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MEDICARE PART B DRUGS: TRENDS IN SPENDING AND UTILIZATION, 2008-2021

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Over the 2008-2021 period, Medicare fee-for-service (FFS) Part B drug spending per enrollee grew on average at 9.2 percent annually. This spending growth was more than triple the rate in Part D (2.6 percent) and nearly 4 times as high as the rate of per capita annual prescription drug spending across all payers (2.4 percent).[a] The Inflation Reduction Act (IRA) includes several new provisions designed to address the rapid rate of increase in Part B drug spending and lower costs for Medicare enrollees.

KEY POINTS

- Medicare fee-for-service (FFS) Part B drug program spending in 2021 was $33 billion; that is about 27 percent of Medicare drug spending, 3.6 percent of total Medicare spending, and 6 percent of the nation's drug spending.[b] Typically, Part B drugs are administered incident to a physician service; unlike Part D drugs, they are not purchased via retail (pharmacy counter) or mail order.

- Medicare Part B drug spending is concentrated among a small number of drugs: the top 20 drugs account for more than 50 percent of spending, while the top 10 account for 40 percent of Part B drug spending in 2021.

- Medicare spending on biologics has grown much more rapidly than spending on non-biologics over the past 13 years. From 2008 to 2021, spending growth on biologics accounted for nearly all (89 percent) of

[a] National Health Expenditures, Total Retail Prescription Drug Expenditures (NHE60-30 available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected).

[b] In 2021, spending for Part B drugs (Medicare program spending and cost sharing) was $41 billion of which Medicare program spending was $33 billion. Total US drug spending (retail and non-retail totaling $570 billion) in 2021 is computed by adding non-retail drug spending of $192 billion (estimated as 4.5% of the National Health Expenditures (NHE) based on Altarum's estimate that non-retail drug spending was 4.5% of the NHE) to the NHE's retail drug spending of $378 billion. The $33 billion in FFS Part B drug program spending represents about 9% of the NHE's drug expenditures which include mainly retail drugs. For non-retail drugs expenditures, refer to https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures-2022.

Medicare Part B drug spending growth. Biologics account for about 79 percent of Medicare FFS Part B prescription drug spending in 2021.

- Part B drug spending is shifting from physician offices to hospital outpatient departments: the share of Part B spending in this setting nearly doubled from 23 percent in 2008 to 41 percent in 2021, while the share of spending in physicians' offices declined from 63 percent to 53 percent.

- Medicare Part B drug spending is largely driven by three medical specialties: ophthalmology, oncology, and rheumatology. Drugs to treat cancer continued to account for the largest share of Part B drug program spending and accounted for over half of such spending in 2021.

- Among specific therapies, Part B spending on intravenous immuno-globulin (IVIG), and treatment for osteoporosis, rheumatoid arthritis, and cancer grew the most rapidly with an annual growth rate higher than 10 percent from 2008 to 2021.[a]

- The current Average Sales Price (ASP) payment methodology for Part B drugs may not provide strong incentives for providers to use high-value (i.e., lower cost and higher effectiveness) products.

- Inflation Reduction Act requires manufacturers to pay a rebate to Medicare if the drug's price increase exceeds the quarterly rate of inflation. This provision took effect for Part B on January 1, 2023, which is the first quarterly period for which manufacturers will be required to pay rebates for raising prices that outpace inflation on certain Part B drugs. CMS intends to send the first invoices in 2025 to manufacturers for the 2023 and 2024 rebates.

- The Presidents new lower cost prescription drug law also authorizes Medicare to directly negotiate drug prices for select medications. Part B drugs may be eligible for selection for negotiation starting in 2026 for prices effective in 2028. These provisions will lower costs for the Medicare program.

BACKGROUND

Medicare covers prescription drugs provided during inpatient hospital and skilled nursing facility stays through Part A, retail prescription drugs purchased through pharmacies and by mail order through Part D, and drugs provided in physicians' offices and hospital outpatient departments (HOPDs) through Part B.[b] In 2021, Medicare financed about 24 percent of the nation's prescription drug spending, totaling an estimated $570 billion[c,d] of which spending by Medicare Part D was $105 billion[e] (18 percent) and Medicare Fee-for-Service (FFS) Part B was $33 billion[f] (6 percent). This paper focuses on the drugs provided to FFS beneficiaries in the Medicare Part B

[a] IVIG is used to treat a range of conditions including ones related to autoimmunity, immunodeficiency, and infectious sources.
[b] Medicare enrollees also have the option to enroll in Medicare Advantage (MA or also called Medicare Part C) plans. An MA plan is a private plan that would provide both Parts A and B, and sometimes also Part D benefits, within the same plan.
[c] National Health Expenditures (NHE 04/27/2022 version) provides Medicare drug expenditures of $119.9 billion, or 32% of total retail drug spending of $378 billion in 2021.
https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical
[d] Since the NHE drug spending reflects mainly retail drug spending ($378 billion in 2021), the nation's total drug spending ($570 billion) is estimated by adding non-retail spending using Altarum's estimate that non-retail drug spending was about 4.5% of the total NHE in 2021 (retail spending is 4.5% of $4,255 billion or $192 billion). https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures-2022.
[e] Medicare total expenditures for Part D provided in Tables II.B1 or III.D3 of the Medicare Trustees Report, 2022: https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf.
[f] Medicare spending for all Part B drug estimated by Acumen LLC for ASPE. This spending total is for separately payable Part B drugs and does not include lower cost drugs (less than $135 per day) provided in hospital outpatient departments which are packaged with other services for payment.

program, which over the past few decades have the fastest rate of spending growth for drugs in the Medicare program.

This report presents data on Medicare FFS Part B drug spending and utilization, describes the current pricing system, and discusses the system's financial incentives that could help explain the rising trends in spending.[1,2,3] Spending by enrollees in Medicare Advantage (MA) are not reflected in this report since the claims data underlying the analyses reflected only spending in fee-for-service (FFS) Medicare. This report also examines the potential effect of new policies in the Inflation Reduction Act of 2022 designed to reduce the rate of increase in Medicare Part B drug spending and lower out-of-pocket costs for people with Medicare.

Overview of Part B Drug Payment

Medicare Part B covers certain categories of drugs, including drugs furnished incident to a physician's services (e.g., injectable drugs used in connection with the treatment of cancer or chronic disease, or some vaccines), drugs explicitly covered by statute (e.g., some vaccines, or oral anticancer drugs), and drugs administered with a covered item of durable medical equipment (e.g., inhaled drugs delivered via nebulizer, or insulin via pump). Medicare beneficiaries can receive Part B-covered drugs in several settings, including physician offices and HOPDs.[a] Medicare directly pays providers and suppliers for these drugs, and providers bill beneficiaries for any applicable coinsurance charges.

Over time, Medicare spending for Part B drugs has shifted away from physician offices and toward HOPDs. In 2008, Part B drugs provided in independent physician offices comprised approximately 75 percent of Part B drug spending. By 2021, almost half of Part B drug spending was attributable to those drugs provided in the hospital outpatient setting and the other half in physician offices. From 2008-2021, hospital outpatient Part B drug spending outpaced physician office Part B spending by a factor of 2, growing at a rate of 14 percent annually compared to 7 percent, respectively. This trend is consistent with the increasing vertical integration between hospital systems and physician practices. For example, between 2012 and 2018, the share of physicians employed by hospitals or health systems grew from 25 percent to 44 percent.[4]

89 percent

of growth in Medicare Part B drug spending from 2008 to 2021 was due to spending on biologics.

Generally, payment for most Part B drugs is based on the average sales price (ASP) calculated for each product. By statute, Medicare usually pays 106 percent of ASP (ASP + 6 percent) for drugs provided in physician offices (some exceptions are discussed later in this section); oral anticancer, oral antiemetic, and immunosuppressive drugs; inhalation drugs; home infusion

[a] Section 1881(b)(14) of the Social Security Act requires a bundled Prospective Payment System (PPS) for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD effective January 1, 2011. The bundled per treatment PPS payment includes drugs, laboratory services, supplies, and capital-related costs related to furnishing maintenance dialysis. Under the ESRD PPS, there is a drug designation process to determine whether a new renal dialysis drug or biological product is included in the ESRD PPS bundled payment.

drugs; and clotting factor with infused/injected drugs, with biologics comprising the largest category of these drugs. [a,b,c]

Part B-covered drugs provided in HOPDs are generally divided into two categories for the purpose of payment: packaged drugs and separately payable drugs (unpackaged drugs).

