513.140 Included international data.

(a) General. (1) CMS uses drug pricing information from international data sources, available to CMS at least 20 business days prior to the start of a calendar quarter, meeting the requirements in paragraph (c) of this section for MFN Model drugs from countries included in paragraph (b) of this section.

(2) For purposes of selecting a data source for each MFN Model drug for a calendar quarter, CMS identifies available international drug pricing information data sources 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.

(b) Non-U.S. member countries of the Organisation for Economic Co-operation and Development (OECD). (1) CMS uses available international sales, volume, and pricing data for countries that were non-U.S. OECD member countries as of October 1, 2020 with a GDP per capita that is at least 60 percent of the U.S. GDP per capita as determined by CMS in accordance with this paragraph (b).

(2) Each country's GDP per capita is assessed using data available at the end of the applicable ASP calendar quarter.

(3) Subject to the limitation specified in paragraph (b)(4) of this section, the GDP per capita for a country is the the most recent estimate of GDP per capita based on purchasing power parity for that country available in the U.S. Central Intelligence Agency (CIA) World Factbook.

(4) The country's GDP per capita and U.S. GDP per capita selected from the CIA World Factbook must be for the same year.

(5) CMS identifies countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the GDP per capita for a country by the U.S. GDP per capita and assessing the results.

(c) Identification of international data sources. (1) CMS obtains data from one or more international drug pricing information data sources for purposes of identifying available international drug pricing information for the countries specified in paragraph (b) of this section.

(2) Such data sources must, as determined by CMS -

(i) Utilize a standardized method for identifying drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names;

(ii) Utilize a standard method for identifying drug forms that at a minimum distinguishes among injectable, oral, and other forms of a drug; and

(iii) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 180 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the database.

(iv) Contains international drug pricing information stated in U.S. currency, such as the following:

(A) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, or retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels.

(B) Volume data (for example, number of packages or units sold).

(C) List prices.

(v) Have mechanisms in place to maintain, update, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(3) For each MFN Model drug for a calendar quarter, CMS selects a data source using the following hierarchy.

(i) The data source contains sales and volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) The data source does not have sales and volume data for the applicable ASP calendar quarter, but contains sales and volume data for any prior ASP calendar quarter beginning on or after October 1, 2019 from at least one country described in paragraph (b) of this section. If sales and volume data from a prior ASP calendar quarter are used, CMS uses sales and volume data from the most recent ASP calendar quarter for which both sales and volume data are available.

(iii) The extracted 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.

(iv) The data source contains ex-manufacturer price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(v) The data source contains list price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(vi) If there is more than one data source for an ASP calendar quarter, for each MFN Model drug, CMS selects the data source at the highest level of the hierarchy that contains information from the highest number of countries described in paragraph (b) of this section

and, if available, incorporates discounts and rebates into its drug pricing information, and uses this data source to calculate the MFN Price as described in § 513.210(b).