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 Prospective Payment System (ESRD PPS) if the drug or biological receives the Transitional Drug Add-on Payment Adjustment (TDAPA) 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 Sections 42 CFR 414.804 and 42 CFR 414.904.) Payment limits are available in the ASP pricing files at Healthcare Common Procedure Coding System (HCPCS) code level.

When ASP is Used

- For most drugs and biologicals not paid for on a cost basis or included in a prospective, bundled payment, the payment limit is 106% of ASP.
- For biosimilars, the payment limit is:
  - The biosimilar's ASP plus 6% of the reference biological's ASP, or
  - The biosimilar's ASP plus 8% of the reference biological's ASP temporarily for certain biosimilars as described in section 1847A(b)(8)(B) of the Act.

For more information visit: CMS ASP Website

Contact us at: sec303aspdata@cms.hhs.gov

OTHER PAYMENT METHODOLOGIES

Payment to providers is generally set 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. Some substitutions include:

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. *Section 1847A(c)(6)(B) of the Act*

When WAC is Used

- During the initial sales period when ASP is not yet available, the payment limit is 103% of WAC. *Section 1847A(c)(4)(A)(ii)(I) of the Act*
- For some drugs that do not appear on the ASP pricing files and for which the payment limits are calculated by the Medicare Administrative Contractors (MACs), 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. *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, Medi-Span), as there is no statutory definition.

When AWP is Used

- The payment limits for pneumococcal, influenza, COVID-19, and Hepatitis B Virus vaccines under Medicare for Part B are 95% of AWP. *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. *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. *Section 1927(k)(1) of the Act*

When AMP is Used

- CMS uses AMP when the HHS 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. *Section 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. *SSA 1847A(d)(5)(A)*

When WAMP is 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. *Section 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. *Medicare Claims Processing Manual Chapter 17 20.1.3*

When Contractor Pricing is 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 (NOC) Pricing File, as follows:

- New drugs (before an ASP payment limit is available): for claims with dates of service on or after January 1, 2019, the add-on percentage for WAC-based payments determined by MACs is 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*.