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Report to Congressional Requesters

December 2017

MEDICARE PART B

Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015

Accessible Version

GAO-18-83

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GAO Highlights

Highlights of GAO-18-83, a report to congressional requesters

Why GAO Did This Study

In 2015, Medicare spent about $26 billion on Part B drugs, including injectable drugs, and certain cancer drugs, which are typically administered in a physician's office or hospital outpatient department. GAO was asked to examine Medicare's share of the Part B drug market. This report describes Medicare's market share for high-expenditure Part B drugs paid based on ASP and the characteristics of those drugs.

To determine Medicare's market share for Part B drugs paid based on ASP, GAO used 2015 Medicare FFS claims data—the most recent year available at the time of GAO's analysis—to identify the 50 Part B drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total, GAO analyzed 84 drugs because some were in both groups. GAO used Medicare claims and manufacturer sales data from the Centers for Medicare & Medicaid Services (CMS) to calculate Medicare's market share for each drug in 2015. To examine characteristics of the 84 drugs, such as whether a drug was produced by a single manufacturer, GAO analyzed data from the Food and Drug Administration and Truven Health Analytics' RED BOOK, which publishes drug pricing and product information.

GAO received technical comments on a draft of this report from the Department of Health and Human Services, the agency that oversees CMS, and incorporated these comments as appropriate.

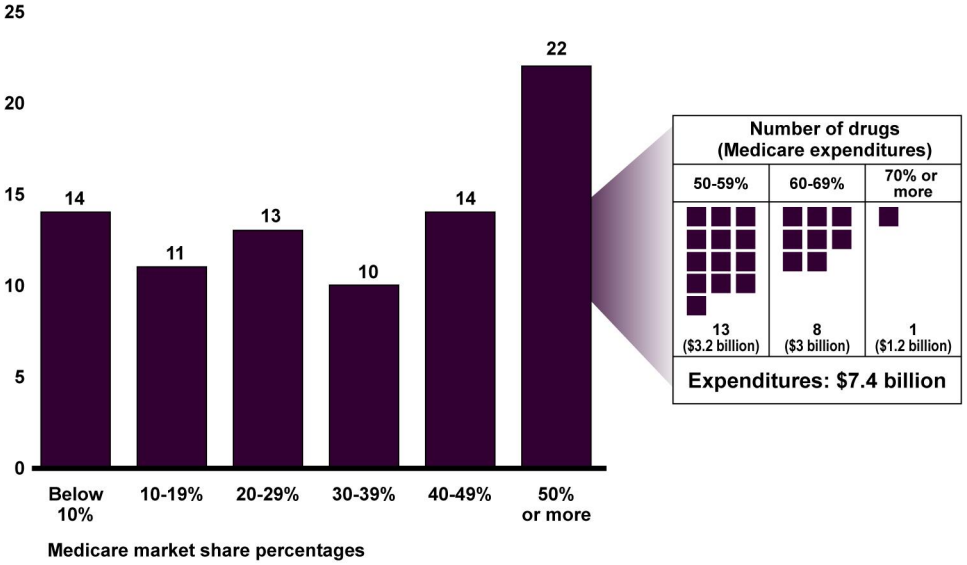
View GAO-18-83. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Medicare bases its payments for most Part B drugs on the average amount that individual purchasers such as physicians paid to manufacturers, net of discounts and rebates, called the average sales price (ASP). For most Part B drugs, Medicare sets the payment rate equal to the ASP plus an additional 6 percent. Medicare's market share—the percentage of total units of a drug sold that were provided to Medicare beneficiaries—is one of several factors that can affect the market price for drugs covered under Part B. By law, Medicare pays the ASP-based rate regardless of how high or low that rate may be, while a private insurer can respond to higher pricing by modifying coverage or eliminating a drug from its benefit package. Thus, when Medicare accounts for a large share of the market for a drug, a manufacturer may have less incentive to price the drug competitively.

In 2015, Medicare's fee-for-service (FFS) program represented 50 percent or more of the market for 22 of the 84 most expensive Part B drugs GAO analyzed. These 22 drugs collectively represented $7.4 billion in spending—or about 30 percent of all Medicare spending on Part B drugs in 2015.

Medicare's Market Share for 84 High-Expenditure Part B Drugs, 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-18-83

Note: GAO defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program. Expenditures reflect the total amount spent by the Medicare fee-for-service program and its beneficiaries.

Among the 22 drugs where Medicare represented the majority of the market, 18 had a single manufacturer. Single manufacturers—lacking direct competitors—may have greater ability to increase a drug's price without seeing sales decline.

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Abbreviations

ASP	average sales price
CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
FFS	fee-for-service
HCPCS	Healthcare Common Procedure Coding System
MedPAC	Medicare Payment Advisory Commission
NDC	National Drug Code

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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December 18, 2017

The Honorable John Yarmuth
Ranking Member
Committee on the Budget
House of Representatives

The Honorable Chris Van Hollen
United States Senate

In 2015, Medicare spent about $26 billion on drugs covered under Part B—which are those typically administered by a physician or under a physician's supervision. Drugs covered under Part B (Part B drugs) include injectable drugs, some oral cancer drugs, and drugs infused or inhaled through durable medical equipment. Due to the high prices of some Part B drugs, Medicare beneficiaries treated with these drugs may face significant financial responsibilities, since they are responsible for 20 percent of the costs. Medicare's payment rates for most Part B drugs are based on the average amount that purchasers such as physicians and wholesalers paid to manufacturers, net of discounts and rebates, referred to as the average sales price (ASP).[1] As such, Medicare's payment rates for most Part B drugs are based on market prices.

There are several factors that can affect the market price for drugs covered under Part B, including Medicare's market share, which we define as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service (FFS) program. When Medicare's market share for a drug is high, manufacturers may have less incentive to price a drug competitively. By law, Medicare pays the ASP rate regardless of how high or low that rate may be.[2] Similarly, when the price paid to manufacturers for a drug increases, so does Medicare's

[1]Rebates are price concessions by manufacturers that are given to purchasers after the drug is delivered, and discounts are price concessions by manufacturers that are reflected in the price purchasers pay for a drug at the time of delivery.

[2]See Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, "The High Cost of Prescription Drugs in the United States, Origins and Prospects for Reform," *Journal of the American Medical Association*, vol. 316, no. 8 (2016).

payment rate for that drug.[3] In contrast, when private insurers collectively have high market share for a given drug, a manufacturer may have greater incentive to price the drug competitively because insurers can respond to high prices or price increases by restricting coverage or eliminating a drug from their benefit packages, which could encourage the use of less expensive alternatives.[4] In addition to Medicare's market share, other market factors affect drug prices. For example, when there is only one manufacturer of a drug (called a single source drug), that manufacturer—lacking direct competitors—may have greater ability to increase the drug's price without seeing sales decline.[5]

You asked us to examine Medicare's share of the Part B drug market in order to help inform the Centers for Medicare & Medicaid Services (CMS) and Congress as they consider whether and how to refine Medicare's payment rate methodology for Part B drugs. This report describes Medicare's market share for high-expenditure Part B drugs paid on the basis of ASP, as well as the characteristics of those drugs.

To determine Medicare's market share for high-expenditure Part B drugs paid on the basis of ASP, we analyzed Medicare FFS claims data for 2015—the most recent full year of data available at the time of our analysis—to identify the 50 Part B ASP drugs with the highest total Medicare expenditures and the 50 drugs with the highest expenditures per beneficiary in 2015.[6] In total we analyzed 84 drugs because 16 of the drugs were in both groups. These 84 drugs accounted for 79 percent of

[3]There is a two-quarter (6-month) lag between the sale and when the payment rate takes effect. For example, drug sales in the first quarter of 2015 would form the basis of the ASP payment rate for that drug in the third quarter of 2015.

