

# Medicare Drug Price Negotiation Program: Manufacturer Agreements for 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. On August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) announced the [10 drugs](#) covered under Medicare Part D selected for the first cycle of negotiations.

October 1, 2023 was the statutory deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 to choose to sign agreements to participate in the Negotiation Program. The below list indicates that drug companies that manufacture all 10 drugs selected for the Medicare Drug Price Negotiation Program for the first cycle have chosen to participate in the Negotiation Program.

Drug Name	Participating Manufacturer
Eliquis	Bristol Myers Squibb
Jardiance	Boehringer Ingelheim
Xarelto	Janssen Pharms
Januvia	Merck Sharp Dohme
Farxiga	AstraZeneca AB
Entresto	Novartis Pharms Corp
Enbrel	Immunex Corporation
Imbruvica	Pharmacyclics LLC
Stelara	Janssen Biotech, Inc.
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc.

## Key Milestones to Date

- On March 15, 2023, 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. Any negotiated prices will be effective beginning in 2026.
- On August 29, 2023, CMS announced the 10 drugs covered under Medicare Part D selected for the first cycle of negotiations. For a list of these drugs, please click [here](#).
- On October 3, 2023, CMS announced that drug companies that manufacture the first 10 drugs selected for the Negotiation Program have chosen to participate in the program.

## 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 has 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:
  - Participating drug companies with a selected drug for the Negotiation Program and the public had an opportunity to submit data and information on the selected drugs and their therapeutic alternatives 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 the drug company 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.

For more information on the Medicare Drug Price Negotiation Program, including the revised guidance and the negotiation process, please click [here](#).