

# Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026



CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law. The new 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. Below is the list of 10 drugs covered under Medicare Part D selected for negotiation for initial price applicability year 2026, based on total gross covered prescription drug costs under Medicare Part D and other criteria as required by the law.

Drug Name	Commonly Treated Conditions	Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023	Number of Medicare Part D Enrollees Who Used the Drug from June 2022-May 2023
Eliquis	Prevention and treatment of blood clots	\$16,482,621,000	3,706,000
Jardiance	Diabetes; Heart failure	\$7,057,707,000	1,573,000
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	\$6,031,393,000	1,337,000
Januvia	Diabetes	\$4,087,081,000	869,000
Farxiga	Diabetes; Heart failure; Chronic kidney disease	\$3,268,329,000	799,000
Entresto	Heart failure	\$2,884,877,000	587,000
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,791,105,000	48,000
Imbruvica	Blood cancers	\$2,663,560,000	20,000
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$2,638,929,000	22,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes	\$2,576,586,000	777,000

Note: Numbers are rounded to the nearest thousands.

For the time period between June 1, 2022 and May 31, 2023, which is the time period used to determine which drugs were eligible for negotiation, about 8,247,000 people with Medicare Part D coverage used these drugs to treat a variety of conditions, such as cardiovascular disease, diabetes, autoimmune diseases, and cancer. These selected drugs accounted for \$50.5 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during that time period.

## Key Milestones to Date:

-  **On March 15, 2023**, the Centers for Medicare & Medicaid Services (CMS) issued initial guidance for the Medicare Drug Price 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 Medicare Drug Price Negotiation Program for the first round of negotiations, which will occur during 2023 and 2024 and will result in prices that will be effective beginning in 2026.
-  **On August 29, 2023**, CMS announced the drugs covered under Medicare Part D selected for the first cycle of negotiations.

### Q: How did CMS select the 10 drugs for the first round of negotiations?

The Inflation Reduction Act specified that CMS select drugs for the first round of negotiations by:

1. Identifying potential qualifying single source drugs — that is, drugs for which at least seven years, or biologics for which at least 11 years, have elapsed between the FDA approval or licensure and the selected drug publication date, and for which there is no generic or biosimilar competition.
2. Excluding certain orphan drugs, low-spend Medicare drugs, and plasma-derived products.
3. Determining the negotiation-eligible drugs — that is, the 50 qualifying single source drugs with the highest total Part D gross covered prescription drug costs under Part D, except for small biotech drugs.
4. Ranking the negotiation-eligible drugs according to highest total Part D gross covered prescription drug costs.

5. Selecting the 10 drugs with the highest total Part D gross covered prescription drug costs after excluding from the ranked list of 50 negotiation-eligible drugs any biologics that qualify for delayed selection as a result of there being a high likelihood that a biosimilar will enter the market within a specified time.

### Q: What was the time period used for determining which drugs were eligible for negotiation?

The time period for the data on total gross covered prescription drug costs under Medicare Part D that was used to determine negotiation-eligible drugs, for initial price applicability year 2026 (the first year of negotiation), was June 1, 2022 through May 31, 2023.

### Q: How many drugs qualified for the Small Biotech Exception?

For initial price applicability year 2026, drug companies submitted requests and information to CMS for four drugs that were determined to be qualified for the small biotech exception.

### Q: How many drugs would have been selected for initial price applicability year 2026, absent the Biosimilar Delay (described in section 1192(f) of the Social Security Act)?

For initial price applicability year 2026, zero drugs would have been selected for initial price applicability year 2026, absent the Biosimilar Delay.

### Q: How is CMS structuring the negotiation process with the drug companies of selected drugs?

CMS is approaching implementation of the new drug law, including the Medicare Drug Price Negotiation Program, with the goal of promoting transparency and engagement. As discussed in detail in the **revised guidance**, CMS set out a process for the first round of negotiations that engages drug companies and the public throughout. The process includes several steps, such as:

- Drug companies with a selected drug for the Negotiation Program and the public will have an opportunity to submit data and information on the selected drugs to CMS no later than October 2, 2023.
- During the Fall 2023, CMS will invite each participating drug company with a selected drug to engage in a meeting on its data submission. CMS will also hold a public patient-focused listening session for each selected drug with patients and other interested parties. The patient-focused listening sessions will be held between October 30, 2023 and November 15, 2023. The listening sessions are subject to change, including postponement and/or cancellation.
- CMS will send an initial offer for each selected drug for which the drug company is participating in the Negotiation Program with CMS' proposal for the maximum fair price and a concise justification no later than February 1, 2024, and companies will have 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired. In developing an initial offer, CMS will consider 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.
- If agreement on a maximum fair price is not reached through the initial offer or counteroffer, CMS will invite each participating drug company for up to three negotiation meetings during Spring and Summer 2024 before the negotiation period ends on August 1, 2024.

## Q: What are the details of the patient-focused listening sessions?

CMS is providing opportunities for public engagement during the negotiation process. These include meetings with participating drug companies with a selected drug in Fall 2023 as well as a CMS-hosted patient-focused listening session for each selected drug. The listening sessions will be open to the public and will provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, to share patient-focused input on therapeutic alternative(s) to the selected drugs, how the selected drugs address unmet medical need, and the impact of selected drugs on specific populations.

The listening sessions are currently planned between October 30, 2023 and November 15, 2023. Registration to apply to be a speaker will open on September 1, 2023 and will close on October 2, 2023. The listening sessions are subject to change, including postponement and/or cancellation. Separately, the public is also invited to submit data on selected drugs, therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts on specific populations by October 2, 2023. More information about the Listening Sessions and how to submit data for CMS to consider in the negotiation process is available [here](#).

Learn more about the Medicare Drug Price Negotiation Program, including a timeline for Initial Price Applicability Year 2026 [here](#).

View a fact sheet from the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) [here](#).