Packaged drugs[d] – Drugs that are low-cost (with a cost per day of less than the threshold amount of $60 in 2009, rising to $135 in 2023), certain types of drugs regardless of cost (e.g., drugs that function as supplies for certain tests or procedures), and drugs that are neither antiemetic nor pass-through drugs are packaged into the payment for other services under the Hospital Outpatient Prospective Payment System (OPPS) when they are provided in HOPDs.[e] In contrast, all of these drugs are paid for separately when provided in physicians' offices. In addition, most drugs for end-stage renal disease are packaged into the prospective payment rate for dialysis in end-stage renal disease.[f]

Separately payable drugs (unpackaged drugs) – CMS makes a separate payment for Part B drugs provided in HOPDs when estimated per-drug per-day costs are greater than a threshold amount (cost per day of less than $60 in 2009, rising to $135 in 2023).[g] The statute grants the Secretary authority to make payments based on each drug's acquisition and overhead costs or use a default payment rate of ASP + 6 percent as required for the same drugs when administered in physicians' offices.[h] CMS also makes separate payments for drugs with pass-through status, regardless of whether they exceed the packaging threshold. *This report focuses on the vast majority of drug spending in Part B that is for separately payable drugs (the unpackaged drugs).*

Some Part B drugs are not paid based on ASP. Preventive vaccines and certain blood products (e.g., albumin) are paid 95 percent of the average wholesale price (AWP) or reasonable cost.[i] Radiopharmaceuticals and compounded drugs billed by physicians are paid at invoice cost or 95 percent of AWP. Recently, CMS was also granted new authority under section 11403 of the IRA to increase Medicare add on payment to providers for

[a] 42 CFR § 414.904 - Average sales price as the basis for payment (https://www.law.cornell.edu/cfr/text/42/414.904).
[b] The sequester reduces benefit payments by 2 percent from April 1, 2013, through April 30, 2020, and January 1, 2021, through March 31, 2030, and by 4 percent from April 1, 2030, through September 30, 2030. Under the sequester, Medicare payments to providers, but not beneficiary coinsurance payments, are reduced by 2 percent. After applying this payment reduction, the payment rate under the 2 percent sequester is effectively ASP + 4.3 percent. (In other words, as the sequester applies to federal payment only (80 percent of total payment while beneficiaries still pay the full 20 percent copay), the effective federal payment under ASP + 6 percent is reduced to ASP+(1.06*(1-2%*80%))) or ASP+4.3%.)
[c] Starting in 2018, biosimilars will each have unique Healthcare Common Procedure Coding System (HCPCS) codes and payments under Medicare Part B. For a biosimilar, Medicare pays at the product's own ASP + 6 percent of the reference biologic's ASP. The reference biologic is generally sold at a higher price than the biosimilar, so the policy is intended to provide a higher payment for the biosimilar as an incentive for the market to grow. Under section 11403 of the Inflation Reduction Act, Medicare payment for certain biosimilar biological products is required to be ASP + 8 percent (rather than 6 percent) of the ASP of the reference biological for a 5-year period defined in the statute.
[d] In this paper, the term packaging refers only to certain drugs paid under the Outpatient Prospective Payment System (OPPS) and not any other payment system.
[e] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 establishes separate payments for drugs and biologics costing at least $50 per administration in 2005 and 2006 (drugs costing less were packaged). CMS updated the cost per day packaging threshold in 2007. OPPS packages items with a per day cost of less than or equal to $125 for calendar year (CY) 2019. For CY 2023, the final packaging threshold amount (to establish a separate payment amount for drugs and biologicals without pass-through status) will be set at $135 per day, a slight increase over the amount for CY 2022.
[f] Medicare covers many kidney dialysis services and supplies for End-Stage Renal Disease (ESRD), including: (1) inpatient dialysis treatments covered under Medicare Part A (Hospital Insurance), and (2) outpatient dialysis treatments & doctors' services covered under Medicare Part B (Medical Insurance) for many services in a Medicare-certified dialysis facility or beneficiaries' home.
[g] See 73 Fed. Reg. 68502, 68642 (Nov. 18, 2008) for CMS's methodology for setting the packaging threshold.
[h] See American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et al. 20-1114 (06/15/2022) (www.supremecourt.gov). The U.S. Supreme Court Sides with 340B Hospitals in Significant $1.6 Billion Part B Drug Payment Ruling (https://www.quarles.com/newsroom/publications/update-u-s-supreme-court-sides-with-340b-hospitals-in-significant-1-6-billion-part-b-drug-payment-ruling).
[i] The Social Security Act (the Act) mandates that OIG compare ASPs with average manufacturer prices (AMPs). If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Act directs the Secretary of Health and Human Services to substitute the ASP-based payment amount with a lower calculated rate. Through regulation, CMS outlined that it would make this substitution only if the ASP for a drug exceeded the AMP by 5 percent in the 2 previous quarters or 3 of the previous 4 quarters. See https://oig.hhs.gov/oei/reports/OEI-03-22-00190.asp.

certain qualifying biosimilar products from 6 to 8 percent for a 5-year period beginning on October 1st, 2022.[a] In addition, if Medicare lacks ASP data for new drugs in their initial period of marketing, Medicare generally pays based on the wholesale acquisition cost (WAC), using a rate of WAC + 6 percent prior to January 2019 and WAC + 3 percent beginning January 2019.[b] Both AWP and WAC are undiscounted list prices that are typically higher than ASP.[c]

Calculation of ASP Based Payment Rate

As described above, many Part B drugs are billed and paid separately in accordance with section 1847A of the Social Security Act that establishes the ASP methodology.[d,e,f] Manufacturers report to CMS quarterly data on price and volume of sales to all purchasers (with limited exceptions) in the U.S. for each National Drug Code (NDC). By definition, the ASP-based payment is the volume-weighted average of the manufacturer's ASP of the NDCs assigned to the same Healthcare Common Procedure Coding System (HCPCS) code.

ASP is net of discounts such as volume discounts, prompt pay discounts, cash discounts, chargebacks, and rebates other than under the Medicaid drug rebate program.[g] Certain sales are exempted from ASP calculation, including sales at nominal charge and sales excluded from the determination of "Best Price" in the Medicaid drug rebate.[5] There was once a discounted ASP rate for drugs furnished at 340B eligible facilities; however, this has since been reversed by a Supreme Court ruling on June 15, 2022.[h] Each HCPCS code generally has a separately calculated ASP. To allow time to submit and calculate these data, the ASP is updated on a two-quarter lag.[i]

Drugs and biologicals paid under Medicare Part B are separated into two categories by statute: (1) single source drugs or biologicals and (2) multiple source drugs. A single source drug or biological is a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003. The Part B payment limit amount (typically, 106 percent of ASP) for a biological product or single source drug will be based on the pricing information for products produced or distributed under the applicable FDA approval.[6]

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[a] Medicare Part B Drug Average Sales Price; Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products (https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice/part-b-biosimilar-biological-product-payment). In addition, an IRA provision will allow, for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available, that the amount payable would be the lesser of the WAC + 3 percent of the biosimilar or the ASP + 6 percent of the reference biological.

[b] For single source drugs, however, payment rate remains at WAC + 6 percent. Changing payment for single source drugs would require Congress to amend Section 1847(b) of the Social Security Act, which sets payment for these drugs at 106 percent of the lesser of ASP or WAC.

[c] An IOG Report in 2005 showed that ASP, which is a statutorily defined price based on actual sales transactions including discounts, was lower than published prices AWP and WAC: https://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf

[d] As described below, multiple source drugs are grouped for purposes of payment. In addition, when provided in hospitals' outpatient departments, drugs that are under a cost per day threshold cost ($125 in 2019) are packaged with associated procedures or visits for payment. In addition, since 2014 drugs used as a supply with diagnostic procedures and drugs used as a supply with surgical procedures are packaged regardless of the cost of the drug.

