

# Issue Brief

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## CMS Issues “Most Favored Nation” Part B Drug Model

The Centers for Medicare & Medicaid Services has released an interim final rule regarding a new payment model for 50 of Medicare’s most costly Part B drugs. The new payment model is being cited as the “Most Favored Nation.”

CMS provided a copy of the rule before it was sent to the Office of the *Federal Register*. This analysis is based on the “early rule.” The rule is now at the *Federal Register* office. A copy is currently available at <https://public-inspection.federalregister.gov/2020-26037.pdf>. It will be published Nov. 27.

The rule is scheduled to be effective 30 days after publication with actual payment changes beginning Jan. 1, 2021. The model is intended to last 7 years.

CMS says it, “believes a nationwide scope is the most appropriate for the MFN Model.” Thus, CMS is codifying in § 513.120 that the MFN Model geographic area includes all states and U.S. territories.

The payment amount for MFN Model drugs will be based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of member countries of the Organization for Economic Co-operation and Development (OECD) with a GDP per capita that is at least

60% of the U.S. GDP per capita. The current list of OECD countries meeting the 60% threshold includes Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland and the United Kingdom.

### COMMENTS

During a Nov. 20 press conference, President Trump suggested this rule may never be implemented because, (1) the pharmaceutical industry continues to vehemently oppose the rule, and will probably challenge it in the courts, and (2) the President said President-elect Biden may not embrace it either.

CMS’ Office of the Actuary “estimates savings of roughly \$64.4 billion in Medicare FFS benefits, \$49.6 billion in Medicare Advantage payments, and \$9.9 billion in Medicaid spending (\$5.7 billion in federal payments and \$4.3 billion in state payments). Overall, OACT estimates that the MFN Model will result in savings of \$85.5 billion, net of the associated change in the Part B premium, in Medicare Part B spending. In addition, OACT estimates that all beneficiaries will save a total of \$28.5 billion from a reduction in the Medicare Part B premium as a result of the MFN Model, and will also see their coinsurance reduced.”

*continued*

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Unfortunately, CMS does not reveal the numbers that would result in the \$85.5 billion in savings target.

This rule contains much redundancy, and lacks, as usual, a table of contents.

The rule is employing a waiver of the normal 60-day period between issuance and an effective date. The Office of Management and Budget says it received the rule in June. Why has it taken 5 months to approve it?

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## PROVISIONS OF THE INTERIM FINAL RULE

The MFN Model is intended to test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as “drugs”) with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

Participants in the MFN Model will include all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN Model drug with limited exceptions. The vast majority of providers and suppliers that furnish separately payable Medicare Part B drugs are physicians and non-physician practitioners, supplier groups (such as a group of physicians or other practitioners), hospital outpatient departments, including on- or off-campus provider-based departments, whether paid under the outpatient prospective payment system or the physician fee schedule, and ambulatory surgical centers.

There will be no specific enrollment activities for MFN participants; rather, participation will be effectuated by the submission of a claim for an MFN drug furnished to an MFN beneficiary, and CMS will apply the MFN payment to such a claim.

CMS will exclude the following providers and suppliers: Children’s hospitals; PPS-exempt cancer hospitals; critical access hospitals; Indian Health Service facilities; Rural Health Clinics; Federally Qualified Health Centers; hospitals that are not subsection (d) hospitals and are paid on the basis of reasonable costs subject to a ceiling under Section 1886(b) of the Act; and extended neoplastic disease care hospitals. In addition, for the first and second quarter of performance year one, CMS will exclude acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis in accordance with a waiver under such model of section 1833(t) of the Act.

### MFN Model Drugs

The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending.

CMS lists the 50 drugs for the first year of the model (2021) in the following table.

