Part B Drug Payment Limits Overview

Background

Certain drugs, biologicals, and other products (e.g., skin substitutes) 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 covered drug or biological on a quarterly basis. Medicare pays for most separately payable drugs and biologicals at a rate of ASP plus 6%, 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

Manufacturers report ASP sales data to CMS after the end of each calendar quarter. The reported manufacturer's ASP accounts for United States (US) drug sales (with certain exclusions) and includes many price concessions such as discounts as defined in section 1847A(c) of the Act. CMS uses these data to calculate the ASP payment limits on a quarterly basis. (Refer to 42 CFR § 414.804 and 42 CFR § 414.904.) Payment limits are available in the ASP pricing files at the Healthcare Common Procedure Coding System (HCPCS) code level. If there are multiple National Drug Codes (NDCs) within a HCPCS code, CMS calculates a weighted-average ASP. 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% of ASP.
- For biosimilars, the payment limit is:
  - 106% of the reference product's ASP, or
  - 108% of the reference biological's ASP temporarily for certain biosimilars as described in section 1847A(b)(8)(B) of the Act.

Payment to providers is generally at a rate of 106% of ASP. Exceptions to this general rule are listed in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 17 unless statute, regulation, or policy supersedes the Manual.

OTHER PAYMENT METHODOLOGIES

Wholesale Acquisition Cost (WAC)

WAC is the manufacturer's list price for wholesalers or direct purchasers in the US, 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 103% of WAC. Refer to Section 1847A(c)(4)(B)(i) of the Act.
- For some drugs that do not appear on the ASP pricing files and for which the Medicare Administrative Contractors (MACs) calculate the payment limits, the payment limit is 106% of WAC.
- In some cases when the ASP is greater than WAC for a single-source drug or biological, the payment limit is 106% of WAC. Refer to Section 1847A(b)(4) of the Act.
- For biosimilars whose reference biological's ASP is greater than WAC, the 6% or 8% 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, MediSpan), 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% of AWP. Refer to Section 1842(o)(1)(A)(iv) of the Act.
- For OPPS drugs, the payment limit is 95% of AWP when a HCPCS code has not been assigned. Refer to Section 1833(t)(15) of the Act.

Average Manufacturer Price (AMP)

AMP is the average price paid to the manufacturer for the drug in the US 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% higher than its AMP; the ASP for the billing code has exceeded the AMP for the billing code by 5% 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).

OTHER PAYMENT METHODOLOGIES

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% and will remain in effect for one quarter after publication. Refer to 42 CFR § 414.904 (d)(3).

Contractor Pricing

MACs may develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing files. For more information on Contractor Pricing, refer to the Medicare Claims Processing Manual Chapter 17 20.1.3.

When is Contractor Pricing Used

Generally, MACs may set payment limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing 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, there is an add-on percentage of up to 3%.
- 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.

Payment for Drugs Covered as Additional Preventive Services (DCAPS)

The authority to provide payment limits for a DCAPS drug is described in 1833(a)(1)(W)(ii) of the Act. DCAPS, e.g., HIV PrEP drugs, are paid using ASP methodology. When ASP data are not available for a particular DCAPS drug, CMS uses an alternative pricing mechanism as described below. For more information on DCAPS, refer to Section 42 CFR § 410.152(o).

- First, CMS determines the payment limit for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey.
- If NADAC pricing data are not available for a particular DCAPS drug, CMS uses drug pricing information from the Department of Veterans Affairs' Federal Supply Schedule (FSS) pharmaceutical pricing database that is publicly available at the NDC level and published at the U.S. Department of Veterans Affairs Office of Procurement, Acquisition and Logistics Pharmaceutical Prices website.
- If ASP data, NADAC prices, and FSS prices are not available, the payment limit would be the invoice price determined by the MAC.