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United States Government Accountability Office
Washington, DC 20548

October 12, 2012

The Honorable Herb Kohl
Chairman
Special Committee on Aging
United States Senate

The Honorable Dick Durbin
United States Senate

Subject: *Medicare: High-Expenditure Part B Drugs*

In 2010, the Medicare program and its beneficiaries spent about $19.5 billion on Part B drugs[1]—drugs that are commonly administered by a physician or under a physician's close supervision in physicians' offices and hospital outpatient departments.[2] Some of these drugs are particularly expensive for Medicare, either because they are used by a large number of beneficiaries or because their prices are high. These drugs generally differ from drugs beneficiaries obtain through Medicare Part D, which are usually self-administered and for which Medicare, its beneficiaries, and the states spent $61.7 billion in 2010.[3]

Medicare bases its payments for most Part B drugs on the average sales price (ASP), which is calculated from data that manufacturers report quarterly to the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services 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 by the private market.

You asked us to analyze trends in utilization and expenditures for high-expenditure Part B drugs and to estimate Medicare's proportion of total U.S. expenditures for these high-expenditure drugs. This report examines (1) the Part B drugs for which

[1]Medicare Part B covers certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies. Under certain circumstances, drugs that are usually administered to outpatients may be administered to inpatients and covered by Medicare Part A.

[2]In this report the terms "drugs" refers to chemically synthesized drugs and biologicals unless otherwise specified. Biologicals are products derived from living sources, including humans, animals, and microorganisms.

[3]Medicare Part D is a voluntary program through which Medicare covers outpatient prescription drugs. The estimate of total expenditures includes beneficiary payments for premiums but excludes beneficiary expenditure-sharing.

Medicare expenditures were highest in 2010 and the utilization and spending trends for these high-expenditure Part B drugs from 2008 to 2010, and (2) nationwide spending levels for the total U.S. population for these high-expenditure Part B drugs in 2010 and Medicare's percentage of total U.S. spending.

To identify the highest-expenditure Part B drugs in 2010 (the latest year for which data were available) and examine their utilization and spending trends, we used the CMS National Claims History 5 Percent Sample for physician, hospital outpatient, and durable medical equipment (DME) claims for 2008, 2009, and 2010.[4] We calculated the total amount spent on each Part B-covered drug in 2010 by the Medicare fee-for-service (FFS) program and by or on behalf of its beneficiaries and then ranked the drugs by total expenditures.[5] We identified the 55 drugs with the highest total 2010 Medicare expenditures—that is, expenditures by the Medicare program and expenditures by or on behalf of beneficiaries—and examined the number of beneficiaries using each of these drugs and the average annual cost per beneficiary.[6] For these 55 drugs, we also examined changes in total expenditures, beneficiary utilization, and prices from 2008 to 2010. We obtained information on the purpose and other characteristics of these drugs from the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and manufacturers.

To estimate Medicare's share of total U.S. spending for these 55 high-expenditure Part B drugs, we obtained estimates of total 2010 U.S. expenditures—excluding Medicare FFS—for each of the drugs from IMS Health, a company that collects and analyzes health care data. To make these estimates, IMS Health used its national claims database, which contains commercial health plan claims for more than 60 million unique patients from more than 80 health plans across the United States.[7] IMS Health used claims for all beneficiaries who had been enrolled throughout 2010, but removed claims from Medicare supplemental health insurance policies to avoid double counting these claims, which were also included in the Medicare claims. IMS Health then used age-gender population information reported by the U.S. Census to project its claims data to the entire insured U.S. population, excluding the Medicare FFS population. To estimate total spending and utilization for the U.S. non-Medicare population, IMS Health made the assumption that beneficiaries not included in IMS Health's claims database, including those insured through certain government programs such as Medicaid, the Veterans Health Administration, and TRICARE,[8] had expenditures similar to the commercially insured population of the same age

[4]For each claim type, the CMS National Claims History 5 Percent Sample file contains a random sample of all claims paid by Medicare.

[5]Our ranking of highest-expenditure Part B drugs is a snapshot of total spending in 2010. The list of highest-expenditure Part B drugs will change over time as new drugs enter the market and drug utilization changes. CMS has noted that, while outside the scope of our analysis, several extremely expensive injectable products entered the market during or after 2010, including Provenge, Jevtana, Benlysta, and others.

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

[7]IMS Health's national claims data base is called the LifeLink Health Plan Claims Database.

[8]TRICARE is the Department of Defense's health care system for active duty and retired uniformed service members and their families.

and gender. We used these projections plus 2010 Medicare FFS claims to estimate the spending on each of the 55 drugs for the total U.S. insured population in 2010, thereby enabling us to estimate Medicare's share of spending for these drugs.

While we believe our analytical approach allows us to achieve our objectives, our analysis has some limitations. IMS Health projected expenditures from a large national claims database but, by definition, projections are subject to error. Furthermore, according to IMS Health, hospital outpatient expenditures are underrepresented by an unknown amount. To the extent that Part B drugs may, in certain circumstances, be paid under Part A, Medicare expenditures and utilization are also underrepresented by an unknown amount in the estimates of total U.S. expenditures.

We ensured the reliability of the Medicare claims data used in this report by performing appropriate electronic data checks and by interviewing agency officials who were knowledgeable about the data. We also checked total expenditures for the 55 highest-expenditure Part B drugs in the claims data against the published total expenditures for these drugs in CMS's Part B National Summary Files.[9] IMS Health removed from its claims database cases where expenditure fields were not populated, and in cases where the paid amount was greater than the allowed amount, replaced the paid amount with the allowed amount. It also allowed only three claims per patient per day per code. When there were more than three, the three claims with the largest allowed amounts were retained. We found that the Medicare and IMS data were sufficiently reliable for the purposes of our analysis.

We conducted our work 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.

Results in Brief

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, which totaled $19.5 billion. The number of Medicare beneficiaries who received each of these drugs varied from 15.2 million receiving the influenza vaccines to 660 hemophilia A patients receiving a group of biologicals known collectively as factor viii recombinant, which had the largest average annual cost per beneficiary—$217,000.[10] Our analysis showed that most of the 55 drugs increased in expenditures, prices, and average annual cost per beneficiary from 2008 to 2010. The 5 drugs with the largest increase in Medicare expenditures over this time period

[9]This check resulted in the removal of one drug (factor viii recombinant) from our 2008 analyses of utilization and expenditures due to low reported expenditures in the 2008 Medicare claims data.

