Medicare Drug Price Negotiation
What It Is and What's Next

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Milliman

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Agenda

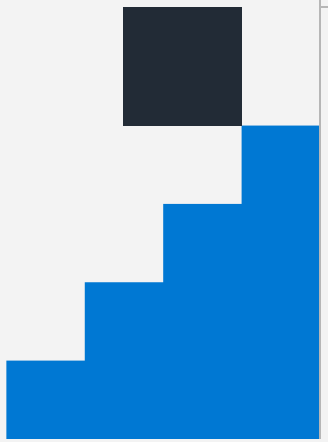
- Overview of Medicare Drug Price Negotiation Program
- 2026 & 2027 Negotiated Drugs and Key Insights
- Considerations for Health Plans
- Draft IPAY 2028 Guidance

What is Medicare Price Negotiation?

Overview of Medicare Price Negotiation

The Inflation Reduction Act establish the Medicare Drug Price Negotiation Program to negotiate maximum fair prices (MFPs) for **single-source drugs and biologics** in Medicare Part B and Part D.

Drugs are selected from the **top 50 highest gross spending drugs** (for both Part B and D) with exclusions apply. Costs are grouped across active moieties, rather than a particular drug marketing name.



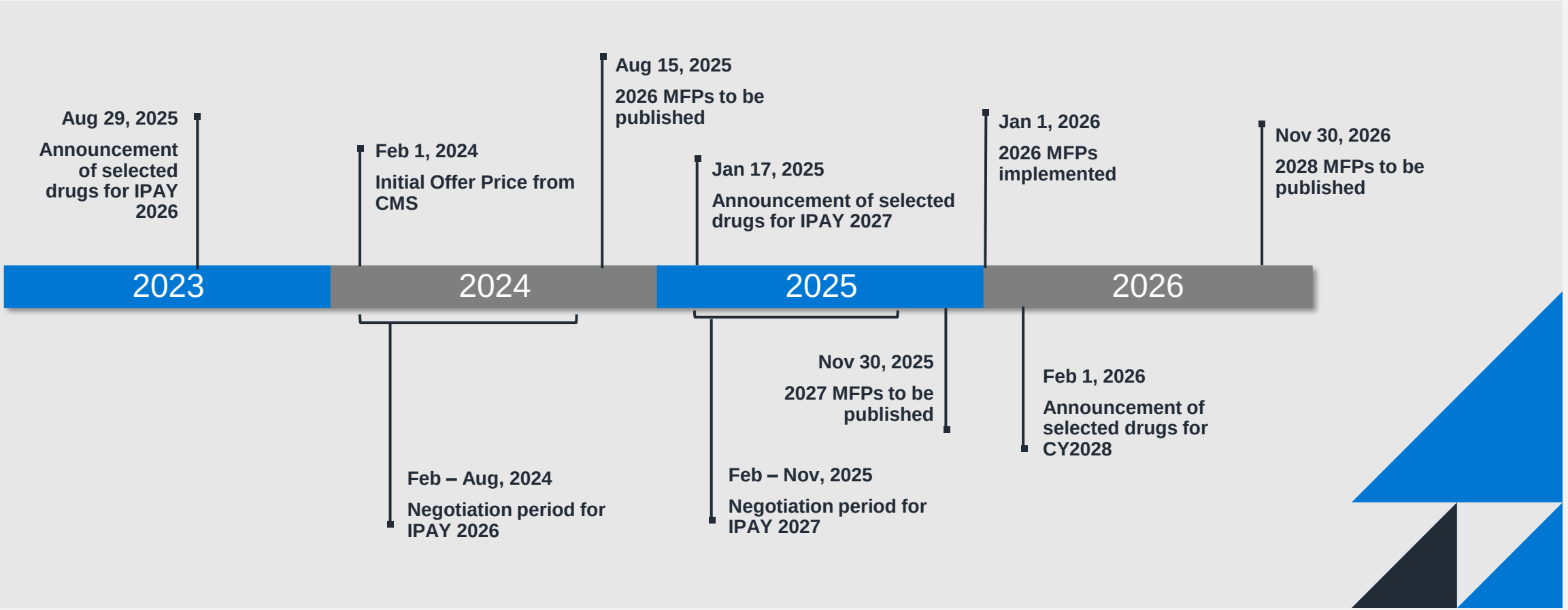
Drugs are eligible for selection at different points based their launch date and the type of molecule.

