Average Sales Price (ASP) Quarterly Publication Process

Frequently Asked Questions

Version 2.0

Date: January 17, 2025

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Revision History

Table 1: Revision History

Version Number	Date	Author/Editor	Description of Change
0.1	12/06/2023	Index Analytics	Initial draft
0.2	12/20/2023	HHS/OGC	Edited document; provided feedback
0.3	01/09/2024	CMS	Edited document; provided feedback
0.4	01/11/2024	Index Analytics	Incorporated feedback from CMS
0.5	02/22/2024	CMS	Edited document; provided feedback
1.0	03/04/2024	Index Analytics	Incorporated feedback from CMS
1.1	03/11/2024	Index Analytics	Incorporated additional feedback from CMS
2.0	01/17/2025	Index Analytics	• Updated to refine answers • Incorporated additional feedback from CMS • Adjusted the numbering to include each individual question for reference purposes • Added *Section 5 - Alternate ID Data Entry Questions* • Incorporated additional questions to address Calendar Year (CY) 2025 Physician Fee Schedule (PFS) final rule • Various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections

Purpose

The purpose of this document is to provide answers to Frequently Asked Questions (FAQs) from interested parties about Average Sales Price (ASP) data collection, calculation, and publication processes, as well as the system that the Centers for Medicare & Medicaid Services (CMS) uses to collect ASP data from manufacturers.

1. General Questions

This section covers general Average Sales Price (ASP) questions.

1.1 *Why do manufacturers have to report ASP data to CMS?*

This reporting is required by law.

Specifically, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included several provisions related to drug coverage and payments in the Medicare program. One of the provisions established ASP reporting requirements for Medicare Part B covered outpatient drugs and biologicals with a Medicaid drug rebate agreement not paid on a cost or prospective payment system basis.

The scope of the ASP data reporting requirement was expanded per Section 401 of the Consolidated Appropriations Act (CAA), 2021. CAA 2021 required all manufacturers of drugs and other products (e.g., skin substitutes) payable under Medicare Part B, to begin reporting ASP data to CMS.

This provision amended Section 1847A of the Social Security Act (the Act) to add new Section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS quarterly beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in Sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. With this amendment, all manufacturers participating in Medicare Part B are required to report data regardless of whether the manufacturer has a Medicaid drug rebate agreement in place or not.

CMS reviews and analyzes the ASP data to calculate the payment limits for drugs, biologicals, and other products (e.g., skin substitutes) payable under Medicare Part B. The calculated payment limits correspond to the Healthcare Common Procedure Coding System (HCPCS) codes for the drugs, biologicals, and other products.

When applicable, CMS maps (i.e., crosswalks) National Drug Codes (NDCs) to HCPCS for payment purposes. CMS publishes files called crosswalks to help the public (including entities that submit manufacturer average sales price data and providers who bill for drugs) understand which drug products (identified by NDCs) are assigned to which HCPCS billing codes.

More information on statutes, regulations, and rulings that apply to ASP pricing and ASP reporting is listed on the Medicare Part B Drug Average Sales Price website.

1.2 *Can CMS provide guidance regarding ASP reporting and other policies?*

Generally, CMS does not give specific or individual ASP reporting guidance to manufacturers or third-party vendors. ASP reports are subject to specific statutory requirements. You can find the statutory requirement regarding ASP reporting and how to calculate the ASP in Sections 1847A and 1927(b) of the Act, and codified in the regulation text at 42 CFR Part 414 Subpart J and Subpart K.

1.3 *What happens if a manufacturer does not provide the required information by the reporting deadline?*

CMS will report any known issues with timely reporting to the Office of Inspector General (OIG). Under Section 1847A(d)(4) and 1927(b)(3)(C) of the Act, a failure to provide timely information shall result in a penalty of $10,000 for each day that such information goes unreported.

1.4 *If a manufacturer has general questions or needs guidance related to ASP reporting, how should they contact CMS?*

Manufacturers can submit questions to sec303aspdata@cms.hhs.gov. We can provide confirmation that your submission has been received but are not able to confirm the accuracy of the data submitted. We can direct you to official guidance and information posted on our website, and regulatory sites, but are not able to provide specific guidance pertaining to your specific product. CMS will not offer specific ASP instruction outside of published guidance. Please pay attention to all deadlines, as late submissions will not be incorporated into the ASP pricing files. CMS will acknowledge every email that is received in the ASP Mailbox, generally within 24 hours. We will respond to your question as quickly as we can. In certain cases, CMS may not be able to respond to your inquiry until after the ASP pricing files have been published.

2. Reporting of ASP Data Questions

This section covers the basics of who, what, when, and where, as it applies to the manufacturer reporting and CMS processing of Average Sales Price (ASP) data.

2.1 *Who must report ASP data to CMS?*

All manufacturers of drugs and biologicals payable under Medicare Part B must report ASP data, including items, services, supplies, and products that are paid as drugs or biologicals.

