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MEDICARE

Information on Highest-Expenditure Part B Drugs

Statement of James Cosgrove
Director, Health Care

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GAO Highlights

Highlights of GAO-13-739T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In an October 2012 report, GAO examined the levels and trends in expenditures, utilization, and average annual per beneficiary costs for the most expensive Medicare Part B drugs (GAO-13-46R). Unlike Medicare Part D, Part B covers drugs that are commonly administered by a physician or under a physician's close supervision, such as chemotherapy drugs. Many Part B drugs may be expensive for the Medicare program either because their prices are high or because they are used by a large number of beneficiaries. In 2010, the Medicare program and its beneficiaries spent about $19.5 billion on Part B drugs, about 9 percent of total Part B expenditures.

In this statement, GAO highlights the findings from the 2012 report on (1) the Part B drugs for which Medicare expenditures were highest in 2010 and the utilization and expenditure trends for these drugs from 2008 to 2010, and (2) nationwide spending levels for the total U.S. insured population for these high-expenditure Part B drugs in 2010 and Medicare's percentage of total U.S. spending.

GAO calculated the total expenditures for each drug using the Centers for Medicare & Medicaid Services' national claims files for physicians, hospital outpatient, and durable medical equipment and ranked the drugs, selecting the top 55 for analysis of utilization and average annual per beneficiary cost. In addition, GAO obtained estimates of total U.S. expenditures for each of the drugs from IMS Health, a company that collects and analyzes health care data, to estimate Medicare's share of total U.S. spending for these drugs.

View GAO-13-739T. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Medicare expenditures for Part B drugs in 2010 were concentrated among relatively few drugs. The 55 highest-expenditure Part B drugs represented $16.9 billion in spending, or about 85 percent of all Medicare spending on Part B drugs, and the 10 highest-expenditure drugs accounted for about 45 percent of all Part B drug spending in 2010. Most of these drugs were under patent and could be purchased only from a single manufacturer. The number of Medicare beneficiaries who used the 55 drugs ranged from over 15 million beneficiaries who received the influenza vaccine to 660 beneficiaries who used a drug that treats hemophilia. The annual per beneficiary cost of the Part B drugs GAO examined also varied widely in 2010, from $13 for influenza vaccine to over $200,000 for factor vii recombinant to treat hemophilia. Spending, utilization, and prices increased for most of the 55 drugs between 2008 and 2010, with the drugs that showed the greatest increases in expenditures also showing the greatest increases in utilization.

Five Highest-Expenditure Medicare Part B Drugs, 2010

2010 rank by total Medicare expenditures	Brand name(s)	Condition(s) treated	Total 2010 expenditures for Medicare beneficiaries (millions)
1	Epogen/Procrit (end-stage renal disease (ESRD) use)[a]	Anemia in ESRD patients	$2,000
2	Rituxan	Cancer; rheumatoid arthritis	1,302
3	Lucentis	Wet age-related macular degeneration (AMD)	1,180
4	Avastin	Cancer; wet AMD	1,130
5	Remicade	Various autoimmune disorders	900

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the National Institutes of Health, and drug manufacturers.

[a]ESRD is a condition of permanent kidney failure.

Spending on Medicare beneficiaries accounted for the majority of estimated total U.S. spending for 35 of the 55 highest-expenditure drugs in 2010. For 17 of these drugs, Medicare spending accounted for more than two-thirds of total U.S. spending. Of the $16.9 billion Medicare spent for the 55 highest-expenditure Part B drugs, $11 billion, or 65 percent, was spent on drugs for which Medicare was the largest U.S. payer.

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee:

I am pleased to be here today as you discuss reforms to improve the Medicare Part B drug program. Unlike Medicare Part D,[1] Part B covers drugs that are commonly administered by a physician or under a physician's close supervision, such as chemotherapy drugs.[2] Many of these drugs are particularly expensive for the Medicare program, either because they are used by a large number of beneficiaries or because their prices are high. Furthermore, both the utilization and cost of these drugs are increasing. In 2010, the Medicare program and its beneficiaries spent about $19.5 billion on Part B drugs, about 9 percent of total Part B expenditures.