- 7 years for small molecule or 11 years for biological

Negotiated drugs are **required to be covered on formularies** and do not pay Manufacturer Discount Program (MDP) payments.

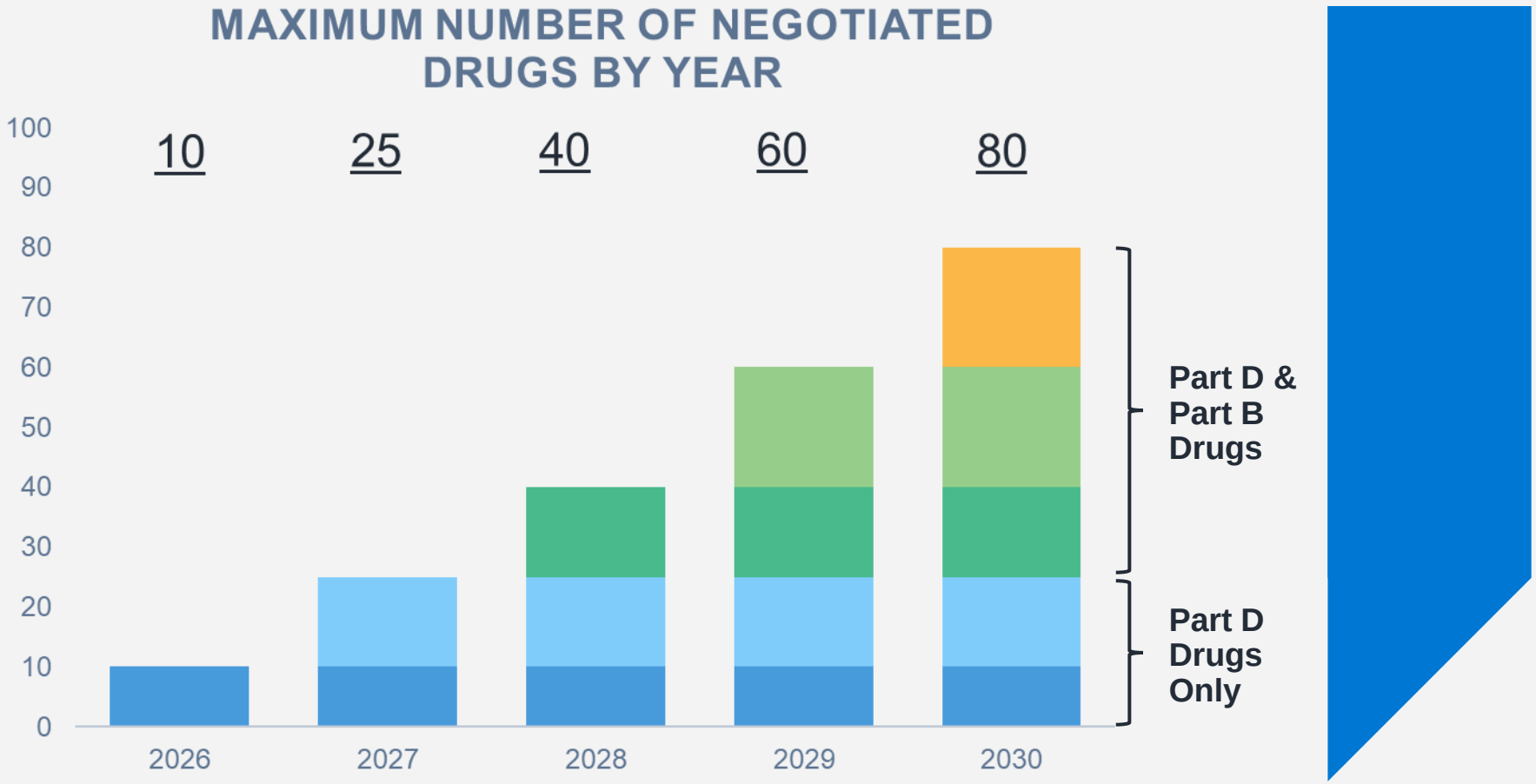
Timeline for selection and implementation of Medicare drug price negotiation

