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UNDERSTANDING MEDICARE DRUG PRICE NEGOTIATION

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PROGRAM OVERVIEW

- For the first time, Medicare can negotiate drug prices directly
- Negotiations begin with a small slate of drugs (10) and expand over time.
- Single-source drugs without generic or biosimilar competition are eligible at all.
 - What is single-source drug?
 - What is competition?

2026

First negotiated
prices take effect

100

Total drugs subject to
negotiation by 2031

9 mo+

Minimum delay after
generic/biosimilar entry

CMSAUTHORITY

Scope of Authority & Process

CMS’s Authority

- Negotiate a “maximum fair price” (MFP) for selected high-cost, single-source drugs in Parts B and D.
- Compile the annual list of eligible drugs, ranked by total expenditures.
- Weigh manufacturer cost data, market data, and alternative-treatment availability.
- Program implemented via guidance/instruction (not notice-and-comment rulemaking) for its first years, with judicial review foreclosed on several determinations.

Process

- Identify drugs subject to negotiation
- Negotiate with the manufacturer of each identified drug

Medicare Drug Price Negotiation Program: Top 50 Negotiation-Eligible Drugs for Initial Price Applicability Year 2028



In accordance with Section 30.4 of the [Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028](#) (“Final Guidance”), CMS has published a list of 50 top negotiation-eligible drugs (inclusive of the 15 selected drugs) ranked by combined Total Expenditures under Part B and Part D, information on the National Drug Code (NDC)-9s NDC-11s, and Healthcare Common Procedure Coding System (HCPCS) codes for the negotiation-eligible drugs, as applicable.

Rank	Drug Name	Total Medicare Part B and Part D Prescription Drug Expenditures from November 2024-October 2025 ¹	NDC-9s	NDC-11s	HCPCS Code (if applicable) ²
1	TRULICITY	\$4,898,378,000	000021433, 000021434, 000022236, 000023182, 500903483, 500903484, 500905467, 500906453, 500906456, 500906571, 500907589	00002143301, 00002143361, 00002143380, 00002143401, 00002143461, 00002143480, 00002223601, 00002223661, 00002223680, 00002318201, 00002318261, 00002318280, 50090348300, 50090348400, 50090546700, 50090645300, 50090645600, 50090657100, 50090758900	
2	BIKTARVY	\$3,904,486,000	500906247, 619582501, 619582505, 619582506, 705183080	50090624700, 61958250101, 61958250102, 61958250103, 61958250501, 61958250601, 70518308000, 70518308001, 70518308002, 70518308003	
3	ORENCIA	\$2,450,065,000	000032187, 000032188, 000032814, 000032818	00003218710, 00003218713, 00003218811, 00003218851, 00003218890, 00003218891, 00003281411, 00003281811	J0129
4	COSENTYX	\$2,327,442,000	000780639, 000781056, 000781070, 000781168	00078063941, 00078063968, 00078063997, 00078063998, 00078105697, 00078105699, 00078107068, 00078107096, 00078116861	J3247
5	EPLEADA	\$1,847,504,000	506760600	50676060012, 50676060056	

ELIGIBILITY CRITERIA

Which Drugs Are Even Eligible?



