

Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026



In August 2022, President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law. The law makes improvements to Medicare by expanding benefits, lowering drug costs, and improving the sustainability of the Medicare program for generations to come. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

For the first time, the law provides Medicare the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. The Centers for Medicare & Medicaid Services (CMS) **selected** ten drugs covered under Medicare Part D for the first cycle of negotiations for initial price applicability year 2026 and engaged in voluntary negotiations with the drug companies for the selected drugs. Below is the list of negotiated prices, which the statute refers to as Maximum Fair Prices (MFPs), for 10 drugs covered under Medicare Part D that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies.

CMS negotiated in good faith consistent with the requirements of the law on behalf of people with Medicare and the Medicare program. Throughout the negotiation process, the CMS team took into account the factors outlined in the law in negotiating these prices, which supports the need for innovation and drug development with better prices for people with Medicare and the Medicare program.

CMS engaged in genuine, thoughtful negotiations with each participating drug company. CMS developed an initial offer for each drug, consistent with the process described in the statute and the agency's guidance, and each manufacturer responded with a counteroffer. CMS held three meetings with each participating drug company to discuss the offers and counteroffers, discuss evidence, and attempt to arrive at a mutually acceptable price for the drug. During the course of the negotiation process, CMS revised its offers for each of the drugs upward in response to these discussions. Likewise, many drug companies revised their counteroffers for their drugs downward, based on the discussions with CMS. For five of the selected drugs, this process of exchanging revised offers and counteroffers resulted in CMS and the drug company reaching an agreement on a negotiated price for the drug in association with a negotiation meeting. In four of these cases, CMS accepted a revised counteroffer proposed by the drug company. For the remaining five selected drugs, CMS sent a written final offer to those drug companies, consistent with the process described in its guidance, and in each instance, the drug company accepted CMS's offer on or before the statutory deadline.

Impact of the Negotiated Prices

Overall Medicare Spending and Out-of-Pocket Spending in 2023:

For the time period between January 1, 2023, and December 31, 2023, about 8.8 million of the 54 million people with Medicare Part D coverage were dispensed these drugs to treat a variety of conditions, such as cardiovascular disease, diabetes, autoimmune diseases, and cancer. These selected drugs accounted for \$56.2 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during 2023. During that same time period, people with Medicare Part D prescription drug coverage spent \$18.9 billion in out-of-pocket costs for all drugs covered under Part D, including \$3.9 billion out-of-pocket for these drugs selected for negotiation.

Estimated Medicare Net Savings in 2023:

Compared to 2023 Medicare spending net of all rebates and certain fees and payments, if the prices agreed to between CMS and participating drug companies under the Negotiation Program had been in effect during 2023, the negotiated prices would have saved an estimated \$6 billion in net covered prescription drug costs, which would have represented 22% lower net spending in aggregate.

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 ever 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.

Key Milestones for the First Cycle of Negotiations:

- **On February 1, 2024** – CMS sent an initial offer for each selected drug, with a concise justification for the initial offer, to each respective participating drug company.
- **By March 2, 2024** – Each participating drug company responded to the initial offer for a negotiated price with a counteroffer.
- **Spring/Summer 2024** – CMS and participating drug companies conducted in-person and hybrid negotiation meetings, through which an agreement for a negotiated price was reached for several of the selected drugs.
- **July 15, 2024** – CMS sent final offers to any participating drug company where an agreement was not reached in connection with the negotiation meetings.
- **July 15-July 31, 2024** – Participating drug companies where an agreement was not reached in connection with the negotiation meetings had the opportunity to review CMS' final offers and respond to CMS.
- **August 1, 2024** – The negotiation period ended with agreement reached for negotiated prices between CMS and participating drug companies for 10 selected drugs.

Q: How did CMS structure the negotiation process with the drug companies of selected drugs?

CMS is implementing the new drug law, including the Negotiation Program, with the goal of promoting transparency and engagement. As discussed in detail in the [revised guidance for initial price applicability year 2026](#), CMS set out a process for the first cycle of negotiations that engaged drug companies and the public throughout. The process included several steps, such as:

- Drug companies and the public had an opportunity to submit data and information on the selected drugs to CMS by October 2, 2023.

