



## Payment Limit Calculations When Manufacturers Report Negative or Zero ASP Data

In accordance with sections 1927(b)(3), 1847A(c), and 1847A(f) of the Social Security Act (the Act) and regulation [42 CFR 414 Subpart J](#), manufacturers of drugs and biological products payable under Medicare Part B must report average sales price (ASP) data to the Centers for Medicare & Medicaid Services (CMS). CMS generally calculates the payment limits for drugs payable under Part B on a quarterly basis using the manufacturer's ASP (as defined in [§414.902](#)).

For each National Drug Code (NDC), in most cases, the manufacturer's ASP, as reported by the manufacturer, 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 manufacturer's ASP data are not positive. For example, a manufacturer could correctly report that an NDC has a negative or zero-dollar value for the ASP with a positive, negative, or zero number of units sold, or a positive dollar value for the manufacturer's ASP with a negative or zero number of units sold. These scenarios are referred to as "negative or zero manufacturer's ASP data." If used to calculate a payment limit, negative or zero ASP data could result in a negative or zero payment limit, which would require CMS to collect payment from providers and suppliers for a drug, rather than make a payment for a drug. Negative or zero payment limits for a drug are not reasonable because Medicare does not expect to collect payment from providers and suppliers for their provision of separately payable drugs. As finalized in the Calendar Year (CY) 2025 Physician Fee Schedule (PFS) final rule, CMS will consider negative or zero manufacturer's ASP data "unavailable" for the purposes of calculating a payment limit. **[1]**

In that final rule, CMS finalized a methodology for calculating payment limits based on the manufacturer's ASP for the most recent quarter for which data are available when a manufacturer reports negative or zero ASP data for a drug or biological product. The final rule addresses circumstances in which either some or all NDCs for a billing and payment code have negative or zero manufacturer's ASP data; in which negative or zero manufacturer's ASP data are reported for a drug that has been discontinued; and vary further depending on whether a drug is multiple source or single source (both as defined in [§ 414.902](#)). The methodology is codified at [§ 414.904\(i\)](#) and a summary is provided below.

**[1]** Refer to [89 FR 97710](#) for the CY 2025 PFS final rule.



### Negative or Zero Manufacturer's ASP Data Reported for Some, but Not All NDCs

In the case that a drug separately payable under Part B has negative or zero manufacturer's ASP data reported for some, but not all NDCs associated with a billing and payment code for that drug, CMS will calculate the payment limit using only NDCs with positive ASP data and omit NDCs with negative or zero ASP data for that drug. This methodology applies to both single source drugs and biological products, including biosimilar biological products (hereinafter referred to as "biosimilars," and both as defined at [§414.902](#)), and multiple source drugs.



# Payment Limit Calculations When Manufacturers Report Negative or Zero ASP Data

A policy for multiple source drugs for which the absence of ASP data for an NDC would result in a significant change (that is, a 10 percent or greater change) in the ASP payment limit compared to the payment limit of the previous quarter was finalized in the CY 2011 PFS final rule ([75 FR 73461](#) through [73465](#)). The methodology finalized in the CY 2025 PFS final rule is not intended to override that existing policy; rather, the methodology addresses circumstances not addressed in previous rulemaking and thus fills a policy gap.



## Multiple Source Drugs With Only Negative or Zero Manufacturer's ASP Data

If a multiple source drug that is separately payable under Medicare Part B has only negative or zero ASP data reported for all NDCs associated with its billing and payment code—and at least one of those NDCs is still actively marketed (i.e., not discontinued)—then CMS will use the most recent calendar quarter in which at least one NDC had positive ASP data. Specifically, CMS will carry forward all positive manufacturer's ASP data from that prior quarter to calculate the payment limit for the current quarter.



## Single Source Drugs with only Negative or Zero Manufacturer's ASP Data, Excluding Biosimilar Biological Products

For single source drugs, excluding biosimilars, separately payable under Part B that have negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug where at least one NDC for the drug is actively being marketed (that is, not discontinued), CMS will set the payment limit for the given quarter at the lesser of the following:

1. 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for a quarter. If the payment limit from the quarter with the most recently available positive manufacturer's ASP data was based on 106 percent of the wholesale acquisition cost (WAC) because of the application of [§414.904\(d\)\(1\)](#), that payment limit would be carried over; or
2. 106 percent of the WAC for the given quarter. If there is more than one WAC per billing unit for the drug, the payment limit would be set using the lowest WAC per billing unit.



## Payment Limit Calculations When Manufacturers Report Negative or Zero ASP Data

CMS will only use the lesser of the positive manufacturer's ASP or WAC data from that previous quarter until positive manufacturer's ASP data are available for a future quarter. Once positive manufacturer's ASP data for a drug are available again in a future quarter, CMS would use those data to calculate a payment limit.



### Biosimilars With Only Negative or Zero Manufacturer's ASP Data

When negative or zero manufacturer's ASP data are reported for all NDCs for a biosimilar for a given quarter, CMS will set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter, and
- 6 percent (or 8 percent for qualifying biosimilar biologics, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference product (as defined in § 414.902) for the given quarter.

In these circumstances, CMS will use the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter until positive manufacturer's ASP data are available for a future quarter.



### Discontinued Drugs

Generally, for single source drugs and multiple source drugs for which negative or zero manufacturer's ASP data are reported for all NDCs and for which all relevant applications (for example, new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs)) have a marketing status of "discontinued" on the FDA website, the drug will be priced by Medicare Administrative Contractors (MACs) consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual for developing payment limits for covered drugs when CMS does not supply the payment allowance limit on the Medicare Part B Drug Payment Limit File.

Should a previously discontinued drug be reintroduced under the same FDA approval (NDA or BLA), the pricing limit would be calculated as appropriate utilizing the methodologies described above.