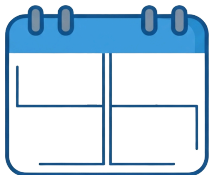




Understanding the Medicare Part B Drug Payment Limit File

To provide additional clarity on the content of the Medicare Part B Drug Payment Limit File, this fact sheet includes information on a few key elements of the ASP calculation process.



Let's start by explaining the quarterly payment limit file publication timeline.

Historically, CMS maintains a database of over 9,000 National Drug Codes (NDCs) for Part B-covered drugs each quarter. This database is reviewed alongside all manufacturer-submitted ASP data for payment limit calculations. **Products are not automatically added to the payment limit file, but may be added during the established submission windows as defined in *Table 1* below, pending all criteria are met.** These are the steps from data submission through publication of the payment limit file:

1. Manufacturers sell drugs and biological products payable under Medicare Part B and record financial information for the calendar quarter.
2. The manufacturer calculates the manufacturer's ASP for each NDC of a drug payable under Medicare Part B for the quarter ([42 CFR § 414.804\(a\)](#)) and must submit the data to CMS no later than 30 days after the last day of each calendar quarter ([42 CFR § 414.804\(a\)\(5\)](#)).
3. CMS aggregates and analyzes the quarterly sales data submitted by manufacturers using reference and compendia data from the same sales quarter to determine eligibility criteria. This includes, but is not limited to:
 - Micromedex Red Book® and Medi-Span® Price Rx®, which provide information on drug prices and descriptions.
 - Food and Drug Administration (FDA) databases, including [Drugs@FDA](#) (database for FDA-approved products for human use), [Purple Book](#) (database for FDA-licensed biological products), and [Approved Drug Products with Therapeutic Equivalence Evaluations](#) (commonly known as the Orange Book).
4. CMS calculates payment limits, which are usually based on ASP ([42 CFR § 414.904](#)) for the Healthcare Common Procedure Coding System (HCPCS) code. There are certain limitations ([42 CFR § 414.904\(d\)](#)) and exceptions ([42 CFR § 414.904\(e\)](#)) to the use of ASP for payment limit purposes.



Understanding the Medicare Part B Drug Payment Limit File

5. CMS publishes the Medicare Part B Drug Payment Limit File on the [Medicare Part B ASP website](#) for public notice of payment limits calculated for drugs and biological products paid under Medicare Part B. The Medicare Part B Drug Payment Limit File is updated quarterly, and the payment limits are associated with what is called a “two-quarter lag.” A “two-quarter lag” is the time between the first day of the sales quarter and the first day of the quarter when the payment limit based on that sales quarter becomes effective. Refer to **Table 1** below.

- Generally, CMS releases files a few days before the effective date of the upcoming quarter. Preliminary files are available several days before the final files are released to contractors, allowing for correspondence on payment rate accuracy.
- The Medicare Part B Drug Payment Limit File may include three separate documents:
 - The “Medicare Part B Drug Payment Limit File,” which contains the payment allowance limits and applicable substitutions for the drugs that have met all the criteria for the quarter.
 - The “NDC-HCPCS Crosswalk” file, which links each NDC to its associated HCPCS code. **Note:** There are other crosswalk files posted on the CMS website, but only the NDC-HCPCS crosswalk file listed on the [Medicare Part B ASP website](#) should be referenced for payment limits.
 - If needed, CMS may also publish the “NOC Pricing File,” which contains payment allowance limits for Medicare Part B Not Otherwise Classified (NOC) drugs.

Table 1 features the timeline for data collection, including the publication of compendia data, through the Medicare payment effective date.

Table 1: Timeline for Data Collection

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



There are a few important notes to consider regarding the posted payment limit and crosswalk files, which may provide potential reasons why a drug is not included in the payment limit file.

- The Medicare Part B Drug Payment Limit File is intended to facilitate Medicare Part B claims processing for non-institutional providers and program administration. Hospital outpatient departments should refer to Outpatient Prospective Payment System (OPPS) payment files.
- CMS follows a **quarterly** cycle, as outlined in **Table 1**, to collect data from manufacturers to calculate and publish payment limits in the payment limit file. CMS also uses reference prices from the respective publicly posted drug pricing compendia data. Data provided or made publicly available after the last day of the calendar quarter, as noted in the Inclusion Cutoff Date column in **Table 1**, may be included in the following quarterly file.
- CMS will continue to review the existing drugs on the payment limit file each quarter for continued inclusion. Each quarter, the payment limit file may undergo several types of content changes to ensure the data are accurate and complete. Some content changes include:
 - Additions occur when new HCPCS codes or NDC-HCPCS mappings are reported and incorporated, reflecting the newly payable product's Date of First Sale. For definition purposes, the First Marketing Date refers to the date on which the FDA determines marketing of a new product can begin. Date of First Sale is the date in which the first claim is filed or is paid by Medicare for the drug or biological product.
 - For new drugs and biological products, CMS does not use partial quarter ASP data to determine the payment limit during the initial period. (Refer to discussion in the CY 2011 Physician Fee Schedule (PFS) final rule ([75 FR 73465](#) through [73466](#))).) Once a complete quarter of ASP data has been submitted to CMS, generally, the ASP-based payment limit may be included in the payment limit file.
 - CMS will remove drugs and biological products that have been discontinued, recalled, no longer payable under Medicare Part B, inactive after six quarters, or otherwise deemed ineligible.
 - CMS may make modifications to the Medicare Part B Payment Limit File by adjusting existing entries, such as updating ASP values following manufacturer restatements, correcting data entry errors, or applying negative ASP adjustments. CMS may contact manufacturers to address minor clerical or formatting mistakes, ensuring that field labels, code structures, and file formats conform to CMS standards.
 - Should CMS restate a drug's payment limit, CMS will identify restated payment limits in the updated payment limit file with a date descriptor. For more information on restatements, refer to the Medicare Part B Average Sales Price (ASP) Restatement Policy Overview fact sheet.



