

Medicare Drug Price Negotiation: Lessons from the First Ten Drugs Selected



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School of Pharmacy



Moderator and Speakers

- Introduction and Background
 - Sean D. Sullivan, PhD, Professor University of Washington; Visiting Professor, London School of Economics and Political Science
- Experience at CMS on the First Ten Products
 - Kristi Martin, MPA, MA, Chief of Staff/Senior Advisor CMS
- What Might CMS do? A Replication of the MFP
 - Inmaculada Hernandez, PharmD, PhD, Professor, University of California, San Diego
- Moderated Discussion - All



Selection of Negotiation-Eligible Drugs

How Many Drugs?

- 10 Part D drugs published August 29, 2023 (MFP Implemented in 2026)
- Up to 15 Part D drugs selected - **February 1, 2025** (MFP Implemented in 2027)
- Up to 15 Part B and D drugs selected in 2026 (MFP Implemented in 2028)
- Up to 20 Part B and D drugs selected in 2027 and beyond (MFP Implemented in 2029)



10 drugs selected by CMS in August 2023 for direct price negotiations effective 2026

CMS list				
Rank	Product	Company	TA/ Indication	GME (actual)
1	Eliquis	BMS	Cardiovascular	\$16.5B
2	Jardiance	BI	Cardiovascular, Diabetes	\$7B
3	Xarelto ¹	Janssen	Cardiovascular	\$6B
4	Januvia	MSD	Diabetes	\$4.1B
5	Farxiga	AstraZeneca	Diabetes, Cardiovascular	\$3.3B
6	Entresto	Novartis	Cardiovascular	\$2.8B
7	Enbrel	Immunex (Amgen)	Immunomodulators	\$2.8B
8	Imbruvica	Pharmacyclics (Abbvie)	Oncology	\$2.6B
9	Stelara ¹	Janssen Biotech	Immunomodulators	\$2.6B
10	Novolog, Fiasp	Novo Nordisk	Diabetes	\$2.6B



What Did We Learn from the Selection of the First Ten?

- > Selection strictly followed the statutory provisions - based on Total Part D Gross Covered Prescription Drug Costs, not net expenditures.
- > 7 out of 10 drugs are for CV and metabolic conditions and likely heavily discounted.
- > Two drugs (Ibrance, Xtandi) not on the list would have offered more potential savings - but their selection would not have followed the law.
- > Stelara selected in spite of FDA approved biosimilar. Substantial competition not yet achieved.
- > One drug (Novolog, Fiasp, etc) was selected because the products were aggregated across all dosages and formulations based on active moiety/active ingredient.



Factors for Negotiating the Initial Offer and Final MFP

Manufacturer Specific Data for the Selected Drug

- Research and Development Costs and Recoupment
- Current Unit Costs of Production and Distribution
- Prior Federal Financial Support
- Patents, Exclusivities, and Approvals
- Market Data, Revenue, and Sales Volume Data
- non-Federal Avg Mfr Price



Factors for Negotiating the Initial Offer and Final MFP

Negotiation-eligible drugs will be subject to an MFP negotiated between CMS and the manufacturer, with 3 potential rounds of negotiation meetings. MFP will be adjusted annually based on CPI-U.

To formulate an initial offer, CMS intends to:

- 1) Identifying therapeutic alternative(s), if any, for the selected drug;
- 2) Use the Part D net price for the therapeutic alternative(s) that are Part D drugs and/or Part B average sales price (ASP) for the therapeutic alternatives that are Part B drugs to determine a starting point in developing an initial offer; and
- 3) Evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)), including productivity, independence, quality of life, and whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations;
- 4) Consider costs and outcomes, so long as the QALY is not part of the evidence package;
- 5) Apply further adjustments by the manufacturer specific factors outlined in the law to determine the initial offer price.
- 6) CMS will not make or accept any offers for the maximum fair price that is above the statutorily defined ceiling price in the law.