[e] Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions for payment of hospitals' outpatient department services, the Secretary has the authority to base payment for these drugs on hospitals' average acquisition costs and consider overhead/handling costs in setting payment. The Secretary can also use the same payment as for physicians' offices instead of calculating acquisition costs. In recent years, CMS has chosen the latter option so that most drugs are paid the same rate in the two sites of service.

[f] For further detail on ASP calculations by CMS, please see the ASPE Issue Brief, "Medicare Part B: Pricing and Incentives", at https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives.

[g] CMS receives ASP data for Part B drugs net of the rebates and price concessions, which are not separately reported. Part D discounts are not included in reported ASP.

[h] See American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et al. 20-1114 (06/15/2022) (www.supremecourt.gov). The U.S. Supreme Court Sides with 340B Hospitals in Significant $1.6 Billion Part B Drug Payment Ruling (https://www.quarles.com/newsroom/publications/update-u-s-supreme-court-sides-with-340b-hospitals-in-significant-1-6-billion-part-b-drug-payment-ruling).

[i] In a previous report on Part B drugs, we outlined the data flows over time. See https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//197396/Part-B-Drugs-Trends-Issue-Brief.pdf

This contrasts with multiple source drugs, which are drugs (typically, small molecule brands and generics) with two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book. There are two types of biosimilar products, "biosimilars" and "interchangeable biologics". Biosimilars are highly similar to and have no clinically meaningful differences from an originator biologic that is already FDA-approved. An interchangeable biosimilar is a biosimilar that meets additional requirements that allow it to be substituted for an originator biologic without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs, i.e., "pharmacy-level substitution". While the payment limit amount for multiple source drugs is the volume-weighted average of the pricing information for all of the products within a Healthcare Common Procedure Coding System (HCPCS) code,[a] reference biologics and their biosimilars are billed separately. This means that when generic small molecule drugs enter the market at a lower price point, a brand's payment rate will decrease because the ASP pricing is a volume-weighted average of all products within a HCPCS code, which could include brands and generics. The volume-weighted average calculation methodology may improve price competition by ensuring reimbursements to providers are the same for generics and branded small molecule drugs.

In contrast, biosimilar products are not grouped with the reference biologic product for purposes of Medicare Part B payment.[b] This means that the market entry of a biosimilar therapy that is cheaper than its reference biologic *may* have no direct effect on the payment rate of the reference biologic, in contrast to the beneficial effect of generic competition for small molecule drugs described above.[7]

CMS clarified through rulemaking in 2017 that FDA-approved biosimilars of the same reference product would be billed and paid under a unique HCPCS code for each biosimilar.[c] The 6 percent add-on is based upon the ASP of the reference product, resulting in an add-on that is often greater than 6 percent of the biosimilar ASP.[8] CMS included an additional modification in accordance with section 11403 of the Inflation Reduction Act of 2022 to temporarily increase the add-on payment for certain qualifying biosimilars to 8 percent of the reference product.[d] Exhibit 1 illustrates the various pricing calculations for Medicare Part B drugs.

[a] HCPCS codes are discussed in the Data and Methods section below

[b] CMS changed its policy on the assignment of billing codes for biosimilars in second quarter 2018. Prior to that, if there were multiple biosimilars for a given originator biologic, all biosimilars were assigned to the same billing code (while the originator biologic remained in its own billing code). Beginning second quarter 2018, each biosimilar receives its own billing code.

[c] See Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 Fed. Reg. 52976-53371. Available at https://www.federalregister.gov/documents/2017/11/15/2017-23953/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

[d] Section 11403 of the Inflation Reduction Act requires a temporary, 5-year increase in the Medicare Part B payment for certain qualifying biosimilars that have an ASP that is not more than the ASP of the reference biological product. Such qualifying biosimilars will be paid ASP + 8 percent (rather than + 6 percent) of the reference biological product's ASP. This temporary add-on payment is intended to increase access to and utilization of biosimilars and promote competition in the marketplace (https://www.cms.gov/files/document/biosimilar-faqs.pdf).

Exhibit 1. Illustrative Example of Medicare Payments for Prescription Drugs in Part B

			Part B Payment[a]	Example (absent the sequester)				
				Sales Price	Market share	Average Sales Price (ASP)	Add on Rate and Amount	Medicare Payment (ASP + Add-on)
Small molecule drugs	Single source	Brand	ASP + 6 percent	$50.00	100 percent	$50.00	6 percent of ASP =$3.00	$53.00
	Multiple source	Brand	Volume-weighted average of ASP for brand and generic +6 percent	$50.00	50 percent	(0.5*50) +(0.25*20) +(0.25*15) =$33.75	6 percent of ASP =$2.03	$35.78
		Generic 1		$20.00	25 percent			
		Generic 2		$15.00	25 percent			
Biologics		Reference	ASP + 6 percent	$50.00		$50.00	6 percent of ASP = $3.00	$53.00
		Biosimilar 1	Biosimilar 1's ASP + 6 percent of reference ASP	$20.00	50 percent	$20.00	6 percent of reference ASP = $3.00	$23.00
		Biosimilar 2	Biosimilar 2's ASP + 6 percent of reference ASP	$15.00	40 percent	$15.00	6 percent of reference ASP = $3.00	$18.00
		Qualifying Biosimilar 3	Biosimilar 3's ASP + 8 percent of reference ASP	$20.00	10 percent	$18.00	8 percent of reference ASP = $4.00	$24.00

DATA AND METHODS

This study used Medicare claims data (carrier, durable medical equipment, and outpatient hospital files) from 2008 to 2021 for Medicare FFS Part B spending and utilization.[b] In addition, we also used the ASP data files and the Medicare drug spending dashboard for Part B drugs hosted by CMS.[c]

Part B drugs are billed using Healthcare Common Procedure Coding System (HCPCS) codes.[d] A service is defined as an occurrence of a HCPCS code on a claim for a beneficiary in a day. Part B reimbursement is split into three categories: outpatient (HOPD), physician offices ("carrier"), and durable-medical equipment (DME). Outpatient as a setting captures hospital outpatient departments (HOPD), and carrier as a setting captures independent physician offices when total payments are split by place of service. For the remainder of this brief the carrier

[a] Part B payment is limited when ASP is available and is published in the ASP Drug Pricing File.
[b] The claims data were processed by Acumen for ASPE.
[c] ASP data files are available at: https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice. The Medicare drug spending dashboard data are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs
[d] HCPCS codes (that are paid under ASP) for carrier and DME were obtained from the CMS ASP file while the codes for outpatient come from the CMS Addendum B file. AWP priced drugs in the carrier and DME data were also included.

setting will be referred to as the physician office setting. The analytical data exclude lines on claims reporting payment under one cent, lines with denied payments, or lines where Medicare is not the primary payer.[a]

In addition, our analysis excludes spending by enrollees in Medicare Advantage (MA), as the claims data reflected only spending in the fee-for-service (FFS) Medicare. Since Medicare Part B enrollment in FFS has been flat since 2008, spending increases observed in the claims data for this study were driven by either price or per beneficiary utilization increase, not by enrollment increases.[b,c] Since the claims data used for this report reflected only spending in the FFS Medicare, Medicare spending for drugs is actually higher than the FFS spending numbers stated in this report. Future research is needed to compare utilization of Part B drugs in MA plans to FFS Medicare.

RESULTS

Pharmaceutical Spending Trends

As displayed in Exhibit 2, growth in Part B drug spending per enrollee since 2008 was more rapid than growth in spending under Part D or national drug spending as calculated for the National Health Expenditures (NHE). During 2008-2021, average annual FFS Part B drug spending per enrollee grew 9.2 percent per year, more than three times as fast as Part D (2.6 percent) and nearly four times as fast as the NHE prescription drug spending in general (2.4 percent).[d] Part B drug spending also grew more rapidly than overall Part B spending (9.2 vs. 6.3 percent). Consequently, the share of Part B spending that went to prescription drugs doubled from 8.2 percent in 2008 to 17.1 percent in 2021. In the following sections we examine more detailed trends that may help to explain the rapid growth in Part B drug spending.