This requirement applies to manufacturers as defined at 42 CFR § 414.802 as follows:

Manufacturer means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs, or a retail pharmacy licensed under State law):

- Production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis
- Packaging, repackaging, labeling, relabeling, or distributing prescription drug products

2.2 What data must be reported?

CMS primarily uses ASP as the reference payment limit for drugs and biologicals payable under Medicare Part B that are not paid for on a cost or prospective payment basis. The data must include details such as the manufacturer's name, the drug's National Drug Code (NDC) or Alternate ID, its ASP, as well as sales volume including the manufacturer's sales to all purchasers in the United States with limited exceptions (refer to Section 1847A(c)(1)(A), (2) of the Act).

2.3 What is the definition of United States for the purposes of reporting ASP data?

For the purposes of reporting ASP data, the United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa, as defined in 42 CFR § 447.502.

2.4 What is an example of a drug paid on a cost or prospective payment basis?

Examples of drugs paid on a cost or prospective payment basis include:

- Certain drugs furnished by End Stage Renal Disease (ESRD) facilities.
- Drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.
- Drugs used with Hospital Outpatient Prospective Payment System (OPPS) services whose costs are packaged into the cost of the services.

2.5 When must data be reported?

As stated at 42 CFR § 414.804, the manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the previous quarter. ASP payment limits reflect sales that occurred two quarters prior (also known as a two-quarter lag).

Table 2 provides an example of ASP data collection dates for each sales quarter.

Table 2: ASP Data Collection Dates Example

Quarter	Sales Dates	Close of the Manufacturer's Data Submission Window	Medicare Payment Effective Date
1	January 1 to March 31	April 30	July 1
2	April 1 to June 30	July 30	October 1
3	July 1 to September 30	October 30	January 1
4	October 1 to December 31	January 30	April 1

2.6 What is the general process for payment limit determination and publishing the ASP pricing files?

Refer to *Figure 1* for a visual depiction of the general process flow for ASP payments.

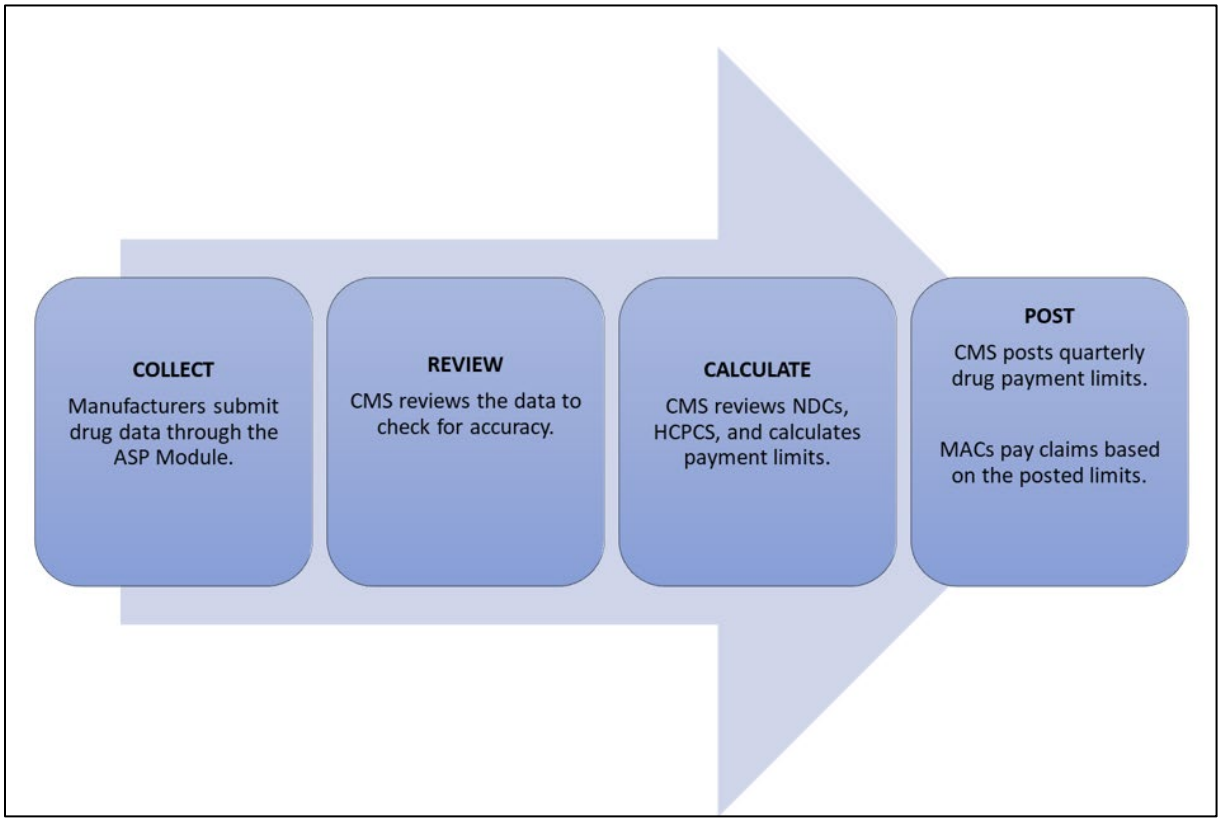

Figure 1: General Process Flow for ASP Payment Process

2.7 Where are ASP data submitted?

CMS uses the Fee for Service Data Collection System (FFSDCS) ASP module to collect ASP data. Manufacturers must submit data through the ASP module by manually typing in the required data or by uploading their data using the Financial Data Template, which includes submission instructions.