My statement will highlight findings from our October 2012 report on high-expenditure Part B drugs.[3] In that report we examined (1) the Part B drugs for which Medicare expenditures were highest in 2010 and the utilization and expenditure trends for these drugs from 2008 to 2010, and (2) nationwide spending levels for the total U.S. insured population for these high-expenditure Part B drugs in 2010 and Medicare's percentage of total U.S. spending.[4] These findings provide a look at the highest-expenditure Part B drugs in 2010. During or after 2010, several extremely expensive products entered the market—Provenge and Jevtana used to treat prostate cancer, and Benlysta used to treat lupus, among others. Given that costly new drugs entered the market and generic versions of other drugs became available, a snapshot taken today would likely show a somewhat different set of drugs.

[1]Medicare Part D is a voluntary program through which Medicare covers outpatient drugs.

[2]Medicare Part B covers certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies. Part B drugs are commonly administered in physicians' offices and hospital outpatient departments. In this testimony the term "drugs" refers to chemically synthesized drugs and biologicals unless otherwise specified. Biologicals are products derived from living sources, including humans, animals, and microorganisms.

[3]GAO, *Medicare: High-Expenditure Part B Drugs*, GAO-13-46R (Washington, D.C.: Oct.12, 2012).

[4]For this testimony, we use the term Medicare spending to refer to spending by the Medicare program and spending by or on behalf of Medicare beneficiaries.

To identify the highest-expenditure Part B drugs, we used the Centers for Medicare & Medicaid Services' (CMS) national claims files for physicians, hospital outpatient, and durable medical equipment. We calculated the total expenditures for each drug and ranked the drugs, selecting the top 55 for further analysis. We also obtained utilization and average annual per beneficiary cost from the claims files. We obtained information on the purpose and other characteristics of these drugs from the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and manufacturers. We obtained estimates of total U.S. expenditures for each of the drugs from IMS Health, a company that collects and analyzes health care data, thereby enabling us to estimate Medicare's share of spending for these drugs.

We conducted the work for our October 2012 report that forms the basis for our findings from August 2011 through August 2012 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 to our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

Background

Medicare bases its payments for most Part B drugs on the average sales price (ASP), which is calculated from price and volume data that manufacturers report quarterly to CMS, the agency within the Department of Health and Human Services (HHS) that administers Medicare. ASP is the average price, after rebates and discounts, of all sales of a specified drug in the United States; consequently, Medicare's payment rates for Part B drugs are based on prices set in the private market. Payment to physicians for most drugs is set by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) at 106 percent of ASP.[5] Until recently, CMS set payment for separately payable Part B drugs administered in hospital outpatient departments at a rate that has varied between 104 and 105 percent of ASP, but in 2013, CMS set the payment rate at 106 percent of ASP.

[5]Pub. L. No. 108-173, § 303(c)(1),117 Stat. 2066, 2239 (adding Social Security Act (SSA) § 1847A(b)).

The MMA directed the HHS Office of Inspector General (OIG) to compare ASP to the average manufacturer price (AMP), and authorized CMS to lower reimbursement for drugs with ASPs that exceed AMPs by 5 percent or more.[6] OIG's most recent annual report found that there were 58 drug codes in 2011 for which ASP exceeded AMP by at least 5 percent. Beginning in 2013, as authorized by the MMA, CMS is implementing a policy to substitute AMP-based prices in such cases. Specifically, CMS will substitute 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a drug code that exceeds the 5 percent threshold in two consecutive quarters or three of four quarters.[7]

In a 2005 report, we analyzed the use of ASP to set payment rates for Part B drugs, and we determined that it was a practical approach compared with methods based on alternative data sources.[8] Nonetheless, we had concerns about CMS's lack of certain information on ASP, and characterized it as "a black box." Specifically, we stated that CMS did not have sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs and had no data that would allow it to validate the underlying reasonableness of prices. CMS did not obtain price and volume data by purchaser type—for example, physicians, hospitals, and other health care providers. Furthermore, a sufficient empirical foundation did not exist for setting the payment rate for Part B drugs at 6 percent above ASP. The addition of 6 percent to the price is relatively small for a $10 drug, but it is substantial for a $100,000 drug.