Drugs Selected for Negotiation and Indications

Leading indication
Other indications

Drug	Indication
Eliquis (apixaban)	Atrial fibrillation, Treatment and prevention of DVT and PE
Xarelto (rivaroxaban)	Atrial fibrillation, Treatment and prevention of DVT and PE, DVT, CAD, PAD
Jardiance (empagliflozin)	T2DM, HF, CKD
Farxiga (dapagliflozin)	T2DM, HF, HF with CKD
Januvia (sitagliptin)	T2DM
Fiasp & Novolog (insulin aspart)	Glycemic control
Entresto (sacubatril-valsartan)	HF
Enbrel (etanercept)	RA, Plaque Psoriasis, AS, Psoriatic Arthritis
Stelara (ustekinumab)	Crohn’s disease, Plaque Psoriasis, Psoriatic Arthritis, Ulcerative Colitis
Imbruvica (ibrutinib)	CLL/SLL, Waldenstrom’s macroglobulinemia, cGVHD

Abbreviations: AS, ankylosing spondylitis; CAD, coronary artery disease; cGVHD, chronic graft-versus-host disease; CKD, chronic kidney disease; CLL, chronic lymphocytic leukemia; DVT, deep vein thrombosis; HF, heart failure; PAD, peripheral artery disease; SLL, small lymphocytic leukemia; T2DM, type 2 diabetes mellitus

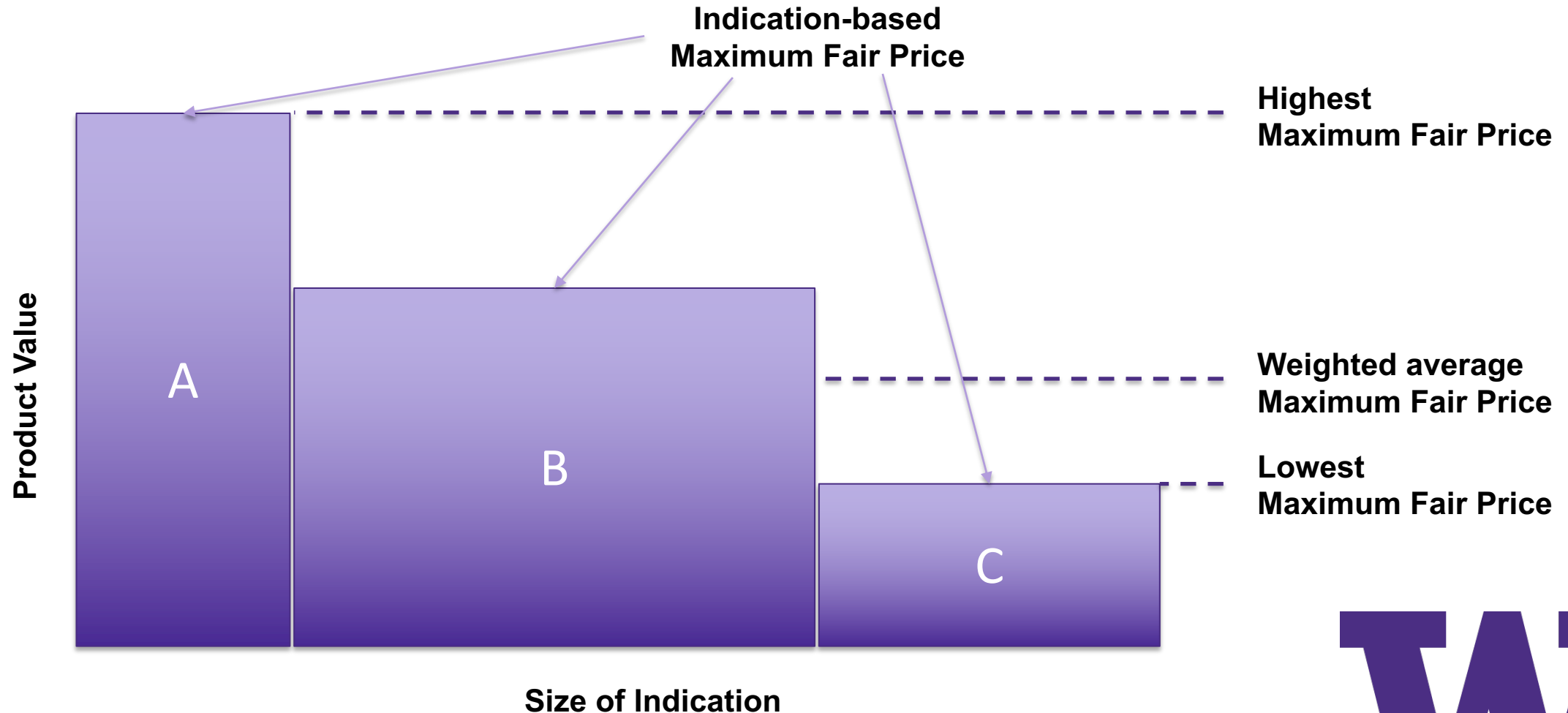


What might we learn from the first round of negotiation?

