Most Favored Nation (MFN) Model & 2021 Medicare Physician Fee Schedule (MPFS) Highlights

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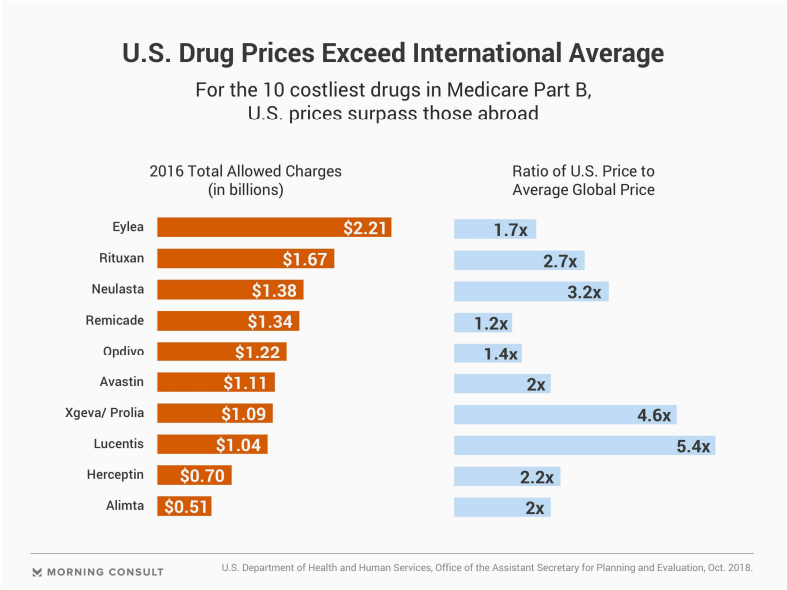
MFN Model

Why is CMS acting now?

- Spending on Part B drugs has risen too fast; U.S. prices are high compared to other nations' prices
- Estimated savings:
  - CMS Office of the Actuary estimates $85.5B reduction in Part B spending
  - In addition, OACT estimates $28.5B in Part B premium savings
- CMS is implementing the model via interim final rule with comment period, claiming that relief on high drug costs has taken on new urgency during the pandemic



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International Pricing Index (IPI) vs. MFN

IPI	MFN
Proposed a system of third-party vendors in Part B	No new middlemen vendors; buy-and-bill system stays the same
Random geographic selection	Nationwide applicability
Five (5) year duration	Seven (7) year duration
Set reimbursement at the **average** of a set of international prices	Set reimbursement at the **lowest** of a set of international prices
Replace percentage add-on with flat fee	Replace percentage add-on with flat fee
Goal was to include 50% of Part B drug spend; at a minimum, initially the drugs listed in HHS ASPE report	50 single-source drugs and biologics that encompass a high % of Medicare spending during year one
No quality measurement	Beneficiary survey on care experiences
No exemption	Limited financial hardship exemption after year 1
Advance Notice of Proposed Rulemaking	Interim Final Rule with Comment Period

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Where, who, when:
Everyone, everywhere, for seven years

- Demo will include all states and U.S. territories
- Demo will last for 7 performance years, to begin on January 1, 2021
  - After conclusion: two years of monitoring
- Participation is mandatory
  - Very limited financial hardship exemption

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MFN aims to overhaul Part B drug payment

- Three main aspects of Part B drug reimbursement are:
  - **Drug payment:** model moves away from Average Sales Price (ASP)
  - **Add-on payment:** model moves away from percentage-based add-on
  - **Administration payment:** unaffected by the model
- Under the MFN model, CMS will change reimbursement for a list of 50 single-source drugs and biologics that encompass a high percentage of Medicare spending during year 1
  - Demo includes biosimilars, but excludes generics
  - More drugs may be added in future; CMS does not foresee removing drugs

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Of the 50, these nine are identified by CMS as prescribed by rheumatologists:

- J1745 (Infliximab not biosimilar 10mg)
- J0129 (Abatacept injection)
- J0717 (Certolizumab pegol inj 1mg)
- J1602 (Golimumab for iv use 1 mg)
- J3262 (Tocilizumab injection)
- J3357 (Ustekinumab sub cu inj, 1 mg)
- J2507 (Pegloticase injection)
- J9312 (Inj., rituximab, 10 mg)
- J0897 (Denosumab injection)

Rheumatology listed as #1 prescribing specialty

Rheumatology listed as #3 prescribing specialty

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But there are more!