CMS and HHS recently announced the next 15 drugs selected for IPAY 2027



How many drugs will be selected for negotiation?

Medicare Part B and D Drug Negotiation begins with 10 eligible products in 2026 and grow over time



- Top 50 (D and B) highest cost single source drugs are eligible for selection. Exclusions include:
  - Small biotech (2026-2028)
  - Single indication orphan products
  - Low-spend Medicare drugs
  - Plasma-derived products
- Only Part D for 2026 and 2027
- Selected products are exempt from MDP
- Biosimilar manufacturers can petition for the delay of biologic negotiation if the expected biosimilar launch is within two years.
- Products can be removed from the negotiation list beginning the year nine months after the launch of a generic or biosimilar.

How does CMS define a “drug” for price negotiation?

The initial list of 10 drugs for price negotiation provides lessons with respect to how drugs are likely to be selected in future years, in accordance with the IRA and CMS guidance.

The combination of active ingredients, not the formulation, defines a drug

The selection of drugs to be negotiated is based on aggregating all drugs that share the same active moiety (i.e., the same combination of active ingredients). As such, the selection is not specific to any one dosage form or strength. For example, Enbrel’s selection extends to both the vial and Sureclick versions of the drug.

CMS criteria may result in selected drugs facing generic competition prior to 2026

The determination of whether a drug is a qualifying single-source brand only considers whether a generic or biosimilar has bona fide marketing or availability as of the selection date. Five selected drugs may have key patents expire and could potentially have generic or biosimilar competition before 2026: Xarelto, Farxiga, Entresto, Stelara, and Novolog.

Unbranded versions offered by the primary manufacturer do not prevent a drug from negotiation

For example, Novolog’s manufacturer, Novo Nordisk, also produces an unbranded version of Novolog, which has a different price from the branded version. The presence of this alternative does not preclude Novolog from selection because the alternative is available through Novolog’s primary manufacturer. Furthermore, the unbranded version will also be subject to MFP.

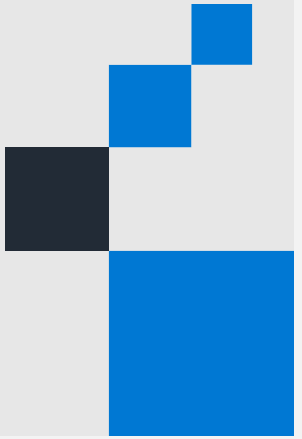
Source: https://www.milliman.com/en/insight/medicare-price-negotiation-paradigm-shift-part-d-access-cost

Impact of generic & biosimilar launches

If a separate manufacturer produces an unbranded version of the selected drug, selected drugs can come off the negotiated products “list” and / or MFPs could not actually go into effect at the planned date.

CMS reviews data each month to monitor the uptake of any approved generic or biosimilar alternatives to selected drugs.

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	Result with respect to selected drug for the Negotiation Program
January 17, 2025 through November 1, 2025	Selected drug remains a selected drug for 2027, though MFP does not apply; selected drug ceases to be a selected drug in 2028
November 2, 2025 through March 31, 2027	Selected drug remains a selected drug and MFP applies for 2027; selected drug ceases to be a selected drug in 2028.
April 1, 2027 through March 31, 2028	Selected drug remains a selected drug and MFP applies for 2027 and 2028; selected drug ceases to be a selected drug in 2029.