Although payment for most Part B drugs is based on ASP, some are paid on a different basis. Vaccines, infusion drugs furnished with durable medical equipment, and blood products are paid at 95 percent of average wholesale price (AWP), which is the manufacturer's average price to wholesalers, but AWP is not defined in law and does not account for

[6]AMP represents the average of actual transaction prices paid to manufacturers for a given drug and is typically less than any of a drug's published compendium prices, which are list prices suggested by drug manufacturers.

[7]42 C.F.R. § 414.904 (2012).

[8]GAO, *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*, GAO-06-17R (Washington, D.C.: Oct. 31, 2005).

prompt pay or other discounts, rebates, and reductions.[9] In cases where the ASP of a new drug during the first quarter of sales is unavailable, payment may be set at 106 percent of the wholesale acquisition cost (WAC), which the Social Security Act defines as the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions, for the most recent month for which information is available.[10]

For some drugs such as drugs used to treat cancer, certain new drugs, and orphan drugs (drugs used to treat rare diseases), Medicare makes additional payments, known as transitional pass-through payments, for 2 to 3 years when these drugs are administered in the hospital outpatient setting. For new drugs, pass-through status is intended to make the drugs accessible to beneficiaries while a pricing history is developed and the price is established.

New drugs generally are patented and, while under patent, can be manufactured only by the patent holder. Patents generally last for 20 years from the date of application. After the patent expires and generic forms of the drug are marketed at significantly lower prices, the price of the original drug usually falls.

Total Expenditures, Utilization, Average Costs per Beneficiary, and Trends for Part B Drugs from 2008 through 2010

Medicare expenditures for Part B drugs in 2010 were concentrated among relatively few drugs. In 2010, the 55 highest-expenditure Part B drugs represented $16.9 billion in spending, or about 85 percent of all Medicare spending on Part B drugs. Generic alternatives were not available for most of the 55 drugs. Most remained under patent and could be purchased only from a single manufacturer.

The 10 highest-expenditure drugs, shown in table 1, accounted for about 45 percent of all Part B drug spending in 2010. Of these 10 drugs, 8 were biological products and 4 had orphan drug marketing exclusivity in

[9]Prompt pay discounts may be provided when the purchaser pays in advance or within a prescribed time period.

[10]SSA § 1847A(c)(6)(B). The list price is to be determined as reported in wholesale price guides or other publications of drug pricing data.

2010.[11] None of the 10 highest-expenditure drugs had a generic version approved by FDA in 2010.

Table 1: Ten Highest-Expenditure Medicare Part B Drugs, 2010

2010 rank by total Medicare expenditures	Brand name(s)	Drug description	Classification	Condition(s) treated	Total 2010 expenditures for Medicare beneficiaries (dollars in millions)
1	Epogen/Procrit (end-stage renal disease (ESRD) use)	Epoetin alfa, ESRD[a]	Biological	Anemia in ESRD patients	$2,000
2	Rituxan[b]	Rituximab injection	Biological	Cancer; rheumatoid arthritis	1,302
3	Lucentis	Ranibizumab injection	Biological	Wet age-related macular degeneration (AMD)	1,180
4	Avastin[b]	Bevacizumab injection	Biological	Cancer; wet AMD	1,130
5	Remicade[b]	Infliximab injection	Biological	Various autoimmune disorders	900
6	Neulasta	Injection, pegfilgrastim 6mg	Biological	Prevent infection in chemotherapy patients	888
7	Aranesp (non-ESRD use)	Darbepoetin alfa, non-ESRD	Biological	Anemia in chemotherapy patients	504
8	Epogen/Procrit (non-ESRD use)	Epoetin alfa, non-ESRD	Biological	Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients	443
9	Alimta[b]	Pemetrexed injection	Drug	Cancer	394
10	Taxotere	Docetaxel injection	Drug	Cancer	387
	Total				**$9,128**

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

[a]ESRD, a condition of permanent kidney failure, is also known as stage 5 chronic kidney disease.