- > We know the statutory ceiling, but what about a price "floor"?
 - 6/10 products will need to have Medicare discounts below the ceiling, which will provide signal of go-forward discount magnitude e.g., additional GTN discount or tied to reference prices such as VA.
 - The prices being used for negotiation are in 2022 USD, for implementation in 2026.
- > What evidence is valued most by CMS?
 - Selection of assets within same class/TA & indication provide insights on possibility of differential pricing e.g. differences in evidence packages, therapeutic alternatives, reference prices
 - Same class: Xa inhibitors (Eliquis, Xarelto) & SGLT2 inhibitors (Farxiga, Jardiance).
 - Same indication: Type 2 diabetes (Januvia, Jardiance, Farxiga, Novolog/ Fiasp) from 3 classes (DPP-IV, SGLT2, insulin)



Integrating CER and prices in a multi-indication market



Further complications: different doses, formulations, etc.

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Many, Many Questions.....

- > How were therapeutic alternatives selected? What role did clinical guidelines and patient input play in the process?
- > How has comparative evidence been collected and used? Has CMS conducted its own NMA's or relied on submissions alone?
- > The Guidance calls for RWE. Has CMS generated its own RWE using its own data? If so, what types of studies has it undertaken?
- > Will CMS develop a value framework to integrate the comparative clinical evidence, real world evidence, price benchmarks to arrive at the MFP?



ISPOR 2024

Medicare Drug Price Negotiation Program: Lessons and Experience to Date

Kristi Martin, Chief of Staff and Senior Advisor, Center for Medicare
Centers for Medicare & Medicaid Services (CMS)

May 6, 2024



CMS applying early lessons

- First cycle of negotiations are underway, and CMS is also preparing for the second cycle of negotiations.
- On May 3, CMS released draft guidance that describes how CMS intends to implement the Negotiation Program for initial price applicability year 2027:
 - Builds on the revised guidance for initial price applicability year 2026, and
 - Applies the experience of CMS and early lessons learned to date from the negotiation process.
- This draft guidance also sets forth additional policies regarding manufacturer effectuation of the MFP in 2026 and 2027, including the use of a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between pharmaceutical supply chain entities.
- Given the timing overlap between the development of this draft guidance and the negotiation period for initial price applicability year 2026, CMS may make additional adjustments in the final guidance based on the agency's experience, including experience from the first cycle of negotiations.

Draft guidance speaks to early learnings

- Approach for considering: (1) the manufacturer-reported data elements and (2) evidence about alternative treatments in developing an initial offer to participating drug companies.
- Plans for CMS to receive patient-focused information on selected drugs for consideration in its initial offer development.
- Process and format for the offer and counteroffer exchange between CMS and drug companies.
- Requirements and parameters for exchange of data among dispensing entities (e.g., pharmacies) and participating drug companies, via a Medicare Transaction Facilitator (MTF), to provide data needed to facilitate access to MFPs of selected drugs for dispensing entities and to provide claim-level data elements to Primary Manufacturers where a selected drug was dispensed to a person who was verified to be MFP-eligible.
- Solicitation of comment on options for the MTF to provide a voluntary payment facilitation functionality for participating drug companies and dispensing entities to help support access to the MFP.
- Requirements participating drug companies must meet in making the MFP available to MFP-eligible individuals and dispensing entities.

CMS is seeking feedback

- Revisions in the draft guidance build on lessons learned from implementing the Negotiation Program to date, and CMS welcomes comments on these policies.
- This draft guidance is open for a 60-day public comment period, which has been extended based on feedback CMS received from interested parties in response to the 30-day comment period provided for the revised guidance for initial price applicability year 2026.
- More information on how to submit comments can be found in the draft guidance. Comments received by 11:59 PT on July 2, 2024, will be considered for final guidance.
- CMS anticipates issuing final guidance for initial price applicability year 2027 and for manufacturer effectuation of the MFP in 2026 and 2027 in fall 2024.