Single-source only

No competing generic or biosimilar currently on the market



High total spend

Ranked among the highest total expenditure drugs in the prior 12 months



Time on market

Part D: 7+ years | Part B: 9+ years |
Biologics: 13+ years

Exempt From Negotiation

Orphan drugs

Approved to treat only rare diseases

Low-spend drugs

Accounting for less than \$200M Medicare spending

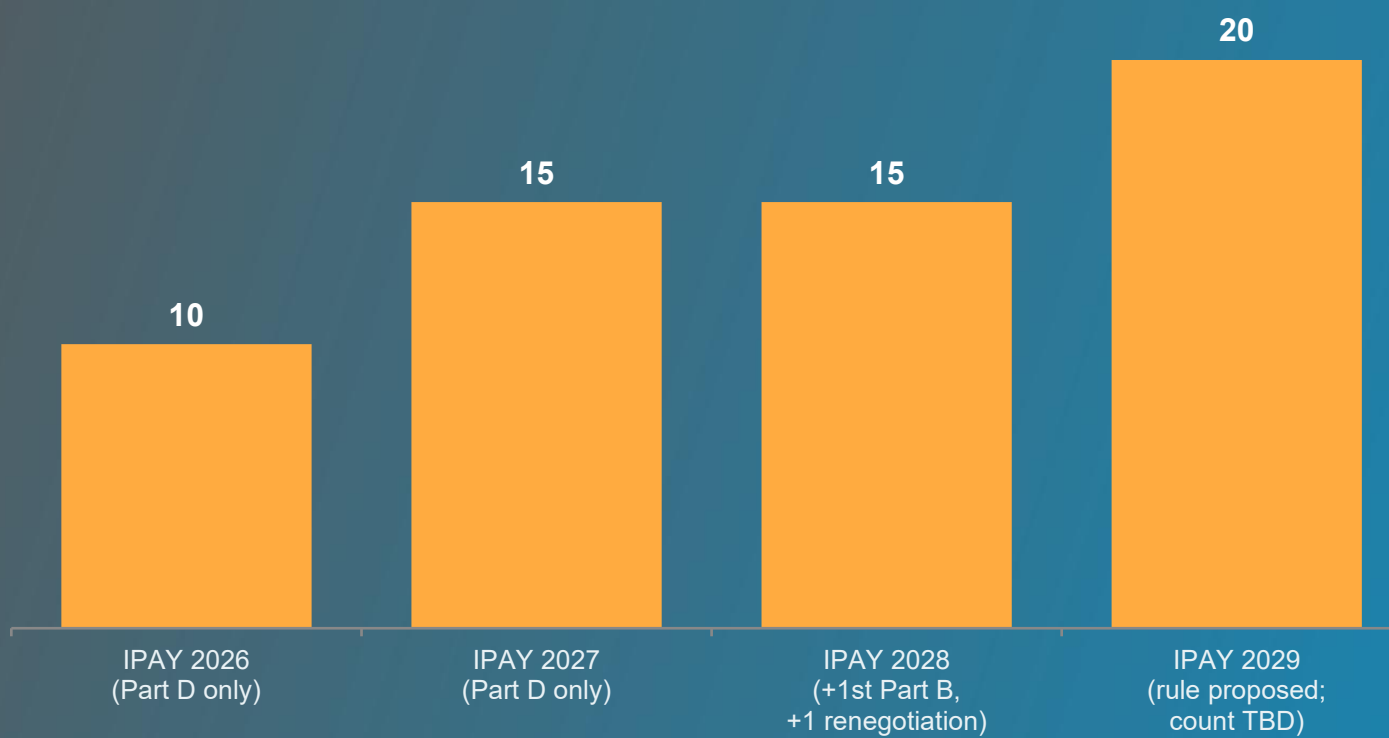
Plasma-derived / biosimilar-imminent

Delay up to 2 years if a competitor is highly likely to launch soon (rebate owed if it doesn't)

Note: The 2025 reconciliation law (OBBBA) broadened the orphan-drug exclusion — see the 2029 Rulemaking slide.

SELECTION TIMELINE

Number of Drugs Selected Per Year



Projected Savings for People with Medicare Part D Coverage:

When the negotiated prices go into effect in 2026, people enrolled in Medicare prescription drug coverage would save under the projected defined standard benefit design an estimated \$1.5 billion. These savings from the Negotiation Program are in addition to savings from other cost saving provisions in the Inflation Reduction Act, such as the first lever cap on out-of-pocket drug costs for people with Medicare.