2.8 Are submitted ASP data kept confidential?

Data collected through the ASP module will not be released or shared with the public. We cannot release information about specific manufacturers or specific products due to statutory confidentiality provisions that limit the release of ASP data as specified in Section 1847A(f) of the Act, which include confidentiality provisions in Section 1927(b)(3)(D) of the Act.

2.9 Our company recently acquired these products. Who is responsible for reporting for this quarter?

The company who is actively marketing and selling the product should report sales for the NDC/Alternate ID associated with their company. In other words, the previous company should

report sales through the end of their ownership. Your company should begin reporting on your sales after the acquisition date. If your company is going to sell the product under a different name and/or NDC/ALT ID, please make sure to register your product first.

2.10 *If a manufacturer has a private label contract to manufacture a product for a distributor, who should submit the ASP?*

Generally, the labeler of the final product (owner of the product ID) must report the ASP data.

2.11 *If a manufacturer sells their product(s) to one or more distributors, who should submit the ASP?*

Generally, manufacturers are required to report ASP data, not the wholesalers or distributors.

2.12 *If a manufacturer sells their product(s) to physician offices at a higher price than to hospitals, is it compliant to only report the physician office sales in order to maintain a high ASP?*

Section 1847A of the Act states that the manufacturer's ASP includes "the manufacturer's sales to all purchasers" so all sales should be reported.

3. System Technology Questions

This section covers questions on the Fee for Service Data Collection System (FFSDCS) ASP module and technical support.

3.1 *How do users register for the FFSDCS ASP module?*

Manufacturers who have not previously reported Average Sales Price (ASP) to CMS may visit the CMS Enterprise Portal to register for the system. Users must create an Identity Management (IDM) account in the CMS Enterprise Portal before accessing the ASP module. Instructions on how to register are provided in the ASP Data Collection System user guide located in the Resource Library on the CMS ASP Education and Outreach page.

3.2 *Why are users required to enter their IDM credentials to access the FFSDCS ASP module?*

CMS uses the IDM system to verify the identities of all people requesting access to their applications hosted on the CMS Enterprise Portal. The ASP module is integrated with the CMS Enterprise Portal and is only accessible through the Portal.

3.3 *What is the difference between a Submitter and a Certifier?*

The Submitter and Certifier should be two different authorized representatives from the drug manufacturer.

The End-User or Submitter role is for drug manufacturer representatives with authority to provide and submit ASP data to CMS.

The Certifier role is for drug manufacturer representatives with authority to review the information entered by the Submitter for accuracy and completion. The Certifier verifies the submission of the reported data. As stated in 42 CFR § 414.804(a)(7), the Certifier should be the manufacturer's Chief Executive Officer (CEO) or Chief Financial Officer (CFO) or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

3.4 *What resources are available for FFSDCS ASP module users?*

Refer to the Medicare Part B Drug ASP website for user guides and data templates for use within the system.

3.5 *Where can I find definitions for fields in the ASP Data Collection System?*

Definitions for fields in the ASP Data Collection System can be found in three places:

- As hover-over tool tips when entering data manually;
- On the Instructions Tab of both the financial and product data templates within the ASP Data Collection System; and
- In the Appendix section of the user guides.

3.6 *Who can I reach out to for technical support?*

For questions related to the FFSDCS ASP module or technical support within the module, please use the contact information in *Table 3*.

Table 3: ASP Module Technical Support Contact Details

Contact Detail	Description
Email	ASPHelpDesk@dcca.com
Phone	1-844-876-0765
Availability	Available 9:00 a.m. to 6:00 p.m. Eastern Standard Time (EST), Monday through Friday

4. General Data Entry Questions

This section covers general data entry questions for submitting Average Sales Price (ASP) data.

4.1 *What is a unit of a drug?*

The term "unit" is used in multiple fields throughout the ASP Data Collection System. For the purposes of ASP data submissions, the term "unit" (defined at Section 1847A(b)(2)(B) and codified at 42 CFR § 414.802) is defined, in regards to each 11-digit National Drug Code (NDC) (including package size) associated with a drug or biological, as the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a NDC varies.

Note that the definition of “unit” is different than the term “billing unit” (defined in Section 1847A(b)(6)(B) of the Act), which means the identifiable quantity associated with the billing and payment code.

4.2 What if no units or drugs were sold in a quarter?

Manufacturers should report zero sales for the NDC if no “units” and no drugs were sold during that quarter. Additionally, zero or negative sales can be reported in the case of a recall.

4.3 Are there any circumstances where manufacturers should report data based at the Healthcare Common Procedure Coding System (HCPCS) level rather than NDC level?