[10]Hemophilia A is a hereditary bleeding disorder caused by a lack of blood clotting factor viii. Without enough factor viii, the blood cannot clot properly to stop bleeding.

also had the largest increase in the number of beneficiaries receiving each drug. Four of the 10 drugs which showed the greatest increase in expenditures were also among the 10 drugs showing the greatest price increases.

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 the 35, Medicare spending accounted for more than two-thirds of total U.S. spending, defined as spending by the insured population in the United States.

Background

Medicare Part B generally covers drugs and biologicals administered under a physician's direct supervision, including those administered in physician offices and in hospital outpatient departments that are not usually self-administered. These include drugs infused through DME, certain vaccines (influenza, pneumococcal, and hepatitis B)[11], osteoporosis drugs, oral cancer drugs if the same drug is available in injectable form, antinausea drugs used as part of an anticancer chemotherapeutic regimen, erythropoiesis-stimulating agents,[12] blood clotting factors for hemophilia patients, injectable drugs, and immunosuppressive drugs for transplant patients. The Medicare program pays 80 percent of the expenditures for Part B drugs and the beneficiary is responsible for the remaining 20 percent, which may be paid by supplemental coverage such as a Medicare supplemental health insurance policy,[13] an employer-sponsored retiree health plan, or Medicaid. As of 2009, nearly 90 percent of Medicare Part B beneficiaries had some form of supplemental coverage.

Payment to physicians is set at 106 percent of ASP for most Part B drugs they administer; however, payment for some Part B drugs is set on a different basis. Vaccines, infusion drugs furnished through DME, and blood products are paid at 95 percent of average wholesale price (AWP), which is the manufacturer's average price to wholesalers.[14] 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 is the manufacturer's list price to wholesalers. If the WAC is not yet available for the new drug, payment is based on the invoice price. Payment for Part B drugs administered in hospital outpatient departments is

[11]Influenza, pneumococcal, and hepatitis B vaccines for certain individuals are covered only under Medicare Part B, regardless of the setting in which they are furnished (for example, even when provided to an inpatient during a hospital stay covered under Medicare Part A). Other vaccines, such as the shingles vaccine, are covered under Medicare Part D.

[12]Erythropoiesis-stimulating agents are used to stimulate the bone marrow to produce red blood cells.

[13]A Medicare supplemental health insurance policy is health insurance sold by private insurers that covers Medicare deductibles and copayments as well as some services that Medicare FFS does not cover.

[14]The prices used to determine payment rates for the vaccines and blood products are updated to reflect current AWPs. For DME infusion drugs, payment is based on the AWP in effect on October 1, 2003.

determined based on ASP, though the rate can vary from year to year. In 2010, it was 104 percent of ASP.[15]

Additionally, for certain drugs such as drugs used to treat cancer, some new drugs, and orphan drugs,[16] which are drugs used to treat rare diseases, Medicare makes additional payments for some drugs administered in the hospital outpatient setting, known as transitional pass-through payments, which can be paid for 2 to 3 years.[17] 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 can be patented and, while under patent, can be manufactured or sold solely by the patent holder. Patents generally last for 20 years from the date of application.[18] After the patent expires and generic forms of the drug are marketed at significantly lower prices, the price of the original drug usually falls.[19]

Orphan drug status is granted by FDA to drugs that treat rare diseases—those that affect fewer than 200,000 people in the United States or for which there is no reasonable expectation of recovering the costs of development and marketing—and confers several benefits on the drug sponsor, including a 7-year period of market exclusivity.[20]

[15]Part B drugs in the hospital outpatient setting are paid separately if the per day expenditure of the drug exceeds a certain threshold set by CMS each year. In 2010, this threshold was $65 per day.

[16]Orphan drug status is granted by FDA to drugs and biologics that treat rare diseases. FDA provides this designation to medications intended to prevent, diagnose, or treat conditions that affect fewer than 200,000 people in the United States or to those that affect more than 200,000 persons, but whose sponsors have no reasonable expectation of recovering the costs of developing and marketing a treatment drug.

[17]In 2010, Medicare paid for pass-through drugs at 106 percent of ASP. The additional pass-through payment amount for 2010, therefore, was the difference between this amount and the usual payment limit of 104 percent of ASP for non-pass-through drugs in the hospital outpatient setting in 2010.

[18]Patents may be applied for and granted at any time during the development and testing of the drug. As a consequence, a sponsor may have fewer than 20 years to market the drug exclusively under the patent.

[19]Biological products do not have generic equivalents, but biosimilars or follow-on biologics serve a similar function. A biosimilar is a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency.

[20]During this 7-year period, FDA may not approve applications to market other versions of the same drug for the same diseases or conditions. See 21 U.S.C. § 360cc. This period can run concurrently with a patent term or not. It is granted for FDA-approved uses of a drug. Other benefits of orphan status may include a tax credit of 50 percent of the cost of conducting human clinical testing, research grants for clinical testing of new therapies to treat orphan diseases, and exemption from the fees that are typically charged when sponsors submit NDAs for FDA's review.

The Highest-Expenditure Medicare Part B Drugs Represented Most Part B Drug Spending in 2010 and Most Showed Increases in Spending, Utilization, and Price from 2008 to 2010

The 55 highest-expenditure Part B drugs accounted for 85 percent of all Part B drug spending in 2010. Utilization and annual spending per beneficiary for these drugs varied widely, but, like spending, generally increased between 2008 and 2010. Enclosure I contains a complete list of the 55 highest-expenditure Part B drugs in 2010.

Fifty-five Highest-Expenditure Part B Drugs Accounted for Three-Quarters of Part B Drug Expenditures in 2010

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, which totaled $19.5 billion. The 10 highest-expenditure Part B drugs accounted for about 45 percent of all Part B drug spending in 2010. Eight of the 10 most expensive were biological products as shown in table 1, and 4 of the 10 had orphan drug marketing exclusivity in 2010.[21] None of the 10 highest-expenditure drugs had a generic version approved by FDA in 2010. Enclosure II provides information on the expenditures, utilization, and average annual per beneficiary cost for the 55 Part B drugs. Enclosure III provides a list of all the 55 drugs that had orphan drug marketing exclusivity in 2010. Enclosure IV provides information on the generic availability of the 55 highest-expenditure Part B drugs.