[b]These products had orphan drug marketing exclusivity for specific FDA-approved indications in 2010.

Many of the high-expenditure Part B drugs are used in cancer treatment. Of the 55 highest-expenditure drugs, cancer and its side effects were treated by more drugs (23) than any other set of conditions in 2010. Other conditions treated by several drugs included immune system disorders

[11]Rtiuxan, Avastin, Remicade, and Almita had orphan drug marketing exclusivity.

(13), cardiovascular disease and testing (5), chronic kidney disease (5), asthma and lung diseases (3), and prevention of organ transplant rejection (3).[12]

The number of Medicare beneficiaries in 2010 who used the 55 drugs we reviewed varied widely. Utilization of the 55 highest-expenditure Part B drugs ranged from over 15 million beneficiaries who received the influenza vaccine to 660 beneficiaries who used factor viii recombinant to treat hemophilia A. Although Epogen to treat beneficiaries with end-stage renal disease (ESRD) was Medicare's most expensive Part B drug in 2010,[13] table 2 shows that other drugs among the top 55 were used by more beneficiaries, including two vaccines (to prevent influenza and pneumonia). Apart from the vaccines, the greatest number of beneficiaries (891,000) used Lexiscan, a chemical stress agent used to test heart function in patients who cannot take a stress test on a treadmill.

[12]Some drugs were used to treat more than one type of condition.

[13]Regardless of age, most individuals with ESRD, a condition of permanent kidney failure, are eligible for health care coverage under Medicare. Beginning in 2011, CMS implemented bundled payments for drugs and services to Medicare dialysis facilities, which treat ESRD, in part to discourage excessive use of separately billable drugs such as Epogen. Since then, Medicare has not paid separately for 5 of the 55 drugs in our analysis when they are used to treat chronic kidney disease: Epogen/Procrit, Aranesp, Zemplar, Venofer, and Hectorol.

Table 2: Ten Most Utilized High-Expenditure Medicare Part B Drugs, 2010

Brand name(s)	Condition(s) treated	Utilization (number of unique Medicare beneficiaries)
Influenza vaccine (various)	Prevent influenza	15,229,920
Pnuemovax 23, Pnu-Imune	Prevent meningitis and pneumonia	1,692,940
Lexiscan	Stress agent for myocardial perfusion imaging	890,920
Venofer	Anemia in chronic kidney disease patients	329,260
Epogen/Procrit (End-stage renal disease (ESRD) use)	Anemia in ESRD patients[a]	323,920
Zemplar	Hyperthyroidism in chronic kidney disease patients	230,700
Reclast	Osteoporosis prevention and treatment; treat Paget's disease of bone	218,060
Avastin	Cancer; wet age-related macular degeneration	171,560
Synvisc/Synvisc-One	Osteoarthritis of the knee	168,560
Aloxi	Prevent nausea and vomiting in chemotherapy and surgical patients	164,000

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

[a]ESRD, a condition of permanent kidney failure, is also known as stage 5 chronic kidney disease.

The annual per beneficiary cost of the Part B drugs we examined also varied widely in 2010. The influenza vaccines had the lowest average per beneficiary cost ($13). Table 3 shows that factor viii recombinant, although used by the smallest number of Medicare beneficiaries, had the highest average per beneficiary cost—$217,000.