[4]See, for example, Darius Lakdawalla and Wesley Yin, "Insurer Bargaining and Negotiated Drug Prices in Medicare Part D," National Bureau of Economic Research Working Paper No. 15330, September 2009, which discusses similar pricing dynamics at work in the Medicare Part D program.

[5]In some cases, there can be competition among multiple single source drugs that have similar health effects because providers can choose from among that group of drugs.

[6]There were 17 drugs with high per-beneficiary expenditures that each had fewer than 50 unique beneficiaries in calendar year 2015. We excluded these drugs, which accounted for $36 million in total expenditures and 262 unique beneficiaries. We defined Medicare expenditures as the total amount spent by the Medicare FFS program and its beneficiaries. Our spending estimates do not include drugs for which Medicare's payment is bundled with that of a related service—which occurs for many drugs administered in hospital outpatient departments—or spending for the administration or dispensing of the drugs.

total Medicare spending for Part B drugs in 2015. (For the complete list of the 84 drugs, see app. I.) Using the Medicare FFS claims data together with data submitted to CMS by manufacturers on the number of units sold and average price of each drug in 2015, we calculated Medicare's market share for a given drug as the percentage of total units of a drug sold by its manufacturer(s) in 2015 that were provided to beneficiaries in Medicare FFS.[7] To examine the characteristics of the 84 drugs in our sample, such as whether the drug was produced by a single manufacturer or was brand -name or generic, we used Medicare claims data, the Food and Drug Administration's National Drug Code (NDC) Product Summary File, and Truven Health Analytics' RED BOOK.[8] For a more in-depth discussion of our data and methods, see appendix II.

To assess the reliability of the Medicare claims data and other data sources described above, we reviewed relevant documentation, performed electronic data checks for missing data or obvious errors, and interviewed agency officials familiar with these data sources. We also benchmarked our results against published sources by, for example, comparing the drug expenditure amounts from the Medicare claims data to information published by CMS. We determined that the data used in this report were sufficiently reliable for the purposes of our analysis.

We conducted this performance audit from November 2016 to December 2017 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.

[7]We measured the total units of a drug sold in Medicare billing units, which are dosages established within each drug's Healthcare Common Procedure Coding System (HCPCS) billing code. For example, if the Medicare billing unit for a given drug, according to its HCPCS code, is 100 milligrams, and the quantity administered is 200 milligrams, then the units billed would be two.

[8]RED BOOK publishes information on drug characteristics and drug pricing.

Background

Medicare Part B Drugs

Part B drugs are typically administered by a physician or under a physician's supervision, in the office or at a hospital outpatient department. Key characteristics of Part B drugs include the following:

- *Single Source or Multisource*. Single source drugs have only one manufacturer. Multisource drugs have at least two, and often several, versions produced by different manufacturers.
- *Synthetic or Biologic*. Drugs covered under Medicare Part B comprise both synthetic and biological drugs (called biologics). Synthetic drugs are produced from chemical ingredients and have small, well-defined chemical structures. Biologics are made in living systems using components made from living entities and may replicate natural substances such as enzymes, antibodies, or hormones.
- *Brand-Name or Generic*. A brand-name drug is marketed under a proprietary, trademark-protected name. A generic drug is chemically equivalent to its branded counterpart and is generally marketed by multiple manufacturers under a nonproprietary name. Generic drugs have the same dosage, strength, and active ingredients as the brand-name product. Generic versions of a drug may become available after the patent on the brand-name drug expires. Biologics do not have generic alternatives, but there are biosimilars—which are highly similar, but not identical to the original product—referred to as a reference biologic.[9]
- *Therapeutic Category*. Drugs with similar health effects are grouped into the same therapeutic category.[10] For example, drugs used to treat diseases of the eye would be part of the ophthalmologic therapeutic

[9]Biosimilars can only be highly similar to the biologic product they are designed to resemble due to processes associated with translating biologics from living cells in the laboratory to mass-production molecules. As of September 2017, four biosimilars were approved for marketing in the United States, and all four had reference biologics that were covered under Part B.

[10]Therapeutic categories we used to categorize the drugs in this report are aligned to the American Hospital Formulary Service Pharmacologic-Therapeutic Classification System maintained by the American Society of Health-System Pharmacists.

category, and drugs used to treat heart disease would generally be in the cardiovascular category.

Medicare Payment for Part B Drugs

Part B drugs generally are purchased by physicians or hospitals, which are reimbursed for those costs by Medicare and private insurers.[11] The majority—about $23 billion, or 88 percent—of the approximately $26 billion that Medicare spent on Part B drugs was for those paid on the basis of ASP in 2015.[12] To set its ASP rates, Medicare collects quarterly data from drug manufacturers on the ASP and total sales of each drug (see fig. 1).[13] For most Part B drugs paid at ASP, the Medicare payment rate is the ASP rate plus 6 percent.[14] Beneficiaries are generally responsible for 20 percent of the payment rate for Part B drugs, which may be covered all or in part by a supplemental health insurance policy, such as an employer-sponsored retiree health plan, or by Medicaid.

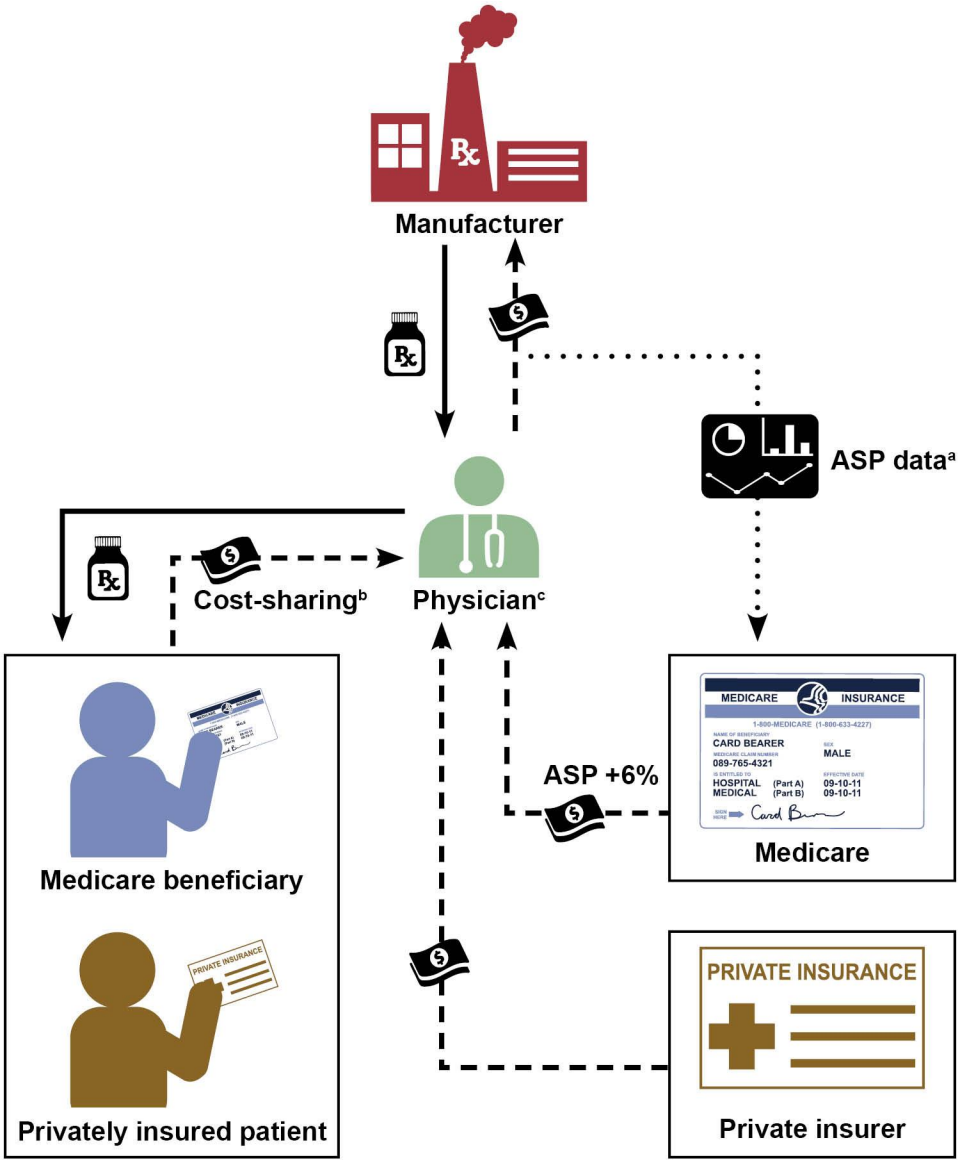
[11]Wholesale purchasers also buy Part B drugs and then sell them to physicians and hospitals.