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

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 (ESRD use)	Epoetin alfa, ESRD[a]	Biological	Anemia in end-stage renal disease (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]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

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

Medicare spent most—$2 billion—on the drug Epogen/Procrit[22] for the treatment of anemia in end-stage renal disease (ESRD) patients.[23] The second most expensive drug was Rituxan, which is used to treat non-Hodgkin's lymphoma, a type of cancer, and rheumatoid arthritis. Lucentis, the third most expensive drug, is used to treat wet age-related macular degeneration (AMD), an eye condition, and during this period Avastin, a cancer drug which was the fourth most expensive, also was used off-label

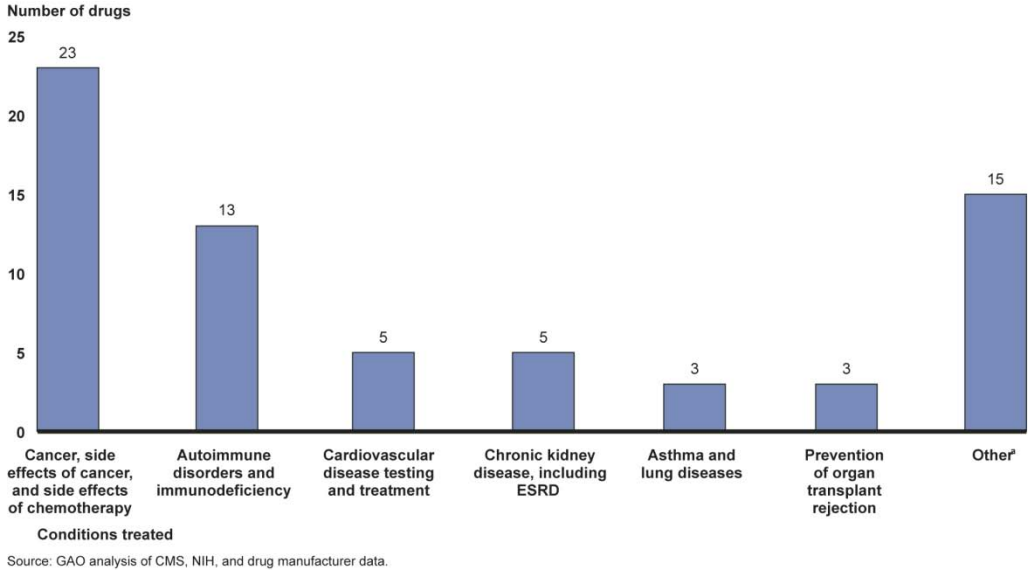
[22]Epogen/Procrit for the treatment of anemia in non-ESRD patients was the eighth most expensive Part B drug in 2010. ESRD is also known as stage 5 chronic kidney disease.

[23]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.

to treat wet AMD.[24] There was considerable interest by physicians and other experts in using Avastin for this purpose in part because the expenditure per treatment was significantly less than for Lucentis. However, it was not known whether Avastin was comparable to Lucentis in efficacy. A clinical trial determined that Avastin and Lucentis were equally effective, but the first trial results were not available until 2011, and so did not affect utilization in 2010.

Of the 55 highest-expenditure Part B drugs, cancer and its side effects were treated by more drugs (23 drugs) than any other set of conditions in 2010. (See figure 1.) Other conditions that were treated by several drugs included immune system disorders such as rheumatoid arthritis (13 drugs) and chronic kidney disease (5 drugs).

Figure 1: Conditions Treated by the 55 Highest-Expenditure Medicare Part B Drugs, 2010



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

Notes: The sum of the high-expenditure Medicare Part B drugs exceeds 55 because some drugs were used to treat more than one type of condition.

[a]Other includes conditions such as wet age-related macular degeneration, osteoarthritis of the knee, myelodysplastic syndrome, anemia in HIV and uterine fibroid patients, and prevention of influenza, pneumonia, and meningitis.

Utilization of High-Expenditure Part B Drugs Ranged from Millions of Beneficiaries for Vaccines to Hundreds for Hemophilia Drugs in 2010

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.[25] Although Epogen to treat beneficiaries with ESRD was Medicare's most expensive Part B drug in 2010, other drugs among the top 55 were used by more beneficiaries, including two vaccines (influenza and

[24]Off-label use refers to using a drug for a condition or patient population for which the drug has not been approved by FDA or in a manner that is inconsistent with the information found in the drug's labeling that has been approved by FDA. We did not separate expenditures on Avastin for cancer and for wet AMD.

[25]Hemophilia A is a hereditary bleeding disorder caused by a lack of blood clotting factor viii. Without enough factor viii, the blood cannot clot properly to stop bleeding.

pneumococcal). Apart from the vaccines, the greatest number of beneficiaries (891,000) used Lexiscan, which is a chemical stress agent used to test heart function in patients who cannot take a stress test on a treadmill (see table 2).

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 (ESRD use)	Anemia in end-stage renal disease (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 (AMD)	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]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

Average Annual per Beneficiary Costs for 55 Highest-Expenditure Medicare Part B Drugs Ranged from over $200,000 to $13 in 2010

We also examined the average annual per beneficiary cost of each drug and found that factor viii recombinant, although used by the smallest number of Medicare beneficiaries, was the most costly drug on an average annual per beneficiary cost basis—the average annual cost was about $217,000 for each beneficiary who used it in 2010 (see table 3). The influenza vaccines had the lowest average annual per beneficiary cost ($13). The high average annual per beneficiary cost for factor viii recombinant drugs results in part from the complexity of the production process; consequently, even having several brand names available has not reduced the average annual per beneficiary cost for this drug. Remodulin and Ventavis follow with average annual per beneficiary costs of about $131,000 and $84,000, respectively; both are used to treat pulmonary hypertension (high blood pressure in the lungs due to narrowing of the pulmonary arteries). Primacor, at an average annual per beneficiary cost of about $63,000, is used to treat acute decompensated heart failure (a type of acute heart failure). Apart from these four drugs, no drug cost more than $26,000 per beneficiary per year in 2010.

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 (dollars)
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.

Most Changes in Expenditures, Utilization, and Price from 2008 to 2010 Were Increases

Expenditures for drugs generally increased from 2008 to 2010, although some decreased. Medicare expenditures for 42 of the 55 most expensive Part B drugs increased from 2008 to 2010, while 12 decreased.[26] Changes in Medicare expenditures from 2008 to 2010 for the 55 highest-expenditure Part B drugs in 2010 ranged from a 9,550 percent increase to a 40 percent decrease.[27] Utilization also generally increased from 2008 to 2010. The drugs that showed the greatest increases in expenditures were Lexiscan (9,550 percent), Treanda (7,440 percent), Privigen (836 percent), Reclast (141 percent), and Myfortic (107 percent); these drugs also showed the greatest increases in utilization (see table 4). Enclosure V provides information on the 55 highest-expenditure Medicare Part B drugs by changes in expenditures, utilization, and price. The first four of these drugs had been approved by FDA in 2007 or early 2008, and it took some months for their use to spread.[28] Also, in late 2008 and 2009 Reclast was approved for additional uses, such as for the treatment of osteoporosis in men.

