: We developed this list based on coupon programs associated with the 50 highest-expenditure Medicare Part B drugs using data on Medicare claims paid based on ASP in 2013. We identified which of these 50 Part B drugs had coupon programs at the time of our analysis (2015) based on information from manufacturers and their websites. We obtained data from Truven Health Analytics' MarketScan® Commercial Claims and Encounters Database on the estimated number of privately insured patients nationally who used drugs with coupon programs and the out-of-pocket costs these patients incurred. See app. II for more detail on our data sources and methodology.

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**Appendix III: Estimated Out-of-Pocket Costs of  
Privately Insured Patients for Drugs with  
Coupon Programs in 2015**

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<sup>a</sup>Percentage of patients with out-of-pocket costs and average annual out-of-pocket cost are estimated at the drug level. In some cases, a drug comprised national drug codes (NDC) with coupon programs and NDCs without coupon programs in 2015.

<sup>b</sup>Values are based on 2013 data from Truven Health Analytics and have been adjusted for inflation to 2015 dollars using the Consumer Price Index for All Urban Consumers.

<sup>c</sup>Also includes Kogenate FS BIO-SET, Recombinate, ReFacto, and Xyntha.

<sup>d</sup>Also includes Flebogamma 10% DIF, Flebogamma 5% DIF, Gamunex, Gamunex-C, and Octagam.

# Appendix IV: GAO Contact and Staff Acknowledgments

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## GAO Contact

James Cosgrove, (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov)

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## Acknowledgments

In addition to the contact named above, William Black (Assistant Director), Ramsey Asaly, Namita Bhatia-Sabharwal, George Bogart, Muriel Brown, William A. Crafton, Kelsey Kennedy, Dan Lee, Maria Maguire, Lauren Metayer, and Beth Morrison made key contributions to this report.

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*Medicare: Information on Highest-Expenditure Part B Drugs.* [GAO-13-739T](#). Washington, D.C.: June 28, 2013.

*Medicare: High-Expenditures Part B Drugs.* [GAO-13-46R](#). Washington, D.C.: October 12, 2012.

*Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain.* [GAO-06-971T](#). Washington, D.C.: July 13, 2006.

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