[12]The remaining 12 percent of expenditures was for drugs paid on the basis of different methodologies. For example, several Part B drugs, including certain vaccines and drugs provided through durable medical equipment, are paid for on the basis of average wholesale prices or reasonable cost and not on the basis of ASP. See 42 U.S.C. §1395u(o)(1).

[13]The drug manufacturers that submit sales data to CMS include those that participate in the Medicaid drug rebate program. As such, they are required to submit data to CMS on all sales of Part B drugs to all U.S. purchasers, including physicians, hospitals, and wholesale distributors. See 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. The manufacturers' data do not include nominal sales to certain entities, or sales or discounts to other federal agencies and programs, such as the Department of Veterans Affairs, the Department of Defense, and Medicare Part D plans. See 42 C.F.R. § 414.804(a)(5)(2016).

[14]Since 2005, the Medicare payment rate for most Part B drugs acquired by a physician's office has been set at 106 percent of manufacturers' reported ASP for the drug. See 42 U.S.C. § 1395w-3a(b)(1). Due to the impact of sequestration—the cancellation of budgetary resources under presidential order implemented pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, as amended—some programs, projects, and activities across the federal government received spending reductions. Therefore, Part B drug payment rates to both physicians and hospitals were reduced to approximately 104 percent of ASP in 2015. See 2 U.S.C. § 901a(6). Under current law, sequestration of direct spending to achieve budgetary goals may be required every year through fiscal year 2025.

Figure 1: How Market Purchases Determine a Drug's Average Sales Price (ASP)



Source: GAO. | GAO-18-83

[a]Drug manufacturers submit data quarterly to the Centers for Medicare & Medicaid Services on sales of Part B drugs to most U.S. purchasers, including physicians, hospitals, and wholesale distributors. Sales must be reported net of rebates, discounts, and other price concessions. The data submitted by manufacturers do not include, for example, nominal sales to certain entities and sales to other federal agencies (e.g., the Department of Veterans Affairs), and Medicare Part D plans. There is a two-quarter (6-month) lag between the sale and when the ASP payment rate takes effect.

[b]Cost sharing, if required, may be charged in the form of coinsurance or a copayment.

[c]In addition to physicians, hospitals, outpatient facilities, and drug wholesalers purchase Part B drugs from manufacturers.

To improve Medicare's methodology for setting Part B drug payment rates and increase price competition among certain drugs with similar health effects, the Medicare Payment Advisory Commission (MedPAC) recommended a series of reforms to the ASP methodology in its June 2017 report to Congress.[15] Specifically, MedPAC recommended the use of consolidated billing codes for a reference biologic and its biosimilars to encourage competition.[16] In addition, over the longer term, MedPAC recommended a new alternative program to ASP it termed the Drug Value Program, which providers would voluntarily enroll in and use private vendors to negotiate drug prices with manufacturers.[17]

Medicare's Market Share Was 50 Percent or More for 22 of 84 High-Expenditure Part B Drugs; Most High-Expenditure Drugs Had a Single Manufacturer

Medicare's market share was 50 percent or higher (which we refer to as higher market share) for 22 of the 84 Part B ASP drugs we analyzed, and these 22 drugs accounted for $7.4 billion in Medicare expenditures in calendar year 2015 (see fig. 2). Furthermore, 36 of the 84 high-

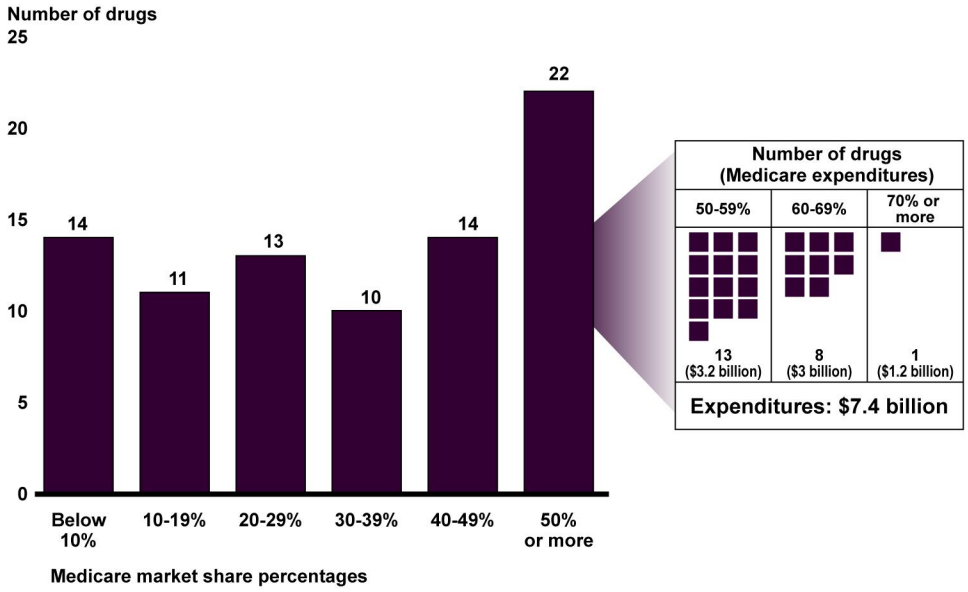
[15]See Medicare Payment Advisory Commission, *Report to Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 2017).

[16]The recommended new policy would assign a common billing code to a reference biologic and its biosimilars, resulting in a single rate paid for all products billed under that code. Whereas under current ASP policy, a reference biologic has its own billing code, and all biosimilar products associated with a particular reference biologic are grouped together under a single billing code separate from the reference biologic. In reviewing a draft of this report, CMS officials stated that CMS does not have the statutory authority to implement MedPAC's recommended policy.

[17]Also, in 2016 CMS issued a proposed rule to test alternatives to the Part B payment method. 81 Fed. Reg. 13230, 13258 (Mar. 11, 2016). The proposed payment model was designed to address concerns 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. The first phase of the proposed payment model would have changed 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 have implemented value-based pricing strategies, such as varying payment rates based on drugs' clinical effectiveness and decreasing beneficiary coinsurance for drugs deemed high in value. However, CMS withdrew the proposed rule after the public comment period, citing the complexity of the issues related to the proposed model design and a desire for greater stakeholder input. 82 Fed. Reg. 46182 (Oct. 4, 2017).

expenditure drugs had a Medicare market share at or above 40 percent. Across all of the 84 Part B drugs in our analysis, Medicare's market share ranged from less than 1 percent to 71 percent.

Figure 2: Medicare's Market Share for 84 High-Expenditure Part B Drugs Paid on the Basis of Average Sales Price, Calendar Year 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-18-83

Notes: We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program.