Yes, the sales for certain drugs that contain variable amounts of product, such as radiopharmaceuticals and blood clotting factors, should be reported to CMS at the HCPCS level rather than the NDC level. CMS maintains and publishes a list of these drugs on a quarterly basis to the ASP Reporting page under the Reporting Resources Section. If you are a manufacturer of a drug that contains variable amounts of product, please check the “ASP Report in Units Other than NDC” document prior to submitting your financial data for the quarter. Should you have any questions, please contact sec303aspdata@cms.hhs.gov.

4.4 The ASP Data Collection System asks for the manufacturer’s average sales price. How is that calculated?

The manufacturer's ASP is defined in Section 1847A(c) of the Act and its calculation is codified at 42 CFR § 414.804(a), which states the manufacturer's ASP for a quarter for a drug represented by a particular 11-digit NDC must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit NDC (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

4.5 Should manufacturers include prices negotiated by prescription drug plans in their average sales price data submitted to CMS?

Manufacturers should exclude any prices negotiated by a prescription drug plan (including a Medicare Advantage plan) or by a qualified retiree prescription drug plan (as defined in Section 1860D-22(a)(2)) on behalf of Part D eligible individuals.

4.6 Where should I go for information about applying for a HCPCS code?

Refer to the HCPCS website for information on how to apply for a HCPCS code or contact HCPCS@cms.hhs.gov for more information.

4.7 *Do manufacturers need to provide information for both brand and generic NDCs?*

Yes, ASP data need to be submitted for both brand and generic NDCs.

4.8 *What is the manufacturer-reported Wholesale Acquisition Cost (WAC)?*

WAC (as defined at Section 1847A(c)(6)(B) of the Act) means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

CMS may calculate payment based on the manufacturer's submitted WAC for a drug in the following circumstances:

1. For a single source drug or biological, the payment limit under Section 1847A of the Act is the lesser of the ASP or the WAC.
2. The payment methodology in cases where the ASP during the first quarter of sales is unavailable is based on either the manufacturer's WAC or the Medicare payment methodologies in effect on November 1, 2003.

Therefore, manufacturers must report WAC for all single source drugs and biologicals (including new drugs and biologicals) each reporting period. In submitting the WAC, manufacturers must report the WAC in effect on the last day of the reporting period. (Refer to 70 FR 70221.)

4.9 *How can I correct a mistake I made while submitting ASP data?*

There are two types of data we collect in the ASP Data Collection System: product data and financial data. Product data are typically entered only once when a new drug is available. After product data have been entered, some fields may not be changed online. To correct product data for an existing product, please contact the ASP Help Desk at asphelpdesk@dcca.com for assistance. Financial data are entered quarterly for all drugs and biologicals separately payable under Medicare Part B. If you made an error while entering financial data before it is certified, you can reupload or reenter the information. If the financial data have been certified, you will need to re-submit the financial data in the ASP Data Collection System on the **Restatement Tab**.

5. Alternate ID Data Entry Questions

This section covers data entry questions for submitting Average Sales Price (ASP) data for products with Alternate IDs.

5.1 *How do we select an Alternate ID for our skin substitute product?*

Skin substitute products are not assigned National Drug Codes (NDCs) by the Food and Drug Administration (FDA). Manufacturers self-select the Alternate ID, also referred to as an ALT ID, to distinguish between their different drug or biological products. An Alternate ID can be any combination of letters or numbers unique to the product (i.e., Stock Keeping Number (SKN) or

product number). In the ASP Data Collection System, the ALT ID can be a maximum of 23 characters and special characters (colon, dash, period) are allowed. ALT IDs are used to help CMS identify individual products for our volume-weighted average payment limit calculations.

5.2 *Why does the company's website need to display product information as part of the ASP data submission process?*

CAA 401 adapted Section 1847A of the Social Security Act giving the Secretary the ability to verify submitted data for accuracy. In other words, CMS is required to verify product data submitted by all drug manufacturers. For drugs with NDCs, that information is available through third-party resources, such as FDA, DailyMed, Medi-Span, and other compendia. For skin substitute products, there is not a collective source of information, so CMS relies on manufacturers to accurately provide this information and have it publicly available for providers and beneficiaries as well. CMS wants to ensure the transparency of available product information. The product information provided to CMS should be available to the public as well; therefore, CMS is not able to accept emailed product catalogs.

5.3 *What information needs to be available on the company website?*

The following items must be identical in both the ASP Data Collection System and on your website with a URL that reflects your company's name and not on a third-party website such as Woundcare.com: the product name, ALT ID, and the product size and quantity information. CMS would not be opposed to having additional verification information for your products displayed on your website such as the generic name, Healthcare Common Procedure Coding System (HCPCS) code, and FDA approval information.

5.4 *What happens if the product data submitted to CMS do not match what is publicly available on the company's website?*

It is imperative that the data are identical in both places . Any discrepancies between the data entered into the ASP Data Collection System and the product information listed on the company's website must be addressed prior to entering the data. Information that is not verified will not be included in the ASP calculation process or the ASP pricing files. Additionally, if CMS is not able to validate all of the reported data, we reserve the right to not calculate a payment limit using only the data that are verifiable.

