## Help deliver a message to Congress:
## STOP THE MOST FAVORED NATION EXPERIMENT ON VULNERABLE MEDICARE PATIENTS!

The Coalition of State Rheumatology Organizations (CSRO) is offering this toolkit of resources to help members get involved in stopping the misguided Most Favored Nation (MFN) Model.

In this toolkit you will find:

1. **MFN overview:** To help you understand the impact of the proposal.
2. **Key messages**: To help you talk about the Model to policymakers, patients, and other rheumatologists. What will the Model do, what rheumatology drugs are included, and how will your patients be affected?
3. **Email to Congress**: To help you contact Congress. The email template provided is just suggested language to get you started. Please customize and personalize it, because Members of Congress pay more attention to individualized letters than to boilerplate text. The template is just a starting point!
4. **For your reference**: The full list of drugs included in the Model.



CSRO
Coalition of State Rheumatology Organizations

# MFN Overview:
## The Basic Facts

The Model will apply to the fifty highest-spend Part B fee-for-service drugs, as identified by CMS. The Model will apply nationwide and participation is mandatory; enrollment will occur automatically upon submission of a claim for one of the fifty identified drugs. The Model begins on January 1, 2021 and will last for seven years.

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

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

Replacing the ASP with the MFN Price

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

Replacing the percentage add-on with a flat fee

The Model will replace the current 6% add-on fee with a flat fee of $148.73 per dose, to be updated with inflation. This part becomes effective on January 1, 2021 (no phase-in).

## MFN Overview: Impact on Rheumatology

### What rheumatology drugs are included in the MFN?

*The Most Favored Nation targets the top 50 Medicare Part B drugs and treatments. Twelve of these are drugs commonly used in rheumatology practices.*

1. **J1745 (Infliximab not biosimilar 10mg)**
2. **J0129 (Abatacept injection)**
3. **J0717 (Certolizumab pegol inj 1mg)**
4. **J1602 (Golimumab for iv use 1 mg)**
5. **J3262 (Tocilizumab injection)**
6. **J3357 (Ustekinumab sub cu inj, 1 mg)**
7. **J2507 (Pegloticase injection)**
8. **J9312 (Inj., rituximab, 10 mg)**
9. **J0897 (Denosumab injection)**
10. **J2350 (Injection, ocrelizumab, 1 mg)**
11. **J2323 (Natalizumab injection)**
12. **J7324 (Orthovisc inj. per dose)**

For these nine, CMS identifies rheumatology as the #1 prescribing specialty

**GI, neurology, allergy/immunology, and other products are included as well, so the impact on infusion centers who also serve non-rheumatology patients is even greater. Included at the end of this toolkit is the full table from the rule with the fifty drugs, for reference.**

## Key Messages & Talking Points
## The MFN Model

**The MFN would implement a nationwide, mandatory "test" to automatically lower reimbursement for the top 50 Medicare Part B drugs based on international drug prices. Over one fifth of the drugs included in the Model are routinely used by rheumatology patients.**

**The MFN Model suffers from serious procedural and substantive flaws that will result in Medicare beneficiaries losing access to critical medicines – as CMS explicitly acknowledges in the rule!**

- **CMS is rolling out this nationwide, mandatory demo with no meaningful opportunity for comment, leaving patients and their doctors with a month to figure out implementation.**
  - The government is using the "Innovation Center" to roll out a nationwide Medicare Part B program change that will harm vulnerable beneficiaries. This far exceeds acceptable boundaries of what the Innovation Center should test.
  - Since the Model begins nearly a month before the comment period closes, CMS has provided affected patients and physicians with no meaningful opportunity to provide input.

- **Patients will lose access to critical medicines.**
  - CMS acknowledges that "beneficiaries may experience access to care impacts" as a result of the Model, including receiving an alternative therapy "that may have lower efficacy or greater risks" or even "postponing or forgoing treatment." This is not a gamble we can take with the vulnerable beneficiaries who rely on these medicines.
  - The Model's expected outcome rests entirely on the hope that pharmaceutical manufacturers will lower their prices enough in the next three weeks. Many rheumatology practices have already started to curtail ordering Part B medications for Medicare patients because of the potential losses starting in January, which means that many patients will be without treatment as early as the first week of January.
  - CMS was aware this would happen: in the rule, the agency explicitly acknowledges that a portion of the Model's savings "is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."
  - In the case of progressive and debilitating diseases such as rheumatoid arthritis, even a few weeks of delay can result in severe pain and irreversible joint damage.