Expenditures reflect the total amount spent by the Medicare fee-for-service program and its beneficiaries.

To identify high-expenditure Part B drugs for this analysis, we used Medicare fee-for-service claims data for calendar year 2015 to determine the 50 drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total we analyzed 84 drugs because 16 drugs were in both groups.

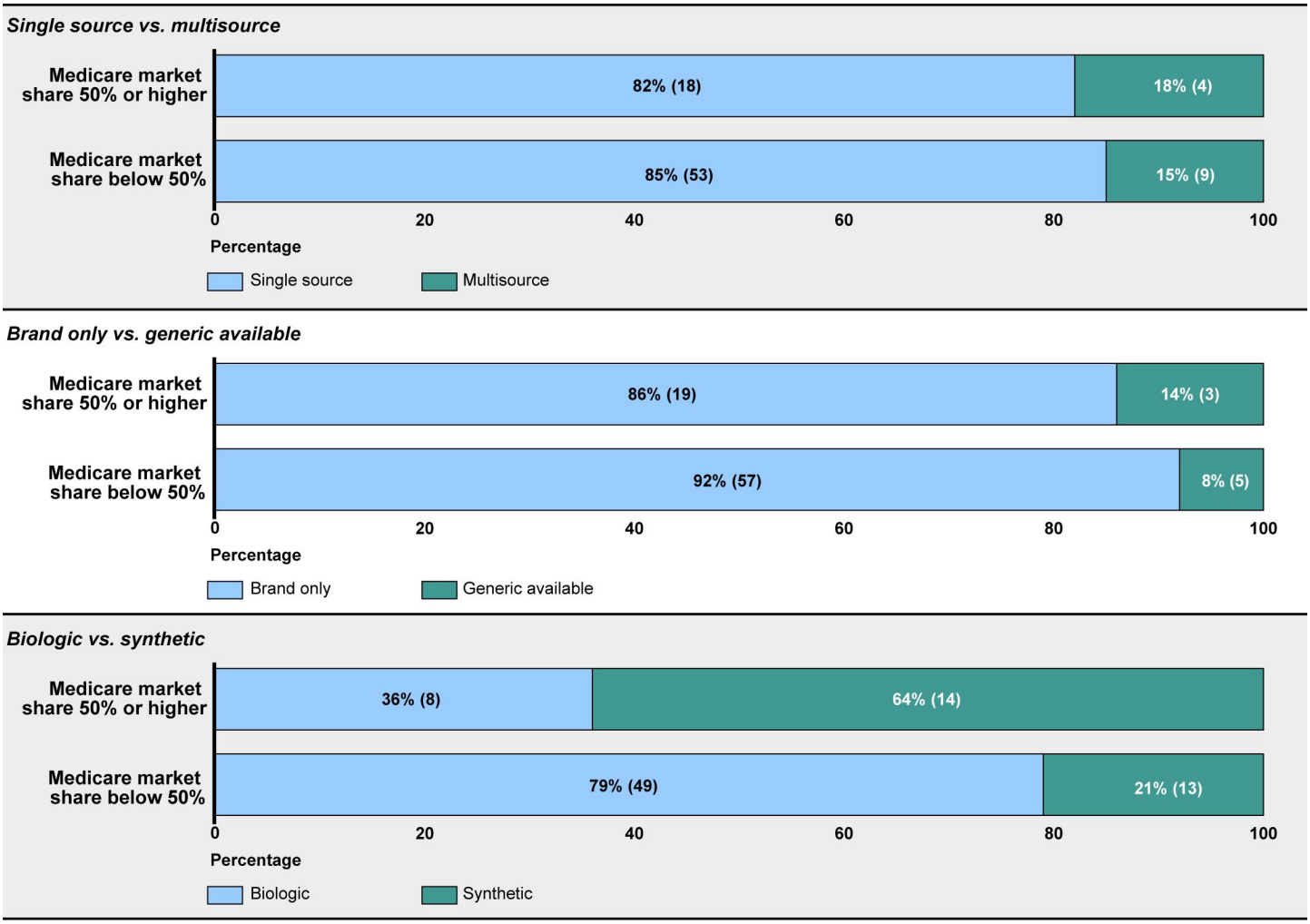
Consistent with our prior work, the predominant characteristics of the high-expenditure Part B drugs we analyzed—regardless of Medicare's market share—were that they were single source and lacked a generic alternative.[18] Specifically, 82 percent (18 out of 22) of the higher market share drugs we analyzed were single source, and 86 percent (19 out of

[18]See *Medicare Part B: CMS Should Take Additional Steps to Verify Accuracy of Data Used to Set Payment Rates for Drugs*, GAO-16-594 (Washington, D.C.: July 1, 2016).

22) lacked a generic alternative.[19] The drugs with Medicare market share below 50 percent (which we refer to as lower market share drugs) were similar in terms of these characteristics (see fig. 3). However, in terms of composition, there were differences between drugs with higher and lower market share. Sixty-four percent of the higher market share drugs were synthetic, compared to only 21 percent of the drugs with lower Medicare market share.

[19]We identified the drugs for our analysis according to the HCPCS codes, each of which can cover multiple drug products. Therefore, it is possible to have a multisourced brand-name drug. For example, the brand-name drugs Eligard and Lupron (both leuprolide acetate suspension) are manufactured by two different companies, but are both covered by HCPCS J9217. For more information on our data sources and methods, see appendix II.

Figure 3: Comparison of Characteristics for 84 High-Expenditure Part B Drugs Paid on the Basis of Average Sales Price, Calendar Year 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services, Food and Drug Administration, and RED BOOK data. | GAO-18-83

Notes: We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program.

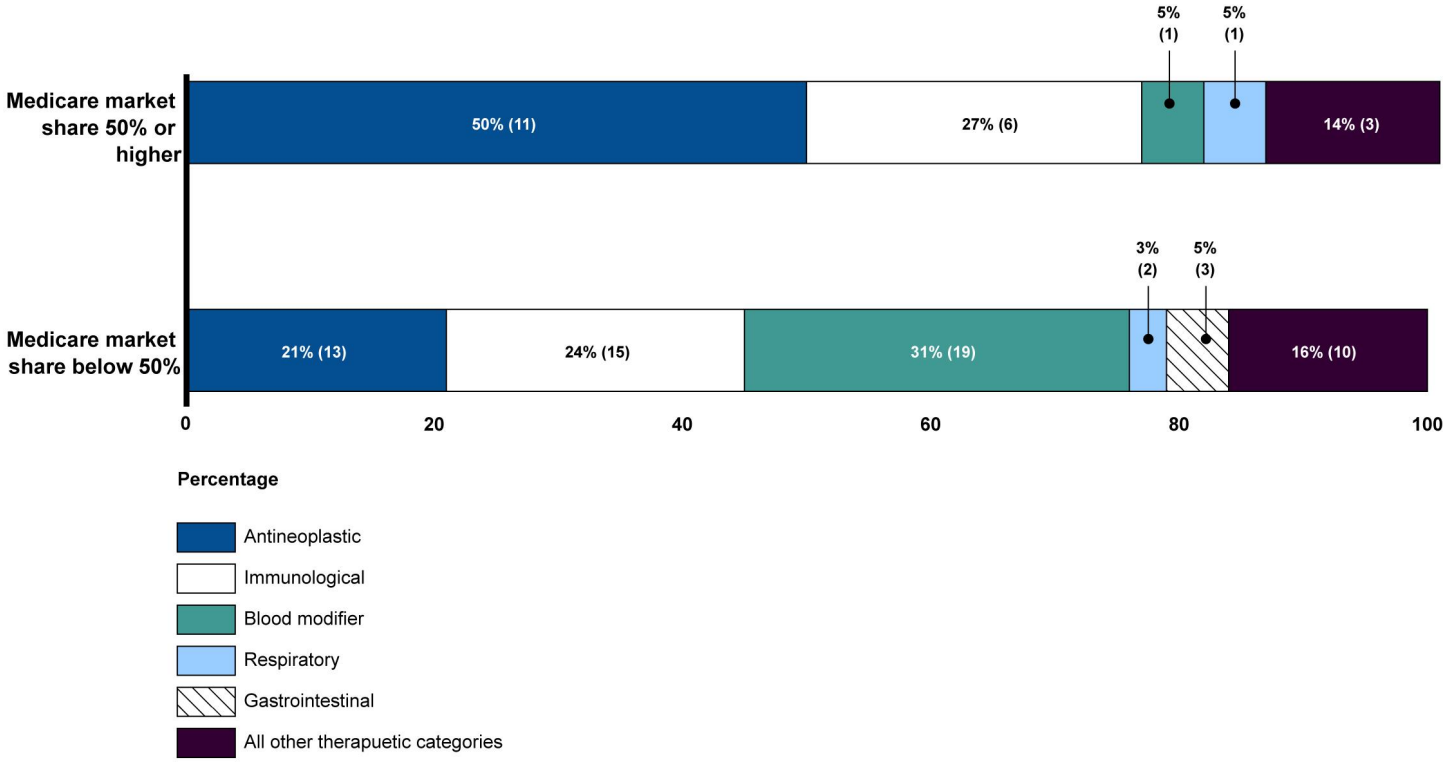
To identify high-expenditure Part B drugs for this analysis, we used Medicare fee-for-service claims data for calendar year 2015 to determine the 50 drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total we analyzed 84 drugs because 16 drugs were in both groups.