Open for 60-day public comment

- Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027:
<https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>
- The Small Biotech Exception and Biosimilar Delay initial Information Collection Request (ICR):
<https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pa-listing>

What's next?

IPAY 2026 – First Cycle of Negotiations

- **March 2, 2024** – Deadline for participating drug companies to accept the initial offer of a maximum fair price or propose a counteroffer, if desired. Companies have 30 days from receiving CMS' initial offer to respond.
- **Spring/Summer 2024** – CMS will provide up to three negotiation meetings with participating drug companies, if a counteroffer is provided by the drug company and CMS does not accept the counteroffer.
- **August 1, 2024** – The negotiation period will end.
- **September 1, 2024** – CMS will publish the negotiated maximum fair prices for drugs selected for negotiation for 2026 for drug companies participating in the Negotiation Program.
- **March 1, 2025** – Deadline for CMS to publish the explanation of the maximum fair prices that have been negotiated for drugs selected for negotiation for 2026.
- **January 1, 2026** – Maximum fair prices negotiated for selected drugs become effective.

IPAY 2027 – Second Cycle of Negotiations

- **February 1, 2025** – Deadline for CMS to publish the list of up to 15 drugs covered by Part D selected for negotiation for initial price applicability year 2027.
- **February 28, 2025** – Deadline for participating drug companies for initial price applicability year 2027 to sign agreements to participate in the Negotiation Program.
- **March 1, 2025** – Deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2027 and that have signed an agreement to participate in the Negotiation Program to submit manufacturer-specific data to CMS for consideration in the negotiation of a maximum fair price. In addition, this is the deadline for the public to submit data on therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts to specific populations, among other considerations.

If you have questions or additional feedback, please email:
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An External, Independent Replication of Medicare Drug Price Negotiation

