

# 513.210 Model payment methodology for MFN Model drugs.

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(a) Payment amount. The total allowed payment amount for 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. The total allowed payment equals -

(1) For each billing unit in the HCPCS code descriptor of the MFN Model drug, the MFN Drug Payment Amount determined in accordance with paragraphs (b), (c) and (d) of this section, as applicable, where the allowed MFN Drug Payment Amount does not exceed the billed amount on the claim for the MFN Model drug as described in § 513.200(a); and

(2) The alternative add-on payment determined under § 513.220.

(b) Calculation of the MFN Drug Payment Amount with Available International Drug Pricing Data. CMS selects an available international drug pricing information data source described in § 513.140(c) for at least one country specified in § 513.140(b) for an MFN Model drug, and calculates, in advance of each calendar quarter for a performance year, the applicable MFN Drug Payment Amount for one billing unit of an MFN Model drug using the following steps:

(1) Available international drug pricing data. (i) For the MFN Model drug, using the data source selected in accordance with § 513.140(c)(3) (except for a data source described in § 513.140(c)(3)(iii)), CMS identifies available international drug pricing data for the MFN Model drug, by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable. CMS extracts available drug pricing data for the countries specified in § 513.140(b) from the selected international drug pricing information data source. CMS uses the extracted data that have complete package size information and only for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor, as determined by CMS. If a data source described in § 513.140(c)(3)(iii) is selected, CMS uses such extracted data.

(ii) When international drug pricing data with sales and volume data are available, CMS excludes from the calculation of the unadjusted country-level price under paragraph (b)(2) of this section international drug pricing data without both sales and volume data, with less than \$1,000 in quarterly sales (expressed as U.S. currency), or with less than 1,000 units in quarterly volume.

(iii) CMS converts the extracted volume data to the MFN Model drug's HCPCS code billing unit level, as applicable.

(iv) CMS adjusts the extracted volume data, as applicable, before converting the extracted volume data to the MFN Model drug's HCPCS code billing unit level when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product, as determined by CMS.

(v) CMS limits the number of HCPCS code billing units when -

(A) The package labeling indicates a limited amount of drug is to be used from the package; and

(B) The HCPCS code dosage is per dose.

(2) Calculate the unadjusted country-level price for the MFN Model drug by country.

(i) Using the drug pricing data extracted and adjusted in accordance with paragraph (b)(1) of this section, CMS calculates the unadjusted country-level price for the MFN Model drug by country, using the calculation that is applicable.

(ii) If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows:

(A) CMS sums the adjusted volume data (as specified in paragraph (b)(1)(iii) of this section) for the drug.

(B) CMS sums the total sales for the drug (that remain after performing the exclusions in paragraph (b)(1)(ii) of this section).

(C) CMS divides the sum determined in paragraph (b)(2)(ii)(B) of the section by the sum determined in paragraph (b)(2)(ii)(A) of this section, resulting in an average price per unit of drug, where the unit of drug is the same as the HCPCS code billing unit.

(iii) If an international drug pricing information data source with ex-manufacturer or list prices is used, the applicable calculation is as follows:

(A) For each extracted ex-manufacturer or list price, CMS calculates the number of HCPCS billing units in the package by dividing the amount of drug in the package by the amount of drug represented in one HCPCS billing unit.

(B) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the package, resulting in a price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(C) CMS sums the price per unit of drug calculated in paragraph (c)(3)(iii)(B) of this section.

(D) CMS divides the sum calculated in paragraph (c)(3)(iii)(C) of this section by the number of ex-manufacturer or list prices that were summed in paragraph (c)(3)(iii)(C) of this section, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(iv) CMS performs the applicable calculation for each country specified in § 513.140(b) for which international drug pricing information is available in the selected data source.

(3) Calculate the GDP adjuster for each country. (i) CMS calculates the GDP adjuster by dividing the country's GDP per capita by the U.S. GDP per capita for the same year.

(ii) In cases where the resulting ratio exceeds 1.0, the GDP adjuster is set to 1.0.

(iii) Subject to the limitations specified in paragraph (b)(3)(iv) of this section, the GDP per capita for a country is the most recent estimate of GDP per capita based on purchasing power parity for that country available in the CIA World Factbook at the end of the applicable ASP calendar quarter.

(iv) Limitations. (A) The country's GDP per capita and U.S. GDP per capita must be for the same year.

(B) The GDP per capita used must be for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

(4) Apply the GDP adjuster to calculate the GDP-adjusted country-level price. CMS applies the applicable GDP adjuster identified in paragraph (b)(3) of this section to each unadjusted country-level price identified in paragraph (b)(2) of this section to calculate the GDP-adjusted country-level price by dividing each unadjusted country-level price by the applicable GDP adjuster.

(5) Identify the lowest GDP-adjusted country-level price. CMS identifies the lowest GDP-adjusted country-level price for the MFN Model drug. Except as provided in paragraph (b)(7) of this section, the price identified is the MFN Model drug's MFN Price.