[26]We removed factor viii recombinant from our analysis of change in expenditures from 2008-2010 because we were not confident that the expenditures for 2008 were valid.

[27]Percent change in expenditures is calculated as the difference between 2010 and 2008 expenditures as a percentage of 2008 expenditures.

[28]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.

Most price changes from 2008 to 2010 were also increases but the range was smaller—from an increase in price of 51 percent to a decrease of 38 percent.[29] Four of the 10 that increased most in expenditures also were among the 10 that increased most in price. Ventavis increased the most (51 percent) followed by Pneumovax 23/ Pnu-Immune (36 percent), the vaccine used to prevent pneumonia.

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 biologicals 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.

Medicare Beneficiaries Accounted for the Majority of Total U.S. Spending for Most of the Highest-Expenditure Medicare Part B-Covered Drugs in 2010

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 (see table 5). Of the $16.9 billion Medicare spent for the 55 highest-expenditure Part B drugs, $11.0 billion, or 65 percent, was spent on drugs for which spending for Medicare beneficiaries accounted for the majority of total U.S. expenditures. Enclosure VI provides information on the percentage spent on Medicare beneficiaries for the 55 highest-expenditure Part B drugs.

[29]Percent change in average price is calculated as the difference between 2010 and 2008 average prices as a percentage of the 2008 average price.

Table 5: High-Expenditure Medicare Part B Drugs for Which Spending on Medicare Beneficiaries Exceeded Two-thirds of Total U.S. Spending, 2010

2010 rank by total Medicare expenditures	Brand name(s)	Condition(s) treated	Spending on Medicare beneficiaries (dollars in millions)	Spending on total U.S. insured population (dollars in millions)	Percentage spent on Medicare beneficiaries (percent)
47	Myfortic	Prevent transplant kidney rejection; treat Crohn's disease	$80	$86	92.2%
18	Prograf	Prevent transplant organ rejection; treat fistulizing Crohn's disease	267	290	92.1
52	Brovana	Symptoms of chronic obstructive pulmonary disease	70	77	91.3
22	Pulmicort	Prevent wheezing, shortness of breath, and troubled breathing in asthma and lung disease patients	245	273	89.6
33	Aranesp (ESRD use)	Anemia in end-stage renal disease (ESRD) patients[a]	162	182	88.7
45	Primacor, Primacor in Dextrose	Acute decompensated heart failure	87	101	85.6
40	Cellcept	Prevent transplant organ rejection; treat Crohn's disease	113	133	84.9
1	Epogen/Procrit (ESRD use)	Anemia in ESRD patients	2,000	2,381	84.0
14	Zemplar	Hyperthyroidism in chronic kidney disease patients	324	389	83.3
3	Lucentis	Wet age-related macular degeneration (AMD)	1,180	1,486	79.5
44	Dacogen	Myelodysplastic syndrome	100	130	77.1
28	Vidaza	Myelodysplastic syndrome	187	245	76.3
48	Ventavis	Pulmonary arterial hypertension	79	104	76.1
19	Venofer	Anemia in chronic kidney disease patients	257	350	73.5
8	Epogen/Procrit (non-ESRD use)	Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients	443	609	72.7
42	Hectorol	Hyperthyroidism in chronic kidney disease patients	105	150	69.8
7	Aranesp (non-ESRD use)	Anemia in chemotherapy patients	504	755	66.7

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

[a]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

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. Twenty-nine percent of these 35 drugs were biologicals, compared to 42 percent of all 55 drugs.

Agency Comments

CMS provided us with technical comments, which we incorporated as appropriate.

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As agreed with your offices, 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 CMS Administrator and other interested congressional committees. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions regarding this report, please contact me 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 report. Individuals making key contributions to this report include Phyllis Thorburn, Assistant Director; Zhi Boon; Linda Galib; and Andrew Johnson.

James C. Cosgrove
Director, Health Care

Enclosure I

General Information on the 55 Highest-Expenditure Medicare Part B Drugs, 2010

Brand name(s)	Drug description	Healthcare Common Procedure Classification System (HCPCS) code(s)[a]	Classification	Condition(s) treated
Abraxane	Paclitaxel protein bound	J9264	Drug	Cancer
Alimta	Pemetrexed injection	J9305	Drug	Cancer
Aloxi	Palonosetron HCl	J2469	Drug	Prevent nausea and vomiting in chemotherapy and surgical patients
Aranesp (non-ESRD use)[b]	Darbepoetin alfa, non-ESRD	J0881	Biological	Anemia in chemotherapy patients
Aranesp (ESRD use)	Darbepoetin alfa, ESRD	J0882	Biological	Anemia in end-stage renal disease (ESRD) patients
Avastin	Bevacizumab injection	C9257, J9035, Q2024	Biological	Cancer; wet age-related macular degeneration (AMD)
Botox	OnabotulinumtoxinA injection	J0585	Biological	Various conditions
Brovana	Arformoterol non-comp unit	J7605	Drug	Symptoms of chronic obstructive pulmonary disease
Cellcept	Mycophenolate mofetil oral	J7517	Drug	Prevent transplant organ rejection; treat Crohn's disease
Dacogen	Decitabine injection	J0894	Drug	Myelodysplastic syndrome
Doxil	Doxorubicin HCl liposome injection	J9001	Drug	Cancer
Eligard, Lupron Depot, Lupron Depot-PED	Leuprolide acetate suspension	J9217	Drug	Prostate cancer; various other conditions
Eloxatin	Oxaliplatin	J9263	Drug	Cancer
Epogen/Procrit (ESRD use)	Epoetin alfa, ESRD	Q4081	Biological	Anemia in ESRD patients
Epogen/Procrit (non-ESRD use)	Epoetin alfa, non-ESRD	J0885	Biological	Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients
Erbitux	Cetuximab injection	J9055	Biological	Cancer
Faslodex	Fulvestrant injection	J9395	Drug	Cancer
Flebogamma, Flebogamma DIF	Immune Globulin Intravenous (Human)	J1572	Biological	Primary immunodeficiency
Gammagard Liquid	Immune Globulin Intravenous (Human)	J1569	Biological	Primary humoral immunodeficiency; multifocal motor neuropathy