May 6, 2024

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Overview of the Project

Funding



The
Commonwealth
Fund

Objectives



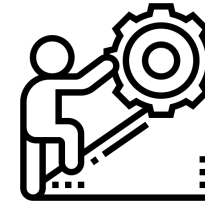
Improve
transparency



Assess
data sources



Estimate
savings



Challenges &
lessons learned

Collaborating Institutions



S. Sullivan
E. Cousin



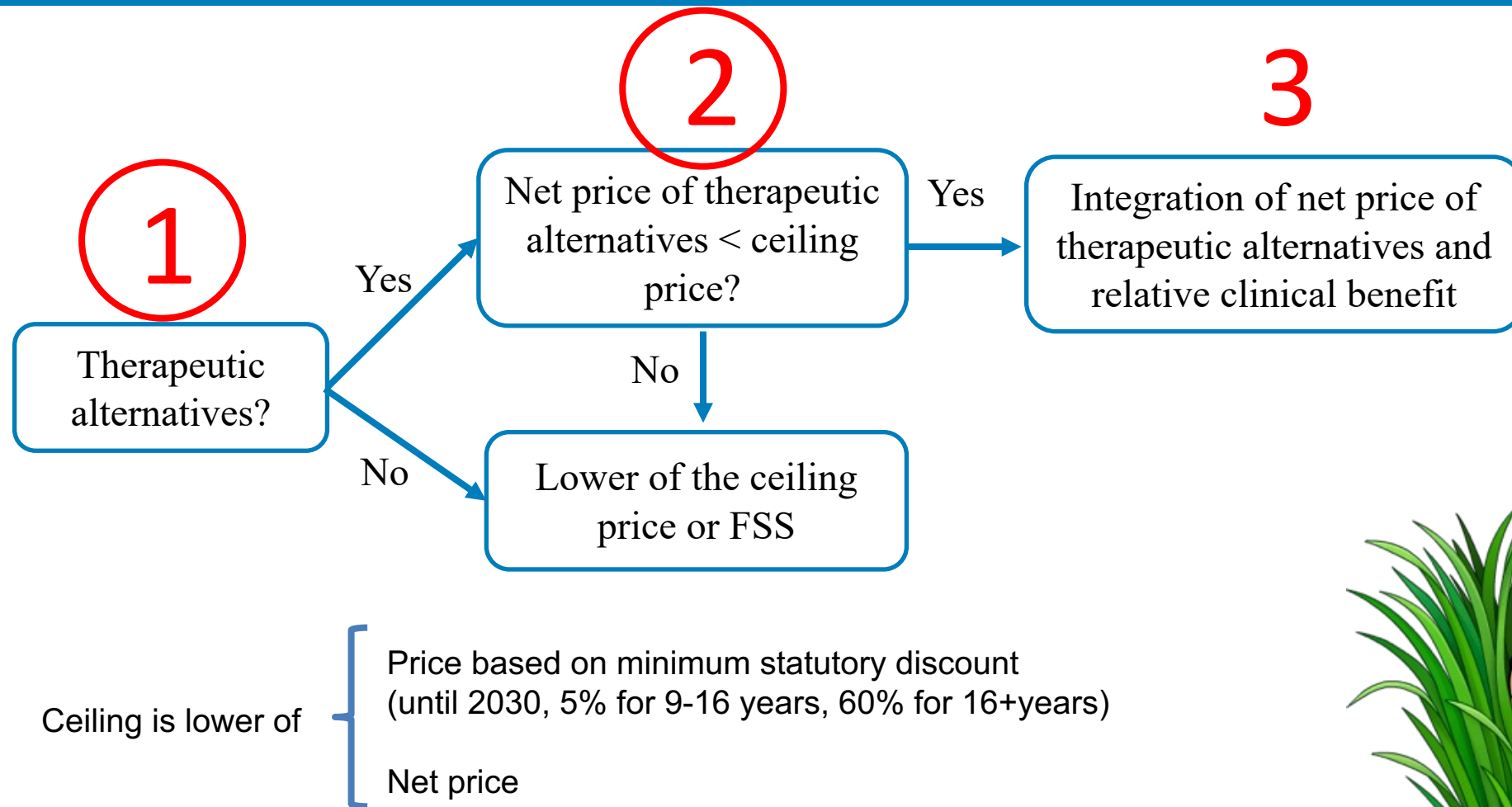
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T. Cameron A. Kirihennedige
N. Gabriel I. Hernandez



Starting point of initial price offer: Very Simplified Overview



*Other factors will be used to adjust price offer: unmet need, population-specific data, R&D costs, production and distribution costs, % of R&D subsidized by federal funds





Selection of Therapeutic Alternatives

1. Identification of FDA- approved indications
2. Estimation of prevalence of each indication
3. Review of clinical guidelines
4. Interpretation of CMS guidance
 - Prioritization of drugs within class

Medicare drug price negotiation: The complexities of selecting therapeutic alternatives for estimating comparative effectiveness

Inmaculada Hernandez, PharmD, PhD; Emma M. Cousin, PharmD; Olivier J. Wouters, PhD;
Nico Gabriel, MA; Teresa Cameron, MS; Sean D. Sullivan, BScPharm, PhD

Drug Selected for Negotiation	Therapeutic Alternatives
Eliquis (apixaban)	Pradaxa (dabigatran), Xarelto (rivaroxaban), Warfarin
Xarelto (rivaroxaban)	Pradaxa (dabigatran), Eliquis (apixaban), Warfarin
Jardiance (empagliflozin)	Invokana (canagliflozin), Farxiga (dapagliflozin), Steglatro (ertugliflozin)
Farxiga (dapagliflozin)	Invokana (canagliflozin), Jardiance (empagliflozin), Steglatro (ertugliflozin)
Januvia (sitagliptin)	Onglyza (saxagliptin), Tradjenta (linagliptin) , Nesina (alogliptin), Farxiga (dapagliflozin) Invokana (canagliflozin), Jardiance (empagliflozin), Steglatro (ertugliflozin), Bydureon (exenatide), Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Ozempic (semaglutide)
Fiasp & Novolog (insulin aspart)	Humalog (insulin lispro), Admelog (insulin lispro)
Entresto (sacubatril-valsartan)	captopril, enalapril, lisinopril, ramipril, candesartan, losartan, valsartan
Enbrel (etanercept)	Humira (adalimumab), Cimzia (certolizumab) , Remicade (infliximab), Simponi (golimumab)
Stelara (ustekinumab)	Skyrizi (risankizumab)
Imbruvica (ibrutinib)	Calquence (acalabrutinib), Brukinsa (zanubrutinib)