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

Formulary Guidance on MFP Drug Placement

Drug price negotiation in Part D will create new dynamics and considerations for Part D payers.

Negotiated products must be covered on every Part D formulary when MFPs are in effect.

- This includes all dosage forms / strengths of a selected drug and authorized generics when produced by the primary brand manufacturer (e.g., Enbrel vial + Sureclick, Novolog + AG insulin aspart)

CMS will require "reasonable justification" for non-preferred formulary tiering / utilization management criteria for negotiated drugs.

Per Negotiation Program guidance, CMS intends to review to assess the following:

- Any instances where Part D sponsors place selected drugs on non-preferred tiers
- Any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class
- Any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy)
- Any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

Source: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov)

How are MFPs determined?

Based on IPAY 2027 Final Guidance and IPAY 2028 Draft Guidance

CEILING PRICE

Ceiling for the MFP shall not exceed the lower of the following:

- The sum of the plan-specific enrollment weighted amount, net of DIR and ERPOSA
- The lesser of the annual ASP or WAC for Part B drugs
- Amount equal to the applicable percent of the lower of the following:
  - Avg Non-FAMP CY2021 increased by the increase in CPI-U from 9/2021 – 9/2025
  - Avg Non-FAMP CY2025

INITIAL OFFER

Identifying Indications and Therapeutic Alternatives:

- CMS identifies the FDA-approved indications for the selected drug and potential therapeutic alternatives, excluding any FDA-approved indications used solely in a setting in which the selected drug is not billed under Part B or Part D

Developing a Starting Point:

- The starting point for the initial offer is the lower of:
  - Part D net price of therapeutic alternatives(after accounting for rebates and CGDP/MDP payments)
  - ASP/WAC of therapeutic alternatives
  - MFPs of therapeutic alternatives selected in prior years
  - Federal Supply Schedule (FSS) or “Big Four Agency” price for selected drugs with no therapeutic alternative

NEGOTIATION FACTORS

CMS qualitatively adjusts the starting point by considering:

- Comparative clinical effectiveness and benefits of the selected drug versus therapeutic alternatives
- The drug's impact on specific populations (e.g., elderly, disabled)
- The extent to which the drug addresses unmet medical needs

