PART B DRUGS PAYMENT SYSTEMS

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Medicare Part B covers drugs and biologics that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs). It also covers certain drugs and biologics furnished by pharmacies and suppliers. In 2023, Medicare and its beneficiaries paid about $54 billion dollars for Part B–covered drugs, biologics, and other products paid under the Part B drug payment systems. Medicare beneficiaries are generally liable for 20 percent cost sharing, with some exceptions. For ease of reference, we use the term "drug" to refer to drugs and other products paid under the Part B drug payment systems (unless otherwise noted).

The Inflation Reduction Act of 2022 (IRA) made several changes to Medicare payments and beneficiary cost sharing for Part B drugs. As discussed below, several of these policies became effective in 2022, 2023, or 2024, including a Medicare Part B drug inflation rebate, changes to biosimilar payment rates, and changes to cost sharing for Part B insulin. In addition, beginning in 2028, Medicare will have authority to negotiate prices for certain Part B drugs.

Aggregate Medicare Part B drug spending has been growing rapidly, rising at an average annual rate of about 9 percent per year since 2009. The largest driver of spending growth between 2009 and 2023 was the change in the average price that Medicare paid for drugs, reflecting price increases for existing products; launch of new, higher-priced products; and shifts in the mix of drugs.

Defining the products that Medicare buys

For a drug to be covered under Part B, it must be reasonable and necessary for the diagnosis or treatment of an illness or injury. (Four types of vaccines that are preventive services are also covered under Part B through specific statutory provisions.) Medicare Part B's coverage of a drug can also depend on several other factors—the type of drug, the route of administration, the setting in which the drug is administered, and the patient's diagnosis.

Physician office and HOPD drugs—Drugs administered by infusion or injection in physician offices and HOPDs compose the largest category of Part B drugs.[1] To be covered by Part B in these settings, the drug must be considered by Medicare to be not usually self-administered. A few examples include certain drugs to treat cancer, macular degeneration, and rheumatoid arthritis.

Preventive vaccines—Medicare Part B covers certain preventive vaccines that are explicitly listed in statute—influenza, pneumococcal, hepatitis B (for intermediate- and high-risk populations), and COVID-19 vaccines.

Pharmacy-supplied drugs—Medicare Part B covers oral anticancer drugs, oral antiemetic drugs, and immunosuppressive drugs that meet certain criteria.[2]

Inhalation drugs—Medicare Part B covers inhalation drugs that require administration with a Part B–covered nebulizer.

Home infusion drugs—Medicare Part B covers a small group of drugs infused in the home. To be covered by Part B, the drug must require administration using a Part B–covered infusion pump and administration of the drug in the home must be reasonable and necessary.[3] A few examples include certain intravenous drugs for heart failure and pulmonary arterial hypertension and subcutaneous immune globulin (for immunodeficiency and certain autoimmune conditions).

Clotting factor—Medicare Part B covers clotting factor products when self-administered by beneficiaries with hemophilia.

Part B coverage of a drug typically begins with the product's approval by the Food and Drug Administration (FDA). In some cases, Medicare covers drugs that are not FDA approved (e.g., older drugs that predate the development of the FDA approval process).

Medicare generally covers Part B drugs for their FDA-labeled indications (although in certain circumstances, Medicare may limit coverage based on clinical evidence). In addition, Medicare covers some drugs for off-label indications. For example, in physician offices and HOPDs, statute requires Medicare to cover cancer drugs for indications not approved by the FDA if the drug's off-label use is supported by selected third-party drug compendia. For noncancer drugs in these settings, Medicare has the discretion to cover off-label indications as long as the use is judged to be reasonable and necessary.

Beneficiary cost sharing

For Part B drugs, beneficiaries generally face 20 percent cost sharing, except for preventive vaccines, which have no cost sharing. Under the hospital outpatient prospective payment system (OPPS), cost sharing for Part B drugs furnished on a single day in the HOPD is capped by the inpatient deductible.[4] For Part B–covered insulin furnished via a durable medical equipment pump, monthly cost sharing has been capped at $35 since July 1, 2023.

Setting the payment rates

The prices of drugs covered by Medicare Part B range widely. Some of the most commonly used Part B drugs such as corticosteroids and vitamin B-12 injections are inexpensive, with an average annual payment per user of less than $25. In contrast, 14 of the 20 products that account for the greatest Part B drug expenditures have an annual payment per user that ranges from roughly $6,000 to $91,000 per year; some products are priced much higher. As of 2023, 16 of the top 20 highest-expenditure Part B drugs were biologics.

Most Part B drugs are paid based on the average sales price (ASP).[5] By statute, Medicare pays 106 percent of ASP (ASP + 6 percent) for drugs furnished in physician offices; oral anticancer, oral antiemetic, and immunosuppressive drugs; inhalation drugs; home infusion drugs; and clotting factor.

