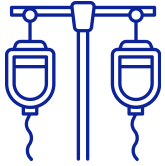


Background



Certain drugs, biologicals, and other products are eligible for separate payment under Medicare Part B, up to a specified payment limit. Section 1847A and section 1842(o) of the Social Security Act (the Act) provide more detailed explanations of the different pricing methodologies, including Average Sales Price (ASP). Generally, CMS publishes the specified payment limit applicable to each drug or biological on a quarterly basis. Most drugs and biologicals separately payable under Medicare Part B have a payment limit of ASP plus 6 percent, but in some instances, the payment limit is established using a different methodology. Part B payment limits may also apply to certain drugs paid under the End-Stage Renal Disease (ESRD) Prospective Payment System if the drug or biological receives the Transitional Drug Add-on Payment Adjustment or is used for reasons other than the treatment of ESRD, and the Outpatient Prospective Payment System (OPPS) if the drug or biological is not paid for as part of a prospective, bundled payment.

Average Sales Price (ASP) Payment Limit

All Part B drug manufacturers must report ASP data for Part B-covered drugs and biological products and related items, services, supplies, and products that are paid as drugs or biological products. They must calculate the manufacturer's ASP each calendar quarter and submit it no later than 30 days after the last day of each calendar quarter. The manufacturer's ASP must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (NDC) (with certain exclusions, refer to the 'ASP Report in Units other Than NDC' document found at the bottom of the [ASP Reporting page](#)) and then deducting many price concessions such as discounts as defined in section 1847A(c) of the Act. CMS uses these data to calculate payment limits quarterly. (Refer to sections [42 CFR § 414.804](#) and [42 CFR § 414.904](#).) Payment limits are published in the Medicare Part B Drug Payment Limit File at the Healthcare Common Procedure Coding System (HCPCS) code level. For more information on the specifics of that calculation, refer to [Frequently Asked Questions \(FAQs\): ASP Data Collection](#).

When is ASP Used?

- For most drugs and biologicals not paid on a cost basis or included in a prospective, bundled payment, the payment limit is 106 percent of ASP. If there are multiple NDCs within a HCPCS code, CMS calculates a volume-weighted ASP.
- For biosimilars, the payment limit is:
 - The biosimilar's ASP plus 6 percent of the reference biological's ASP, or
 - The biosimilar's ASP plus 8 percent of the reference biological's ASP for qualifying biosimilars as described in section 1847A(b)(8)(B) of the Act.

Other Payment Methodologies

Payment limits are usually 106 percent of ASP. Exceptions to this are listed in the [Medicare Claims Processing Manual, Pub. 100-04, Chapter 17, section 20.1.3](#), unless statute, regulation, or policy supersedes the Manual. Some substitutions include:

Wholesale Acquisition Cost (WAC)

WAC is the manufacturer's list price for wholesalers or direct purchasers in the U.S., not including prompt payment or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug pricing data (e.g., RedBook, Medi-Span). Typically, WAC is higher than ASP, but the magnitude of the difference varies. For more information on WAC, refer to section 1847A(c)(6)(B) of the Act.

When is WAC Used?

- During the initial sales period when ASP is not yet available, the payment limit is an amount not to exceed 103 percent of WAC. Refer to section 1847A(c)(4)(B)(i) of the Act.
- For some drugs that do not appear on the Medicare Part B Payment Limit File (other than new drugs), Medicare Administrative Contractors (MACs) may determine payment limits by calculating 106 percent of the lesser of the lowest-priced brand or median generic WAC.
- In some cases, when the ASP is greater than WAC for a single-source drug or biological, the payment limit is 106 percent of WAC. Refer to section 1847A(b)(4) of the Act.
- For biosimilars whose reference biological's ASP is greater than WAC, the 6 percent or 8 percent add-on payment is based on the reference biological's WAC.

Average Wholesale Price (AWP)

AWP is set using industry-recognized AWP reference sources (e.g., RedBook, Medi-Span), as there is no statutory definition.

When is AWP Used?



- The payment limits for pneumococcal, influenza, COVID-19, and Hepatitis B Virus vaccines under Medicare for Part B are 95 percent of AWP. Refer to section 1842(o)(1)(A)(iv) of the Act.
- For OPPS drugs, the payment limit is 95 percent of AWP when a HCPCS code has not been assigned. Refer to section 1833(t)(15) of the Act.