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	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	\$113.00	\$527.00	79%	\$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	\$119.00	\$495.00	76%	\$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	\$178.50	\$556.00	68%	\$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,355.00	\$7,106.00	67%	\$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	\$197.00	\$573.00	66%	\$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$4,695.00	\$13,836.00	66%	\$2,988,560,000	23,000
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%	\$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	\$231.00	\$521.00	56%	\$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	\$295.00	\$628.00	53%	\$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	\$9,319.00	\$14,934.00	38%	\$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

CYCLE 3 — IPAY 2028

The 2028 Cycle Breaks New Ground

15 + 1

Drugs newly selected,
plus 1 renegotiation

\$27B

Combined Medicare spend on
those drugs, year before selection (6% of
Part B&D total expenditures)

1st

Cycle to include
Part B drugs

- On January 27, 2026, CMS selected 15 drugs for the third negotiation cycle — the first to draw from Part B as well as Part D — plus one drug chosen for the program's first renegotiation.
- CMS's September 2025 final guidance for this cycle incorporated Medicare Advantage claims data to help identify high-spending Part B drugs.
- Part B drug selected — Botox and plasma-derived claim

MAXIMUM FAIR PRICE THRESHOLDS

MFP Thresholds — % of Non-Federal Average Manufacturer Price

75%

of avg.
manufacturer price

**9–11 years
on market**

65%

of avg.
manufacturer price

**12–15 years
on market**

60%

of avg.
manufacturer price

**16+ years
on market**

Manufacturers may accept HHS's proposal or submit a counteroffer before the price is finalized.

PRICING FACTORS

Factors Considered in Setting the MFP



Manufacturer costs

Research, development, production, and distribution costs specific to the drug



Market data

Sales volume, revenue, and pricing trends in the marketplace



Alternative treatments

Availability and clinical role of therapeutic alternatives



Negotiation process

HHS proposes a price; manufacturer may accept or counter with its own data

CMS must solicit manufacturer data before making an initial offer .

PROGRAM TRANSPARENCY

What CMS Discloses About Negotiated Prices

Published

- A public explanation of how CMS arrived at each maximum fair price, for every selected drug.
- General discussion of clinical benefit, unmet medical need, and therapeutic alternatives considered.
- The final negotiated MFP itself and its effective date.

Kept Confidential

- The statutory negotiation ceiling CMS was working within.
- Manufacturer-specific R&D, recoupment, and production/distribution cost data.
- CMS's own initial price offer — the benchmark from which negotiations began.

These disclosures still help manufacturers and researchers shape R&D, trial design, and evidence strategy for drugs that may be selected in future cycles.

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Medicare Drug Rebate and Negotiations Group

Maximum Fair Price (MFP) Explanation for Enbrel

Introduction

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) into law. For the first time, the law provides Medicare with the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) issued [initial guidance](#) for the Medicare Drug Price Negotiation Program (the “Negotiation Program”), including requests for public comment on key elements. On June 30, 2023, CMS issued [revised guidance](#) detailing the requirements and parameters of the Negotiation Program for the first cycle of negotiations.¹ CMS engaged in negotiations with participating manufacturers between October 1, 2023 and August 1, 2024. These negotiations resulted in agreements establishing prices (which the IRA refers to as “maximum fair prices” or “MFPs”) that will be effective beginning in 2026 (the first cycle of negotiations is referred to as negotiations for “initial price applicability year 2026” because any agreed-upon prices will be effective in 2026). CMS published the agreed-upon MFPs on August 15, 2024.

The MFP explanation for Enbrel for the agreed-upon MFP that resulted from the negotiations for initial price applicability year 2026 with Immunex Corporation, the manufacturer of Enbrel (the “Primary Manufacturer”), provides information about the negotiations for Enbrel. This information includes CMS’ perspective on the data considered that had the greatest impact in CMS’ determination of offers and consideration of counteroffers during the negotiation process through which the parties reached agreement on an MFP.² In some respects, the Primary Manufacturer had a different perspective on the relevant data. The parties to the negotiation had productive exchanges during the negotiation meetings described below in which they discussed their respective views, and these exchanges resulted in the exchange of offer(s) and counteroffer(s) among the parties and, ultimately, an agreed-upon MFP for Enbrel.