Exhibit 2. Pharmaceutical Spending Trends: National Health Expenditures (NHE), Medicare Part D and Part B, 2014-2021*

Category	2014	2015	2016	2017	2018	2019	2020	2021	Percent Change 2008-2021
Medicare Part B Total Spending ($B)	265.9	279	293.4	313.7	337.2	370.3	418.6	405.5	6.30%
Part B FFS Drug Allowed Charges ($B)	21.8	24.1	27.5	30.6	33.5	37.3	38.8	40.5	8.70%
Part B FFS Drug Program Payment ($B)	17.2	19	21.8	24.3	26.6	29.7	31.1	32.7	8.90%
Part B FFS Drug Program Payment per Enrollee ($)	520	571	647	721	798	897	965	1,061	9.20%
Medicare Part D Spending per Enrollee ($)	1,928	2,149	2,313	2,248	2,079	2,069	2,157	2,100	2.60%
NHE Retail Drug spending per capita ($)	913	973	970	971	992	1,030	1,051	1,099	2.40%

Sources: (1) Analysis of physician office, durable medical equipment, and outpatient claims data 2006-2021 by Acumen for ASPE. Program payment amount does not include beneficiary cost-sharing; (2) Medicare Trustees Reports, 2022 and 2023

[a] The study uses the HCPCS-NDC crosswalk available from CMS (https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files) to determine the brand/generic status of a drug: (1) generic HCPCS were linked to at least one generic NDC, (2) brand HCPCS were not linked to any generic NDCs, (3) unmatched HCPCS were not present on the CMS HCPCS-NDC crosswalk.

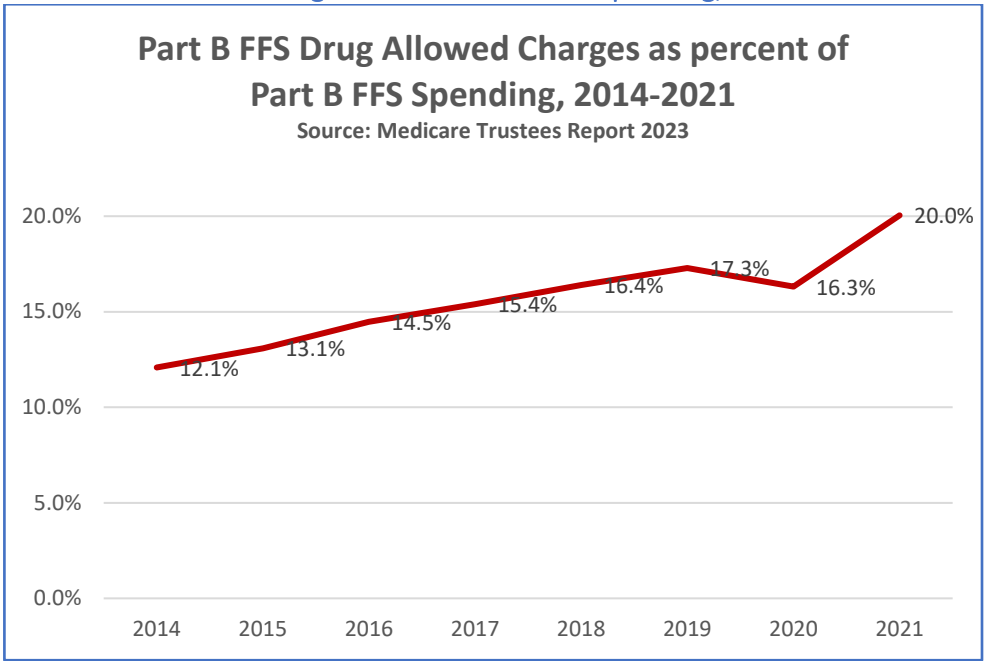
[b] Part B enrollment in fee-for-service was about 32 million in 2008, declining slightly to 30.8 million in 2021 (derived from Medicare Trustees Report 2023, Table V.B3)). https://www.cms.gov/oact/tr/2023.

[c] Even though Part B enrollment in FFS remained flat during 2008 to 2021, the share of FFS enrollment in Part B dropped from 76 percent in 2008 to 53 percent in 2021 reflecting the growth in enrollment in MA from about 10 million in 2008 to 28 million enrollees in 2021.

[d] Because biologics account for about 79 percent of Medicare Part B FFS prescription drug spending in 2021, there has been little opportunity to reduce Medicare Part B spending growth through generic substitution, as has occurred in Medicare Part D and in retail pharmacy overall.

Notes: (1) Total Part D spending (Trustees Reports, 2022; Table III.D3) is the sum of Benefits payments by Medicare and administrative expenses. Units are specified in the Category sub-headings: $ refers to dollars, and $B to billion dollars. (2) the NHE values are on an incurred basis, as opposed to the cash basis for Part B and Part D, and they do not include administrative costs.

Exhibit 3. Part B FFS drugs' share of Part B FFS spending, 2014-2021



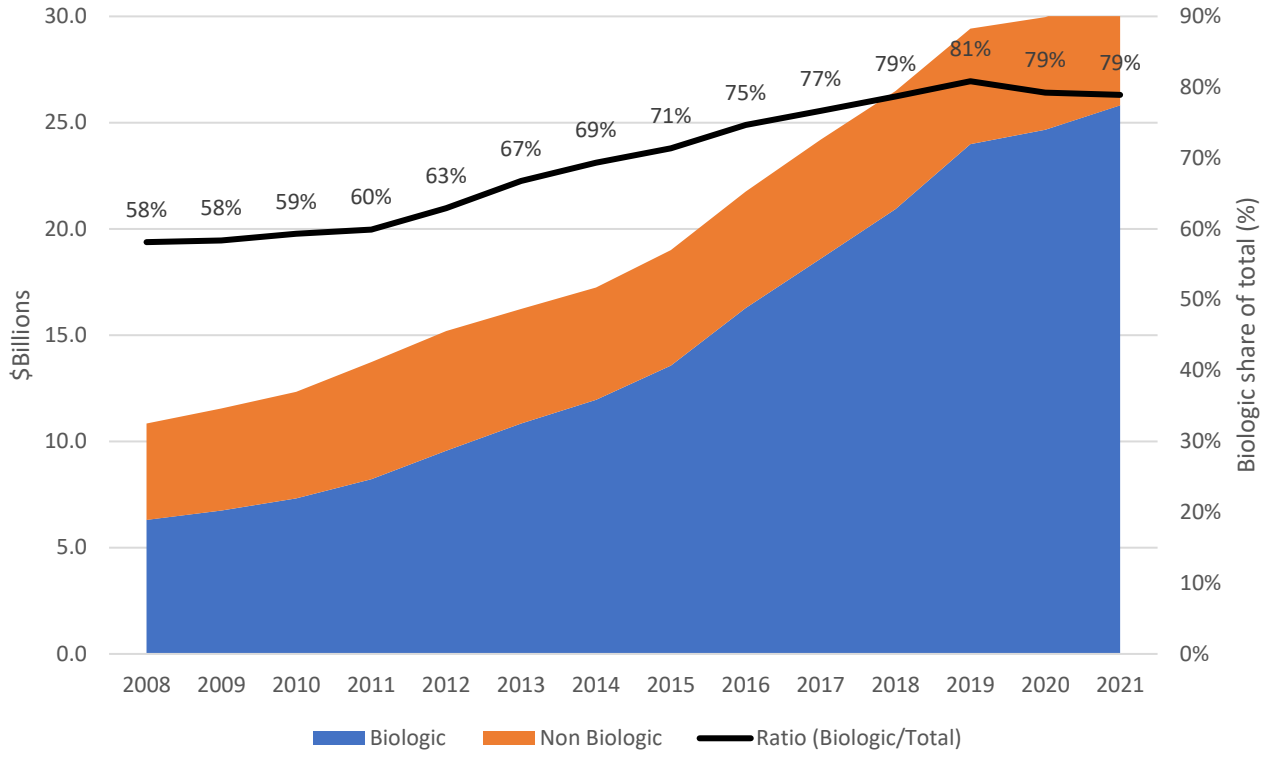
Trends in Biologics and Biosimilars

A notable trend in Part B drug spending has been the growth in spending for biologics which have grown more rapidly than non-biologics over the past fifteen years, increasing from 58 percent of Part B drug spending in 2008 to 79 percent in 2021 (Exhibit 4).[a] In 2021, Medicare Part B spending for biologic drugs was $25.8 billion compared with $5.3 billion for non-biologic drugs. From 2008 to 2021, spending for biologics accounted for 89 percent of Medicare Part B drug spending growth.[b] As displayed in Exhibit 5, biosimilars have only recently begun to penetrate the Part B market as of 2021, accounting for only 4.9 percent of spending.[c]

The rapid growth of biologics in Part B has greatly reduced the potential for generic drugs to moderate spending as they do under Part D. Since brands and their generic competitors are billed under the same HCPCS code, it is not possible to identify the generic utilization. We can only estimate the share of spending on both the brand and generic drugs billed under these codes and thus, the potential for generic use. In 2021, HCPCS for which a generic was available accounted for 2% of Part B drug spending, down from 7% in 2011.