5.5 *How do we calculate the strength of our skin substitute patch?*

In most cases, the strength is calculated by finding the area of the product by multiplying the length times the width. For example, for a square patch with sides of 4 centimeters, the area of the product would be 16 square centimeters. For a disc, you would calculate the area by multiplying Pi times the radius squared.

6. ASP Calculation Process Questions

This section covers questions on how the Average Sales Price (ASP) is calculated.

For more information on relevant statutes, regulations, and rulings, please visit the Medicare Part B Drug Average Sales Price website.

6.1 *How is the ASP payment limit calculated?*

Once data are submitted by manufacturers, CMS calculates the payment limits. The payment limit is based on the volume-weighted average of the manufacturer(s)' ASPs for those drug products in the applicable billing and payment code (i.e., Healthcare Common Procedure Coding System (HCPCS) code).

CMS uses a "crosswalk" file for manufacturers to reference, which links each National Drug Code (NDC) to its associated HCPCS code. CMS also may reference drug pricing compendia, which include information on drug prices and descriptions.

The methodology in Section 1847A of the Act determines payment limits for drugs separately payable under Medicare Part B. Payment limit calculations are set forth at Section 1847A(b) of the Act and codified at 42 CFR § 414.904.

For multiple source drugs, the ASP for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' ASPs for those drug products. The ASP is determined by:

(A) Computing the sum of the products (for each NDC assigned to such drug products) of the manufacturer's average sales price without dividing such price by the total number of billing units for the NDC for the billing and payment code and the total number of units sold; and
(B) Dividing the sum determined under (A) by the sum of the products (for each NDC assigned to such drug products) of the total number of units sold and the total number of billing units for the NDC for the billing and payment code.

For single source drugs, the ASP is the volume-weighted average of the manufacturers' ASPs for all NDCs assigned to the drug or biological product. The ASP determined by:

(A) Computing the sum of the products (for each NDC assigned to such drug products) of the manufacturer's ASP, determined by the Secretary without dividing such price by the total number of billing units for the NDC for the billing and payment code and the total number of units sold; and
(B) Dividing the sum determined under clause (A) by the sum of the products (for each NDC assigned to such drug products) of the total number of units sold and the total number of billing units for the NDC for the billing and payment code.

6.2 *Is the ASP always used to calculate the payment limit?*

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 of those exceptions include:

Wholesale Acquisition Cost (WAC)

WAC is the manufacturer's list price for wholesalers or direct purchasers in the United States, 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. In some cases, Part B drug payments are based on WAC:

- During the initial sales period when ASP is not yet available, the payment limit is 103% of WAC as referenced in 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 as referenced in 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.

In some cases, Part B drug payments are based on AWP:

- The payment limits for pneumococcal, influenza, COVID-19, and Hepatitis B Virus vaccines under Medicare for Part B are 95% of AWP as defined in Section 1842(o)(1)(A)(iv) of the Act.
- For Hospital Outpatient Prospective Payment System (OPPS) drugs, the payment limit is 95% of AWP when a HCPCS code has not been assigned as referenced in 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.

In some cases, Part B drug payments are based on AMP:

- 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).

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.

In some cases, Part B drug payments are based on WAMP:

- 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 limits for covered Part B 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.

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): the payment limit is based either on the published WAC or invoice pricing.

Other

Certain codes include an additional clotting factor furnishing fee. A notation of the additional furnishing fee is included in the ASP pricing files.

6.3 *How are payment limits determined for biosimilar biological products?*

Generally, the payment limit for biosimilars equals the ASP of the biosimilar product plus 6% of the ASP of the corresponding reference product's ASP. There is a temporary payment increase for biosimilars for an applicable 5-year period during which ASP of the biosimilar product plus 8% of the ASP for the corresponding reference product is used if the ASP for the biosimilar is less than that of its reference product. For existing qualifying biosimilar biological products for which payment was made using ASP as of September 30, 2022, the applicable 5-year period began on October 1, 2022. For new qualifying biosimilar biological products for which payment is first made using ASP between October 1, 2022, through December 31, 2027, the applicable 5-year period begins the first day of the calendar quarter of such payment. A notation of the 8% reference product add-on is included in the ASP pricing files.

6.4 *In cases where drugs and biologicals are not listed on the quarterly ASP pricing files, how is the payment limit calculated?*

MACs develop payment limits for covered drugs, based on a percentage of the wholesale acquisition cost as reflected in published resources (e.g., Redbook, Price Alert, etc.) or invoices, when CMS does not include the payment limit on the ASP pricing files.

The absence or presence of a HCPCS code and the payment allowance limits in the ASP pricing files does not indicate Medicare coverage of the drug. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. Coverage determinations may be made by the local MACs or through National Coverage Determinations (NCDs).

