



Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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Medicare Drug Manufacturers Have Chosen to Participate in the First Round Price Negotiation Program

The Centers for Medicare & Medicaid (CMS) have announced that the 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. The negotiations with participating drug companies for the selected drugs will occur in 2023 and 2024 with the negotiated prices effective beginning in 2026.

These selected drugs account 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 between June 1, 2022 and May 31, 2023, which is the time period used to determine which drugs were eligible for negotiation. Medicare enrollees taking the 10 drugs covered under Part D selected for negotiation paid a total of \$3.4 billion in out-of-pocket costs in 2022 for these drugs.

The 10 companies participating in the Medicare Drug Price Negotiation Program are as follows:

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 PenFill	Novo Nordisk Inc

October 1, 2023, was the deadline for companies with a drug selected for the Negotiation Program to choose whether to sign agreements to participate in the negotiation process for 2026. Participating companies with a drug selected for the Negotiation Program had by October 2, 2023, to submit manufacturer-specific data for CMS to consider in the negotiations. Additionally, October 2, 2023, was



the deadline for the public to submit data on therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts to specific populations.

Other key upcoming dates for implementation include:

- 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 patient-focused listening session for each
 selected drug. The patient-focused listening sessions, which will include participation from patients,
 beneficiaries, caregivers, consumer and patient organizations, and other interested parties, will be
 held between October 30, 2023 and November 15, 2023. The listening sessions are subject to
 change, including postponement and/or cancellation.
- February 1, 2024: CMS sends an initial offer of a maximum fair price for a selected drug with a justification to each drug company participating in the Negotiation Program.
- August 1, 2024: The negotiation period ends.
- September 1, 2024: CMS will publish the maximum fair prices that have been negotiated for drugs selected for negotiation for 2026.

Comment

The *Inflation Reduction Act* gave Medicare the ability to negotiate prescription drug prices.

The drug industry's lobbying arm (Pharma) is still trying to reverse this item both legislatively and judicially. Nonetheless, it is interesting to see the drug manufacturers themselves willing to at least meet with CMS.