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IN FOCUS

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Medicare Part B Drugs Overview

Introduction

Between 2017 and 2022, spending on drugs dispensed outside of retail settings grew nationally at an annual rate of 9.4%, outpacing the 6.5% annual growth in spending on drugs in retail settings, such as retail pharmacies. The Medicare program covers these nonretail drugs, such as novel oncology and immunology treatments, under Part B. The annual growth rate in per enrollee spending under Fee-for-Service (FFS) Medicare for all Part B drugs was over three times the growth rate of Medicare Part D drugs between 2008 and 2021, and four times that of prescription drug spending in the United States in general. This In Focus provides an overview of the drugs covered under Medicare Part B, how they are reimbursed under FFS Medicare, and relevant policy developments relating to these drugs.

Medicare Coverage Background

Medicare is a federal program that pays for covered health care services of qualified beneficiaries. There are four distinct parts of Medicare: Part A (hospital insurance), Part B (supplementary medical insurance), Part C (also known as Medicare Advantage), and Part D (an outpatient prescription drug benefit). Together, Parts A and B of Medicare are often referred to as Original or Fee-for-Service Medicare. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS). Medicare beneficiaries enrolled in both Parts B and D can access outpatient prescription drugs through each benefit, depending on the type of drug and/or its route of administration. Medicare Part D covers the majority of self-administered outpatient prescription drugs dispensed in retail pharmacies, while Part B covers a variety of drugs (described below) that are typically not self-administered or available through retail pharmacy settings.

Medicare Part B Drugs

In general, for drugs to be covered under Medicare Part B, they must fall within a Medicare benefit category, be deemed to be reasonable and necessary for the diagnosis or treatment of an illness or injury, and not be excluded by statute. The largest category of Part B drugs is those administered in physicians' offices and hospital outpatient departments (HOPDs), rather than in retail settings such as a retail pharmacy. This includes drugs that are furnished incident to a physician's services and typically not self-administered, such as injectable drugs for the treatment of rheumatoid arthritis or an infusion of chemotherapy. A small number of self-administered drugs are covered under Part B rather than Part D under certain conditions, such as pre-exposure prophylaxis (PrEP) for HIV prevention, oral anticancer drugs, oral antiemetics, and immunosuppressive drugs.

Drugs that are supplies to an item of Durable Medical Equipment (DME) also qualify as Part B drugs. For example, Part B covers insulin provided through a pump that qualifies as DME, certain inhalation drugs that are administered through a nebulizer, and certain drugs that are infused at home through a qualifying infusion pump.

Medicare Part B also covers drugs for the treatment of End-Stage Renal Disease (ESRD), as well as certain preventive vaccines: the influenza vaccine, the COVID-19 vaccine, the pneumococcal vaccine, and the hepatitis B vaccine (subject to certain restrictions). Blood clotting factors, whether self-administered or administered in an inpatient or outpatient setting, are also set in statute as Part B drugs.

Payment for Part B Drugs

The payment system for Part B drugs differs considerably from the Part D drugs payment system. Under FFS Medicare, beneficiaries generally pay 20% coinsurance for Part B drugs after meeting the Part B deductible, with the exception of insulin products, for which there is a fixed $35 copayment amount, and preventive vaccines, for which there is no cost-sharing. Providers receive a payment for administering a Part B drug generally made through payment systems such as the Physician Fee Schedule (PFS) or the Hospital Outpatient Prospective Payment System (OPPS), depending on the setting. In addition to administration payment, FFS Medicare uses a variety of different methodologies to reimburse providers for the cost of the Part B drug itself.

Average Sales Price Methodology

Since January 2005, FFS Medicare has paid for most Part B drugs based on 106% of the volume-weighted Average Sales Price (ASP) for each drug. The ASP is defined in statute as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions provided by the manufacturer.

Manufacturers must provide CMS with data on their ASP amounts and the volume of sales for each drug (reported by national drug code, NDC) on a quarterly basis. There is a two-quarter lag between the sales period for which ASPs are reported by drug manufacturers and the effective date of the reimbursement amount. During this lag, or in certain other cases, CMS may substitute ASP with other pricing measures, such as Average Wholesale Price (AWP) or wholesale acquisition cost (WAC). Medicare also pays supplying fees to pharmacies for certain drugs, such as inhalation therapies, in addition to the ASP payment.