Across all the drugs we examined, 77 percent (65 out of 84) were in one of three therapeutic categories:

- *Antineoplastic*. Drugs that inhibit or prevent the proliferation of neoplasms—abnormal growths of tissue. Primarily used to treat cancer.
- *Immunological*. Drugs that modify the immune response, either by enhancing or suppressing it. Used for a wide variety of treatments, including various cancers, rheumatoid arthritis, and multiple sclerosis.
- *Blood modifier*. Drugs that enhance or inhibit the clotting or thinning of blood, treat hemophilia, and stimulate bone marrow production.

However, the leading therapeutic categories differed between drugs with higher and lower Medicare market share. Among the drugs with Medicare market share at or above 50 percent, the leading category was antineoplastic, followed by immunological, whereas among the group with lower Medicare market share, the leading category was blood modifier followed by immunological (see fig. 4).

Figure 4: Therapeutic Categories for 84 High-Expenditure Part B Drugs Paid on the Basis of Average Sales Price, Calendar Year 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services, Food and Drug Administration, and RED BOOK data. | GAO-18-83

Notes: We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program.

Antineoplastic agents are substances that inhibit or prevent the proliferation of neoplasms—abnormal growths of tissue—often associated with cancer. Immunological drugs modify the immune response, either by enhancing or suppressing it. Blood modifier agents enhance or inhibit the clotting or thinning of blood.

Totals may not add to 100 percent due to rounding.

To identify high expenditure Part B drugs for this analysis, we used Medicare fee-for-service claims data for calendar year 2015 to determine the 50 drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total we analyzed 84 drugs because 16 drugs were in both groups.

The drugs with the highest Medicare market share have been approved by the Food and Drug Administration to treat conditions that are more prevalent among the Medicare population. For example, two of the five drugs with the highest Medicare market share are Lucentis and Eylea, with Medicare market shares of 71 percent and 65 percent, respectively. Both are approved to treat age-related macular degeneration, a common

disease among those aged 50 and older where the eyes deteriorate.[20] Brovana, with Medicare market share of 65 percent, is approved to treat chronic obstructive pulmonary disease, a respiratory illness that is more prevalent among older age groups.[21] In contrast, most of the drugs we analyzed with the lowest Medicare market share—below 10 percent—are approved to treat hemophilia and related conditions that are uncommon among the Medicare population. For more information on the drugs we analyzed, including their therapeutic categories, see appendix I.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services, the agency that oversees CMS. The department provided us with technical comments, which we incorporated as appropriate.

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 of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions regarding this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for

[20]Together, Lucentis and Eylea accounted for $3 billion in expenditures and had 120,000 and 180,000 beneficiaries, respectively, in 2015. See table 1, appendix I, for more information.

[21]Chronic obstructive pulmonary disease is an umbrella term used to describe progressive lung diseases such as emphysema, chronic bronchitis, and nonreversible asthma. It is characterized by increasing breathlessness, and has no cure.

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 III.

James Cosgrove
Director, Health Care

Appendix I: Expenditures, Beneficiaries, and Characteristics of 84 High-Expenditure Part B Drugs Paid on the Basis of Average Sales Price

We used Medicare fee-for-service (FFS) claims data for calendar year 2015 to identify the highest expenditure Part B drugs paid based on average sales price (ASP)—the 50 with the highest total expenditures and the 50 with the highest expenditures per beneficiary.[1] In total we analyzed 84 drugs because 16 drugs were in both groups. The following tables summarize information on the 84 drugs we analyzed, including Medicare's market share, expenditures, and other characteristics. We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare FFS program.

Table 1: Medicare Expenditures and Utilization for 84 High-Expenditure Part B Drugs Paid on Average Sales Price, Calendar Year 2015, by Medicare Market Share

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
J2778	Lucentis (Ranibizumab injection)	71	1,168	5	119,623	9,765	98
J9025	Vidaza (Azacitidine injection)	66	143	42	8,901	16,102	80
J0178	Eylea (Aflibercept injection)	65	1,841	1	180,018	10,227	96

[1]There were 17 drugs with high per-beneficiary expenditures that each had fewer than 50 unique beneficiaries in calendar year 2015. We excluded these drugs, which accounted for $36 million in total expenditures and had 262 unique beneficiaries.

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
J7605	Brovana (Arformoterol non-comp unit)	65	182	33	68,729	2,645	153
Q2043	Provenge (Sipuleucel-t auto cd54+)	64	173	36	1,795	96,327	18
J9395	Faslodex (Fulvestrant injection)	64	188	32	15,220	12,339	90
J9043	Jevtana (Cabazitaxel injection)	64	75	62	2,122	35,406	37
J7518	Myfortic (Mycophenolic acid)	62	118	48	27,538	4,292	125
J9047	Kyprolis (Carfilzomib injection)	60	230	27	5,559	41,354	34
J0897	Xgeva (Denosumab injection)	59	926	7	354,737	2,609	156
J9302	Arzerra (Ofatumumab injection)	59	15	122	356	41,306	35
J2796	NPlate (Romiplostim injection)	58	160	39	3,759	42,624	32
J9307	Folotyn (Pralatrexate injection)	58	18	115	201	88,626	21
J9315	Isodax (Romidepsin injection)	57	31	92	412	75,805	23
J9305	Almita (Pemetrexed injection)	53	552	9	21,901	25,201	51
A9606	Xofigo (Radium Ra223 dichloride)	53	125	46	2,841	44,127	31
J9217	Eligard (Leuprolide acetate suspension)	53	280	18	145,826	1,921	169
J9041	Velcade (Bortezomib injection)	53	510	10	20,998	24,275	54