(6) Identify Applicable ASP. CMS identifies the applicable ASP for the applicable quarter.

(7) Compare the MFN Price to the applicable ASP. CMS compares the price determined in paragraph (b)(5) of this section to the applicable ASP identified in paragraph (b)(6) of this section. The MFN Price equals the applicable ASP if the applicable ASP is less than the price determined in paragraph (b)(5) of this section.

(8) Phase-in. CMS identifies the applicable phase-in formula based on the applicable performance year as follows:

(i) Performance year 1: 75 percent applicable ASP and 25 percent MFN Price.

(ii) Performance year 2: 50 percent applicable ASP and 50 percent MFN Price.

(iii) Performance year 3: 25 percent applicable ASP and 75 percent MFN Price.

(iv) Performance year 4: 100 percent MFN Price.

(v) Performance year 5: 100 percent MFN Price.

(vi) Performance year 6: 100 percent MFN Price.

(vii) Performance year 7: 100 percent MFN Price.

(9) Final calculation steps. (i) CMS applies the applicable phase-in formula to the applicable ASP and the MFN Price. Subject to any applicable adjustments as provided in paragraph (d) of this section, the amount determined in this paragraph is the MFN Drug Payment Amount.

(ii) Subject to the limitation in paragraph (b)(iii) in this section, CMS recalculates the MFN Drug Payment Amounts for prior quarters when revised international drug pricing information is available in the data source that was used to calculate the MFN Price and applicable ASP updates are available from CMS. CMS prospectively applies the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates.

(iii) MFN Drug Payment Amounts may be recalculated for the prior four calendar quarters of the model.

(c) Frequency of MFN Drug Payment Amount updates. CMS updates the MFN Drug Payment Amounts on a calendar quarter basis. CMS publishes the quarterly MFN Drug Payment Amounts on the MFN Model website in advance of the calendar quarter in which the MFN Drug Payment Amounts apply, along with any recalculated MFN Drug Payment Amounts for prior quarters.

(d) Exceptions. (1) Payment for MFN Model drugs for which no international drug pricing data are available. If, as of the first calendar quarter during which an MFN Model drug has been included in the MFN Model Drug HCPCS Codes List in accordance with § 513.130, no international sales, volume or pricing information meeting the requirements described in § 513.140(c) - including data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website - is available from any country described in § 513.120(b) for any calendar quarter beginning on or after October 1, 2019 through the applicable quarter, the MFN Drug Payment Amount is the applicable ASP.

(2) Payment for MFN Model drugs that are in short supply. If an MFN Model drug is reported as “Currently in Shortage” by FDA, beginning with the first day of the next calendar quarter after the date on which it is reported in shortage, the MFN Drug Payment Amount is the applicable ASP. CMS calculates payment in accordance with paragraph (b) of this section as of the first day of the calendar quarter after the date upon which the drug is no longer reported as “Currently in Shortage” by FDA.

(3) Adjustment to phase-in formula. (i) CMS accelerates the phase-in of the MFN Price by 5 percentage points at the next quarterly update to calculate the MFN Drug Payment Amount for the MFN Model drug where both of the following conditions are met:

(A) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U.

(B) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the MFN Price.

(C) For purposes of paragraphs (d)(3)(i)(A) and (B) of this section, the cumulative percentage increase means the cumulative percentage change from the end of the baseline to the end of the applicable ASP calendar quarter.

(D) The baseline in paragraph (d)(3)(i)(C) of this section for an MFN Model drug is the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1. If there is not an applicable ASP for the first quarter of performance year 1 for an MFN Model drug, the baseline for that MFN Model drug is the ASP calendar quarter for the first applicable ASP based on the manufacturer's average sales price for that MFN Model drug that occurs after the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1.

(ii) For purposes of paragraph (d)(3)(i) of this section, if the cumulative percentage increase in CPI-U or MFN Price is negative, CMS uses zero as the cumulative percentage increase in CPI-U or MFN Price, as applicable.

(iii) The application of an acceleration of the phase-in formula continues for the duration of the model performance period.

(iv) CMS applies an additional acceleration of the phase-in formula for each calendar quarter where the conditions specified in paragraph (i) are met.

(4) Adjustment for rapid increases in the applicable ASP or any monthly U.S. list prices beyond inflation and MFN Price after the full phase-in of the MFN Price. If the conditions described in paragraphs (d)(3)(i)(A) and (B) of this section are met after the full phase-in of the MFN Price for an MFN Model drug, for each calendar quarter thereafter, CMS decreases the MFN Drug Payment Amount equal to largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U and in the MFN Price, respectively, determined quarterly.

(5) Limitation on MFN Drug Payment Amount. The MFN Drug Payment Amount cannot exceed the non-model drug payment amount for claim lines submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

(e) Blood clotting factor furnishing fee. When applicable, the blood clotting furnishing fee under § 410.63(c) of this chapter is payable along with the MFN Drug Payment Amount.