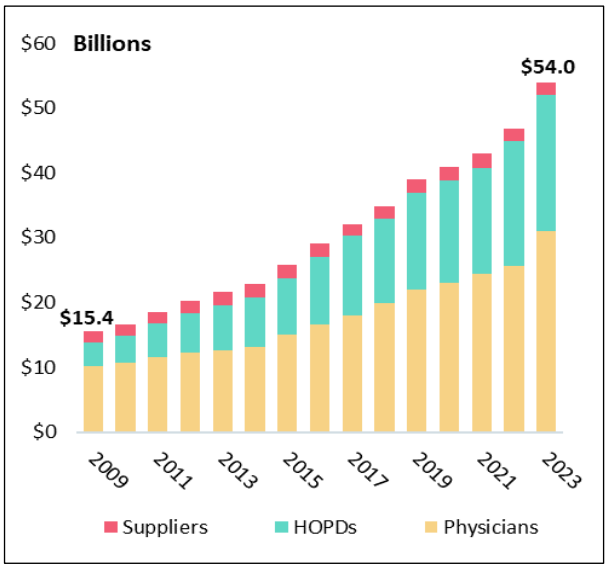
Non-ASP Pricing Methodologies

Some Part B drugs are not paid for under the ASP methodology. For example, preventive vaccines are reimbursed at 95% of AWP, or in certain settings, a payment based on reasonable cost. Most drugs for the treatment of ESRD are folded into the ESRD Prospective Payment System, which pays a bundled rate for the services associated with dialysis treatment. Certain drugs provided in HOPDs, such as those that do not meet a cost threshold, are paid for through the Outpatient Prospective Payment System.

Expenditures on Part B Drugs

As shown in **Figure 1**, expenditures on Part B drugs have grown steadily in recent years, with an increasing proportion of expenditures concentrated in HOPDs. Over half of 2023 expenditures were on three therapeutic classes: antineoplastics (anti-cancer drugs), ophthalmic agents, and skin substitutes. Expenditures on skin substitutes have increased substantially over the past five years, but recently finalized changes to their payment methodology could result in reduced expenditures on certain types of skin substitutes in the future, as some products will no longer be reimbursed using ASP.

Figure 1. FFS Medicare Spending on Part B Drugs, 2009-2023, in Nominal Dollar Amounts



Source: MedPAC and Acumen LLC analysis of Medicare claims data.

Notes: Suppliers include pharmacies, DME suppliers, and other nonphysician or HOPD sites that dispense Part B drugs. Data exclude those drugs furnished by critical access hospitals, Maryland hospitals, and dialysis facilities. Expenditures include both program payments and beneficiary cost sharing. Data reflect all Part B drugs, whether they were paid based on the average sales price or other methods. Data exclude blood and blood products (other than clotting factor).

Recent Policy Developments

Congress has acted several times in recent decades to modify coverage of and payment for Part B drugs. Most recently, P.L. 117-169, the FY2022 reconciliation law, included several provisions designed to reduce program expenditures. Section 11403 temporarily increased the payment for qualifying biosimilars from 100% of their ASP plus 6% of their reference product's ASP to 100% of their ASP plus 8% of their reference product's ASP for the third quarter of 2022 through the fourth quarter of 2027. This payment increase was intended to improve access to biosimilars and encourage price-based competition between biosimilars and their reference products, and, over time, to lower expenditures on biologics, which have been a significant driver of increased Part B drug expenditures.

P.L. 117-169 also created the Medicare Drug Price Negotiation Program (MDPNP), which allows the Secretary of Health and Human Services to negotiate the prices of certain high-expenditure Part B and Part D drugs. Part B drugs became eligible for negotiation in 2026, and five-Part B-covered high-expenditure drugs were chosen for negotiation. The negotiated maximum fair prices (MFPs) for these drugs are to go into effect in 2028. Medicare would then reimburse providers for those drugs at 106% of the MFP rather than 106% ASP, and beneficiary coinsurance would similarly be based on 20% of MFP.

Since the passage of P.L. 117-169, a number of modifications to the MDPNP have been considered. P.L. 119-21, the FY2025 reconciliation law, included a provision that expanded the number of drugs that are excluded from negotiation. Other legislation, such as S. 1836, the SMART Prices Act (119th Congress), would expand the number of drugs negotiated each year, while other bills, such as H.R. 4299, the Protecting Patient Access to Cancer and Complex Therapies Act (119th Congress), would maintain the 106% of ASP payment to providers for negotiated drugs and have the MFP effectuated to Medicare as a manufacturer rebate, rather than as a rebate to providers.

Another approach to reducing expenditures for Part B drugs has been Most-Favored Nation (MFN) pricing models. Studies have consistently found higher list prices for brand-name drugs in the United States compared with other countries, and MFN models generally incorporate these international reference prices as constraints on domestic reimbursement. An initial MFN model for Part B drugs created by the Center for Medicare and Medicaid Innovation (CMMI) under the first Trump Administration was challenged in court and subsequently withdrawn.

CMMI has issued a notice of proposed rulemaking on a new MFN demonstration: the GLOBE (Global Benchmark for Efficient Drug Pricing) model. The GLOBE model builds on inflation rebates created by the IRA for Part B drugs. Drug manufacturers are required to pay the federal government a rebate if the payment amount of certain Part B drugs exceeds those drugs' inflation-adjusted payment amount. The GLOBE model would create an alternative rebate payment calculation for certain high-expenditure rebatable Part B drugs, based on the difference between the drug's payment amount and an international benchmark.

Some bills have also proposed their own MFN methodologies, through legislation such as S. 1753/H.R. 3391, the End Price Gouging for Medications Act, which would direct the Department of Health and Human Services to establish international reference pricing benchmarks for drugs and apply them as ceiling prices across programs.

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