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges, after exclusions (in dollars)	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
1	J0178	Aflibercept injection	\$2,982,942,674	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
2	J9271	Inj pembrolizumab	\$2,815,337,226	Hematology/Oncology	Internal Medicine	Medical Oncology
3	J9299	Injection, nivolumab	\$1,878,981,569	Hematology/Oncology	Internal Medicine	Medical Oncology
4	J9312	Inj., rituximab, 10 mg	\$1,865,991,330	Hematology/Oncology	Internal Medicine	Rheumatology
5	J0897	Denosumab injection	\$1,721,580,561	Hematology/Oncology	Internal Medicine	Rheumatology
6	J2778	Ranibizumab injection	\$1,295,341,479	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
7	J2505	Injection, pegfilgrastim 6mg	\$1,242,697,080	Hematology/Oncology	Internal Medicine	Medical Oncology
8	J9035	Bevacizumab injection	\$1,099,476,084	Hematology/Oncology	Internal Medicine	Medical Oncology
9	J1745	Infliximab not biosimil 10mg	\$1,010,328,165	Rheumatology	Gastroenterology	Internal Medicine
10	J0129	Abatacept injection	\$968,556,135	Rheumatology	Internal Medicine	Hematology/Oncology
11	J9355	Inj trastuzumab excl biosimi	\$851,042,669	Hematology/Oncology	Internal Medicine	Medical Oncology
12	J9145	Injection, daratumumab 10 mg	\$843,712,153	Hematology/Oncology	Internal Medicine	Medical Oncology
13	J2350	Injection, ocrelizumab, 1 mg	\$703,104,359	Neurology	Hematology/Oncology	Internal Medicine
14	J1300	Eculizumab injection	\$562,413,430	Neurology	Hematology/Oncology	Internal Medicine
15	J9305	Pemetrexed injection	\$539,680,121	Hematology/Oncology	Internal Medicine	Medical Oncology
16	J9022	Inj, atezolizumab,10 mg	\$486,551,001	Hematology/Oncology	Internal Medicine	Medical Oncology
17	J9173	Inj., durvalumab, 10 mg	\$476,638,073	Hematology/Oncology	Internal Medicine	Medical Oncology
18	J2353	Octreotide injection, depot	\$466,969,222	Hematology/Oncology	Internal Medicine	Medical Oncology
19	J0717	Certolizumab pegol inj 1mg	\$458,757,878	Rheumatology	Internal Medicine	Nurse Practitioner
20	J9041	Inj., velcade 0.1 mg	\$436,302,629	Hematology/Oncology	Internal Medicine	Medical Oncology
21	J2357	Omalizumab injection	\$423,947,996	Allergy/Immunology	Internal Medicine	Pulmonary Disease
22	J0585	Injection, onabotulinumtoxinA	\$389,236,097	Neurology	Physical Medicine and Rehab	Ophthalmology
23	J1602	Golimumab for iv use 1mg	\$368,492,761	Rheumatology	Internal Medicine	Nurse Practitioner
24	J3380	Injection, vedolizumab	\$362,050,123	Gastroenterology	Hematology/Oncology	Internal Medicine
25	J9264	Paclitaxel protein bound	\$333,264,824	Hematology/Oncology	Internal Medicine	Medical Oncology
26	J9228	Ipilimumab injection	\$331,065,114	Hematology/Oncology	Internal Medicine	Medical Oncology
27	J9217	Leuprolide acetate suspension	\$331,012,840	Urology	Hematology/Oncology	Internal Medicine
28	J9306	Injection, pertuzumab, 1 mg	\$318,023,592	Hematology/Oncology	Internal Medicine	Medical Oncology
29	J9047	Injection, carfilzomib, 1 mg	\$296,821,394	Hematology/Oncology	Internal Medicine	Medical Oncology
30	J3262	Tocilizumab injection	\$279,068,051	Rheumatology	Internal Medicine	Hematology/Oncology
31	J1930	Lanreotide injection	\$278,600,806	Hematology/Oncology	Internal Medicine	Medical Oncology
32	J3357	Ustekinumab sub cu inj, 1 mg	\$264,386,412	Rheumatology	Gastroenterology	Dermatology
33	J0881	Darbepoetin alfa, non-esrd	\$258,409,215	Hematology/Oncology	Internal Medicine	Medical Oncology
34	J2323	Natalizumab injection	\$255,449,074	Neurology	Hematology/Oncology	Internal Medicine
35	J2796	Romiplostim injection	\$248,212,119	Hematology/Oncology	Internal Medicine	Medical Oncology
36	J9034	Inj., bendeka 1 mg	\$219,156,831	Hematology/Oncology	Internal Medicine	Medical Oncology
37	J0885	Epoetin alfa, non-esrd	\$187,518,352	Hematology/Oncology	Internal Medicine	Nephrology
38	Q2043	Sipuleucel-t auto cd54+	\$182,158,187	Urology	Hematology/Oncology	Internal Medicine
39	J2182	Injection, mepolizumab, 1mg	\$177,640,239	Allergy/Immunology	Internal Medicine	Pulmonary Disease
40	J1439	Inj ferric carboxymaltos 1mg	\$173,008,338	Hematology/Oncology	Internal Medicine	Medical Oncology

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges, after exclusions (in dollars)	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
41	J9042	Brentuximab vedotin inj	\$162,519,904	Hematology/Oncology	Internal Medicine	Medical Oncology
42	J9055	Cetuximab injection	\$162,477,948	Hematology/Oncology	Internal Medicine	Medical Oncology
43	J9354	Inj, ado-trastuzumab emt 1mg	\$157,438,453	Hematology/Oncology	Internal Medicine	Medical Oncology
44	Q5111	Injection, udenyca 0.5 mg	\$155,483,502	Hematology/Oncology	Internal Medicine	Medical Oncology
45	J7324	Orthovisc inj per dose	\$152,408,630	Orthopedic Surgery	Physician Assistant	Sports Medicine
46	J2785	Regadenoson injection	\$150,339,213	Cardiology	Interventional Cardiology	Internal Medicine
47	J0517	Inj., benralizumab, 1 mg	\$136,977,827	Allergy/Immunology	Internal Medicine	Pulmonary Disease
48	J2507	Pegloticase injection	\$123,947,596	Rheumatology	Internal Medicine	Hematology/Oncology
49	J9176	Injection, elotuzumab, 1mg	\$123,725,659	Hematology/Oncology	Internal Medicine	Medical Oncology
50	J9311	Inj rituximab, hyaluronidase	\$121,583,613	Hematology/Oncology	Internal Medicine	Medical Oncology

### Model Payment Methodology for MFN Model Drugs

CMS will calculate an MFN Drug Payment Amount for each drug on the MFN Model Drug HCPCS Codes List based on an MFN Price, which will be derived from the lowest GDP-adjusted country-level price, based on non-U.S. OECD member countries with a GDP per capita that is at least 60% of the U.S. GDP per capita.