[a] In 2021, biologics and biosimilars accounted for 79% of Medicare total spending with only 40% of service counts.
[b] The computation of the growth share from 2008 to 2021 is: (25.8-6.3) $billion for biologics / (32.7-10.8 $billion) for Medicare Part B drug spending equals 89.2% of spending growth.
[c] Although the first biosimilar was approved by FDA in 2015, the delayed market penetration was due to a number of factors including patent litigation and lack of knowledge of biosimilars by providers.

Exhibit 4. Medicare Part B Program FFS Spending for Drugs: Biologic vs. non-Biologic, 2008-21



Source: Analysis of physician office, durable medical equipment, and outpatient claims data 2008-2021 by Acumen for ASPE.

Spending by Drug Class, Physician Specialty, and Setting

Exhibit 5 compares Medicare spending levels for Part B drugs reimbursed under the ASP methodology in 2008 with 2021 by various categories. Biologics represent the vast majority of Part B drug spending, comprising 78.9 percent of total spending, growing at a rate of 11.5 percent annually from 2008-2021. Drugs to treat cancer continued to account for the largest share of Part B drug program spending and accounted for over half of spending in 2021.

Note that data on physician specialties only include claims from physician offices and durable medical equipment and exclude outpatient hospital claims where much of the high-cost biologic drugs are provided. Among physician specialties who are billing in the physician office setting, spending on drugs was predominately managed by oncologists; however, because spending from oncologists grew at a lower rate (3.7 percent) than the overall Part B average, this share of Part B spending fell from 39.2 percent to 20.9 percent between 2008 and 2021. Ophthalmologists had the fastest growth rate of drug spending following the approval of multiple macular degeneration therapies, growing at a 15 percent rate annually from 2008-2021 and reaching 11.0 percent of total Part B drug spending by 2021 (up from 5.4 percent in 2008).

In terms of therapy type, Part B spending on intravenous immuno-globulin (IVIG), osteoporosis, rheumatoid arthritis, and cancer grew the most rapidly with an annual growth rate higher than 10 percent from 2008 to 2021. IVIG is used to treat a range of conditions, including autoimmune, immunodeficient, rheumatologic and infectious conditions. Finally, in terms of place of service, hospital outpatients experienced the highest rate of spending growth on Part B drugs, growing at a rate of 13.8 percent from 2008-2021.

Exhibit 5. Medicare Part B Drug Spending by Biologic, Therapeutic Type, Specialty, Place of Service: 2008 and 2021

Category		2008		2021		2008-2021 Average
		Program Payment ($M)	Percent Of Total (%)	Program Payment ($M)	Percent Of Total (%)	Annual Payment % Change
All		10,843.8		32,716.0		
Biologic/non-biologic	Biologic	6,303.8	58.1%	25,816.9	78.9%	11.5%
	Biosimilar	-	-	1,603.4	4.9%	
	Non Biologic	4,540.0	41.9%	5,295.7	16.2%	1.2%
Therapeutic Type	Anti-Coagulant	31.3	0.3%	0.2	0.0%	-31.9%*
	Antigen	18.1	0.2%	6.2	0.0%	-7.9%
	Blood Clotting	269.4	2.5%	639.0	2.0%	6.9%
	Cancer	4,786.7	44.1%	17,404.0	53.2%	10.4%
	Clot Buster	45.7	0.4%	59.1	0.2%	2.0%
	IG Intramuscular Admin	0.7	0.0%	0.1	0.0%	-13.5%
	Immunosuppressive	426.3	3.9%	933.7	2.9%	6.2%
	Intravenous Immuno-globulin (IVIG)	344.8	3.2%	1,473.0	4.5%	11.8%
	Oral Anti-Nausea	7.0	0.1%	0.8	0.0%	-15.6%
	Oral Cancer	2.1	0.0%	0.0	0.0%	-45.4%
	Osteoporosis	356.9	3.3%	1,838.6	5.6%	13.4%
	Rheumatoid Arthritis	757.8	7.0%	3,148.0	9.6%	11.6%
	Single Antigen Admin	15.8	0.1%	22.9	0.1%	2.9%
	Others	*3,781.2*	34.9%	*7,190.4*	22.0%	
Physician Specialty *(Carrier and DME files only)*	Specialty: Oncology	4,251.9	39.2%	6,834.2	20.9%	3.7%
	Specialty: Ophthalmology	583.8	5.4%	3,594.6	11.0%	15.0%
	Aflibercept injection (Eylea) 2013-19	*859.7*	7.9%	2,744.0	8.4%	*9.3%*
	Bevacizumab injection (Avastin)	*761.3*	7.0%	305.5	0.9%	*-6.8%*
	Ranibizumab injection (Lucentis)	*588.1*	5.4%	*838.5*	2.6%	*2.8%*
	Specialty Rheumatology	519.9	4.8%	*2,079.1*	6.4%	11.3%
	Specialty Primary	428.3	3.9%	*1,666.5*	5.1%	11.0%
	Specialty Urology	214.3	2.0%	278.4	0.9%	2.0%
	Specialty Infectious	26.1	0.2%	128.6	0.4%	13.0%
	Other Specialty	1,042.4	9.6%	2,256.9	6.9%	6.1%
	Others	*3,777.1*	34.8%	*15,877.7*	48.5%	

Source: Analysis of carrier (physician office), durable medical equipment, and outpatient claims data 2008-2021 by Acumen for ASPE. Data include Part B covered drugs administered in physicians' offices and furnished by suppliers, covered drugs in hospital outpatient departments; and reflect only Part B drugs paid under the ASP + 6 percent. The Healthcare Common Procedure Coding System (HCPCS) codes and prices for physician office and Durable Medical

Equipment (DME) were obtained from the CMS ASP file, those for outpatient come from the CMS Addendum B file. Lines with denied payments or Medicare as secondary payer were dropped. Total payments (include Medicare program payments and beneficiary cost sharing) and reflect the sequester's payment reduction since 2013. The analyses started in 2008 when most Part B drugs in outpatient departments were paid under the ASP.

Concentration of Part B Spending

As shown in Exhibit 6, a relatively small number of Part B drugs account for a significant share of the spending. The top 20 drugs in terms of Medicare Part B payment, all of which are biologics, account for more than 50 percent of total payments, and the top 10 account for more than 40 percent of total payments in 2021. For high-cost drugs such as pembrolizumab,[a] in 2021, total Medicare spending was more than $4 billion, Medicare spending per user was $52,740, and annual cost-sharing per user was $10,941. In 7 of the 10 drugs that accounted for most of the Part B drug expenditures in 2021, Medicare spending per user ranges from about $17,000 to over $300,000 per year. To see the broad disease indications and prescribing specialties for these top 20 drugs, see Exhibit 8 below.