On the basis of the factors described below and the related considerations and evidence, CMS negotiated with the Primary Manufacturer in good faith and consistent with the requirements of the law on behalf of people with Medicare and the Medicare program. Throughout the negotiation process and in accordance with the IRA, CMS’ goal was to achieve agreement with the Primary Manufacturer on the lowest possible MFP for Enbrel that would be consistent with the process defined in the IRA for these price negotiations. CMS believes that the agreed-upon MFP achieves this aim. The negotiation process

CYCLE 4 — IPAY 2029

From Guidance to Rulemaking

1st

Cycle run through formal
notice-and-comment rulemaking

60 days

Public comment period,
closing August 17, 2026

\$8.8B+

Estimated cost of OBBBA's
expanded orphan-drug exclusion

- On June 12, 2026, CMS published its first proposed rule for the negotiation program, covering the fourth cycle (IPAY 2029); the IRA had authorized guidance-only implementation for just the first three cycles.
- The 2025 reconciliation law (OBBBA) broadened the program's orphan-drug exclusion; the Congressional Budget Office pegged that change at roughly \$8.8 billion over 10 years, while CMS's own analysis in the proposed rule estimates an even higher cost.

NONCOMPLIANCE PENALTIES

Enforcement Has Teeth

10×

the difference between
actual price and MFP, for
selling above the cap

\$1M

civil penalty per day of
violating the HHS
agreement

\$100M

penalty per item of
knowingly false information
provided

65–95%

excise tax depending on
days of noncompliance

LITIGATION OVER COLORADO PDAB

- Patent preemption
- Dormant Commerce Clause
- Due process
- Preliminary injunction (July 1, 2026)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-3452-DDD-STV

AMGEN INC, et al.,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official
capacity as Chair of the Colorado
Prescription Drug Affordability Review
Board, et al.,

Defendants.

ANSWER

Wholesale Acquisition Cost.

Defendants’ Response: Defendants deny the allegations in paragraph 76.

77. The Board’s uncritical adoption of the federal MFP reflected its failure to determine a methodology of its own for establishing an upper payment limit. As one Board member stated: “I know a lot of people are concerned. How are you going to come up with that price? What is the calculation? Where’s the research? Well, in this instance, it was already done at that level” (referring to the federal MFP for Medicare sales).²⁰

Defendants’ Response: Defendants admit that during its August 22, 2025, deliberations regarding the Enbrel UPL rule, the Board discussed the Maximum Fair Price for Enbrel that Amgen negotiated with the Centers for Medicare and Medicaid Services pursuant to the federal Inflation Reduction Act. Defendants deny the remaining allegations in paragraph 77.

78. At the fourth and final rulemaking hearing, held on October 3, 2025, the

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

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No. 1:25-cv-3452-DDD-STV

PLAINTIFFS’ MOTION FOR
PRELIMINARY INJUNCTION

wholesale acquisition cost. Costello Decl. ¶ 9.⁶

The Board’s uncritical reliance on the federal MFP for Medicare sales as its sole basis for determining the state upper payment limit reflected the lack of any meaningful statutory standards to guide the Board’s price-setting discretion, as well as the Board’s disregard of its statutory responsibility to “determine by rule the methodology for establishing an upper payment limit.” Colo. Rev. Stat. § 10-16-1407(2). The Board never claimed to have performed any analysis to determine that the MFP would be an appropriate UPL for Colorado. One Board member admitted that the Board was in effect abdicating its own responsibility for determining an

LITIGATION

- Takings
- Due process
- Compelled speech
- Nondelegation
- Excessive fines
- Administrative Procedure Act

EYE ON THE IRA

FOREFRONT

IRA Litigation: Pharma's Failed Challenges To Medicare Drug Pricing

Andrew Twinamatsiko and Sarah Wetter • March 13, 2026

To date, every court that has considered substantive challenges to the Medicare drug price negotiation program has ruled against the pharmaceutical industry, dismissing both constitutional and statutory arguments.