Medicare also pays ASP + 6 percent for separately payable Part B drugs furnished in HOPDs under the OPPS. For 340B hospitals, Medicare established a lower rate (ASP – 22.5 percent) for Part B drugs (except for those with pass-through status) between 2018 and 2022; however, in June 2022, the Supreme Court ruled that CMS's approach to establishing the lower payment amount was not consistent with its statutory authority.[6] In October 2022, CMS reverted to a payment rate of ASP + 6 percent for drugs furnished by 340B hospitals going forward; for drugs administered in the first part of 2022, hospitals could resubmit claims to obtain the higher ASP + 6 percent rate.[7]

In some settings, payment for some Part B drugs is bundled into payment for other services. Under the OPPS, low-cost drugs (with a cost per day of less than $140 in 2025) and certain types of drugs regardless of cost (e.g., drugs that function as supplies for certain tests or procedures) are bundled into the payment for other related services under the OPPS.[8] Most drugs for treatment of beneficiaries with end-stage renal disease are bundled into the prospective payment rate for outpatient dialysis.

A few types of Part B drugs—preventive vaccines, certain blood products, radiopharmaceuticals in physician offices, and compounded drugs—are paid under alternate methodologies instead of ASP + 6 percent.[9] Critical access hospitals and Maryland hospitals are also exempt from the ASP payment system.

In addition to Medicare's payment for a drug, Medicare makes an additional, separate payment to the physician or hospital for administering the drug (that is, for the act of injecting or infusing the product into the patient). The drug administration payment rates are determined under the physician fee schedule or OPPS, depending on the location of the service. Medicare also pays a dispensing or supplying fee

to pharmacies or other suppliers that dispense beneficiaries' inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs. In addition, Medicare pays a furnishing fee to providers of clotting factor products. For Part B–covered home infusion drugs, Medicare makes a separate payment to the supplier for the infusion pump and related supplies. Medicare also pays for nurse visits and other professional services associated with the provision of Part B–covered home infusion drugs.

Beginning January 1, 2023, manufacturers of Part B single-source drugs, biologics, and biosimilars are required to pay Medicare a rebate if the ASP for their product grows faster than inflation.[10] For products that incur a rebate, beginning April 2023, cost sharing is based on the inflation-adjusted ASP.

When drugs are furnished in single-dose containers or single-use packages, Medicare pays providers for the full labeled amount of drug in the container or package, including any portion that is not needed for the patient and is discarded. When drugs are furnished from multiple-dose containers, Medicare pays the provider only for the amount of drug administered to the patient and does not pay for discarded drug amounts. Beginning January 2023, manufacturers are required to provide a refund to Medicare for certain discarded amounts of Part B drugs furnished from a single-dose container or single-use package.

ASP payment system

Under the ASP payment system, Medicare pays providers ASP + 6 percent for the drug. ASP reflects the average price realized by the manufacturer for its sales, broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on manufacturers' sales to most purchasers net of manufacturer rebates, discounts, and price concessions (with certain exceptions).

Manufacturers report ASP data to CMS quarterly.[11] Since 2005, manufacturers with Medicaid rebate agreements have been required to report ASP data and, beginning 2022, manufacturers of Part B–covered drugs without a rebate agreement are also required to report ASP data.[12]

The ASP + 6 percent payment rates are updated quarterly. To permit time for manufacturers to submit ASP data and for CMS to calculate the payment rates, there is a two-quarter lag in the data used to set the ASP + 6 percent rates. That means, for example, that the ASP + 6 percent payment for the third quarter of the year is based on sales data from the first quarter of the year.

Payments for single-source drugs and originator biologics, multisource drugs, and biosimilars are set differently. Each single-source drug and originator biologic is paid under its own billing code at a rate equal to 106 percent of its own ASP. For multisource drugs, both the brand and generic versions are paid under a single billing code at the same rate (i.e., 106 percent of the weighted average ASP for all products assigned to that code). Each biosimilar is paid under its own billing code at a rate equal to 100 percent of its own ASP + 6 percent or, in certain circumstances, 8 percent of the originator biologic's ASP.[13] A biosimilar can receive an 8 percent add-on calculated based on the originator's ASP for up to five years (i.e., the first five years on the market for biosimilars launched before 2028 or five years beginning October 1, 2022, for biosimilars on the market as of that date) as long as the biosimilar's ASP does not exceed the originator's ASP.

ASP is the average price from the manufacturer's perspective. An individual provider or supplier may purchase a drug for more or less than ASP for a number of reasons. For example, prices paid might vary across purchasers of different sizes (e.g., due to volume discounts) or across types of purchasers (e.g., physicians, hospitals, and pharmacies). In addition, the two-quarter lag in ASP data can result in the average provider acquisition cost for a drug being different from the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that price change is reflected in the ASP data used to pay providers.

