Average Sales Price (ASP) Quarterly Publication Process

Frequently Asked Questions

Version 1.1

Date: March 11, 2024

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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

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 ASP questions.

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 the Medicare Part B Program, 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 the Part B Drug Program 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 ASP 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.

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.

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.

2. Reporting of ASP Data Questions

Questions in this section cover the basics of who, what, when, and where, as it applies to the manufacturer reporting and CMS processing of ASP data.

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.

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 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 (see section 1847A(c)(1)(A), (2) of the Act).

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 Section 42 CFR 447.502

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 OPPS services whose costs are packaged into the cost of the services.

When must data be reported?

As stated at 42 CFR 414.804, the manufacturer's average sales price 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 for calendar year (CY) 2023.

Table 2: ASP Data Collection Dates Example

Sales Period	Close of the Sales Period Quarter	Close of the Manufacturer's Data Submission Window	Medicare Payment Effective Quarter
First Quarter of CY 2023	March 31, 2023	Sunday, April 30, 2023	Third Quarter of CY 2023
Second Quarter of CY 2023	June 30, 2023	Sunday, July 30, 2023	Fourth Quarter of CY 2023
Third Quarter of CY 2023	September 30, 2023	Monday, October 30, 2023	First Quarter of CY 2024
Fourth Quarter of CY 2023	December 31, 2023	Tuesday, January 30, 2024	Second Quarter of CY 2024

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.

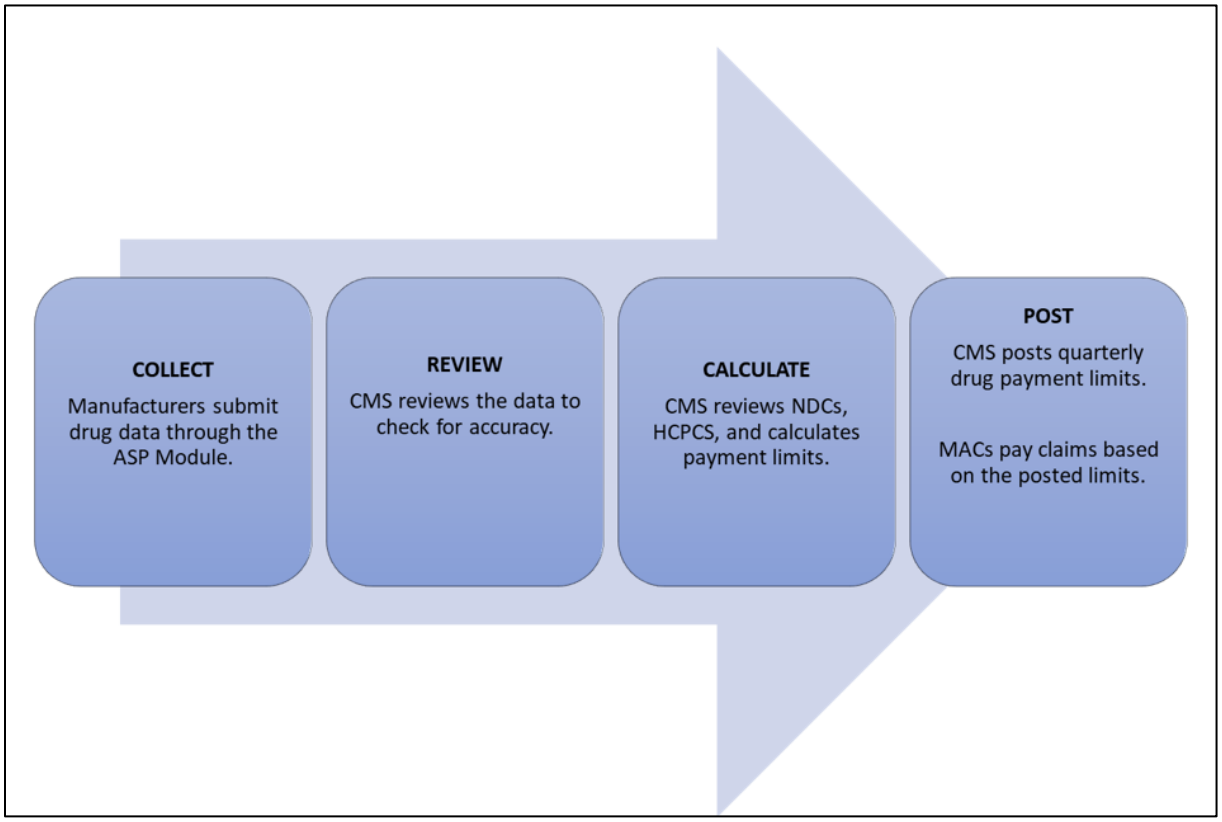

Figure 1: General Process Flow for ASP Payment Process

Where is 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.

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.