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
J9303	Vectibix (Panitumumab injection)	51	80	59	2,613	30,429	43
J1602	Simponi Aria (Golimumab for iv use)	50	128	45	7,725	16,519	78
J0894	Dacogen (Decitabine injection)	50	104	50	4,529	22,995	57
J9033	Treanda (Bendamustine injection)	50	313	13	12,136	25,753	50
J9055	Erbitux (Cetuximab injection)	48	246	22	8,759	28,077	46
J9264	Abraxane (Paclitaxel protein bound)	47	279	19	17,801	15,688	82
J2353	Sandostatin Lar Depot (Octreotide injection depot)	47	383	12	10,866	35,216	38
J9228	Yervoy (Ipilimumab injection)	46	218	28	2,332	93,616	20
J9310	Rituxan (Rituximab injection)	45	1,575	2	68,352	23,036	56
A9543	Zevalin Y-90 (Y90 ibritumomab rx)	44	4	179	91	44,453	30
J2469	Aloxi (Palonosetron HCl)	44	180	34	152,653	1,178	193
J9035	Avastin (Bevacizumab injection)	44	1,128	6	208,100	5,422	114
J1459	Privigen (Ivig privigen injection 500 mg)	43	208	30	9,669	21,499	59
J3262	Actemra (Tocilizumab injection)	43	159	40	10,141	15,694	81
J7686	Tyvaso (Treprostinil non-comp unit)	42	216	29	1,966	109,776	17

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
Q4074	Ventavis (Iloprost non-comp unit dose)	41	51	77	385	132,542	16
J7325	Synviscone (Synvisc or Synvisc-one)	40	144	41	162,337	884	209
J9354	Kadcyla (Ado-trastuzumab emt injection 1 mg)	40	106	49	2,175	48,846	29
J2505	Neulasta (Pegfilgrastim injection 6 mg)	39	1,270	3	96,570	13,153	87
J0129	Orencia (Abatacept injection)	38	457	11	20,716	22,079	58
J1568	Octagam (Octagam injection)	37	167	38	8,161	20,520	65
J0881	Aranesp (Darbepoetin alfa, non-end-stage renal disease (ESRD))	37	297	14	58,231	5,104	118
J9042	Adcetris (Brentuximab vedotin injection)	36	62	68	827	75,401	24
J0221	Lumizyme (Lumizyme injection)	32	56	71	114	487,341	3
J1300	Soliris (Eculizumab injection)	31	234	24	621	376,636	4
J2507	Krystexxa (Pegloticase injection)	31	18	113	287	62,990	27
J8521	Xeloda (Capecitabine 500 mg oral 1 tab per unit)	31	196	31	12,209	7,317	106
J1745	Remicade (Infliximab injection)	30	1,256	4	58,449	21,483	60
J9355	Herceptin (Trastuzumab injection)	29	649	8	19,930	32,548	41

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
C9027	Keytruda (Pembrolizumab injection)	28	96	54	2,306	41,424	33
J1930	Somatuline Depot (Lanreotide injection)	28	27	95	1,045	26,135	49
J2323	Tysabri (Natalizumab injection)	26	291	16	7,236	40,181	36
J1561	Gamunex-C (Gamunex-C/ Gammaked)	25	284	17	10,313	27,497	47
J9306	Perjeta (Pertuzumab injection 1 mg)	25	168	37	5,851	28,645	45
J2785	Regadenoson (Regadenoson injection)	23	119	47	567,048	209	268
J7626	Budesonide (Budesonide non-comp unit)	23	234	25	136,468	1,713	175
J1569	Gammagard liquid (Gammagard liquid injection)	21	233	26	10,950	21,312	61
J1786	Cerezyme (Imuglucerase injection)	21	42	86	176	237,726	9
J1640	Panheamtin (Hemin 1 mg)	21	10	138	107	95,872	19
J2357	Xolair (Omalizumab injection)	20	275	20	13,248	20,738	64
J0717	Cimzia (Certolizumab pegol injection 1 mg)	20	177	35	9,926	17,858	71
C9453	Opdivo (Nivolumab injection)	19	134	43	5,540	24,120	55
C9025	Cyramza (Ramucirumab injection)	19	47	81	1,556	29,931	44

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
J1442	Neupogen (Filgrastim g-csf injection 1 mcg)	18	129	44	39,138	3,290	142
J0180	Fabrazyme (Agalsidase beta injection)	18	52	75	264	195,346	12
J3385	VPRIV (Velaglucerase alfa)	17	27	96	104	260,288	7
J0585	Botox (Onabotulinumtoxina injection)	15	256	21	116,587	2,195	161
J9017	Trisenox (Arsenic trioxide injection)	13	7	156	208	32,733	40
J0256	Aralast NP (Alpha 1 proteinase inhibitor)	12	68	64	923	73,635	25
J0257	Glassia (Glassia injection)	12	6	159	118	49,857	28
J0885	Procrit (Epoetin alfa, non-ESRD)	11	294	15	85,873	3,426	137
Q9979	Lemtrada (Alemtuzumab injection)	10	11	134	133	84,640	22
J9027	Clofar (Clofarabine injection)	3	2	200	75	32,513	42
J7187	Humate-P (Humate-P injection)	3	24	102	343	69,507	26
J7190	Hemofil M (Factor VIII)	3	26	97	161	162,205	15
J7195	Benefix (Factor IX recombinant)	2	55	72	279	196,109	11
J3357	Stelara (Ustekinumab injection)	2	31	91	1,155	27,158	48

Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example (description)	Medicare's market share (percentage)	Total expenditures (dollars in millions)	Rank in expenditures	Unique beneficiaries	Expenditures per beneficiary (dollars)	Rank in expenditures per beneficiary
Q9975	Eloctate (Factor VIII Fc fusion recombinant)	2	27	94	91	301,426	5
J7193	Alphanine SD (Factor IX non-recombinant)	1	15	123	81	179,853	14
J7201	Alprolix (Factor IX Fc fusion recombinant)	1	32	90	66	489,607	2
J7189	Novoseven RT (Factor VIIa)	1	100	52	187	535,684	1
J7192	Advate (Factor VIII recombinant nos)	1	234	23	957	245,013	8
J7198	Feiba NF (Anti-inhibitor)	1	47	80	169	276,560	6
J7186	Alphanate (Antihemophilic VIII/VWF comp)	1	12	131	60	192,538	13
J7185	Xynta (Xyntha injection)	0.37	16	119	80	199,023	10
Q3027	Avonex (Beta interferon injection im 1 mcg)	0.37	4	174	136	32,968	39

Source: GAO analysis of Centers for Medicare & Medicaid Services and RED BOOK data. | GAO-18-83

Notes: We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program.

Expenditures reflect the total amount spent by the Medicare fee-for-service program and its beneficiaries, and include only those for claim line items that Medicare paid based on ASP.

We defined a drug at the HCPCS level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP. Some HCPCS cover more than one brand-name drug.

To identify high-expenditure Part B drugs for this analysis, we used Medicare fee-for-service claims data for calendar year 2015 to determine the 50 drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total we analyzed 84 drugs because 16 drugs were in both groups.