Brand name(s)	Drug description	Healthcare Common Procedure Classification System (HCPCS) code(s)[a]	Classification	Condition(s) treated
Gamunex	Immune Globulin Intravenous (Human)	J1561	Biological	Primary humoral immunodeficiency; chronic inflammatory demyelinating polyneuropathy; idiopathic thrombocytopenic purpura
Gemzar	Gemcitabine HCl injection	J9201	Drug	Cancer
Hectorol	Doxercalciferol injection	J1270	Drug	Hyperthyroidism in chronic kidney disease patients
Herceptin	Trastuzumab injection	J9355	Biological	Cancer
Hyalgan, Supartz	Solution of sodium hyaluronate	J7321	Drug	Osteoarthritis of the knee
Hycamtin	Topotecan injection	J9350, J9351	Drug	Cancer
Lexiscan	Regadenoson injection	C9244, J2785	Drug	Stress agent for myocardial perfusion imaging
Lucentis	Ranibizumab injection	J2778	Biological	Wet AMD
Myfortic	Mycophenolic acid	J7518	Drug	Prevent transplant kidney rejection; treat Crohn's disease
Neulasta	Injection, pegfilgrastim 6mg	J2505	Biological	Prevent infection in chemotherapy patients
Neupogen	Filgrastim injection, 300 and 480 mcg	J1440, J1441	Biological	Prevent infection in cancer, bone marrow transplant, chronic neutropenia, and HIV patients; prepare blood for leukapheresis in chemotherapy patients
Orencia	Abatacept injection	J0129	Biological	Rheumatoid arthritis
Pneumovax 23, Pnu-Imune	Pneumococcal vaccine	90732	Biological	Prevent meningitis and pneumonia
Primacor, Primacor in Dextrose	Milrinone lactate 5 mg injection	J2260	Drug	Acute decompensated heart failure
Privigen	Immune Globulin Intravenous (Human)	J1459, Q4097	Biological	Primary humoral immunodeficiency; chronic immune thrombocytopenic purpura
Prograf	Tacrolimus oral per 1 MG	J7507	Drug	Prevent organ transplant rejection; treat fistulizing Crohn's disease
Pulmicort	Budesonide non-comp unit	J7626	Drug	Prevent wheezing, shortness of breath, and troubled breathing in asthma and lung disease patients
Reclast	Zoledronic acid	J3488	Drug	Osteoporosis prevention and treatment; treat Paget's disease of bone

Brand name(s)	Drug description	Healthcare Common Procedure Classification System (HCPCS) code(s)[a]	Classification	Condition(s) treated
Remicade	Infliximab injection	J1745	Biological	Various autoimmune disorders
Remodulin	Treprostinil injection	J3285	Drug	Pulmonary arterial hypertension
Rituxan	Rituximab injection	J9310	Biological	Cancer; rheumatoid arthritis
Sandostatin Lar Depot	Octreotide injection, depot	J2353	Drug	Acromegaly; diarrhea and flushing caused by carcinoid tumors and vasoactive intestinal peptide secreting adenomas
Synvisc, Synvisc-One	Hylan GF 20	J7322, J7325	Drug	Osteoarthritis of the knee
Taxotere	Docetaxel injection	J9170, J9171	Drug	Cancer
Treanda	Bendamustine HCl injection	C9243, J9033	Drug	Cancer
Tysabri	Natalizumab injection	J2323	Biological	Multiple sclerosis; Crohn's disease
Various brand names	Influenza vaccine	90655, 90656, 90657, 90658, 90662, Q2035, Q2036, Q2037, Q2038	Biological	Prevent influenza
Various brand names	Factor viii recombinant	J7192	Biological	Hemophilia A
Various brand names	Immune globulin, powder	J1566	Biological	Primary defective antibody synthesis; primary immunodeficiency diseases; B-cell chronic lymphocytic leukemia; idiopathic thrombocytopenic purpura; Kawasaki syndrome
Velcade	Bortezomib injection	J9041	Drug	Cancer
Venofer	Iron sucrose injection	J1756	Drug	Iron deficiency anemia in chronic kidney disease patients
Ventavis	Iloprost non-comp unit dose	Q4074, Q4080	Drug	Pulmonary arterial hypertension
Vidaza	Azacitidine injection	J9025	Drug	Myelodysplastic syndrome
Xolair	Omalizumab injection	J2357	Drug	Asthma
Zemplar	Paricalcitol	J2501	Drug	Hyperparathyroidism in chronic kidney disease patients
Zometa	Zoledronic acid	J3487	Drug	High calcium levels and bone disease in cancer patients

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

[a]Healthcare Common Procedure Coding System (HCPCS) is a standard coding system developed to ensure that health care claims are processed in an orderly and consistent manner by Medicare and other health insurance programs.

[b]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

Fifty-Five Highest-Expenditure Medicare B Drugs Ranked by Total Expenditures, Utilization, and Average Annual Per Beneficiary Cost, 2010

	Total expenditures, 2010		Beneficiary utilization, 2010		Per beneficiary cost, 2010	
Brand name(s)	Total (dollars in millions)	Rank by total Medicare expenditures	Number of unique beneficiaries	Rank by beneficiary utilization	Average annual cost per beneficiary (dollars)	Rank by annual cost per beneficiary
Epogen/Procrit (ESRD use)[a]	$2,000	1	323,920	5	$6,175	32
Rituxan	1,302	2	67,520	21	19,281	11
Lucentis	1,180	3	115,760	17	10,196	27
Avastin	1,130	4	171,560	8	6,585	31
Remicade	900	5	59,640	23	15,084	20
Neulasta	888	6	98,460	18	9,015	28
Aranesp (non-ESRD use)	504	7	137,980	14	3,651	38
Epogen/Procrit (non-ESRD use)	443	8	154,720	12	2,862	40
Alimta	394	9	20,740	31	18,990	13
Taxotere	387	10	44,560	28	8,690	29
Herceptin	375	11	14,540	35	25,797	7
Zometa	350	12	90,260	19	3,881	37
Gemzar	349	13	44,660	27	7,820	30
Zemplar	324	14	230,700	6	1,406	46
Velcade	297	15	15,120	34	19,667	10
Eloxatin	290	16	27,260	30	10,649	26
Erbitux	275	17	10,620	38	25,898	5
Prograf	267	18	61,280	22	4,351	35
Venofer	257	19	329,260	4	782	50
Eligard, Lupron Depot, Lupron Depot-PED	256	20	159,700	11	1,600	44
Reclast	245	21	218,060	7	1,122	48
Pulmicort	245	22	142,440	13	1,717	43
Orencia	240	23	20,040	32	11,953	24
Sandostatin Lar Depot	210	24	9,220	40	22,748	9
Influenza Vaccine (various)	193	25	15,229,920	1	13	55
Gammagard Liquid	191	26	10,880	37	17,543	15
Aloxi	190	27	164,000	10	1,161	47
Vidaza	187	28	8,160	43	22,957	8