Exhibit 6. Top 20 Part B Drugs by Total Medicare Payments, 2021

HCPCS code	HCPCS Description	Brand Name	Total Payment ($Millions)	Medicare Payment ($Millions)	Number of beneficiaries (thousands)	Medicare Spending per User ($)	Medicare Spending per Service ($)	Annual Cost-sharing per User ($)	Share of Part B Total Drug Payment (%)
J9271	Injection, pembrolizumab	Keytruda	4,094.60	3,394.30	64	52,740	8,480.03	10,941.94	10.10%
J0178	Aflibercept injection	Eylea	3,423.80	2,744.00	310	8,849	1,673.59	2,192.86	8.50%
J0897	Denosumab injection	Prolia	1,877.00	1,473.30	660	2,233	1,133.46	611.64	4.60%
J9299	Injection, nivolumab	Opdivo	1,614.90	1,335.60	26	51,502	7,221.35	10,743.61	4.00%
J9144	Daratumumab, hyaluronidase	Darzalex	1,076.40	876	13	68,595	6,493.45	15,415.59	2.70%
J2778	Ranibizumab injection	Lucentis	1,045.90	838.5	114	7,329	1,385.95	1,819.11	2.60%
J0129	Abatacept injection	Orencia	1,020.90	807.4	32	25,025	2,937.93	6,674.34	2.50%
J9312	Injection, rituximab, 10 mg	Rituxan	798.6	636.1	37	16,970	5,382.96	4,390.75	2.00%
J1300	Eculizumab injection	Soliris	664.6	570.3	2	336,885	20,375.34	47,136.51	1.60%
J9022	Injection, atezolizumab, 10 mg	Tecentriq	683.6	556.5	13	43,027	6,949.03	9,780.96	1.70%
J2350	Injection, ocrelizumab, 1 mg	Ocrevus	627.3	548.2	13	43,364	24,230.44	6,082.39	1.50%
J1745	Infliximab not biosimilar, 10mg	Remicade	574.6	441	43	10,155	1,719.46	3,105.68	1.40%
J2505	Injection, pegfilgrastim 6mg	Neulasta	549.5	436.4	59	7,396	1,956.60	1,916.48	1.40%
J3380	Injection, vedolizumab	Entyvio	553.4	435.4	16	26,755	4,521.52	7,374.19	1.40%

[a] Keytruda (pembrolizumab) is a prescription medicine used to treat: (1) a kind of skin cancer called melanoma, (2) a kind of lung cancer called non-small cell lung cancer (NSCLC), (3) a kind of cancer called head and neck squamous cell cancer (HNSCC), (4) a kind of bladder and urinary tract cancer called urothelial carcinoma, and (5) some other forms of cancer.

J1569	Gammagard liquid injection	Gammagard Liquid**	534.2	420.4	19	21,980	2,546.51	5,990.36	1.30%
J9305	Injection, pemetrexed nos, 10mg	Almita	494	408.5	18	22,988	4,890.50	4,748.41	1.20%
J0717	Certolizumab pegol injection, 1mg	Cosentyx	515.4	407.7	22	18,732	2,194.50	4,893.57	1.30%
J9145	Injection, daratumumab 10 mg	Darzalex	500.1	401.1	8	48,295	5,256.10	12,376.50	1.20%
J9173	Injection, durvalumab, 10 mg	Imfinzi	473.7	380.8	9	40,706	5,257.10	10,320.45	1.20%
J9228	Ipilimumab injection	Yervoy	418.1	365.4	8	46,631	17,359.62	6,593.02	1.00%
Top 10 Total and program Payments ($Billion)			16.3	13.2					
All Part B Drug Payments ($Billion)			40.5	32.7					
Top 10 share of payments for ALL Part B drugs*			40.2%	40.4%					

Source: Analysis of 2021 physician office, durable medical equipment, and outpatient claims data by Acumen for ASPE. Data include Part B covered drugs administered in physicians' offices and furnished by suppliers, covered drugs in hospital outpatient departments; and reflect only Part B drugs paid under the ASP + 6 percent. The Healthcare Common Procedure Coding System (HCPCS) codes and prices for physician office and DME were obtained from the CMS ASP file, those for outpatient come from the CMS Addendum B file. Lines with denied payments or Medicare as secondary payer were dropped.
Notes: * Total payments (include Medicare program payments and beneficiary cost sharing) and reflect the sequester's payment reduction since 2013. The analyses started in 2006 when most Part B drugs in outpatient departments were paid under the ASP.
** Multiple brand names for IVIG therapies including the following: Bivigam, Carimune, Flebogamma, Gammagard S/D (low IgA), Gammagard Liquid, Gammaked, Gammaplex, Gamunex, Octagam and Privigen.

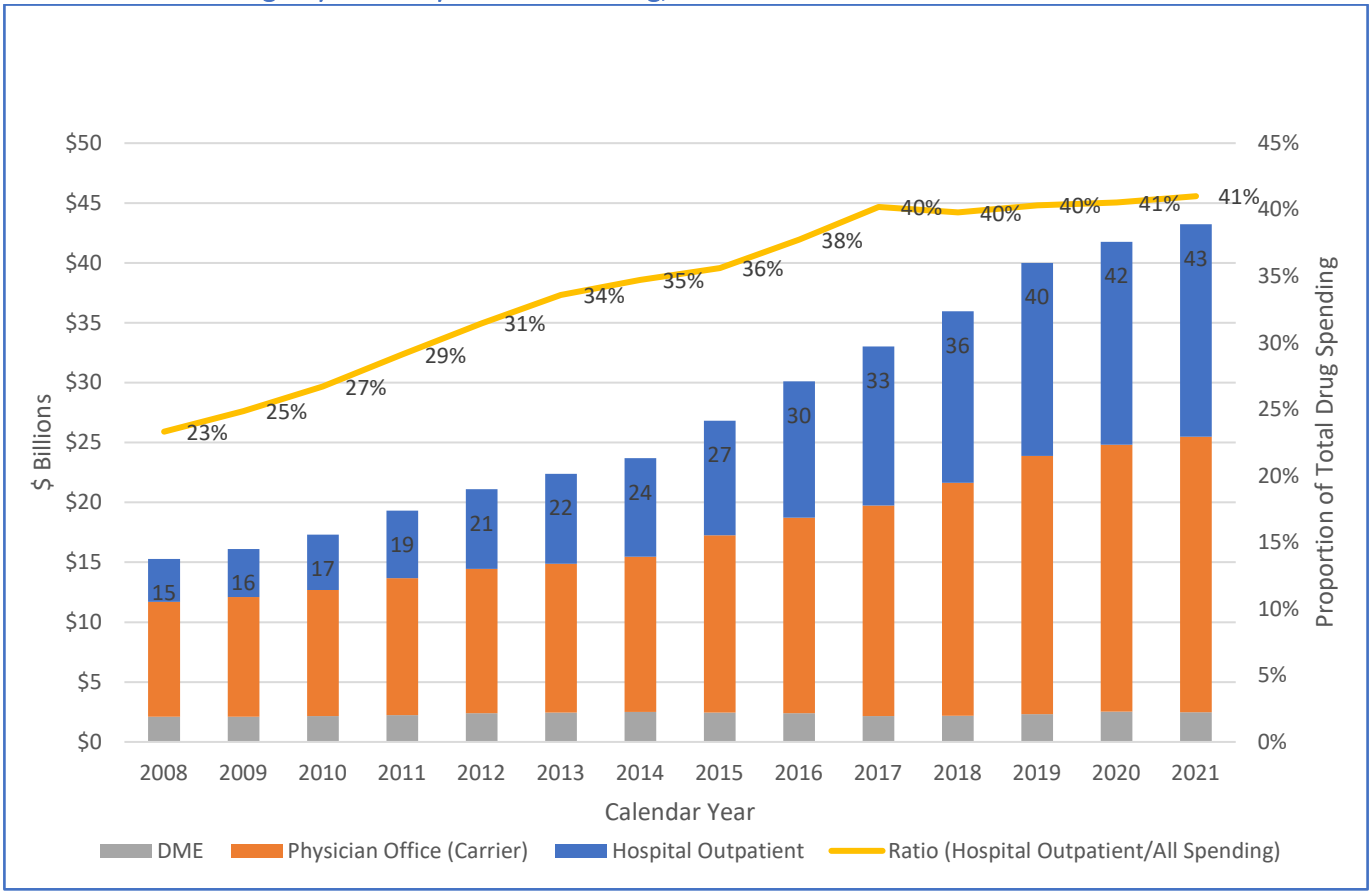
Trends by Provider Setting, 2008-2021[a]

In this section, we compare spending trends for Part B drugs by place of service. We focus on separately paid drugs to be consistent with the other estimates provided in this brief. The three provider settings through which Part B payments flow are physician office, outpatient, and DME settings. DME is for durable-medical equipment and is more relevant for non-drug spending in Medicare Part B. The majority of drug spending and, specifically biologics spending, is performed within the outpatient and physician office settings. The independent physician office setting may be privately owned by a practicing clinician while the outpatient setting captures HOPDs owned by a hospital or larger health system.