6.5 *Are inner NDCs included in the ASP pricing files?*

Some drugs are packaged such that the outer package contains two or more inner packages (e.g., vials of single dose injectable drugs). In these cases, there is typically one NDC on the

outer package (i.e., the “outer” NDC) and a different NDC on the inner package (i.e., the “inner” NDC).

The ASP crosswalk files posted are intended to provide information about the drug products that are used to determine payment limits. Generally, CMS does not use inner NDCs when determining payment limits. Therefore, CMS does not typically include inner NDCs in our crosswalk files. Inner NDCs should only be reported if the product is being sold under the inner NDC.

6.6 *How does CMS calculate ASP for certain drugs for which there is a self-administered version?*

As required by Section 1847A(g) of the Act, the U.S. Department of Health and Human Services Office of Inspector General (OIG) conducts periodic studies to identify NDCs for drug or biological products that are self-administered and for which payment is not made under Medicare Part B. For such products, CMS applies a “lesser of” methodology to the payment limit calculation, if appropriate. The payment limit for the drug or biological billing code would be the lesser of these amounts:

- The payment limit determined under Section 1847A of the Act.
- The payment limit determined under Section 1847A of the Act if the OIG-identified self-administered version(s) are excluded from the calculation.

A notation appears in the ASP pricing files when CMS uses the lesser of methodology.

6.7 *How are payment limits calculated when manufacturers report negative or zero ASP data?*

CMS generally calculates the payment limits for drugs payable under Part B on a quarterly basis using the manufacturer’s ASP (as defined in 42 CFR § 414.902). For each NDC, in most cases, the manufacturer’s ASP is a positive dollar value, along with a positive number of units sold, referred to as “positive manufacturer’s ASP data.” However, it is possible that self-reported manufacturer ASP data are not positive. For example, a manufacturer could report that an NDC has a negative or zero-dollar value for the ASP with a positive, negative, or zero number of units sold. This is referred to as “negative or zero manufacturer’s ASP data.” When manufacturers self-report zero or negative sales data, generally ASP payment limits will be calculated using the most recently available positive ASP data.

6.8 *What does Medicare cover for Pre-exposure Prophylaxis (PrEP) for HIV drugs?*

Starting January 1, 2025, Medicare pays for PrEP for HIV drugs according to the Drugs Covered as Additional Preventive Services (DCAPS) fee schedule to decrease an individual's risk of acquiring HIV. Payment limits for PrEP drugs are included in the ASP pricing files. More information, including the complete list of covered services, can be found on the CMS website. Covered items related to drugs include:

- FDA-approved PrEP using antiretroviral drugs to prevent HIV in individuals at increased risk of acquiring HIV
- Administration of injectable PrEP using antiretroviral drugs to prevent HIV

- Supplying or dispensing the drug regardless of the route of administration (oral and injectable)

6.9 *How are Drugs Covered as Additional Preventive Services (DCAPS) priced?*

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

- 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 Veterans Affairs' Federal Supply Schedule (FSS) pharmaceutical pricing database that is publicly available at the NDC level and published on the U.S. Department of Veterans Affairs Office of Procurement, Acquisition and Logistics website.

If ASP data, NADAC prices, and FSS prices are not available, the payment limit would be the invoice price as determined by the MAC.

7. ASP Publication and Payment Questions

This section covers how Average Sales Price (ASP) is published and used for payment.

7.1 *What is the timeline for ASP submissions to be published?*

There is a two-quarter lag between the time that sales used in the ASP calculation take place and the effective date of the payment limits (for example, ASPs from drugs sold between January and March are used to calculate payment limits used between July and September). Generally, CMS releases files a few days before the effective date of the upcoming quarter. Preliminary files are available several days before the files are released to contractors. Refer to *Table 2* for specifics.

7.2 *How often does CMS update the ASP pricing files with new drugs and information?*

CMS releases ASP pricing files quarterly.

7.3 *Are you able to explain how ASP is calculated for a specific product or provide information about specific manufacturers?*

CMS cannot release information about specific manufacturers or specific products due to statutory confidentiality provisions that limit the release of ASP data as specified in Section 1847A(f), which include confidentiality provisions in Section 1927(b)(3)(D) of the Act.

7.4 *Why is the published ASP payment limit in the ASP pricing files different than my actual acquisition cost?*

The ASP payment limits are calculated based on prices submitted each quarter by manufacturers to CMS. This process is described in Section 1847A of the Act. The published payment limit for a given Healthcare Common Procedure Coding System (HCPCS) code is based on a volume-weighted average of the reported sales prices for all National Drug Codes (NDCs) within that HCPCS code.

HCPCS codes can have multiple NDCs listed within the code and because the ASP payment limit is a volume-weighted average, the ASP payment limit for a multiple source drug may be different than the price of one individual drug.

Please note that the law does not provide CMS with the flexibility or the authority to alter or adjust payment limits. However, the ASP payment limits are recalculated quarterly based on the latest sales information from manufacturers.