Understanding the Medicare Part B Drug Payment Limit File

- The NDC-HCPCS Crosswalk is not meant to be a comprehensive listing of all NDCs that could be billed and paid for under Medicare Part B and does not signify coverage or non-coverage of a product. The crosswalk file is designed to clarify which drug products (identified by NDCs) are assigned to specific HCPCS billing codes and is updated in alignment with each quarterly release of the payment limit files. Generally, the NDCs included are the ones for which there is active marketing and sales within the sales quarter.
- The Medicare Part B Payment Limit File should not be construed as a formulary for drugs and biological products paid under Medicare Part B. The absence or presence of a HCPCS or NDC code and the payment limits in the files do not indicate whether Medicare covers a particular product. Even if a product does not appear on a quarter's file, the local Medicare Administrative Contractor (MAC) may process the Part B claim after determining the payment limit, provided that the claim is reasonable and necessary and meets all necessary requirements for payment as listed in the [Medicare Claims Processing Manual, Pub. 100-04, Chapter 17, section 20.1.2](#) (paragraph 2).
- Some Medicare Part B products may be listed on other CMS addenda or crosswalk files, but it is important to note that these files are not interchangeable to the Medicare Part B Drug Payment Limit File. Other reference files used in various settings are subject to different statutory and regulatory requirements. Some examples include:
 - Updates of Addendum A and Addendum B are posted quarterly to the OPPS website. These addenda are a “snapshot” of HCPCS codes and their status indicators, APC groups, and OPPS payment rates, that are in effect at the beginning of each quarter. The quarterly updates of Addendum A and Addendum B reflect the OPPS Pricer changes that are part of the quarterly OPPS recurring update notification transmittals.
 - The Durable Medical Equipment (DME) NDC-HCPCS crosswalk is specifically used for certain Part B claims submitted by DME suppliers rather than physician offices.



Additionally, there are several specific reasons why a product may not be listed in the Medicare Part B Drug Payment Limit File.

CMS evaluates the criteria for drugs and biological products to determine whether they are included in the Medicare Part B Drug Payment Limit File. Should a drug not be listed on the file, some reasons include, but are not limited to:

- The drug falls under one of the exceptions documented at [42 CFR § 414.904](#).



Understanding the Medicare Part B Drug Payment Limit File

- One or more of the required data elements (HCPCS codes, a full quarter of manufacturer-submitted ASP data, claims data, and/or compendia reference data) are not available during the scheduled quarterly timeframe to calculate the payment limit. New product data must be submitted to CMS by the Inclusion Date of the current sales quarter referenced above in **Table 1**. For example, for the April 1 pricing file, public data must be available by December 31, and all manufacturer data should be reported to CMS by January 30.
- The criteria for the drug to be included or excluded may be under separate policies, such as the National Coverage Determination and the Self-Administered Drug List, periodic studies from the Inspector General, or in rulemaking.
- After data submission, CMS requested additional information from the manufacturer, and no response was received, or a response was provided after the deadline for inclusion.

For More Information:

You can find more information on all policies and regulations regarding Medicare Part B Drugs and ASP on the [ASP Regulations and Policy page](#) on the [Medicare Part B Drug ASP website](#) or by contacting us at sec303aspdata@cms.hhs.gov.

For other Part B Drug-related questions:

- Contact the OPPTS Mailbox at outpatientpps@cms.hhs.gov for questions about OPPTS payments or coinsurance calculations. OPPTS published payment rates can be found in [Addendum A and Addendum B Updates](#) on the CMS website.
- Contact the jurisdiction-specific [DME Medicare Administrative Contractor \(MAC\)](#) for questions about durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).
- Consult [Medicare Claims Processing Manual, Pub. 100-04, Chapter 17](#), for information concerning drugs paid under Medicare Part B, including payment limit calculations and methodologies.
- For information on the payment limit for new drugs and biological products during the initial period of marketing, refer to regulations at [42 CFR § 414.904\(e\)\(4\)](#) and rulemaking in the CY 2019 PFS final rule ([83 FR 59661](#) through [59666](#)) and the CY 2024 PFS final rule ([88 FR 79040](#) through [79042](#)).

Note: CMS cannot release information about specific manufacturers or specific products due to statutory confidentiality provisions that limit the release of Average Sales Price (ASP) data as specified in section 1847A(f), which include confidentiality provisions in section 1927(b)(3)(D) of the Social Security Act. CMS can provide manufacturers with information to the extent allowed by law, but may not be able to provide certain information due to the proprietary nature of the data collected.