Enclosure II

Brand name(s)	Total expenditures, 2010: Total (dollars in millions)	Total expenditures, 2010: Rank by total Medicare expenditures	Beneficiary utilization, 2010: Number of unique beneficiaries	Beneficiary utilization, 2010: Rank by beneficiary utilization	Per beneficiary cost, 2010: Average annual cost per beneficiary (dollars)	Per beneficiary cost, 2010: Rank by annual cost per beneficiary
Lexiscan	181	29	890,920	3	204	53
Treanda	181	30	9,440	39	19,218	12
Neupogen	171	31	53,020	24	3,232	39
Remodulin	170	32	1,300	53	130,772	2
Aranesp (ESRD use)	162	33	31,800	29	5,086	34
Factor viii recombinant (various)	143	34	660	55	216,833	1
Gamunex	142	35	8,420	42	16,862	17
Tysabri	139	36	7,340	46	18,978	14
Botox	136	37	67,860	20	2,008	42
Abraxane	128	38	7,520	44	16,989	16
Synvisc, Synvisc-One	126	39	168,560	9	746	51
Cellcept	113	40	48,740	25	2,322	41
Xolair	110	41	7,420	45	14,774	21
Hectorol	105	42	127,440	16	820	49
Doxil	103	43	9,160	41	11,195	25
Dacogen	100	44	3,860	51	25,858	6
Primacor, Primacor in Dextrose	87	45	1,380	52	62,790	4
Immune globulin, powder (various)	80	46	6,120	47	13,139	22
Myfortic	80	47	19,280	33	4,131	36
Ventavis	79	48	940	54	84,205	3
Privigen	78	49	5,100	49	15,335	19
Hycamtin	75	50	5,840	48	12,768	23
Pnuemovax-23, Pnu-Imune	73	51	1,692,940	2	43	54
Brovana	70	52	45,920	26	1,528	45
Faslodex	70	53	11,700	36	5,959	33
Hyalgan, Supartz	69	54	132,620	15	520	52
Flebogamma, Flebogamma DIF	63	55	4,020	50	15,684	18

Source: GAO analysis of CMS and FDA data.

[a]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

Enclosure III

High-Expenditure Medicare Part B Drugs with Orphan Marketing Exclusivity during 2008 to 2010

2010 rank by total Medicare expenditures	Brand name(s) of orphan drug	Orphan exclusivity in 2008-2010	Orphan exclusivity start date(s) and indication(s), 2008-present	Year(s) of orphan exclusivity expiration
2	Rituxan	Yes	02-18-2010 Treatment of patients previously untreated for CD20-positive chronic lymphocytic leukemia in combination with fludarbine and cyclophosphamide 04-19-2011 For the use of Rituxan (rituximab) in combination with glucocorticoids for the treatment of patients with Wegener's Granulomatosis and Microscopic Polyangiitis	2017, 2018
4	Avastin	Yes	05-05-2009 Treatment of glioblastoma with progressive disease following prior therapy 07-31-2009 Treatment of renal cell carcinoma in combination with interferon alfa	2016
5	Remicade	Yes	05-19-2006 For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; 09-23-2011 For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy	2013, 2018
9	Alimta	Yes	02-04-2004 Treatment of patients with malignant pleural mesothelioma whose disease is either unresectable or who are otherwise not candidates for curative surgery	2011
11	Herceptin	Yes	10-20-2010 Treatment of patients with humana epidermal growth factor receptor 2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease	2017
12	Zometa	Yes	08-20-2001 Treatment of hypercalcemia of malignancy	2008
15	Velcade	Yes	05-13-2003 Treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression on the last therapy 12-08-2006 Treatment of patients with mantile cell lymphoma who have received at least one prior therapy.	2010, 2013
17	Erbitux	Yes	03-01-2006 For use in combination with radiation therapy, for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) and for use as a single agent for the treatment of patients with recurrent or metastatic SCCHN for whom prior platinum-based therapy has failed	2013

2010 rank by total Medicare expenditures	Brand name(s) of orphan drug	Orphan exclusivity in 2008-2010	Orphan exclusivity start date(s) and indication(s), 2008-present	Year(s) of orphan exclusivity expiration
18	Prograf	Yes	03-29-2006 Prophylaxis of organ rejection in patients receiving allogenic heart transplants	2013
28	Vidaza	Yes	05-19-2004 Treatment of patients with the following myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia and requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia	2011
30	Treanda	Yes	03-20-2008 Treatment of patients with chronic lymphocytic leukemia	2015
32	Remodulin	Yes	05-21-2002 Treatment of pulmonary arterial hypertension	2009
35	Gamunex	Yes	09-12-2008 Treatment of chronic inflammatory demyelinating polyneuropathy to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse	2015
43	Doxil	Yes	05-17-2007 For use in combination with bortezomib for the treatment of patients with multiple myeloma who have not previously received bortezomib and have at least one prior therapy	2014
44	Dacogen	Yes	05-02-2006 for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups	2013
48	Ventavis	Yes	12-29-2004 Treatment of pulmonary arterial hypertension in patients with symptoms of moderate or severe heart failure	2011

Source: GAO analysis of CMS and FDA data.

Note: Upon approval by FDA for specific orphan indications, orphan drugs receive marketing exclusivity for a period of 7 years. Other drugs in our analysis have been designated as orphan drugs by FDA, but did not have orphan marketing exclusivity at any point during 2008 to 2010. In addition to the drugs listed above, one drug in our analysis, Gammagard Liquid, has an orphan exclusivity start date of June 22, 2012, for an indication of maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy.

