Fact sheet

FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period

Nov 20, 2020 Medicare Parts A & B

The Centers for Medicare & Medicaid Services (CMS) is announcing a new payment model, the Most Favored Nation (MFN) Model (or the "MFN Model"), and issuing a corresponding Interim Final Rule with Comment Period (IFC). The MFN Model will lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals (hereinafter called "drugs") than the lowest price that drug manufacturers receive in other similar countries. The MFN Model will also pay providers a flat add-on amount for each dose of an MFN drug, instead of a percentage of each drug's cost, removing the tie between drug cost and the add-on amount. Beneficiaries will pay lower coinsurance for these high-cost Part B drugs and will not pay coinsurance on the add-on payment. The MFN Model will require participation of Medicare providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, with certain exceptions, and begin nationally January 1, 2021.

One of the largest drivers of increasing Medicare spending is the growing prices for physician-administered separately payable Medicare Part B drugs, which have risen an average of 11.5 percent annually since 2015, with total spending of approximately $30 billion in 2019. These high, and increasing, costs are borne by Medicare beneficiaries and taxpayers and are the direct result of: (1) a lack of competitive market forces on Medicare Part B drug costs; and (2) an incentive system that pays hospitals, physicians (and non-physician practitioners), and other providers based on the volume of the drugs they use and the prices drug manufacturers set.

Executing on President Trump's mandate to lower drug costs and recent Executive Order on Lowering Drug Prices by Putting America First (September 13, 2020) by announcing the MFN Model, CMS will introduce a most-favored-nation approach in calculating payment for Medicare Part B drugs. The MFN Model will test paying Part B drugs at comparable amounts to the lowest adjusted price[1] paid by any country in the Organisation for Economic Co-operation and Development (OECD)[2] that has a Gross Domestic Product (GDP) per capita that is at least 60 percent of the U.S. GDP per capita. The model will also test a redesign of the percentage add-on payment structure under Medicare Part B to

test a redesign of the percentage add-on payment structure under Medicare Part B to remove incentives for use of higher-cost drugs through a flat per-dose add-on payment, and will include a financial hardship exemption for MFN participants.

The mandatory MFN Model will operate for seven years, from January 1, 2021 to December 31, 2027. Over the course of the model, CMS will monitor and evaluate the impact of the MFN Model on beneficiary access to drugs, program costs, and the quality of care for beneficiaries. Further, CMS commits to assess initial impacts of the MFN Model on quality of care, including access to drugs, prior to beginning performance year 5.

The MFN Model Interim Final Rule with Comment Period is available at: https://innovation.cms.gov/media/document/mfn-ifc-rule.

Background

High drug prices are impacting the wallets of Medicare beneficiaries through increased premiums and out-of-pocket costs. Increases in drug spending are accelerating at a rate that significantly outpaces the growth in spending on other Medicare Part B services, and prices in the U.S. for most Medicare Part B drugs with the highest Medicare spending far exceed prices in other countries. Medicare Part B drug expenditures have increased significantly over time as a result of rising drug prices. The 2020 Medicare Trustees Report noted that drugs have consistently been a major contributor to the overall Medicare Part B trend, with drug spending increasing from 11 percent of total Medicare Part B spending in 2015 to 14 percent in 2019, accounting for 37 percent of the growth in Medicare Part B spending from 2015 through 2019.[3] According to a new U.S. Department of Health & Human Services (HHS) study, between 2006 and 2017, Medicare Part B Fee-For-Service drug spending per enrollee grew at 8.1 percent, more than twice as high as per capita spending on Medicare Part D (3.4 percent) and nearly three times as high as overall retail prescription per capita drug spending (2.9 percent). Moreover, spending and enrollment projections by the CMS Office of the Actuary for the 2021 President's Budget suggest that per capita spending on Medicare Part B physician-administered drugs and separately payable hospital outpatient drugs will grow at a similar annual rate of 8 percent between 2020 and 2027, before consideration of any COVID-19 pandemic impacts.[4]

Medicare Part B pays more than the average in comparable countries for each drug, according to another new HHS study. This anti-competitive system leaves taxpayers and American seniors on the hook for paying the highest drug costs in the world. For example, the top-selling Medicare Part B drug – a common eye drug (Eylea) – was approximately two times as expensive in Medicare Part B as in comparison countries.[5]

As a result, Medicare beneficiaries and the Medicare program are bearing unnecessary, potentially avoidable costs for Medicare Part B drugs. These high costs can cause Medicare

potentially avoidable costs for Medicare Part B drugs. These high costs can cause Medicare beneficiaries to divert scarce resources away from other needs, prompting them to take fewer doses of their medications or abandon treatment altogether.