Part B Drug Payment Limits Overview

Average Manufacturer Price (AMP)

AMP is the average price paid to the manufacturer for the drug in the U.S. by wholesalers for drugs distributed to the retail pharmacy class of trade, excluding “customary prompt pay discounts extended to wholesalers.” This retrospectively calculated price is typically higher than ASP. For more information on AMP, refer to section 1927(k)(1) of the Act.

When is AMP Used?

CMS uses AMP when the Office of Inspector General (OIG) informs CMS that a product’s ASP is at least 5 percent higher than its AMP; the ASP for the billing code has exceeded the AMP for the billing code by 5 percent or more in two consecutive quarters, or three of the previous four quarters immediately preceding the quarter to which the price substitution would be applied; and the AMP for the billing code is calculated using the same set of NDCs used for the ASP for the billing code. Refer to [42 CFR § 414.904\(d\)\(3\)](#).

Widely Available Market Price (WAMP)

WAMP is the price that a prudent physician or supplier would pay for the drug after accounting for the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers. For more information on WAMP, refer to section 1847A(d)(5)(A) of the Act.

When is WAMP Used?

CMS uses WAMP when OIG informs CMS that the ASP has exceeded the WAMP by the applicable threshold percentage of 5 percent and will remain in effect for one quarter after publication. Refer to [42 CFR § 414.904\(d\)\(3\)](#).

Maximum Fair Price (MFP)

Under the Medicare Drug Price Negotiation Program CMS negotiates a maximum fair price (MFP) for certain high-cost, single-source drugs, which are referred to as selected drugs. Refer to [Selected Drugs and Negotiated Prices](#).

When is MFP Used?

- Beginning in the initial price applicability year 2028, for selected drugs payable under Part B, section 1847A(b)(1)(B) of the Act sets the Medicare Part B payment limit during the price applicability period as 106 percent of the MFP.
- For selected drugs having a negotiated price during the initial price applicability year (2026-2027) that have utilization under Medicare Part B, the payment limit will not be based on the MFP unless it is selected for renegotiation as stated in section 1194(f)(3) of the Act.



Part B Drug Payment Limits Overview

Payment for Drugs Covered as Additional Preventative Services (DCAPS)

The authority to provide payment limits for a DCAPS drug is described in 1833(a)(1)(W)(ii) of the Act. Currently HIV pre-exposure prophylaxis (PrEP) drugs are the only drugs paid under this authority. Payment limits for DCAPS are determined using the fee schedule described in [42 CFR § 410.152\(o\)\(3\)](#). Payment limits determined using this fee schedule are updated regularly and published in the [Medicare Part B Payment Limit File](#).

How are DCAPS Paid?

- If ASP data are available, the payment limit is calculated consistent with other drugs and biological products paid using the ASP methodology.
- If ASP data are not available, the payment limit is calculated using the most recently published amount for the drug in [Medicaid's National Average Drug Acquisition Cost \(NADAC\) survey](#).
- If ASP and NADAC pricing data are not available, the payment limit is determined using drug pricing information from the Department of Veteran's Affairs' Federal Supply Schedule (FSS) pharmaceutical pricing database that is publicly available at the NDC level and published at the [U.S. Department of Veteran's Affairs Office of Procurement, Acquisitions and Logistics Pharmaceutical Prices website](#).
- If ASP data, NADAC prices, and FSS prices are not available, the payment limit is the invoice price determined by the MAC.

Contractor Pricing

MACs may develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the Medicare Part B Payment Limit File. For more information on Contractor Pricing, refer to the [Medicare Claims Processing Manual Chapter 17, section 20.1.3](#).

When is Contractor Pricing Used?

Generally, MACs may set payment limits for drugs and biologicals that are not included in the Medicare Part B Drug Payment Limit File or Not Otherwise Classified Pricing File, as follows:

- New drugs (before an ASP payment limit is available): based either on the published WAC or invoice pricing. For claims with dates of service on or after January 1, 2019, when WAC is used, an add-on percentage of up to 3 percent applies.
- For drugs (other than new drugs): based either on the published WAC or invoice pricing. For additional details, refer to [Medicare Claims Processing Manual Chapter 17, section 20.1.3](#).