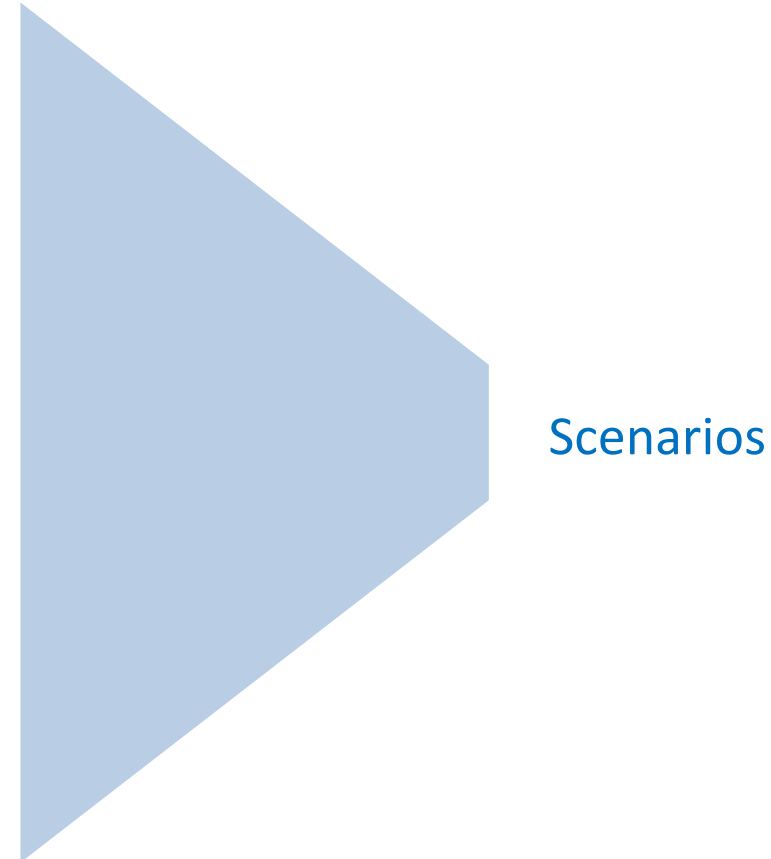
Price Benchmarks

Drugs selected for negotiation

- List price
 - Net price
 - Statutorily defined price
 - Big Four / VA
 - CBO projection (50% net)
- } Ceiling

Therapeutic alternatives

- Net price
- (Gross reimbursement if generic)





Scenario #3: Specific cases

Therapeutic alternatives with net prices < ceiling → Integration

Specific cases:

- Therapeutic alternatives also negotiated (apixaban, empagliflozin)
- Minimum statutory discounts already achieved savings (etanercept) vs not



Scenario #3: Specific cases

Therapeutic alternatives with net prices < ceiling → Integration

Specific cases:

- Therapeutic alternatives also negotiated (apixaban, empagliflozin)
- Minimum statutory discounts already achieved savings (etanercept) vs not



Sources of savings

There are three sources of savings:

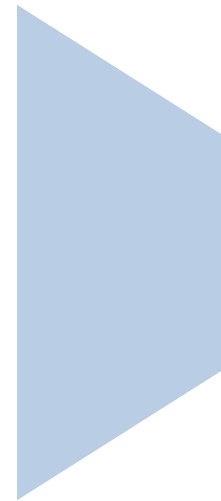
- Savings from minimum statutory discounts $<$ current net price –certain
- Savings from CMS ability to negotiate below the ceiling—uncertain but expected
- Savings from indexing 2026 prices to 2022—depends on counterfactual



Lessons learned & challenges identified

The challenges of applying a standardized but somewhat loose guidance to context-dependent scenarios:

- The rebate context matters
- Circular nature of negotiation of multiple agents in same class
- Concerns on formulary placement and disadvantage of negotiated drugs



Therapeutic classes
selected based on
net spending



Thank you!

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 @ihdezdelso

Moderated Discussion

May 3rd Draft Guidance

<https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>