- J2350 (Injection, ocrelizumab, 1 mg)
- J2323 (Natalizumab injection)
- J7324 (Orthovisc inj. per dose)
- GI, neurology, and other products are included as well, so the impact on infusion centers who see non-rheumatology patients is even greater

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Drug payment: away from ASP towards MFN price

- The MFN price is the lowest per capita GDP-adjusted price of any country in a certain group of comparator countries
  - OECD countries with a per capita GDP greater than 60% of the U.S. GDP
- Demo phases in the new MFN price as follows:
  - Year 1 (2021): 75% ASP/25% MFN price
  - Year 2 (2022): 50% ASP/50% MFN price
  - Year 3 (2023): 25% ASP/75% MFN price
  - Years 4 through 7 (2024 through end of demo): 100% MFN price
- Phase-in accelerates by 5% if ASP or list price rises too fast
- There is no requirement for manufacturers to sell at MFN price; the hope is that they will have no choice

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Illustrative Example: J1745

CMS provides a table of "illustrative" prices for the 50 selected products; below is the example of J1745 (Infliximab not biosimil 10 mg)

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
J1745	Infliximab not biosimil 10mg	10 MG	Q1	$ 61.201	$ 27.427	$ 52.757	Austria
			Q2	$ 59.703	$ 26.741	$ 51.462	Australia
			Q3	$ 54.100	$ 25.685	$ 46.996	Austria
			Q4	$ 52.543	$ 22.508	$ 45.034	Australia

CMS: "We will publish the quarterly MFN Drug Payment Amounts on a CMS website (such as the MFN Model website), similar to how the ASP Drug Pricing Files are posted online prior to the start of the calendar quarter. The performance year 1, quarter 1 MFN Drug Payment Amounts will be published on a CMS website before the start of the MFN Model."

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Add-on payment: away from % towards flat fee

- Demo will replace the add-on fee with a flat fee of $148.73, to be updated with CPI-U
  - Calculated based on 6.1224% of historical applicable ASPs for 2019; intended to keep physicians whole
- For comparison: average 2019 % add-on payment amounts for the 50 year one MFN Model drugs ranged from $10.44 to $2,575.47 per average dose
- Add-on payment part is not phased in: full applicability 1/1/21
- No beneficiary cost-sharing on the add-on payment
- "Per dose" language is unclear
- Note that sequestration will still apply to both the drug payment and the add-on payment

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Rheumatology-specific CMS estimates

- Rheumatology drugs make up 10.9% of the MFN Model drug spend
  - But recall: not all of the drugs prescribed by rheumatology are marked as "rheumatology" by CMS, so real % is likely larger
- CMS estimates 9% average increase across rheumatology for the add-on payment (this does not include estimate of overall impact)
- CMS models distributional impact based on size of the difference between 2019 baseline add-on payments and single per-dose add-on amount
- As a result, the impact is spread unevenly across the specialty:
  - 5th percentile: -47% cut
  - 95th percentile: 356% increase

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For reference: impact on other specialties

- CMS model shows varying topline estimates for other specialties (again, these estimates relate to the add-on payment alone)
- Examples of cuts:
  - Dermatology: -31%
  - Neurology: -21%
  - Gastroenterology: -20%
- Examples of increases:
  - Allergy/Immunology: +46%
  - Ophthalmology: +140%
  - Endocrinology: +194%
- Largest cut estimated: -33% for Gynecological/Oncology
- Larges increase estimated: +1383% for Interventional Cardiology
- Within each specialty, the impact is spread unevenly, whether positive or negative

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Concerns about the demo

- Most importantly, concerns about patient access
  - CMS explicitly states: "While there are significant savings as a result of this model, a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."
- Procedural shortcomings of the proposal: comment period ends almost a month after the demo begins
- Lack of clarity about manufacturers' behavioral response and effect on financial health of practices

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What's next?

- Administration:
  - Stakeholders will file comments, but questionable utility since comment period closes after demo begins
  - Impact of new Administration
- Congress:
  - Political difficulty
  - Limited interest in a delay
- Judiciary: injunctive relief might be best chance

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