Nine of the 55 Highest-Expenditure Medicare Part B Drugs with Generic Products Approved

2010 rank by total Medicare expenditures	Brand name(s)	Generic version approved by FDA	Date of first generic approval
10	Taxotere	Yes	3/8/2011[a]
13	Gemzar	Yes	11/15/2010
14	Zemplar	Yes	7/27/2011[a]
16	Eloxatin	Yes	8/7/2009
18	Prograf	Yes	8/10/2009
22	Pulmicort	Yes	11/18/2008
40	Cellcept	Yes	7/29/2008
45	Primacor, Primacor in Dextrose	Yes (however, some versions of this drug are listed as discontinued)	5/28/2002
50	Hycamtin	Yes	11/29/2010

Source: GAO analysis of CMS and FDA data.

Notes: The date of first generic approval does not necessarily indicate the date on which a generic version was available on the market.

[a]A generic version was approved after 2010, the most recent year of our analysis.

Enclosure V

Fifty-Five Highest-Expenditure Medicare Part B Drugs Ranked Highest to Lowest by Change in Expenditures, Change in Number of Beneficiaries, and Change in Average Price, 2008 to 2010

Change in expenditures, 2008-2010		Change in beneficiaries, 2008-2010		Change in average price, 2008-2010[a]	
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
Gamunex	66.5	Velcade	35.5	Velcade	11.1
Flebogamma, Flebogamma DIF	62.3	Tysabri	34.9	Neulasta	11.1
Velcade	56.9	Gammagard Liquid	32.0	Rituxan	11.0
Lucentis	56.6	Alimta	30.3	Hectorol	10.6
Xolair	55.8	Lucentis	29.6	Herceptin	10.5
Tysabri	50.5	Brovana	28.8	Gemzar	10.0
Alimta	49.7	Synvisc, Synvisc-One	27.8	Dacogen	9.7
Brovana	48.0	Primacor, Primacor in Dextrose	27.8	Alimta	9.5
Hectorol	47.1	Venofer	27.0	Taxotere[b]	9.2
Remodulin	40.7	Sandostatin Lar Depot	22.9	Aloxi	8.6
Synvisc, Synvisc-One	36.0	Remodulin	22.6	Flebogamma, Flebogamma DIF	7.7
Venofer	33.4	Xolair	20.5	Sandostatin Lar Depot	7.1
Sandostatin Lar Depot	29.2	Prograf	19.5	Immune globulin, powder (various)	6.9
Faslodex	27.7	Abraxane	16.8	Abraxane	6.4
Pneumovax 23, Pnu-Imune	26.1	Avastin	14.0	Orencia	6.3
Dacogen	24.6	Zemplar	8.6	Remicade	6.3
Eligard, Lupron Depot, Lupron Depot-PED	24.3	Aloxi	7.2	Brovana	6.0
Herceptin	22.1	Botox	6.7	Epogen/Procrit (non-ESRD use)[c]	5.9

Enclosure V

Change in expenditures, 2008-2010		Change in beneficiaries, 2008-2010		Change in average price, 2008-2010[a]	
Brand name(s)	**Percent change**	**Brand name(s)**	**Percent change**	**Brand name(s)**	**Percent change**
Botox	20.8	Epogen/Procrit (ESRD use)	6.0	Epogen/Procrit (ESRD use)	5.8
Abraxane	20.4	Influenza Vaccine (various)	5.6	Pulmicort	5.5
Aloxi	18.7	Herceptin	4.3	Zometa	4.7
Doxil	16.9	Zometa	4.3	Privigen	3.8
Avastin	15.5	Cellcept	2.8	Botox	3.4
Epogen/Procrit (ESRD use)	11.6	Rituxan	2.8	Lexiscan[d]	2.8
Rituxan	8.7	Eloxatin	0.5	Reclast	2.6
Remicade	8.6	Aranesp (ESRD use)	0.0	Venofer	2.4
Gemzar	8.5	Eligard, Lupron Depot, Lupron Depot-PED	-0.5	Factor viii recombinant (various)	2.1
Neulasta	6.5	Gemzar	-0.8	Faslodex	1.6
Zometa	6.0	Faslodex	-1.5	Aranesp (non-ESRD use)	1.1
Hycamtin	5.1	Remicade	-2.3	Aranesp (ESRD use)	1.1
Neupogen	3.8	Doxil	-2.3	Remodulin	1.0
Prograf	0.3	Dacogen	-3.0	Avastin[e]	1.0
Influenza Vaccine (various)	-0.6	Taxotere	-4.1	Erbitux	-0.1
Erbitux	-2.7	Neulasta	-4.9	Lucentis	-0.1
Taxotere	-4.2	Pneumovax 23, Pnu-Imune	-5.5	Treanda[d]	-0.4
Epogen/Procrit (non-ESRD use)	-6.4	Neupogen	-5.5	Eligard, Lupron Depot, Lupron Depot-PED	-0.5
Aranesp (ESRD use)	-9.1	Ventavis	-7.8	Zemplar	-7.4
Zemplar	-16.2	Pulmicort	-9.3	Hyalgan, Supartz	-9.0
Pulmicort	-16.5	Hycamtin	-12.0	Prograf	-13.4
Hyalgan, Supartz	-17.4	Hyalgan, Supartz	-12.8	Primacor, Primacor in Dextrose	-17.6
Aranesp (non-ESRD use)	-27.8	Erbitux	-14.4	Cellcept	-38.1
Immune globulin, powder (various)	-28.1	Epogen/Procrit, (non-ESRD use)	-17.4	Eloxatin	-38.2
Eloxatin	-39.5	Immune globulin, powder (various)	-32.5	Influenza Vaccine (various)[f]	N/A
Cellcept	-40.3	Aranesp (non-ESRD use)	-33.6	Neupogen[f]	N/A
Factor viii recombinant (various)[g]	N/A	Factor viii recombinant (various)[g]	N/A	Synvisc, Synvisc-One[f]	N/A

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 had an impact on our analysis of new drugs, including Lexiscan and Treanda.

[a]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.

[b]Our analysis of the change in average price for Taxotere includes an adjustment for a change in dosage between 2008 and 2010.

[c]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

[d]Our analysis of changes in price for Lexiscan and Treanda only includes changes from 2009-2010 as 2008 ASP information was not available.

[e]Our analysis of Avastin only includes changes in price for Healthcare Common Procedure Classification System (HCPCS) code J9035 due to dosage differences for other codes used to identify Avastin. Code J9035 accounted for the vast majority of Avastin expenditures in 2010.