Providers and suppliers will continue to purchase MFN Model drugs, furnish such drugs to beneficiaries, submit claims to Medicare, and collect applicable beneficiary cost-sharing. Under the MFN Model, payments for separately payable Medicare Part B drugs will include an alternative drug payment amount and the alternative add-on payment amount, both subject to sequestration, as applicable.

“To create a simple, easily understandable GDP adjuster, each country’s GDP adjuster will be a straight ratio of its GDP per capita based on purchasing power parity divided by U.S. GDP per capita.”

The U.S. GDP per capita for 2017, the most current data available, was \$59,800. The table below presents GDP per capita for 2017 and the GDP adjusters for each non-U.S. OECD member country, based on the U.S. GDP per capita of \$59,800 for 2017, that CMS will use to calculate the MFN Drug Payment Amounts for performance year one, quarter one.

	CIA GDP Per Capita, Based on Purchasing Power Parity (2017)	GDP Adjuster for Performance Year 1, Quarter 1
The following countries have a GDP per capita of at least 60% of U.S. GDP per capita <sup>†</sup>		
Australia	\$50,400	0.843
Austria*	\$50,000	0.836
Belgium*	\$46,600	0.779
Canada*	\$48,400	0.809
Denmark*	\$50,100	0.838
Finland*	\$44,500	0.744

	<b>CIA GDP Per Capita, Based on Purchasing Power Parity (2017)</b>	<b>GDP Adjuster for Performance Year 1, Quarter 1</b>
France*	\$44,100	0.737
Germany*	\$50,800	0.849
Iceland	\$52,200	0.873
Ireland*	\$73,200	1.000**
Israel	\$36,400	0.609
Italy*	\$38,200	0.639
Japan*	\$42,900	0.717
Republic of Korea	\$39,500	0.661
Luxembourg	\$105,100	1.000**
Netherlands*	\$53,900	0.901
New Zealand	\$39,000	0.652
Norway	\$72,100	1.000**
Spain	\$38,400	0.642
Sweden	\$51,200	0.856
Switzerland	\$62,100	1.000**
United Kingdom*	\$44,300	0.741

CMS will use a phase-in approach that will blend the MFN Price with the applicable ASP to allow MFN participants time to adjust to the model payment amounts and processes. The phase-in formula will be stable for a given performance year, whereas the MFN Price and applicable ASP will vary quarterly based on fluctuations in drug prices in the U.S. and in included countries.

The MFN Drug Payment Amount will be based on 100% of the MFN Price starting in performance year four.

<b>Phase-in of MFN Prices by Performance Year</b>	
<b>Performance Year</b>	<b>Blend of the ASP and MFN Price for an MFN Model Drug at the HCPCS Code Level</b>
Year 1	75% applicable ASP and 25% MFN Price
Year 2	50% applicable ASP and 50% MFN Price
Year 3	25% applicable ASP and 75% MFN Price
Year 4	100% MFN Price
Year 5	100% MFN Price
Year 6	100% MFN Price
Year 7	100% MFN Price

Beginning on the rule's page 79, CMS provides an illustrated calculation for each of the 50 MFN drugs cited above. Below is the calculation of the first identified MFN drug. The payment amount is comprised of 75% of the ASP price and 25% of the MFN price for each quarter.

HCPCS Code <sup>†</sup>	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price**	Illustrative MFN Drug Payment	Illustrative MFN Country <sup>††</sup>
J0129	Abatacept injection	10 MG	Q1	\$50.891	\$12.977	\$41.412	Australia
			Q2	\$51.243	\$12.821	\$41.638	Australia
			Q3	\$51.744	\$12.862	\$42.024	Australia
			Q4	\$51.965	\$12.883	\$42.195	Australia

Analysis provided for MHA by  
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CMS says that eligible providers and suppliers participating in the 340B program will be paid the lesser of the MFN amount or the payment they purchase under the 340B program.

### FINAL COMMENT

As usual, there is much more in the rule regarding such subjects as quality, beneficiary protections, increasing the blend amounts if ASP prices rise to quickly, alternative ASP add-on payments and a list of additional OECD countries that currently have GDPs but are less than 60% of the U.S. GDP.

This analysis is based on CMS' early release of the rule which contains 258 pages. The copy at the *Federal Register* is only 229 pages. Most of the changes made appear to be cosmetic. For example, the CMS version contained the rule reference on each page. The *Federal Register* copy has deleted those items.