- **The Model will burden our already strained healthcare infrastructure.**

  - Throughout the pandemic, rheumatology practices have continued to serve patients in need, providing safe infusion sites for people suffering with autoimmune disease. When these practices can no longer afford to provide infusion services as a result of the Model, these patients will either go without infusions or be forced into the nearest hospital outpatient department. Our hospitals are on the frontline of COVID treatment; simple commonsense dictates that we should avoid sending immune-compromised patients there, yet the Model will accomplish the opposite.
  - Additionally, the only two COVID treatments we have thus far are infusible antibody treatments. Now is the time to shore up our nation's infusion capacity. Instead, the Model will result in the loss of infusion centers, which will in turn consolidate larger numbers of COVID-positive and immune-compromised patients into hospital outpatient departments.

- **Drug prices are too high, but reducing Medicare's drug spend by denying beneficiaries access to lifesaving medications should be rejected outright.**
  - Practicing rheumatologists are keenly aware of the rising out-of-pocket burdens on our patients.
  - Given that most patients have Part B wraparound coverage, the drugs covered by Part B provide a more accessible option for patients who cannot afford the large out-of-pocket cost exposures of Part D.
  - The MFN Model, ironically, will significantly reduce patient access to the more accessible option, while doing nothing about the large out-of-pocket burdens of Part D.

**Our message to Congress is:**

**Please stand up for patients and stop the MFN Model from going into effect on January 1.**

# Take Action

## Send a Message to Congress

*There is no such thing as the "perfect" letter to Congress. What makes a letter compelling is your individual story: who you are, where you are from, why you are writing, and what you are asking the Member of Congress to do.*

**Here is a basic outline to consider following when communicating with Congress:**

1. **What is your role, job, or title?**
   - Introduce yourself. Tell the reader or person answering the phone a little more about who you are.

2. **Where are you?**
   - Where in the U.S. are you writing from and about? Help make this personal to them, particularly if you are a constituent in their district.

3. **What impact will the MFN have on you and your patients?**
   - If the Most Favored Nation Model starts on January 1, 2021 as planned, how will it impact you and your patients?

4. **What happens if rheumatology patients delay or abandon their treatments?**
   - The government (CMS) estimates that Medicare beneficiaries will forgo treatment as a result of the Model. What does it mean for RA patients to stop treatment? Why are you concerned about that? How will it impact patients?

5. **What are you asking the reader/Member of Congress to do?**
   - You're asking them to delay implementation of the Model, in light of the significant concerns about patient access identified by CMS and the lack of any opportunity for meaningful input to the agency.

### Sample email or letter template

Below is a sample email you can use as a starting point, but please tailor this text to make it unique, because congressional offices are more likely to dismiss emails that are simply copy-and-paste notes.

**Email:**

**Stop the MFN Model**

As a resident of [town/city, state], I am writing to urge you to take immediate action to delay implementation of the Most Favored Nation (MFN) Model. If Congress does not act, the Model will go into effect on January 1, just over a month after it was proposed – and almost a month before the comment period on the rule even closes.

CMS explicitly says that a portion of the Model's savings come from lost utilization due to beneficiaries losing or forgoing access. [Describe: What happens if RA patients skip, delay, or abandon their treatment?].

I hope you'll agree that this is not a desirable outcome. While we must reduce out of pocket drug costs for patients, reducing Medicare's drug spend by denying beneficiaries access to medicine is not acceptable. I hope you'll consider introducing a delay of the Most Favored Nation Model, so we can work with CMS to arrive at a solution that actually reduces drug costs for patients without disrupting access.

Thank you for your help,

[Insert Your Name and Address]

## For your Reference:

## Drugs Included in 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 | J16 | Golimumab for iv use 1mg | $368,492,761 | Rheumatology | Internal Medicine | Nurse Practitioner |

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| 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 |

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.