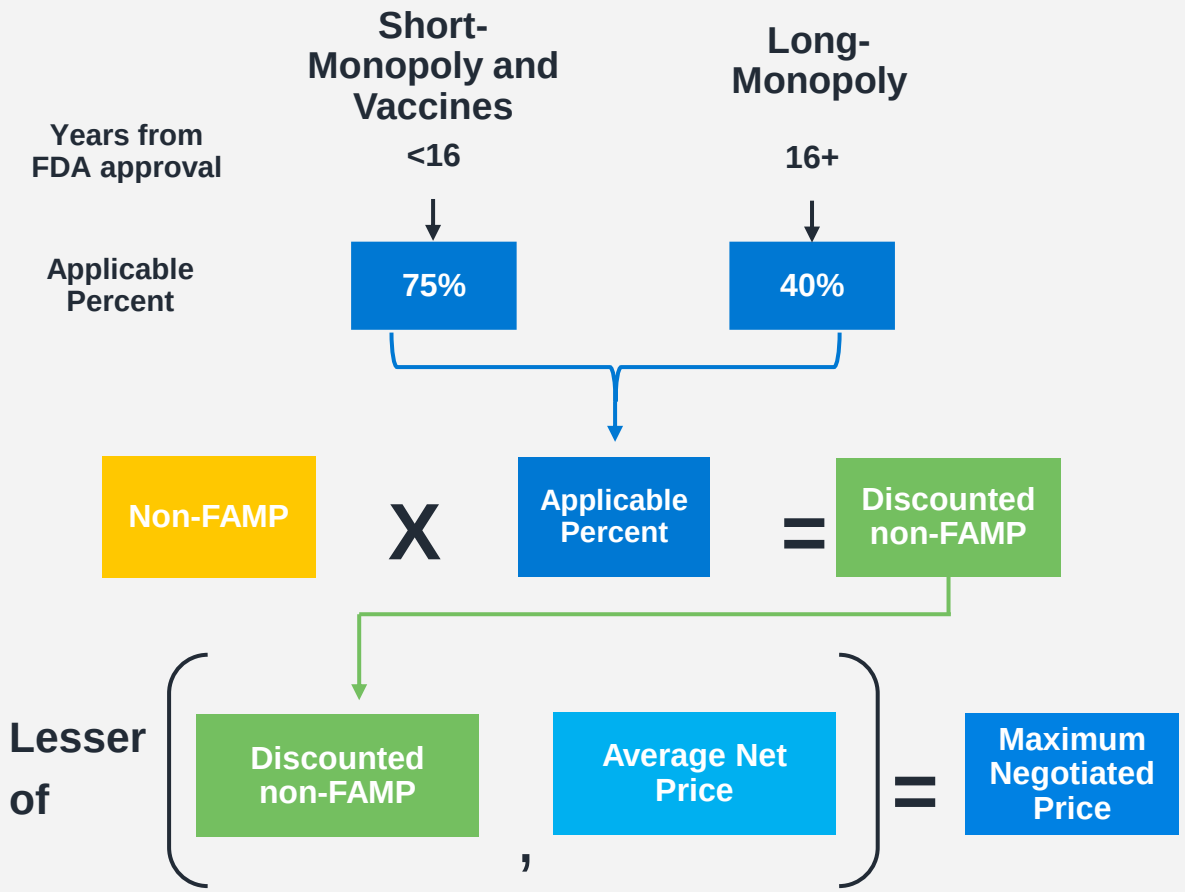
The preliminary price is further adjusted based on manufacturer-submitted data, including:

- Research and development costs and recoupment status
- Current unit costs of production and distribution
- Prior federal financial support
- Patent and exclusivity information
- Market data, revenue, and sales volume

Source: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf

Maximum Negotiated Price

The IRA prescribes the calculation for the selected drug ceiling price, but CMS / HHS may “negotiate” the MFP lower than such ceiling.



2026 Negotiated Drugs and MFPs

Selected drugs accounted for about 20% of total Part D gross costs

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%

Novolog list price reduction effective January 2024

17% MFP differential in 2026 for selected Anticoagulants

Discount on Imbruvica may translate more directly to plan savings

How are point-of-sale (POS) costs and plan costs changing for MFP drugs?

- The public MFP, plus a dispensing fee, will be the new POS price in Medicare for this subset of drugs. The list price (i.e., wholesale acquisition cost) is unchanged via CMS drug price negotiation.
- Drugs with MFPs in effect will no longer be consider applicable for the Manufacturer Discount Program (MDP). The federal government will instead pay these costs via increased reinsurance and the new selected drug subsidy, ultimately holding the plan harmless.
- Given the expectation that MFP discounts may largely replace rebates for negotiated drugs (subject to manufacturer actions), negotiated prices may translate to higher net plan liability than without negotiation in place – depending on how the MFP compares to the former net price.

