

513.130 MFN Model drugs, updates, categories and excluded drugs.

(a) MFN Model drugs. CMS creates and periodically updates the MFN Model Drug HCPCS Codes List as described in this section. The MFN Model Drug HCPCS Codes List designates the MFN Model drugs, which are subject to the MFN Model payments specified in subpart C of this part.

(1) Initial MFN Model Drug HCPCS Codes List. For the beginning of performance year 1, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, and adds the remaining HCPCS codes, after updating such HCPCS codes for any applicable changes, to the MFN Model Drug HCPCS Codes List. Final action claims with dates of service within calendar year 2019 and allowed charges greater than \$0 are used to determine aggregate 2019 Medicare Part B total allowed charges.

(2) Annual Update of the MFN Model Drug HCPCS Codes List. For the start of each subsequent performance year, using Medicare Part B total allowed charge from the next subsequent calendar year, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate Medicare Part B total allowed charges, after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, for the most recent full calendar year, and adds any remaining HCPCS codes not already on the MFN Model Drug HCPCS Codes List to the MFN Model Drug HCPCS Codes List, after updating such HCPCS codes for any applicable changes, effective on the first day of the performance year.

(3) Removal. No more frequently than quarterly, CMS removes HCPCS codes from the MFN Model Drug HCPCS Codes List when CMS becomes aware that all of the National Drug Codes assigned to the HCPCS code have been permanently withdrawn from the U.S. market and the drug has been permanently withdrawn from the U.S. market, the specific HCPCS code included on the MFN Model Drug HCPCS Codes List is terminated with no replacement code available or planned, or an exclusion in paragraph (b)(1) of this section applies.

(4) Maintenance. No more frequently than quarterly, CMS revises HCPCS codes on the MFN Model Drug HCPCS Codes List as necessary to reflect quarterly HCPCS code updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, including adding replacement codes for HCPCS codes that were terminated.

(b) Exclusions. (1) The following are excluded from the MFN Model:

(i) Vaccines specified in section 1861(s)(10) of the Act (influenza, pneumococcal pneumonia, coronavirus disease 2019 (COVID-19), and Hepatitis B vaccines).

(ii) Radiopharmaceuticals.

(iii) Oral anticancer chemotherapeutic agents described in section 1861(s)(2)(Q) of the Act.

(iv) Oral anti-emetic drugs described in 1861(s)(2)(T) of the Act.

(v) Oral immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

(vi) Compounded drugs.

(vii) Intravenous immune globulin products.

(viii) Drugs billed with HCPCS codes that describe a drug product that was approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act;

(ix) Drugs for which there is an Emergency Use Authorization (EUA) from FDA, or FDA approval, to treat patients with suspected or confirmed COVID-19; or

(x) Drugs billed using a not otherwise classified (NOC) or not otherwise specified (NOS) billing and payment code.

(2) The following claims are excluded from the determination of whether a drug is to be included on the MFN Model Drug HCPCS Codes List:

(i) Professional claims with a place of service code indicating a home setting, including home, homeless shelter, assisted living facility, group home, temporary lodging, and custodial care facilities.

(ii) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.