If a drug lacks ASP data, Medicare has alternative methods for paying for the product. When a new single-source drug or biologic or biosimilar to an originator biologic enters the market, Medicare lacks ASP data because it takes time for the manufacturer to report ASP data and for CMS to calculate payment rates based on those data. For the first two to three quarters a new product is on the market, Medicare pays wholesale acquisition cost (WAC) plus 3 percent.[14] WAC is an undiscounted list price that is typically higher than ASP. For drugs that are not new, Medicare may lack ASP data for other reasons, such as the manufacturer having no sales in a particular reporting quarter. In this situation, the payment method varies and may be 106 percent of WAC, 95 percent of average wholesale price, or invoice priced.[15] ■

1 Medicare Part B also covers some drugs in ambulatory surgical centers if they are considered integral to surgery and if they would have been covered in the HOPD if they had been administered in that setting.

2 Immunosuppressive drugs are covered by Part B for beneficiaries who have received a Medicare-covered organ transplant. Part B covers an oral anticancer drug if an infusible or injectable form of the same drug is covered by Part B. An oral antiemetic drug is covered by Part B within 24 or 48 hours of chemotherapy when it replaces a Part B–covered infusible or injectable antiemetic.

3 By statute, Part B also covers intravenous immune globulin (IVIG) administered in the home (a product that according to CMS policy does not require a Part B–covered infusion pump) for patients with primary immune deficiency. For these beneficiaries, Medicare also began covering nurse visits and administration supplies associated with home administration of IVIG effective January 2024.

4 Under the OPPS, the sum of cost sharing for Part B drugs furnished on a single day and for the procedure with the largest copayment on the claim cannot exceed the inpatient deductible ($1,676 in 2025).

5 Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and sales that are exempt from the determination of Medicaid best price (e.g., sales or discounts to other federal programs, 340B-covered entities, state pharmaceutical assistance programs, and rebates to Medicare Part D plans). The types of discounts that must be netted from ASP include volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and charge-backs and rebates (other than rebates under the Medicaid program). Bona fide service fees—for example, fees paid by the manufacturer to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and are for services the manufacturer would otherwise perform in the absence of the service arrangement—are not considered price concessions for the purposes of ASP.

6 OPPS separately payable drugs either have pass-through status or have a cost per day exceeding a threshold ($140 in 2025). By statute, CMS is required to pay pass-through drugs at a rate of ASP + 6 percent. Manufacturers can apply for pass-through status for new drugs or biologics whose cost is not insignificant in relation to the OPPS payments for the procedures or services associated with the new drug or biologic. Pass-through status lasts for at least two years but not more than three years.

7 In 2024, Medicare made separate lump-sum payments to 340B hospitals to compensate for reduced Part B drug payments received in 2018 through 2021.

8 Under the OPPS, drugs packaged into the payment for other services regardless of cost include anesthesia drugs; drugs that function as supplies when used in a diagnostic test or procedure (including contrast agents and stress agents); and drugs that function as supplies when used in a surgical procedure. Prior to 2025, diagnostic radiopharmaceuticals were also packaged into the payment for other services regardless of cost; beginning in 2025, diagnostic radiopharmaceuticals with a per day cost exceeding a diagnostic radiopharmaceutical packaging threshold ($630 in 2025) are separately paid.

9 Preventive vaccines and certain blood products (e.g., albumin) are paid 95 percent of the average wholesale price (AWP) or reasonable cost. Radiopharmaceuticals and compounded drugs billed by physicians are invoice priced by the Medicare claims-processing contractors or paid 95 percent of AWP.

10 The rebate generally applies to single-source drugs, biologics, and biosimilars, but certain types of products are exempt (e.g., low-cost drugs, preventive vaccines, drugs experiencing a shortage or supply-chain disruption, and biosimilars meeting certain criteria). Certain Medicare Part B utilization is also exempt from rebates, such as utilization subject to a 340B discount or Medicaid rebate and utilization for which payment is packaged.

11 To help ensure that ASP data reported by manufacturers are in line with other pricing metrics, Medicare has the authority to substitute a lower amount for the ASP + 6 payment rate in certain situations. If the Office of Inspector General finds that the ASP for a drug exceeds the average manufacturer price (AMP) by 5 percent over several quarters, CMS can establish a payment rate equal to AMP + 3 percent instead of ASP + 6 percent. AMP is the weighted average of retail prices for all of a manufacturer's package sizes of a drug. In recent years, CMS has substituted an AMP-based price for an ASP-based price for a small number of drugs each quarter.

12 Although prior to 2022, manufacturers without a Medicaid rebate agreement were not required to report ASP data, some reported data voluntarily.

13 CMS changed its policy on the assignment of billing codes for biosimilars in the second quarter of 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 retained its own billing code). Beginning in the second quarter of 2018, each biosimilar receives its own billing code.

14 Beginning July 1, 2024, during the initial quarters when ASP data are unavailable for a biosimilar, the biosimilar's payment of WAC + 3 percent is capped by the originator's payment amount.

15 Average wholesale price is a list price that does not represent the actual price in the marketplace. Invoice pricing is an approach used by the Medicare administrative contractors to determine the payment rate for a drug based on an invoice submitted by the provider showing their acquisition cost for the product.