Billing Information for Most Favored Nation (MFN) Model Drugs

For updates and information on the MFN Model status, please see the MFN Model website.

INTRODUCTION

This fact sheet provides Medicare-participating providers and suppliers required to participate in the Most Favored Nation (MFN) Model with information on how to bill their Medicare Administrative Contractors (MACs) for MFN Model drugs during the 7-year model. The model is testing a new way for Medicare Part B to determine the payment amount for included drugs. CMS only includes certain Part B drugs in the model. The payment for a model drug has two parts:

- The MFN Drug Payment Amount
- The per-dose add-on amount

You’ll bill the MFN Drug Payment Amount with the drug’s HCPCS code and the per-dose add-on amount with HCPCS code M1145. We’ll post the MFN Model Drugs HCPCS Code List and the MFN Model payment amounts on the MFN Model website quarterly. The model starts for dates of service (DOS) on or after January 1, 2021.

BACKGROUND

We’re testing the model in all of the United States and territories for 7 performance years (DOS from January 1, 2021, through December 31, 2027). The model interim final rule with comment (CMS-5528-IFC) establishes the parameters of the model. The model is mandatory for Medicare-participating providers and suppliers when:

- Medicare allows separate Part B payment for a drug or biological that is included in the model
- The beneficiary who received the drug meets the requirements for inclusion in the model and you send a claim to Medicare

There are certain participation and claims exclusions shown below.

The MFN Model website has several resources that explain the model payment test in detail. In summary, the model will include approximately 50 Medicare Part B drugs (by HCPCS code) with the highest annual Medicare Part B spending. We make certain exclusions (for example, vaccines are excluded). We’ll calculate the MFN
Drug Payment Amount quarterly using available international drug pricing information that we will phase-in over the first 4 years of the model.

The MFN Drug Payment Amount will be less than or equal to the “applicable Average Sales Price (ASP)” (the non-model payment limit after any non-model add-on amount is removed, for example, 100 percent of the ASP). For example, we’ll base the first quarter 2021 MFN Drug Payment Amounts on 75 percent of the applicable ASP and 25 percent of the lowest GDP-adjusted country-level price of the non-U.S. member countries of the Organisation for Economic Co-operation and Development (OECD) as of October 1, 2020 with a GDP per capita that is at least 60 percent of the U.S. GDP per capita, unless an exception applies. The exceptions either apply an amount equal to the “applicable ASP” or lower the payment amount. The per-dose add-on amount will test an alternative to the non-model percentage add-on. This amount will be the same for each model drug on a per-dose basis, and we’ll update this amount quarterly using an inflation factor. The per-dose add-on amount for the first quarter of 2021 (DOS beginning January 1, 2021, through March 31, 2021) is $148.73. The model payment limits we post on the MFN Model website will reflect the model’s payment policies and are the payment limits that your MAC will apply.

During the 7–year payment model, you’ll continue to buy and bill Medicare for the Part B drugs included in the MFN Model Drug HCPCS Codes List. See the MFN Model Drug HCPCS Codes List. We’ll update this list on a quarterly basis as necessary (for example, annual addition of drugs, updates for HCPCS code changes, potential removal of a drug from the model). The model payment only applies for a beneficiary who gets a model drug from an MFN participant and the beneficiary, on the date of service:

- Has Medicare Part B
- Has Medicare as his or her primary payer
- Is not covered under Medicare Advantage or any other group health plan

You’ll identify these beneficiaries and follow the billing and coding information in this fact sheet.

**BILLING & CODING**

To bill model drugs, you’ll continue to submit claims for the current, appropriate HCPCS codes that you would use in the absence of the model. However, the model replaces the current percentage-based add-on that is generally part of the non-model payment limit with a separately paid, add-on payment per MFN Model drug dose. To bill the MFN per-dose add-on amount, you’ll need to use HCPCS code M1145. You must bill for this add-on payment as part of your claim when billing for model drugs.