- During the Fall of 2023, CMS invited each participating drug company to engage in a meeting on its data submission. Additionally, CMS held public Patient-Focused Listening Sessions for each selected drug with patients and other interested parties.
- CMS sent an initial offer to the participating drug company reflecting CMS' proposal for a negotiated price and a concise justification of the initial offer on February 1, 2024. In developing an initial offer, CMS considered the factors set out by the statute, including evidence related to therapeutic alternatives as well as other factors, such as costs of research and development and production and distribution of the selected drug.
- Participating drug companies had 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired.
- After receiving counteroffers from participating drug companies, CMS and each participating drug company conducted three negotiation meetings during Spring and Summer 2024.
- The negotiation period ended on August 1, 2024.

Q: What information did CMS consider during the negotiations with participating drug companies?

In accordance with the Inflation Reduction Act, CMS considered the statutory factors listed at section 1194(e) of the Social Security Act in determining its initial offers, revised offers, and final offers.

Specifically, for the factors listed at section 1194(e)(1), CMS considered information reported by participating drug companies. This included manufacturer-submitted data on research and development costs, prior federal financial support, unit costs of production and distribution, market/revenue/sales data, and information on patents, FDA exclusivities, and FDA applications and approvals. For the factors listed at section 1194(e)(2) related to evidence about alternative treatments (including therapeutic advances, prescribing information, comparative effectiveness, and unmet medical need), CMS considered information from a wide variety of sources, including: information submitted by participating drug companies, people with Medicare, academic experts, clinicians, caregivers, and other interested parties in response to Information

Collection Requests issued for the Negotiation Program; information provided at the Patient-Focused Listening Sessions hosted by CMS in the Fall of 2023; information shared by participating drug companies during meetings with CMS; and information CMS identified from its own literature searches, including from clinical guidelines and published studies.

Q: How did CMS reach an agreement with participating drug companies on negotiated prices?

CMS engaged in good-faith negotiations with participating drug companies throughout the negotiation period, including through written offers, counteroffer exchanges, and three negotiation meetings for each drug. For certain selected drugs, negotiation meetings resulted in CMS' agreement to the drug company's proposal for a negotiated price or the drug company's agreement to CMS' proposal for a negotiated price, whereas for other selected drugs, agreement was reached with the written final offer.

Q: How does the Medicare program benefit from these negotiations?

Medicare's new ability to negotiate prices for selected drugs will improve drug affordability for people with Medicare, improving access to innovative life-saving treatments for people who need them. If the negotiated prices had been in effect during 2023, compared to the 2023 Medicare prices net of all rebates and certain fees and payments, the negotiated prices would have saved an estimated \$6 billion in 2023 across the 10 drugs, which would have amounted to approximately 22% in savings.

Q: How will people with Medicare get access to these prices? When will these prices be effective?

These negotiated prices will become effective on January 1, 2026. A participating drug company with a selected drug is required to ensure the negotiated price is made available to eligible individuals and to the pharmacies, mail-order services, and other entities that dispense the selected drug to such individuals.

As required by law, Medicare prescription drug plans, including standalone Part D plans and Medicare Advantage-prescription drug plans, must include in their formularies the selected drugs for which CMS and the participating drug company have agreed to a negotiated

price. CMS will use its comprehensive formulary review process for Medicare prescription drug plans to assess any practices that may undermine access to selected drugs for people with Medicare.

CMS will make public an explanation of the agreed-upon negotiated prices by March 2025.

Q: How long do these Negotiated Prices apply? Are they adjusted over time?

In accordance with the Inflation Reduction Act, the negotiated price will apply to a selected drug so long as the selected drug remains in the Medicare Drug Price Negotiation Program. For each year after the first initial price applicability year, CMS will publish an updated negotiated price for each selected drug. The updated price will be equal to the negotiated price that was published for such drug for the previous year, increased by the annual percentage increase in the Consumer Price Index for all urban consumers (United States city average) (CPI-U). The negotiated price of a selected drug would also be updated should CMS and the Primary Manufacturer renegotiate the negotiated price of the selected drug.

Q: How will these negotiated prices impact drugs selected for the second cycle of negotiations?

On May 3, 2024, CMS published **draft guidance for initial price applicability year 2027 (the "draft guidance")**. This draft guidance details requirements and parameters for the second cycle of negotiations for the Negotiation Program, which will occur during 2025 and may result in negotiated prices that would be effective beginning in 2027. If a drug selected for the first cycle of negotiations has a negotiated price and is subsequently identified as a therapeutic alternative to a drug selected for the second cycle of negotiations, the agreed-upon negotiated price from this first cycle of negotiations could serve as an input into the initial offer development process for the drug selected for the second cycle of negotiations. CMS solicited comment on this policy in the draft guidance.