Source: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov)

2027 Negotiated Drugs

When combined with the 10 drugs selected for IPAY 2026, the 25 drugs account for more than one-third of Medicare Part D gross costs in 2024

Drug Name	Commonly Treated Conditions*	Total Part D Gross Covered Prescription Drug Costs from November 2023-October 2024	Number of Medicare Part D Enrollees Who Used the Drug from November 2023 - October 2024
Ozempic; Rybelsus; Wegovy	Type 2 diabetes; Type 2 diabetes and cardiovascular disease; Obesity/overweight and cardiovascular disease	$14,426,566,000	2,287,000
Trelegy Ellipta	Asthma; Chronic obstructive pulmonary disease	$5,138,107,000	1,252,000
Xtandi	Prostate cancer	$3,159,055,000	35,000
Pomalyst	Kaposi sarcoma; Multiple myeloma	$2,069,147,000	14,000
Ibrance	Breast cancer	$1,984,624,000	16,000
Ofev	Idiopathic pulmonary fibrosis	$1,961,060,000	24,000
Linzess	Chronic idiopathic constipation; Irritable bowel syndrome with constipation	$1,937,912,000	627,000
Calquence	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma	$1,614,250,000	15,000
Austedo; Austedo XR	Chorea in Huntington's disease; Tardive dyskinesia	$1,531,855,000	26,000
Breo Ellipta	Asthma; Chronic obstructive pulmonary disease	$1,420,971,000	634,000
Tradjenta	Type 2 diabetes	$1,148,977,000	278,000
Xifaxan	Hepatic encephalopathy; Irritable bowel syndrome with diarrhea	$1,128,314,000	104,000
Vraylar	Bipolar I disorder; Major depressive disorder; Schizophrenia	$1,085,788,000	116,000
Janumet; Janumet XR	Type 2 diabetes	$1,082,464,000	243,000
Otezla	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis	$994,001,000	31,000

Key Insights:

- Of the 25 selected drugs, selected antidiabetic products encompassing nearly 14% of all 2024 Part D gross costs based on a Milliman analyses.
- With the exception of Wegovy, all selected brands for IPAY 2027 have coverage for the majority of beneficiaries in 2025.
- Wegovy's current Part D coverage is limited to its cardiovascular indication due to restrictions on required Part D coverage for therapies indicated for weight management. Wegovy's selection may result in a significant increase in coverage of Wegovy in 2027 as selected drugs are required to be on formulary.
- As generics become available, previously selected drugs will be removed from the list and will no longer have MFPs in place.
- It is difficult to predict whether the 2027 final MFPs will mirror discounts negotiated for IPAY 2026.

Source: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf & https://www.milliman.com/en/insight/medicare-price-negotiation-year-2-selection-expands-therapeutic-areas

What are the impacts to plan sponsors?

In the coming years, negotiations may create new financial, strategic, and operational challenges for Part D plan sponsors

Financial Implications

- **Trade-off between rebates and MFP**
  - Rebates have historically been preferred by plan sponsors because they more directly offset plan liabilities than discounts at the point of sale
  - The discount negotiated by the MFP would need to be greater than the current rebate to result in an equivalent plan sponsor liability relative to a traditional rebate
- **It is prudent to discuss rebate guarantee changes with your PBM**

Source: https://www.milliman.com/en/insight/medicare-price-negotiation-paradigm-shift-part-d-access-cost

Formulary Implications

- **Selected drugs are required to be covered by all Part D plans but can be placed on a non-preferred tier or apply UM if the plan sponsor provides a reasonable justification**
  - Formulary changes to steer utilization and avoid risk if non-negotiated competing drugs are more favorable financially, or vise versa
- **Drugs will continuously be added and removed from the list on an annual basis**

Other Considerations

- **Star Rating impact**
  - Member satisfaction
- **Operational burden**
  - Formulary and benefit restructuring
  - Compliance
- **Selection risk**
  - Increased formulary access to negotiated drugs, formulary and benefit restructuring, and reduced point of sale costs may lead patients to select plans in different ways than today

Draft IPAY 2028 Guidance

Limited changes from IPAY 2027 Final Guidance

Expanded indications for the same drug do not reset the timeframe: CMS will use the earliest FDA approval date for the active moiety / ingredient to qualify a single source drug

CMS is considering different ways to weight market baskets when a drug has multiple indications

Soliciting comments on several issues including alternative approaches to setting initial offer, domestic reference pricing, and which factors should influence rates

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Thank you

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