

513.220 Model alternative add-on payment.

(a) Payment amount. (1) The total allowed alternative add-on payment amount for a separately payable dose of an MFN Model drug furnished to an MFN beneficiary by an MFN participant on a given date of service within a calendar quarter is determined in accordance with this section.

(2) The total allowed alternative add-on payment amount for a claim line does not exceed the billed amount on that claim line.

(b) Calculation of the per-dose alternative add-on payment amount. CMS calculates the per-dose alternative add-on payment for performance year 1, quarter 1 for MFN Model drugs using the following steps:

(1) CMS identifies available Medicare Part B fee-for-service final action claims lines, with dates of service in 2019, for drugs on the initial MFN Model HCPCS Codes List described in § 513.130(a)(1), excluding claims for providers and suppliers specified in § 513.100(c), and claims specified in § 513.100(d), that were furnished by Medicare-participating providers and suppliers, have a separately paid allowed charge greater than \$0, and for which Medicare Part B was the primary payer. If a HCPCS code on the initial MFN Model HCPCS Codes List was not in use during any calendar quarter in 2019, CMS uses the HCPCS code that was applicable for the MFN Model drug during 2019.

(2) CMS identifies the applicable ASP for each calendar quarter of 2019 for the drugs (by HCPCS code as specified in paragraph (b)(1) of this section) included on the initial MFN Model HCPCS Codes List. In the case of a biosimilar biological product, the applicable ASP for the reference biological product is identified and used in paragraph (b)(3) of this section.

(3) CMS multiplies the number of units billed for each claim line described in paragraph (b)(1) of this section by 6.1224 percent of the applicable ASP identified in paragraph (b)(2) of this section for the HCPCS code on the claim line and date of service.

(4) CMS sums the products calculated in paragraph (b)(3) of this section for all claim lines for each MFN Model drug to calculate the total add-on spending amount for each MFN Model drug.

(5) CMS sums the amounts calculated in paragraph (b)(4) of this section to calculate the total pooled add-on spending amount for all MFN Model drugs.

(6) CMS divides the amount calculated in paragraph (b)(5) of this section by the total number of claim lines retained in paragraph (b)(1) of this section, excluding claim lines billed with the JW modifier.

(7) CMS trends the amount calculated in paragraph (b)(6) of this section forward to the applicable ASP calendar quarter for quarter 1 of performance year 1 using the percentage change in CPI-U from July 2019 through October 2020.

(c) Frequency of alternative add-on payment amount updates. For each calendar quarter after quarter 1 of performance year 1, CMS updates the alternative add-on payment by applying a cumulative inflation factor based on the cumulative percentage change in CPI-U from October 2020 through the first month of the prior calendar quarter. If the cumulative percentage change in the CPI-U is negative, CMS uses an inflation factor of 1.

(d) Limitation on the alternative add-on payment. The alternate add-on payment is not payable for claim lines billed -

(1) With the JW modifier; or

(2) By MFN participants that receive an alternative add-on payment for an MFN Model drug under any other model authorized by section 1115A of the Act that tests an alternative approach to the add-on portion of payment for Medicare Part B drugs.