Table 2: Characteristics for 84 High-Expenditure Part B Drugs Paid on Average Sales Price, Calendar Year 2015, by Medicare Market Share

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
J2778	Lucentis (Ranibizumab injection)	71	2006	Ophthalmologic	Biologic	Brand only	Single source
J9025	Vidaza (Azacitidine injection)	66	2004	Antineoplastic	Synthetic	Generic available	Multisource
J0178	Eylea (Aflibercept injection)	65	2011	Ophthalmologic	Biologic	Brand only	Single source
J7605	Brovana (Arformoterol non-comp unit)	65	2007	Respiratory	Synthetic	Brand only	Single source
Q2043	Provenge (Sipuleucel-t auto cd54+)	64	2010	Immunological	Biologic	Brand only	Single source
J9395	Faslodex (Fulvestrant injection)	64	2002	Antineoplastic	Synthetic	Brand only	Single source
J9043	Jevtana (Cabazitaxel injection)	64	2010	Antineoplastic	Synthetic	Brand only	Single source
J7518	Myfortic (Mycophenolic acid)	62	2004	Immunological	Synthetic	Generic available	Multisource
J9047	Kyprolis (Carfilzomib injection)	60	2012	Antineoplastic	Synthetic	Brand only	Single source
J0897	Xgeva (Denosumab injection)	59	2010	Immunological	Biologic	Brand only	Single source
J9302	Arzerra (Ofatumumab injection)	59	2011	Immunological	Biologic	Brand only	Single source
J2796	NPlate (Romiplostim injection)	58	2008	Blood modifier	Biologic	Brand only	Single source
J9307	Folotyn (Pralatrexate injection)	58	2009	Antineoplastic	Synthetic	Brand only	Single source
J9315	Isodax (Romidepsin injection)	57	2010	Antineoplastic	Synthetic	Brand only	Single source

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
J9305	Almita (Pemetrexed injection)	53	2004	Antineoplastic	Synthetic	Brand only	Single source
A9606	Xofigo (Radium Ra223 dichloride)	53	2013	Radiopharmaceutical	Synthetic	Brand only	Single source
J9217	Eligard (Leuprolide acetate suspension)	53	2003	Antineoplastic	Synthetic	Brand only	Multisource[a]
J9041	Velcade (Bortezomib injection)	53	2003	Antineoplastic	Synthetic	Brand only	Single source
J9303	Vectibix (Panitumumab injection)	51	2006	Immunological	Biologic	Brand only	Single source
J1602	Simponi Aria (Golimumab for iv use)	50	2013	Immunological	Biologic	Brand only	Single source
J0894	Dacogen (Decitabine injection)	50	2009	Antineoplastic	Synthetic	Generic available	Multisource
J9033	Treanda (Bendamustine injection)	50	2008	Antineoplastic	Synthetic	Brand only	Single Source
J9055	Erbitux (Cetuximab injection)	48	2004	Antineoplastic	Biologic	Brand only	Single source
J9264	Abraxane (Paclitaxel protein bound)	47	2005	Antineoplastic	Synthetic	Brand only	Single source
J2353	Sandostatin Lar Depot (Octreotide injection depot)	47	2004	Endocrine metabolic	Synthetic	Brand only	Single source
J9228	Yervoy (Ipilimumab injection)	46	2011	Antineoplastic	Biologic	Brand only	Single source
J9310	Rituxan (Rituximab injection)	45	1997	Antineoplastic	Biologic	Brand only	Single source
A9543	Zevalin Y-90 (Y90 ibritumomab rx)	44	2009	Antineoplastic	Biologic	Brand only	Single source
J2469	Aloxi (Palonosetron HCl)	44	2009	Gastrointestinal	Synthetic	Brand only	Single source

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
J9035	Avastin (Bevacizumab injection)	44	2004	Immunological	Biologic	Brand only	Single source
J1459	Privigen (Ivig privigen injection 500 mg)	43	2008	Immunological	Biologic	Brand only	Single source
J3262	Actemra (Tocilizumab injection)	43	2010	Immunological	Biologic	Brand only	Single source
J7686	Tyvaso (Treprostinil non-comp unit)	42	2009	Cardiovascular	Synthetic	Brand only	Single source
Q4074	Ventavis (Iloprost non-comp unit dose)	41	2009	Cardiovascular	Synthetic	Brand only	Single source
J7325	Synviscone (Synvisc or Synvisc-one)	40	2005	Musculoskeletal	Biologic	Brand only	Single source
J9354	Kadcyla (Ado-trastuzumab emt injection 1 mg)	40	2013	Antineoplastic	Biologic	Brand only	Single source
J2505	Neulasta (Pegfilgrastim injection 6 mg)	39	2002	Blood modifier	Biologic	Brand only	Single source
J0129	Orencia (Abatacept injection)	38	2006	Immunological	Biologic	Brand only	Single source
J1568	Octagam (Octagam injection)	37	2004	Immunological	Biologic	Brand only	Single source
J0881	Aranesp (Darbepoetin alfa, non-end-stage renal disease (ESRD))	37	2006	Blood modifier	Biologic	Brand only	Single source
J9042	Adcetris (Brentuximab vedotin injection)	36	2011	Antineoplastic	Biologic	Brand only	Single source
J0221	Lumizyme (Lumizyme injection)	32	2014	Endocrine metabolic	Biologic	Brand only	Single source

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
J1300	Soliris (Eculizumab injection)	31	2007	Blood modifier	Biologic	Brand only	Single source
J2507	Krystexxa (Pegloticase injection)	31	2010	Musculoskeletal	Biologic	Brand only	Single source
J8521	Xeloda (Capecitabine 500 mg oral 1 tab per unit)	31	2003	Antineoplastic	Synthetic	Generic available	Multisource
J1745	Remicade (Infliximab injection)	30	1998	Immunological	Biologic	Brand only	Single source
J9355	Herceptin (Trastuzumab injection)	29	2003	Immunological	Biologic	Brand only	Single source
C9027	Keytruda (Pembrolizumab injection)	28	2014	Antineoplastic	Biologic	Brand only	Single source
J1930	Somatuline Depot (Lanreotide injection)	28	2009	Endocrine metabolic	Synthetic	Brand only	Single source
J2323	Tysabri (Natalizumab injection)	26	2013	Immunological	Biologic	Brand only	Single source
J1561	Gamunex-C (Gamunex-C/ Gammaked)	25	2005	Immunological	Biologic	Brand only	Multisource[a]
J9306	Perjeta (Pertuzumab injection 1 mg)	25	2012	Antineoplastic	Biologic	Brand only	Single source
J2785	Regadenoson (Regadenoson injection)	23	2008	Diagnostic	Synthetic	Brand only	Single source
J7626	Budesonide (Budesonide non-comp unit)	23	2000	Respiratory	Synthetic	Generic available	Multisource
J1569	Gammagard liquid (Gammagard liquid injection)	21	2011	Immunological	Biologic	Brand only	Single source
J1786	Cerezyme (Imuglucerase injection)	21	1999	Gastrointestinal	Synthetic	Brand only	Single source

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
J1640	Panheamtin (Hemin 1 mg)	21	2005	Blood modifier	Biologic	Brand only	Multisource[a]
J2357	Xolair (Omalizumab injection)	20	2003	Respiratory	Biologic	Brand only	Single source
J0717	Cimzia (Certolizumab pegol injection 1 mg)	20	2008	Immunological	Biologic	Brand only	Single source
C9453	Opdivo (Nivolumab injection)	19	2014	Antineoplastic	Biologic	Brand only	Single source
C9025	Cyramza (Ramucirumab injection)	19	2014	Immunological	Biologic	Brand only	Single source
J1442	Neupogen (Filgrastim g-csf injection 1 mcg)	18	1997	Blood modifier	Biologic	Brand only	Single source
J0180	Fabrazyme (Agalsidase beta injection)	18	2003	Endocrine metabolic	Biologic	Brand only	Single source
J3385	VPRIV (Velaglucerase alfa)	17	2010	Gastrointestinal	Synthetic	Brand only	Single source
J0585	Botox (Onabotulinumtoxina injection)	15	1993	Musculoskeletal	Biologic	Brand only	Single source
J9017	Trisenox (Arsenic trioxide injection)	13	2006	Antineoplastic	Synthetic	Brand only	Single source
J0256	Aralast NP (Alpha 1 proteinase inhibitor)	12	2003	Blood modifier	Biologic	Brand only	Multisource[a]
J0257	Glassia (Glassia injection)	12	2010	Blood modifier	Biologic	Brand only	Single source
J0885	Procrit (Epoetin alfa, non-ESRD)	11	1990	Blood modifier	Biologic	Brand only	Multisource[a]