For each dose of a model drug, you’ll submit a claim line with the appropriate drug HCPCS code and number of billing units that reflect the amount of drug furnished. You’ll also bill a claim line with one unit of M1145 for the per-dose add-on amount. If you bill more than one model drug on the same claim, you’ll bill M1145 using one claim line and the number of units billed should be equal to the number of doses of model drugs that you bill on that claim. You’ll generally apply the add-on once per model drug per day unless the number of billing units is so high that multiple claim lines are required to bill the number of HCPCS code dosage units you furnished.
When applicable, you’ll continue to submit a claim line for the amount of discarded drug with the JW modifier. Don’t bill any units of M1145 for a claim line that reports discarded drug.

You’ll continue to bill the JG modifier when applicable. When you use the JG modifier with a model drug HCPCS code, you’ll receive the lower of the MFN Drug Payment Amount or their non-model drug payment amount (less any non-model add-on amount, if applicable). Don’t bill the JG modifier with M1145 for the alternative per-dose add-on payment amount.

We’ll update and post the MFN Drug Payment Amount for model drugs and the per-dose add-on amount to the MFN Model website on a quarterly basis. See the MFN Drug Payment Amounts for performance year 1, quarter 1.

**ADDITIONAL NOTES**

Medicare beneficiaries will pay 20 percent of the MFN Drug Payment Amount, which will be at or lower than the non-model payment limit. The allowed MFN Drug Payment Amount will not exceed the billed amount on the claim for the model drug. There is no Medicare beneficiary copay or deductible applied to the per-dose add-on payment. This protects beneficiaries from increases in their cost-sharing liability.

The add-on should be applied per claim line (except for claim lines billed with the JW modifier), not per billing unit for model drugs on the claim.

If we add a clotting factor drug to the model in the future, we would add the furnishing fee to the MFN Drug Payment Amount.

For those using the Hospital Outpatient Prospective Payment System (OPPS), the OPPS claims processing system will apply the appropriate MFN alternative add-on payment amount (per covered unit) regardless of the charge that the MFN participant submits as the billed amount on the claim line. This claims processing approach allows MFN participants that are paid under the OPPS to opt to submit a token charge to avoid impacting their cost to charge ratio.

If you bill HCPCS M1145 on a claim that doesn’t include a model drug, your MAC will deny the related claim lines using the following messages:

- Claims Adjustment Reason Code (CARC): 16 - Claim/service lacks information or has submission/billing error(s)
- Remittance Advice Remark Code (RARC): M20 - Missing/incomplete/invalid HCPCS
- Group Code: CO (Contractual Obligation)
Excluded MFN Provider and Bill Types:
The model excludes the following providers and related bill types:

- Children’s hospitals - 012x (Hospital IP Part B), 013x (Hospital OP)
- Inpatient Prospective Payment System (IPPS)-exempt cancer hospitals - 012x, 013x
- CMMI Model Participants in the Pennsylvania Rural Health Model (PARHM) - 013x¹
- Nonparticipating providers and suppliers
- Veterans Administration (VA) Demonstration Claims - Demo Code 31
- Federally Qualified Health Centers (FQHCs) - 077x (FQHC)
- Rural Health Centers (RHCs) - 071x (Clinical Rural Health)
- Claims administered by the Durable Medical Equipment (DME) MACs

Excluded MFN Claims and Bill Types:

- Inpatient Part B Only – 012x
- Claims where Medicare Part B isn’t the primary payer (Medicare Secondary Payer (MSP) claims) - Bill Types 013x, 072x for institutional providers

If you submit HCPCS M1145 on a claim that includes an MFN Model drug, but you or your claim type is not included in the model, your MAC will deny the claim line(s) using the following messages:

- CARC: 16 - Claim/service lacks information or has submission/billing error(s)
- RARC: M20 - Missing/incomplete/invalid HCPCS
- Group Code: CO (Contractual Obligation)

RESOURCES

- Contact the MFN Model Help Desk for general questions.
- Contact your MAC for billing and payment questions related to specific claims.

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¹PARHM participants, as well as Maryland Total Cost of Care Model participants, are excluded for the first quarter and second quarter of performance year 1 and will continue to be excluded from the remainder of the model as long as those models incorporate savings on Medicare Part B drug spending under the MFN Model.