As displayed in Exhibit 7, Part B drug spending is shifting to hospital outpatient departments. While overall Part B drug spending on separately paid drugs increased on average 8.9 percent annually, hospital outpatient drug spending increased 13.8 percent annually from $3.6 billion in 2008 to $17.7 billion in 2021.[b] The share of Part B spending in this setting doubled from 23 percent in 2008 to 41 percent in 2021, while the share of spending in physicians' offices declined from 63 percent to 53 percent during that time. As stated earlier, this could be driven by growing rates of vertical consolidation by hospital systems that have purchased independent practices.[9]

[a] Data during 2018 to 2021 reflect the change in 340B payment in the beginning January 2018 when payments to 340B hospitals dropped to ASP - 22.5 percent for separately payable Part B drugs that do not have pass-through status (drugs with pass-through status are paid ASP + 6 percent). The Supreme Court overturned the ASP drop for 340B qualifying hospitals in the summer of 2022; see American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et al. 20-1114 (06/15/2022) (www.supremecourt.gov) and The U.S. Supreme Court Sides with 340B Hospitals in Significant $1.6 Billion Part B Drug Payment Ruling (https://www.quarles.com/newsroom/publications/update-u-s-supreme-court-sides-with-340b-hospitals-in-significant-1-6-billion-part-b-drug-payment-ruling).
[b] Based on our estimated spending for packaged drugs, total Part B drug spending in HOPDs would be approximately $24 billion.

Exhibit 7. Part B Drug Payments by Provider Setting, 2008-2021



Source: Analysis of 2021 physician office (carrier), durable medical equipment, and outpatient claims data by Acumen for ASPE.

DISCUSSION

Spending Trends, Incentives, and Policy Issues

Our results show that Part B drug spending has increased much faster than overall drug spending in the U.S., as well as Part D Medicare drug spending. Some of this spending growth can be attributed to new and effective therapies entering the market. Nonetheless, there are reasons for policy concerns related to the spending growth. Both due to the large share of Part B spending attributable to biologics and statutory requirements, Medicare does not have at its disposal many of the tools used to contain costs and achieve value for retail drugs. For example, the trends related to biologics and generics described above are important factors for explaining this rapid spending growth for Part B drugs relative to those covered under Part D. Under Part D, generic substitution generally occurs rapidly once a brand drug goes off patent, and the price of the generics declines substantially relative to the brand as new generic competitors enter the market.[10] The rapid penetration of generic substitutes for their branded counterparts has held down spending growth.[11] Generics account for nearly 90 percent of Part D claims and 25 percent of spending. However, as described above, HCPCS codes that may include generic utilization account for only 2 percent of Part B drug spending.

Biologics account for most of the growth in Part B spending and these products tend to have higher prices than small molecule drugs. It is still too early to fully evaluate biosimilar market adoption and the factors that may

affect their utilization; however, the recent wave of FDA approvals will likely produce of a wider array of alternatives set to enter the market in the coming years. At the outset of 2022, 21 biosimilars were available for purchase and by the end of 2022 the FDA had approved 40 total biosimilars that are either on or entering the market.[a]

Additional incentives for spending growth in Part B come from the structuring of drug procurement in Part B compared to Part D. Under Part D, notwithstanding the incentives for Pharmacy Benefit Managers (PBMs) to favor higher-cost drugs with larger rebates, Part D plan sponsors and commercial insurers could use a variety of tools - such as tiered copayments, prior authorization and step therapy - to incentivize the use of higher value medicines. Part B, on the other hand, reimburses after physician offices and outpatient facilities prescribe a given therapy with a reimbursement strategy based on the cost the facility pays to acquire the therapy. This system is called the "buy-and-bill" system, in which providers buy the drugs they hold in stock and bill the payer for the therapies they administer.[12]

In addition, there are other concerns that the ASP+6 payment approach may provide incentives that run counter to high-value use of Part B drugs. Physicians can often choose between several similar drugs for treating a patient. Since higher cost drugs bring higher reimbursements, there may be little incentive to provide lower-cost alternatives that may be equally effective. Moreover, the fixed 6 percent of ASP provides a larger dollar "add-on" for higher price drugs than for lower price drugs.[b] The larger dollar "add-on" for the higher price drugs results in increased revenue for the physicians' office and hospitals – creating an incentive to choose the high price drugs as opposed to lower price alternatives of similar effectiveness.

Legislation and court rulings have limited Medicare's ability to modify current pricing mechanisms with value-based policies, such as Least Costly Alternative (LCA). Medicare contractors used LCA pricing from 1995-2010 for selected drugs, under which they covered certain drugs at the rate currently paid for the least costly medically appropriate alternative. However, the United States Court of Appeals for the D.C. Circuit ruled in Hays v Sebelius in 2009 that the ASP statute does not permit Medicare to use the LCA policy for individual drugs.[c] An Office of the Inspector General (OIG) report studying the use of certain drugs to treat prostate cancer showed a shift towards higher cost therapies in the years following the court decision removing LCA authority from the Part B program.[13] OIG suggests CMS be provided legislative authority to re-establish LCA authority in select circumstances for Part B drugs.

There are also statutory requirements that cause differences between Part B and Part D in the tools available to for achieving value in the use of the therapies. Part D plan sponsors and commercial insurers use a variety of PBM tools to influence prescribing choices made by physicians, such as formulary requirements, like prior authorization, step therapy, and tiered cost-sharing. Coinsurance in Part B is established by statute at 20 percent and there are no provisions for varying that rate based on the value of a particular drug or any other criteria.[d] Medicare and its administrative contractors are generally not able to use other formulary management tools used in Part D, such as prior authorization and step therapy.

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[a] See FDA's list of approved biosimilars (total biosimilars in both Part B and Part D markets) at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

[b] The biosimilar policy is trying to equalize the add on payment since it is always based on the reference biologic.

[c] Between July 1, 2007, and March 31, 2008, Medicare also used a consolidated payment approach for two drugs used to treat asthma and chronic obstructive pulmonary disease by assigning them a single billing code and paying the weighted average ASP. The Medicare, Medicaid, and SCHIP Extension Act of 2007 effectively reestablished separate payment rates for these drugs.

[d] Note that only a small number of beneficiaries are subject to the 20 percent coninsurance since most have some type of supplemental coverage, and the inflation rebate provision does change the 20 percent coinsurance rate. Because beneficiaries without supplemental insurance would face higher out-of-pocket costs for more expensive drugs, they may be incentivized to request lower cost options. There is no coinsurance for certain vaccines; further, the coinsurance for any individual service paid under the OPPS (drugs are combined with primary service for this policy) is capped at the inpatient deductible.

The Inflation Reduction Act

The Inflation Reduction Act (IRA) contains provisions that may change incentives for use of Part B drugs, constrain their rate of spending growth, and lower out-of-pocket costs for Part B enrollees. The law specifically provides the following provisions that are relevant for Part B, including temporary higher reimbursements for biosimilars, inflation rebates, and drug price negotiations.

Higher Reimbursements for Biosimilars

The Inflation Reduction Act increases the "add-on" for certain qualifying biosimilars from 6 to 8 percent of ASP for a 5-year period starting in October of 2022.[a] The effect of this payment policy remains to be seen, but greater ASP payment could be helpful in increasing biosimilar adoption and increasing competition in the drug market.[14]

Inflation Rebates

Inflation rebates in Part B require manufacturers of single source drugs and biologics to pay a rebate to Medicare if the drug's price increase exceeds the quarterly rate of inflation.[15] One study found that Part B could have saved nearly $3.7 billion if this provision was in effect during the last three years leading up to 2022.[16] This provision took effect for Part B on January 1, 2023.[17]

Part B drugs that meet certain criteria can be considered for the inflation rebates.[b] Rebate-eligible drugs are single source drug or biological products that include certain biosimilars administered by physicians through infusion or injection. The IRA excludes some drugs, such as Part B preventive vaccines, from rebates.[18]

Drug Price Negotiations

Finally, the IRA requires HHS to negotiate prices for select drugs on behalf of the Medicare program.[19] The law authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs, meaning only those drugs for which there is no generic or biosimilar competition. For the first year of the Negotiation Program, CMS will select up to 10 Part D high expenditure, single source drugs for negotiation, meaning only those drugs for which there is no generic or biosimilar competition. The maximum fair prices that are negotiated for these drugs will apply beginning in 2026. CMS will select up to an additional 15 Part D drugs for negotiation for 2027, up to an additional 15 Part B or Part D drugs for 2028, and up to an additional 20 Part B or Part D drugs for 2029 and subsequent years.[c]

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[a] The statutory language defined these qualifying biosimilars: —For purposes of this subparagraph, the term 'qualifying biosimilar biological product' means a biosimilar biological product described in paragraph (1)(C) with respect to which— "(I) in the case of a product described in clause (ii)(I), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product;" and "(II) in the case of a product described in clause (ii)(II), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product."