7.5 *My product was not included in this quarter's ASP pricing files. Will it be included in next quarter's ASP pricing files?*

CMS evaluates these files quarterly and the contents of the files can change from quarter to quarter, which includes additions or deletions from the ASP file. The crosswalks are not meant to be a comprehensive listing of all NDCs that could be billed and paid for under Medicare Part B.

CMS does not publish an ASP payment limit or crosswalk for all products that are reported by manufacturers or all products that receive HCPCS codes. Several factors, including but not limited to the setting in which the product is used and the volume of use in Medicare Part B, are evaluated before a decision about national pricing is made.

The absence or presence of a HCPCS or NDC code and the payment limits in the files does not indicate whether Medicare covers a particular product. Even if a product does not appear on a quarter's ASP pricing files, it may still be paid by the local contractor that processes the Part B claim, provided that the claim is reasonable and necessary and meets all necessary requirements for payment. In such a case, the local contractor will also determine the payment limit.

7.6 *What if a specific HCPCS code or drug is not found on the ASP pricing files?*

The absence or presence of a HCPCS code or NDC and the payment allowance limits in the ASP pricing files or crosswalks does not indicate whether Medicare pays for a particular drug.

Even if a drug does not appear in a quarter's ASP pricing files, it may still be paid by the Medicare Administrative Contractor (MAC) that processes the Part B drug claim, provided the claim is reasonable and necessary. In such a case, the local contractor will determine the payment limit.

CMS expects providers and manufacturers to rely on the ASP pricing files that include the NDC-HCPCS crosswalk to determine the most appropriate billing and payment code to use.

These files are updated on a quarterly basis and published on the Medicare Part B Drug Average Sales Price website.

You may also review the ASP NDC-HCPCS Crosswalk File for Current Code Assignments.

7.7 How much do drug providers receive for a recently approved generic drug? When will it appear in the ASP pricing files?

CMS does not provide specific coding/billing guidance for individual providers or manufacturers. Therefore, in the absence of a published crosswalk, if individual providers or manufacturers have questions about a specific drug or a specific claim, they may want to reach out to their local MAC for more information. Each local jurisdiction sets up local billing policies for established codes.

7.8 How can I find information about MACs?

Refer to the CMS website to determine the local MAC.

Each jurisdiction sets up local billing policies for established codes. While CMS creates codes and sets Medicare's benefit categories, the MACs determine reasonable and necessary criteria and policies related to when a code will be payable. The information may vary based on geographical area/jurisdiction.

7.9 How do MACs report Part B Drugs that they manually price?

MACs use the Medicare Contractor Reporting Template for Medicare Part B Drugs (ZIP) to report information on all Part B drugs Medicare does not pay on a cost or prospective payment basis when payment limits are not listed in the quarterly ASP pricing files or the Outpatient PPS (OPPS) Pricer.

7.10 The MAC has denied our claim. What can we do?

If a local MAC denies your claims, you have the option to appeal the claim. Please contact your MAC for further instructions on the appeals process.

7.11 What is the difference between the Hospital Outpatient Prospective Payment System (OPPS) Addendum B and ASP pricing files?

The ASP pricing files and the OPPS Addendum B are used in different settings and are subject to different sets of regulations. Separate divisions in CMS maintain the two pricing files. The Division of Data Analysis and Market Based Pricing (DDAMBP) maintains the ASP pricing files, which are used for pricing many drugs that are administered incident to a physician's service, while the Division of Outpatient Care (DOC) maintains Addendum A and Addendum B of the Hospital OPPS. Thus, the list of drugs that appear in the two price files differ.

Visit Addendum A and Addendum B Updates on the CMS website to view OPPS published payment rates. If you have questions about the OPPS payments or coinsurance calculations, please contact the OPPS Mailbox at outpatientpps@cms.hhs.gov.

7.12 *Are the ASP pricing files a comprehensive list of all drugs/NDCs available in the United States?*

The ASP pricing files are based on drug and biological pricing data and information submitted to CMS by manufacturers and are intended to support ASP-based Medicare Part B payments only. ASP payment limits are established at the HCPCS level.

The ASP NDC-HCPCS crosswalk files are intended to help the public (including entities that submit manufacturer ASP data and providers who bill for drugs) understand which drug products (identified by NDCs) are assigned to which HCPCS billing codes. The crosswalk file is not intended to be a comprehensive list of all drugs/NDCs available in the United States.

Please note that the data CMS publishes are intended to facilitate Medicare Part B claims processing only. CMS understands that other third-party companies may use our data but unfortunately, that is beyond our scope. Please reach out to your Plan Administrators or look at the claims processing instructions for more information.

7.13 *Where can I find the Reduced Coinsurance List?*

Refer to the Medicare Prescription Drug Inflation Rebate Program website for the quarterly lists of drugs with adjusted coinsurance.

Appendix A: Glossary of Terms and Definitions

Table 4 provides terms, acronyms, and associated definitions for terms and acronyms in this document.