Model Design

Participants

MFN participants will include Medicare-participating physicians, non-physician practitioners, supplier groups (such as group practices), hospital outpatient departments (HOPDs) including 340 covered entities, Ambulatory Surgical Centers (ASCs), and other providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, with certain exceptions. Certain types of hospitals and clinics will not participate in the model (such as cancer hospitals, children's hospitals, critical access hospitals, rural health centers, federally qualified health centers, and Indian Health Service facilities). Participants in certain other Innovation Center models testing fully capitated or global payment for outpatient hospital services for Medicare FFS beneficiaries, including Medicare Part B drugs, will be 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. The model's geographic area will be nationwide; that is, it will include all states and the U.S. territories.

MFN Model Drugs

The MFN Model will focus on a set of 50 Medicare Part B drugs that encompass a high percentage of Medicare Part B drug spending. CMS identified the list of MFN Model drugs for the first year based on annual Medicare Part B spending in 2019, after excluding certain types of drugs (such as certain vaccines, oral drugs, multiple source drugs, and intravenous immune globulin products) and spending on drugs used at home. Drugs that treat patients with suspected or confirmed coronavirus disease 2019 will also be excluded. CMS will add drugs to the model annually to include drugs that rise to be among the top 50 drugs based on updated annual Medicare Part B spending, after applying certain exclusions. Drugs already included in the model will remain in the model, with limited exceptions.

Model Drug Payment

The current Medicare Part B payment amount for separately payable drugs is typically based on the manufacturer's reported average sales price (ASP) plus 6 percent of the ASP as an add-on amount. For the MFN Model, CMS will test an alternative payment for included drugs that will be based on global prices and include a flat add-on amount for each dose. Instead of paying based on price manufacturers charge in the U.S., Medicare will

each dose. Instead of paying based on price manufacturers charge in the U.S., Medicare will test paying based a formula that phases in the lowest adjusted international price, (the "MFN Price") for the drug that will ensure that by January 2024, Medicare never pays more than the MFN Price for an included drug when furnished by a participating provider or supplier. The MFN Price will be based on the lowest GDP-adjusted price paid by any country that was an OECD member country as of October 1, 2020 and has a GDP per capita (adjusted for purchasing power parity) that is at least 60 percent of the U.S. GDP per capita.

The MFN Price will be phased-in over the first 4 years of the 7-year model, phasing in 25 percent per year for years 1-4, and then continuing at 100 percent of the MFN Price for years 5-7. For example, for the first year the phase-in calculation will use 75 percent of the ASP and 25 percent of the MFN Price. In years 4-7, the MFN Price will be fully phased-in; however, CMS will accelerate the phase-in of the MFN Price for a drug if U.S. prices rise faster than both inflation and the MFN Price. Further, once the MFN Price is fully phased in, CMS will further adjust downward the MFN Drug Payment Amount if U.S. prices rise faster than both inflation and the MFN Price.

To lower what beneficiaries pay, the model payment amount for a drug (before the per-dose add-on) will not exceed the ASP.

Alternative to ASP Add-on Payments

In addition, Medicare will pay MFN participants a flat add-on payment for each dose that is uniform for all included drugs in the MFN Model. The per-dose add-on for the first quarter of 2021 will be $148.73.

The per-dose add-on was calculated using 6.1224 percent of 2019 historic spending for the cohort of drugs included in the first year of the model and will be trended forward with an inflationary factor quarterly. CMS increased the 6 percent add-on from 2019 to equal 6 percent post-sequestration prior to calculating the per-dose add-on and applying an inflationary factor for the model start and quarterly thereafter. Beneficiary cost-sharing will be waived for the per-dose add-on amount, further reducing what beneficiaries will pay for the included drugs.

Quality, Beneficiary, and Provider Protections

Beneficiaries will maintain their choice of provider and treatments. In addition, CMS will provide additional beneficiary protections such as enhanced monitoring and Medicare Beneficiary Ombudsman supports. The MFN Model will also incorporate a survey-based quality measure to monitor beneficiaries' experience of care during the model, and CMS will conduct a variety of analyses to monitor access to the included drugs and assess early effects of the model. CMS will also conduct a model evaluation.

effects of the model. CMS will also conduct a model evaluation.

In addition, the MFN Model will include a financial hardship exemption for certain MFN participants whose revenue is significantly affected by the MFN Model.

For further information, visit the MFN Model website at: https://innovation.cms.gov/initiatives/most-favored-nation-model.

###

---

[1] The price will be adjusted for purchasing power.

[2] Based on membership as of October 1, 2020.

[3] 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Accessed via: https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf

[4] Nguyen X. Nguyen and Steve Sheingold. Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures).

[5] El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices).

7500 Security Boulevard, Baltimore, MD 21244