[b] CMS intends to identify: (1) single source drugs and biological products (as defined in section 1847A(c)(6)(D) of the Act), including biosimilar biological products (as defined in section 1847A(c)(6)(H) of the Act), for which payment is made under Part B, and (2) the applicable HCPCS codes for such drugs and biological products, and then apply certain exclusions. Multiple source drugs (described in section 1847A(c)(6)(C) of the Act) and qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(iii) of the Act) will be excluded. https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

[c] CMS (on behalf of the HHS Secretary) can negotiate maximum fair prices for certain high-expenditure single source Part B or Part D drugs (brand-name drugs without generic or biosimilar equivalents). The maximum fair prices that are negotiated for the first set of drugs subject to negotiation will be in effect beginning in 2026. The number of drugs subject to negotiation is phased in, such that CMS negotiates the prices of (i) 10 drugs covered under Part D for 2026; (ii) an additional 15 drugs covered under Part D for 2027; (iii) an additional 15 drugs covered under Part B or Part D for 2028; and (iv) an additional 20 drugs covered under Part B or Part D for 2029 and each year thereafter (https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-initial-guidance.pdf)

For 2028, the selected drugs must be among the drugs with the highest total expenditures in Medicare over the most recent 12-month period under Part B and Part D and must have been approved or licensed, as applicable, by the Food and Drug Administration for at least 7 years (for drug small-molecule products) or 11 years (for biologics) at the time of selection. Excluded are (i) orphan drugs or biological products that are designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and that are approved for only an indication (or indications) for such disease or condition; (ii) plasma-derived products; (iii) drugs that account for less than $200 million in annual total Medicare expenditures (in 2021 and adjusted annually for inflation); and (iv) certain small biotech drugs (applicable only for initial price applicability years 2026, 2027, and 2028). Manufacturers of drugs selected for negotiation that fail to comply with requirements of the Negotiation Program can be subject to civil penalties and/or excise taxes. If certain requirements are met, a manufacturer of a biosimilar may request a delay from selection for negotiation for up to 2 years.[19]

Exhibit 8 shows the top 20 drugs in Part B by spending in 2021.[a] They were all biologics; 4 have active competition in the market from biosimilar products and 4 have biosimilars in the development pipeline (i.e., clinical trials). Twelve drugs have no biosimilar competition in either the pipeline or on the market.

Exhibit 8. Characteristics of the Top 20 Part B Drugs by Total Medicare Payments, CY 2021

HCPCS code	HCPCS Description	Brand Name	Specialty	Time of First FDA approval[65]	Broad Indication for Drug	Biosimilar on U.S. market (Y/N)	Biosimilar in pipeline (trials or pre-approval)
J9271	Injection, pembrolizumab	Keytruda	Oncology	09/04/14	Cancer	N	N
J0178	Aflibercept injection	Eylea	Ophthalmology	11/18/11	Eye disease	N	Y x 11
J0897	Denosumab injection	Prolia	Oncology/other	06/01/10	Osteoporosis	N	Y x 10
J9299	Injection, nivolumab	Opdivo	Oncology	12/22/14	Cancer	N	N
J9144	Daratumumab, hyaluronidase	Darzalex	Oncology	11/16/15	Cancer	N	N
J2778	Ranibizumab injection	Lucentis	Ophthalmology	06/30/06	Eye disease	Y x 2	Y x 2
J0129	Abatacept injection	Orencia	Rheumatology	12/23/05	Inflammatory disease	N	N
J9312	Injection, rituximab, 10 mg	Rituxan	Oncology/ Rheumatology	11/26/97	Inflammatory disease	Y x 3	N
J1300	Eculizumab injection	Soliris	Rheumatology	03/16/07	Inflammatory disease	N	Y x 2
J9022	Injection, atezolizumab, 10 mg	Tecentriq	Oncology	05/18/16	Cancer	N	N

[a] This list is for illustrative purposes only and does not represent the list for negotiation.

J2350	Injection, ocrelizumab, 1 mg	Ocrevus	Rheumatology	03/28/17	Inflammatory disease	N	N
J1745	Infliximab not biosimilar, 10mg	Remicade	Rheumatology	08/24/98	Inflammatory disease	Y x 3	Y x 2
J2505	Injection, pegfilgrastim, 6mg	Neulasta	Oncology	01/31/02	Cancer	Y x 4	Y x 3
J3380	Injection, vedolizumab	Entyvio	Rheumatology	03/20/14	Inflammatory disease	N	N
J1569	Gammagard liquid injection	Gammagard Liquid**	Oncology/ Rheumatology/ Other	05/02/05	Immune system deficiency	N	N
J9305	Injection, pemetrexed nos, 10mg	Almita	Oncology	02/04/04	Cancer	N	N
J0717	Certolizumab pegol injection, 1mg	Cosentyx	Rheumatology	01/21/15	Inflammatory disease	N	Y x 1
J9145	Injection, daratumumab, 10 mg	Darzalex	Oncology	11/16/15	Cancer	N	N
J9173	Injection, durvalumab, 10 mg	Imfinzi	Oncology	05/01/17	Cancer	N	N
J9228	Ipilimumab injection	Yervoy	Oncology	03/25/11	Cancer	N	N

*Biosimilar market entry and pipeline is as of October 2022 based on the Amerisource Bergen Biosimilars Report (https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-101722-v1.pdf). Pipeline refers to pre-market clinical trials phase 1-3 in which a biosimilar can be in the process to seek FDA approval. Negotiation eligibility is based upon 13-year period granted by the Inflation Reduction Act for biologic drugs upon FDA approval of an originator molecule via the Biologics License Application pathway granted under 351(k) of the Public Health Services Act.[a,20]

[a] See Biologics License Applications (BLA) Process (CBER): Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (https://www.fda.gov/drugs/biosimilars/background-information-list-licensed-biological-products-reference-product-exclusivity-and). 12 years is comprised of two periods: a 4-year application hold on any biosimilar or interchangeable application review 8-year hold on approval of biosimilars + 6-month extension to application review to 4 year or 12-year should pediatric studies be completed (351(m)), or 7 years (orphan drug exclusivity 527 (a)).

CONCLUSION

Spending for Medicare Part B drugs, those administered incident to a physician service, has grown more rapidly than spending under Medicare Part D or overall national drug spending. Currently, Medicare makes payments directly to physicians, suppliers, and hospital outpatient departments for Part B drugs administered to beneficiaries, based on the average prices all purchasers paid, with certain exceptions. The incentives associated with the current payment methodology are generally not consistent with the provision of high-value care to beneficiaries. The direct payment to providers of ASP+6 percent[a] may not encourage providers and suppliers to obtain the lowest possible acquisition prices for their drugs. When there are therapeutic alternatives available, the current methodology is not consistent with value-based purchasing.

Several Part B IRA provisions are intended to align value and incentives. For example, increasing the reimbursement from 6 to 8 percent for certain qualifying biosimilars could encourage providers to use biosimilars over higher-priced reference biologics. The inflation rebates and associated beneficiary coinsurance reductions could reduce incentives for manufacturers to raise their prices beyond inflation and will lower out-of-pocket costs for some people with Medicare. Finally, drug price negotiations could slow the increase in Part B drug spending starting in 2028 and will lower costs for people with Traditional Medicare who take the drugs with negotiated prices. The IRA provides a number of tools to address the rapid rate of growth in Part B drug spending to the benefit of the Medicare program, taxpayers, and patients.

[a] Or ASP + 4.3 percent under the sequester from 2013 to 2027.

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