[f]Change in average price could not be analyzed for the influenza vaccine, Neupogen, or Synvisc/Synvisc-One because the multiple HCPCS codes that are associated with these drugs have different units or dosage amounts.

[g]We removed factor viii recombinant from our analysis of change in expenditures from 2008-2010 because we were not confident that the expenditures for 2008 were valid.

Fifty-Five Highest-Expenditure Medicare Part B Drugs by Percentage Spent on Medicare Beneficiaries, 2010

Brand name(s)	Condition(s) treated	Spending on Medicare beneficiaries (dollars in millions)	Spending on total U.S. insured population (dollars in millions)	Percentage spent on Medicare beneficiaries (percent)	2010 rank by total Medicare expenditures
Myfortic	Prevent transplant kidney rejection; treat Crohn's disease	$80	$86	92.2%	47
Prograf	Prevent transplant organ rejection; treat fistulizing Crohn's disease	267	290	92.1	18
Brovana	Symptoms of chronic obstructive pulmonary disease	70	77	91.3	52
Pulmicort	Prevent wheezing, shortness of breath, and troubled breathing in asthma and lung disease patients	245	273	89.6	22
Aranesp (ESRD use)	Anemia in end-stage renal disease (ESRD) patients[a]	162	182	88.7	33
Primacor, Primacor in Dextrose	Acute decompensated heart failure	87	101	85.6	45
Cellcept	Prevent transplant organ rejection; treat Crohn's disease	113	133	84.9	40
Epogen/Procrit (ESRD use)	Anemia in ESRD patients	2,000	2,381	84.0	1
Zemplar	Hyperparathyroidism in chronic kidney disease patients	324	389	83.3	14
Lucentis	Wet age-related macular degeneration (AMD)	1,180	1,486	79.5	3
Dacogen	Myelodysplastic syndrome	100	130	77.1	44
Vidaza	Myelodysplastic syndrome	187	245	76.3	28
Ventavis	Pulmonary arterial hypertension	79	104	76.1	48

Brand name(s)	Condition(s) treated	Spending on Medicare beneficiaries (dollars in millions)	Spending on total U.S. insured population (dollars in millions)	Percentage spent on Medicare beneficiaries (percent)	2010 rank by total Medicare expenditures
Venofer	Iron deficiency anemia in chronic kidney disease patients	257	350	73.5	19
Epogen/Procrit (non-ESRD use)	Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients	443	609	72.7	8
Hectorol	Hyperthyroidism in chronic kidney disease patients	105	150	69.8	42
Aranesp (non-ESRD use)	Anemia in chemotherapy patients	504	755	66.7	7
Eligard, Lupron Depot, Lupron Depot-PED	Prostate cancer; various other conditions	256	410	62.4	20
Lexiscan	Stress agent for myocardial perfusion imaging	181	299	60.7	29
Reclast	Osteoporosis prevention and treatment; treat Paget's disease of bone	245	408	60.0	21
Faslodex	Cancer	70	117	59.6	53
Alimta	Cancer	394	673	58.5	9
Treanda	Cancer	181	313	58.0	30
Velcade	Cancer	297	527	56.5	15
Zometa	High calcium levels and bone disease in cancer patients	350	630	55.6	12
Erbitux	Cancer	275	495	55.5	17
Gemzar	Cancer	349	629	55.5	13
Neupogen	Prevent infection in cancer, bone marrow transplant, chronic neutropenia, and HIV patients; prepare blood for leukapheresis in chemotherapy patients	171	309	55.5	31
Hycamtin	Cancer	75	134	55.5	50
Remodulin	Pulmonary arterial hypertension	170	308	55.1	32
Doxil	Cancer	103	188	54.4	43
Pneumovax 23, Pnu-Imune	Prevent meningitis and pneumonia	73	135	54.2	51
Rituxan	Cancer; rheumatoid arthritis	1,302	2,490	52.3	2

Brand name(s)	Condition(s) treated	Spending on Medicare beneficiaries (dollars in millions)	Spending on total U.S. insured population (dollars in millions)	Percentage spent on Medicare beneficiaries (percent)	2010 rank by total Medicare expenditures
Sandostatin Lar Depot	Acromegaly; diarrhea and flushing caused by carcinoid tumors and vasoactive intestinal peptide secreting adenomas	210	403	52.1	24
Flebogamma, Flebogamma DIF	Primary immunodeficiency	63	124	50.7	55
Avastin	Cancer; wet AMD	1,130	2,527	44.7	4
Abraxane	Cancer	128	289	44.2	38
Hyalgan, Supartz	Osteoarthritis of the knee	69	159	43.4	54
Orencia	Rheumatoid arthritis	240	564	42.4	23
Synvisc, Synvisc-One	Osteoarthritis of the knee	126	314	40.0	39
Neulasta	Prevent infection in chemotherapy patients	888	2,254	39.4	6
Taxotere	Cancer	387	1,041	37.2	10
Privigen	Primary humoral immunodeficiency; chronic immune thrombocytopenic purpura	78	224	34.9	49
Aloxi	Prevent nausea and vomiting in chemotherapy and surgical patients	190	553	34.4	27
Immune globulin, powder (various)	Primary defective antibody synthesis; primary immunodeficiency diseases; B-cell chronic lymphocytic leukemia; idiopathic thrombocytopenic purpura; Kawasaki syndrome	80	234	34.4	46
Eloxatin	Cancer	290	868	33.4	16
Influenza Vaccine (various)	Prevent influenza	193	603	32.0	25
Botox	Various conditions	136	429	31.8	37
Herceptin	Cancer	375	1,257	29.8	11
Gamunex	Primary humoral immunodeficiency; chronic inflammatory demyelinating polyneuropathy; idiopathic thrombocytopenic purpura	142	481	29.5	35
Xolair	Asthma	110	374	29.3	41
Remicade	Various autoimmune disorders	900	3,229	27.9	5
Factor viii recombinant (various)	Hemophilia A	143	526	27.2	34

Enclosure VI

Brand name(s)	Condition(s) treated	Spending on Medicare beneficiaries (dollars in millions)	Spending on total U.S. insured population (dollars in millions)	Percentage spent on Medicare beneficiaries (percent)	2010 rank by total Medicare expenditures
Gammagard Liquid	Primary humoral immunodeficiency; multifocal motor neuropathy	191	770	24.8	26
Tysabri	Multiple sclerosis; Crohn's disease	139	588	23.7	36

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

[a]End-stage renal disease (ESRD) is also known as stage 5 chronic kidney disease.

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