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
Q9979	Lemtrada (Alemtuzumab injection)	10	2014	Immunological	Biologic	Brand only	Single source
J9027	Clofar (Clofarabine injection)	3	2004	Antineoplastic	Synthetic	Brand only	Single source
J7187	Humate-P (Humate-P injection)	3	2010	Blood modifier	Biologic	Brand only	Single source
J7190	Hemofil M (Factor VIII)	3	2007	Blood modifier	Biologic	Generic available	Multisource
J7195	Benefix (Factor IX recombinant)	2	2007	Blood modifier	Biologic	Brand only	Single source
J3357	Stelara (Ustekinumab injection)	2	2010	Immunological	Biologic	Brand only	Single source
Q9975	Eloctate (Factor VIII Fc fusion recombinant)	2	2014	Blood modifier	Biologic	Brand only	Single source
J7193	Alphanine SD (Factor IX non-recombinant)	1	2003	Blood modifier	Biologic	Brand only	Multisource[a]
J7201	Alprolix (Factor IX Fc fusion recombinant)	1	2014	Blood modifier	Biologic	Brand only	Single source
J7189	Novoseven RT (Factor VIIa)	1	2008	Blood modifier	Biologic	Brand only	Single source
J7192	Advate (Factor VIII recombinant nos)	1	2007	Blood modifier	Biologic	Brand only	Multisource[a]
J7198	Feiba NF (Anti-inhibitor)	1	2010	Blood modifier	Biologic	Generic available	Single source
J7186	Alphanate (Antihemophilic VIII/VWF comp)	1	2007	Blood modifier	Biologic	Generic available	Single source
J7185	Xynta (Xyntha injection)	0.37	2008	Blood modifier	Biologic	Brand only	Single source

			Drug Characteristics				
Healthcare Common Procedure Coding System (HCPCS)	Drug brand-name example[a] (description)	Medicare's market share (percentage)	First year brand-name drug on the market	Therapeutic category	Synthetic or biologic	Brand only or generic available	Single or multisource
Q3027	Avonex (Beta interferon injection im 1 mcg)	0.37	1996	Immunological	Biologic	Brand only	Single source

Source: GAO analysis of Centers for Medicare & Medicaid Services, Food and Drug Administration, and RED BOOK data. | GAO-18-83

Notes: We defined Medicare's market share as the percentage of total units of a drug sold that were provided to beneficiaries in the Medicare fee-for-service program.

Expenditures reflect the total amount spent by the Medicare fee-for-service program and its beneficiaries, and include only those for claim line items that Medicare paid based on ASP.

We defined a drug at the HCPCS level and counted it as a Part B ASP drug if it had at least one claim line item paid based on ASP.

To identify high expenditure Part B drugs for this analysis, we used Medicare fee-for-service claims data for calendar year 2015 to determine the 50 drugs with the highest total expenditures and the 50 drugs with the highest expenditures per beneficiary. In total we analyzed 84 drugs because 16 drugs were in both groups.

[a]A single HCPCS code can cover multiple brand-name drug products. Therefore, it is possible to have a multisourced brand drug.

Appendix II: Data and Methods

This appendix details the data and methodology we used to describe Medicare's market share for high-expenditure Part B drugs paid on the basis of average sales price (ASP) and the characteristics of those drugs.

To determine Medicare's market share for high-expenditure Part B drugs paid on the basis of ASP, we used Medicare fee-for-service (FFS) claims data from 2015, the most recent full year of claims data available at the time of our analysis.[1] We first identified all Part B drug Healthcare Common Procedure Coding System (HCPCS) codes, which the Centers for Medicare & Medicaid Services (CMS) uses to identify certain Medicare services such as Part B drugs for billing purposes. A single HCPCS code can cover multiple drug products with different National Drug Codes (NDC), which are universal product identifiers assigned by the Food and Drug Administration. We used the list of HCPCS codes to identify all claim line items for Part B drugs during 2015. We then restricted the claim line items to those that were paid based on ASP by removing claim line items for drugs and facilities that were paid based on other payment methodologies.[2] Next, we analyzed Medicare expenditures for each drug, defined as the total amount spent by the Medicare FFS program and its beneficiaries, and the number of unique beneficiaries who received the drug to identify the 50 Part B ASP drugs with the highest total Medicare expenditures and the 50 with the highest expenditures per beneficiary in 2015.[3] In total we analyzed 84 drugs because 16 were in both groups. These 84 drugs accounted for 79 percent of total Part B spending in 2015, and represented expenditures

[1]Specifically, we used the June 2016 updates of the Centers for Medicare & Medicaid Services' 2015 100 percent National Claims History file for physician services and durable medical equipment services and the hospital outpatient standard analytical file.

[2]We also removed claim line items where Medicare was not the primary payer and thus did not set the payment rate.

[3]The spending and utilization estimates do not include drugs for which Medicare's payment is bundled with that of a related service—which occurs for many drugs administered in hospital outpatient departments—or spending for the administration or dispensing of the drugs.

per beneficiary that ranged from $209 to $535,684.[4] (For the complete list of these 84 drugs, see app. I.)

We defined Medicare's market share as the percentage of total units of a drug sold by its manufacturer(s) that were provided to Medicare beneficiaries. To calculate Medicare's market share for each of the 84 drugs in our analysis, we used Medicare FFS claims data together with data submitted to CMS by manufacturers on the total number of units sold in 2015 as follows:[5]

(equation) Units of drug provided to Medicare FFS beneficiaries in calendar year 2015 divided by the total units of drug sold by manufacturers in calendar year 2015.

To examine various characteristics of the 84 drugs in our sample we used the claims data, Food and Drug Administration's NDC Product Summary File, and Truven Health Analytics' RED BOOK, which publishes drug pricing and product information. Characteristics we analyzed included

- single source or multisource manufacturer,
- brand-name or generic,
- biologic or synthetic, and
- therapeutic category.

Because the level at which Medicare defines a Part B drug differs from the level used in the Product Summary File and RED BOOK, we used CMS crosswalks to generate a list of NDCs associated with a given HCPCS code, and then summarized the NDC-level drug characteristics

[4]There were 17 drugs with high per-beneficiary expenditures that each had fewer than 50 unique beneficiaries in calendar year 2015. We excluded these drugs, which accounted for $36 million in total expenditures and had 224 unique beneficiaries.

[5]The drug manufacturers that submit sales data to CMS include those that participate in the Medicaid drug rebate program. As such, they are required to submit data to CMS on all sales of Part B drugs to all U.S. purchasers, including physicians, hospitals, and wholes sale distributors. See 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. The manufacturers' data do not include nominal sales to certain entities, and sales or discounts to other federal agencies and programs, such as the Department of Veterans Affairs, the Department of Defense, and Medicare Part D plans. See 42 C.F.R. § 414.804(a)(5) (2016).

at the HCPCS-level. Although CMS's crosswalks do not necessarily include a complete list of all NDCs associated with that HCPCS code, we determined this approach was sufficiently reliable for the purposes of this report.

To assess the reliability of the Medicare claims data, and other data sources described above, we reviewed relevant documentation, performed electronic data checks for missing data or obvious errors, and interviewed agency officials familiar with these data sources. We also benchmarked our results against published sources by, for example, comparing the drug expenditures amounts on the Medicare claims data to information published by CMS. We determined that the data used in this report were sufficiently reliable for the purposes of our analysis.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, individuals who made key contributions to this report included Will Black, Assistant Director; Kristeen McLain, Analyst-in-Charge; George Bogart; Zhi Boon; Daniel Lee; Yesook Merrill; Elizabeth T. Morrison; Ashley Nurhussein; and Vikki Porter.

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