3. ASP Data Collection Technology Questions

Questions in this section cover the Fee for Service Data Collection System (FFSDCS) ASP module, data entry, and technical support.

3.1 Registration and Access to the FFSDCS ASP Module

How do users register for the FFSDCS ASP module?

Manufacturers who have not previously reported 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.

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 to access 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.

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.

What resources are available for FFSDCS ASP module users?

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

3.2 Data Entry

What is a unit of a drug?

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 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.

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.

The ASP Data Collection System asks for the manufacturer’s average sales price, how is that calculated?

The manufacturer's average sales price 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 average sales price 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).

Should manufacturers include discounts given under the Medicare drug discount card program in their average sales price data submitted to CMS?

Manufacturers should exclude prices negotiated for covered discount card drugs under an endorsed discount card program while calculating ASP data. Manufacturers also 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.

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.

How should a manufacturer submit their ASP data using an alternate ID or provide information for both brand and generic NDCs?

ASP data needs to be submitted for both brand and generic NDCs. Additionally, reported data that contain an NDC and/or alternate ID must match a publicly posted source for verification purposes such as a public-facing website.

Generally, CMS does not give specific or individual ASP reporting guidance to individual manufacturers or third-party vendors.

What is the manufacturer-reported WAC?

Wholesale Acquisition Cost (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. (See 70 FR 70221.)

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

If you need to re-submit, please log into the FFSDCS ASP module, and resubmit your submission in the Restatement tab.

3.3 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. ASP Calculation Process Questions

Questions in this section cover how ASP is calculated.

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

How is 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)' average sales prices for those drug products in the applicable billing and payment code (i.e., HCPCS code).

CMS uses a "crosswalk" file for manufacturers to reference, which links each 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 average sales price for all drug products included within the same multiple-source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products. The average sales price 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 average sales price is the volume-weighted average of the manufacturers' average sales prices for all NDCs assigned to the drug or biological product. The average sales price 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, 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.

Is the ASP always used to calculate the payment limit?

Drugs and biologicals not paid on a cost or prospective payments basis are paid based on ASP methodology using quarterly drug pricing data submitted to CMS. Payment to providers is generally 106% of ASP. Exceptions to ASP are described at 42 CFR 414.904(d) and in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 17. Some of those exceptions include:

Wholesale Acquisition Cost (WAC)

As defined in Section 1847A(c)(6)(B) of the Act, 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 and MediSpan. Typically, WAC is higher than ASP, but the magnitude of the difference varies.

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.
- For some drugs that do not appear on the ASP pricing files, 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.

Average Wholesale Price (AWP)

AWP is set using industry recognized AWP reference sources (e.g., RedBook, MediSpan), as there is no statutory definition. 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. The payment for OPPS drugs is 95% of AWP. For drugs that are classified and have a HCPCS code, 95% of AWP pricing may be used if ASP or WAC pricing is not available for a drug. Also, unclassified drugs are paid at 95% of AWP in the OPPS. A notation of 95% AWP is included in the ASP pricing files.

Average Manufacturer Price (AMP)

AMP is defined in Section 1927(k)(1) of the Act as the average price paid to the manufacturer for the drug in the United States 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. CMS uses AMP when OIG informs CMS that 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.

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. 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 1 quarter after publication.

Other

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

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. A notation of the 8% reference product add-on is included in the ASP pricing files.

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

MACs develop payment allowance 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 supply the payment allowance 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).

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.

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.

5. ASP Publication and Payment Questions

Questions in this section cover how ASP is published and used for payment.

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.

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

CMS releases ASP pricing files quarterly.

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 1927(b)(3)(D) of the Act.

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 HCPCS code is based on a volume-weighted average of the reported sales prices for all NDCs within that HCPCS code.

Some HCPCS codes have several NDCs and because the ASP payment limit is a volume-weighted average, the ASP payment limit for a multiple-source drug may be lower 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.

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.

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.

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.

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.

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.

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.

What is the difference between the 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.

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

The ASP crosswalks are based on published drug and biological pricing data and information submitted to CMS by manufacturers and are intended to support ASP-based Medicare Part B payments only.

The crosswalks 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 crosswalks are not intended to be a comprehensive list of all drugs/NDCs available in the United States.

Please note that the data CMS publishes is 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.

Where can I find the Reduced Coinsurance List?

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

If a manufacturer has questions on ASP reporting, how should they contact CMS?

Manufacturers can submit questions to Sec303ASPdata@cms.hhs.gov.

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
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)
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.
Division of Outpatient Care	DOC	DOC develops and maintains the hospital OPPS and the ASC payment system.
Identity Management	IDM	IDM manages connections from a user to a CMS application, establishing trust and granting access at an appropriate level.
Medicare	NA	Medicare is the federal system of health insurance for people over 65 years of age and for certain younger people with disabilities.
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.
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.
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.