



NATIONAL INFUSION CENTER ASSOCIATION

Most Favored Nation Model: An Overview

On November 20, the Administration announced its Most Favored Nation (MFN) Model, which will go into effect on January 1, 2021. This document outlines the basics on the Model and describes what actions NICA is taking to prevent this harmful policy from being rushed into effect.

What will happen to reimbursement?

For fifty drugs identified by CMS, the Model has two main goals:

1. Gradually replace the ASP with the MFN price; and
2. Replace the percentage-based add-on fee with a flat fee.

The MFN price is the lowest per-capita-GDP adjusted price of any country in a certain group of comparator countries. Comparator countries are OECD members with a per capita GDP greater than 60% of U.S. per capita GDP. For the first year, CMS has identified 22 countries that will be in the group based on these criteria. The Model will blend in the new MFN price over the first four years, as follows:

- Year 1 (2021): reimbursement will be a 75% ASP/25% MFN price blend
- Year 2 (2022): 50/50 blend of both prices
- Year 3 (2023): 25% ASP/75% MFN price
- Year 4 through the end of the demo: 100% MFN price

CMS provides illustrative MFN prices for the fifty drugs that are included in Year 1 based on 2019 data, but these are just examples. The agency will post the final/actual reimbursement rates on the Model website before January 1, but gave no specific date for that posting.

Additionally, the Model will replace the current 6% add-on fee with a flat fee of \$148.73 per dose, to be updated over time to account for the effects of inflation. This change does not have a phase-in: it will become effective on January 1, 2021 for all covered drugs.

Administration codes are unaffected by the Model.

Which drugs are included? The Centers for Medicare and Medicaid Services (CMS) identified a list of fifty Part B fee-for-service drugs that will be included for the first year of the Model. This list includes many products used by infusion centers, such as drugs used to treat autoimmune, neurological, and gastrointestinal conditions. The full list is attached. CMS may add additional drugs in the future.

Is my State included? Yes: the Model is nationwide.

When? The Model begins on January 1, 2021, and lasts for seven years. As explained below, the Model will gradually replace the average sales price (ASP) with the MFN price over the first four years of the Model.

Who will participate? Can I opt out? Participation is mandatory. Your enrollment will occur automatically upon submission of a claim for one of the fifty included drugs. CMS includes a very limited financial hardship exemption, but this will not be available for the first year.

What happens next? As CMS has acknowledged, the MFN Model will lead to a loss of beneficiary access to several Part B drugs. This is unacceptable, particularly since people in need of these medicines represent some of Medicare's most vulnerable beneficiaries. NICA is hard at work on several fronts to stop the rushed implementation of this harmful policy:

- **Administration:** To make sure our concerns are aired to all possible audiences, we will file a comment letter objecting to the rule before the end of the year. Because the comment period closes nearly a full month *after* the Model takes effect, however, it is clear that CMS is not interested in meaningful or actionable feedback from stakeholders.
- **Court system:** We have joined with several other plaintiffs to bring a lawsuit in challenging the Model on procedural and substantive grounds and to seek a preliminary injunction that would prevent the Model from going into effect on January 1.
- **Congress:** Finally, we have joined a broad coalition of Part B drug patients, providers, and other stakeholders who are actively urging Congress to delay implementation of the Model.

TABLE 2: PERFORMANCE YEAR 1 MFN MODEL DRUG HCPCS CODES LIST WITH TOP BILLING SPECIALTIES

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 Rehabilitation	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 suspnsion	\$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
41	J9042	Brentuximab vedotin inj	\$162,519,904	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
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

Note: Ambulatory Surgical Center is included as a specialty to show drug utilization in this setting.

*The short description effective as of January 1, 2021.

Table 3 shows the distribution of total 2019 Medicare Part B allowed charges for the drugs identified in Table 2 by provider and supplier type to show the types of providers and suppliers that had claims for these separately payable Medicare Part B drugs in 2019. To assign claims to a provider or supplier type, we considered the type of MAC that processed the claim, type of bill, provider number, revenue center, line place of service code, and specialty of the health care practitioner associated with the drug claim line.