Table 4: Glossary of Terms, Acronyms, and Definitions

Term	Acronym	Definition
Average Manufacturer Price	AMP	AMP is the price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. Federal law defines the price.
Average Sales Price	ASP	ASP refers to the price at which an organization typically sells a certain class of good or service. CMS uses manufacturer-reported ASPs, based on manufacturers' actual quarterly drug sales, to calculate provider payment amounts for these drugs. Federal law defines the price.
Average Wholesale Price	AWP	An AWP is an estimate of the price retail pharmacies pay for drugs from their wholesale distributor.
Biosimilar Biological Product	NA	Biosimilar biological product means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act. 42 CFR § Part 414 Subpart K (Section 902)
Calendar Year	CY	Calendar year is the period of time beginning on January 1 and ending on December 31 of each year.
Centers for Medicare & Medicaid Services	CMS	CMS is a federal agency within the U.S. Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards.
Chief Executive Officer	CEO	A CEO is the highest-ranking officer or Administrator in charge of management with a corporation.
Chief Financial Officer	CFO	A CFO is the corporate executive having financial authority to make appropriations and authorize expenditures for a firm.
Consolidated Appropriations Act, 2021	CAA	The CAA establishes protections for consumers related to surprise billing and transparency in health care. The No Surprises Act (NSA) is part of the CAA.
DailyMed	NA	The DailyMed searchable database provides the most recent labeling submitted to the FDA by companies and currently in use (i.e., "in use" labeling).
Department of Health and Human Services	HHS	HHS is a Cabinet Department of the U.S. government with the mission to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

Term	Acronym	Definition
Division of Data Analysis and Market Based Pricing	DDAMBP	The DDAMBP collects data to set payments for prescription drugs covered under Medicare Part B; collects data to set payments for clinical lab tests; develops payment policy for ambulance services; and performs data analyses.
Division of Outpatient Care	DOC	DOC develops and maintains the hospital OPPS and the ASC payment system.
Eastern Standard Time	EST	EST is the standard time in the 5th time zone west of Greenwich, reckoned at the 75th meridian. This time zone is in the eastern part of the United States.
End Stage Renal Disease	ESRD	ESRD is an irreversible decline in kidney function that is severe enough to be fatal without dialysis or transplantation.
Frequently Asked Question	FAQ	An FAQ is a commonly asked question pertaining to a topic.
Healthcare Common Procedure Coding System	HCPCS	HCPCS is a set of healthcare procedure codes based on the American Medical Association current procedural terminology (Commonly pronounced Hick-Picks).
Identity Management	IDM	IDM manages connections from a user to a CMS application, establishing trust and granting access at an appropriate level.
Medicaid	NA	Medicaid is the federal system of health insurance for people requiring financial assistance.
Medicare	NA	Medicare is the federal system of health insurance for people over 65 years of age and for certain younger people with disabilities.
Medicare Administrative Contractor	MAC	Jurisdictional MACs administer Medicare claims under CMS direction.
Medicare Modernization Act	MMA	The MMA, or Medicare Prescription Drug, Improvement, and Modernization Act, is a federal law.
Medicare Part B	NA	Medicare Part B is the part of Medicare that covers doctor services, outpatient hospital care, and other medical services that Part A does not cover such as physical and occupational therapy, X-rays, medical equipment, or limited ambulance service.
Medi-Span	NA	Medi-Span is a publication that alerts clinicians and pharmacists to information about avoidable medication errors, inappropriate dosing, and adverse events.
National Coverage Determination	NCD	An NCD is a general outline of coverage which is applicable regardless of which MAC is administering claims for a region.
National Drug Code	NDC	The NDC is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologicals the FDA recognizes.
Not Otherwise Classified	NOC	NOC codes apply when a more specific HCPCS code is not available for a given service or procedure.

Term	Acronym	Definition
Office of Inspector General	OIG	The OIG works to fight waste, fraud, and abuse and to improve the efficiency of Medicare, Medicaid and more than one hundred other Department of Health & Human Services (HHS) programs.
Outpatient Prospective Payment System	OPPS	CMS started the OPPS under Section 1833(t) of the Act to pay for Medicare Part B hospital outpatient items and services and other items such as: Medicare Part B hospital outpatient items and services; Part B inpatient hospital services when Medicare can't pay under Part A because a patient exhausted Part A benefits or isn't entitled to them; and Community mental health center (CMHC) partial hospitalization services and certain inpatient hospital services.
Physician Fee Schedule	PFS	The PFS is a complete listing of fees Medicare uses to reimburse doctors.
Price Alert	NA	Medi-Span's Price Alert is an average wholesale pricing database.
Redbook	NA	The Redbook provides comprehensive access to current and accurate drug pricing and description information. The Redbook covers FDA-approved drug products, including prescription drugs, over-the-counter drugs, and nondrug products.
Skin Substitute	NA	Skin substitutes are a heterogeneous group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds.
Social Security Act	SSA	The SSA is a law that provides income to retired workers aged 65 or older and to persons with certain qualifying disabilities.
Wholesale Acquisition Cost	WAC	WAC refers to the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.
Widely Available Market Price	WAMP	WAMP is defined in Section 1847A(d)(5)(A) as 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.