Table 3: Ten High-Expenditure Medicare Part B Drugs with Highest Average Annual per Beneficiary Cost, 2010

Brand name(s)	Condition(s) treated	Classification	Average annual cost per beneficiary
Factor viii recombinant (various)	Hemophilia A	Biological	$216,833
Remodulin	Pulmonary arterial hypertension	Drug	130,772
Ventavis	Pulmonary arterial hypertension	Drug	84,205
Primacor, Primacor in Dextrose	Acute decompensated heart failure	Drug	62,790
Erbitux	Cancer	Biological	25,898
Dacogen	Myelodysplastic syndrome	Drug	25,858
Herceptin	Cancer	Biological	25,797
Vidaza	Myelodysplastic syndrome	Drug	22,957
Sandostatin Lar Depot	Acromegaly, diarrhea, and flushing caused by cancerous tumors and vasoactive intestinal peptide secreting adenomas	Drug	22,748
Velcade	Cancer	Drug	19,667

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

Spending, utilization, and prices increased for most of the 55 most expensive Part B drugs between 2008 and 2010. Expenditures for 42 of these 55 drugs increased during those years, with the drugs that showed the greatest increases in expenditures also showing the greatest increases in utilization. The four drugs for which spending and utilization increased most were Lexiscan, Treanda, Privigen, and Reclast (see table 4). These drugs were approved by FDA in 2007 or early 2008, and it took some months for their use to spread.

Table 4: Ten High-Expenditure Part B Drugs with Largest Changes in Expenditures, Utilization, and Average Price from 2008 to 2010

Change in expenditures, 2008-2010[a]		Change in utilization, 2008-2010		Change in average price, 2008-2010[b]	
Brand name(s)	Percent change	Brand name(s)	Percent change	Brand name(s)	Percent change
Lexiscan	9,550.4	Lexiscan	11,008.7	Ventavis	51.5
Treanda	7,440.2	Treanda	3,271.4	Pneumovax 23, Pnu-Imune	36.0
Privigen	836.3	Privigen	381.1	Myfortic	22.0
Reclast	140.7	Reclast	136.8	Hycamtin	17.5
Myfortic	106.9	Myfortic	73.4	Gammagard Liquid	15.4
Primacor, Primacor in Dextrose	94.0	Hectorol	71.1	Doxil	14.1
Ventavis	93.6	Flebogamma, Flebogamma DIF	46.7	Tysabri	12.3
Vidaza	81.9	Orencia	45.4	Vidaza	11.6
Gammagard Liquid	69.2	Vidaza	41.7	Gamunex	11.3
Orencia	66.9	Gamunex	36.7	Xolair	11.2

Source: GAO analysis of CMS and FDA data.

Notes: Our analysis excludes expenditures and utilization in 2008 that were reported using a not otherwise classified code, which may have artificially increased the changes shown for new drugs, including Lexiscan and Treanda.

[a]We removed factor viii recombinant biological from our analysis of change in expenditures from 2008-2010 because Medicare claims expenditures for 2008 were lower than values in CMS's Part B National Summary Files and we were not confident that the reported expenditures for 2008 were valid.

[b]The change in price analysis was based on the unweighted average ASP across four quarters in each year, and does not include prices for drugs when supplied through infusion equipment.

Most price changes from 2008 to 2010 were also increases but the range was smaller—from an increase of 52 percent to a decrease of 38 percent. Four of the 10 drugs that increased most in expenditures were among the 10 that increased most in price.

Medicare's Proportion of Total U.S. Spending on Highest-Expenditure Part B Drugs

Spending on Medicare beneficiaries accounted for the majority of estimated total U.S. spending for 35 of the 55 highest-expenditure Part B drugs in 2010. For 17 of these drugs, Medicare spending accounted for more than two-thirds of total U.S. spending. Of the $16.9 billion Medicare spent for the 55 highest-expenditure Part B drugs, $11 billion, or 65 percent, was spent on drugs for which Medicare was the largest U.S. payer. Treatment of cancer and its side effects, autoimmune disorders and immunodeficiency, and chronic kidney disease were the most common uses of the 35 drugs for which Medicare spending was the majority of U.S. spending.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other members of the subcommittee have.

For questions about this testimony, please contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made key contributions to the testimony include Phyllis Thorburn, Assistant Director; George Bogart; Linda Galib; Andrew Johnson; and Elizabeth T. Morrison.