

CMS Announces Manufacturer Participation in Second Cycle of Medicare Drug Price Negotiation










Today, the Centers for Medicare & Medicaid Services (CMS) announced that agreements have been signed with manufacturers of the 15 drugs covered under Medicare Part D selected for the second cycle of the Medicare Drug Price Negotiation Program (Negotiation Program). This is an important step in the process which initiates the negotiation period between the manufacturer and CMS. All 15 drugs selected for the second cycle of the Negotiation Program and the associated manufacturers are listed below:

Drug Name	Participating Manufacturer
Austedo; Austedo XR	Teva Branded Pharmaceutical Products R&D, Inc.
Breo Ellipta	GlaxoSmithKline Intellectual Property Development Ltd. England
Calquence	AstraZeneca UK Limited
Ibrance	Pfizer Inc.
Janumet; Janumet XR	Merck Sharp & Dohme LLC
Linzess	AbbVie Inc.
Ofev	Boehringer Ingelheim Pharmaceuticals, Inc.
Otezla	Amgen Inc.
Ozempic; Rybelsus; Wegovy	Novo Nordisk Inc.
Pomalyst	Bristol-Myers Squibb Company
Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.
Trelegy Ellipta	GlaxoSmithKline Intellectual Property Development Ltd. England
Vraylar	AbbVie Inc.
Xifaxan	Salix Pharmaceuticals Inc.
Xtandi	Astellas Pharma US, Inc.

A brief summary of the history of the second cycle and next steps in the process is included below:

Major Actions to Date

-  **May 3, 2024** – CMS issued draft guidance for the second cycle of negotiations, including requests for public comment.
-  **October 2, 2024** – CMS issued **final guidance** detailing the requirements and parameters of the Negotiation Program for the second cycle of negotiations, which will occur during 2025. Any negotiated prices will be effective beginning in 2027.
-  **January 17, 2025** – CMS announced the 15 drugs covered under Medicare Part D selected for the second cycle of negotiations. For a list of these drugs, please click [here](#).
-  **February 26, 2025** – CMS issued **this infographic** to provide additional insight into the Drug selection process for the second cycle of negotiations.
-  **February 28, 2025** – Drug companies that manufacture the drugs selected for the second cycle of the Negotiation Program had a statutory deadline to choose to sign agreements to participate in the Negotiation Program.
-  **March 1, 2025** – 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 alternative(s) to CMS.
-  **March 14, 2025** – CMS announced the drug companies that manufacture the 15 drugs selected for the Negotiation Program that have chosen to participate in the program.

The CMS process for the second cycle of negotiations will include robust engagement with drug companies and the public, including the following steps:

- Invite each participating drug company with a selected drug to engage in a meeting on its data submission.
- Host 15 patient-focused roundtable events (one for each selected drug) that will be open to patients, patient advocacy organizations, and caregivers. These events are intended to collect patient-focused input on topics such as patient experience, therapeutic alternative(s) to the selected drugs, the extent to which the selected drugs address unmet medical needs, and the impact of selected drugs on specific populations. For additional information or to register, please click [here](#). Participant registration is open until March 19, 2025.
- Host one town hall meeting for practicing clinicians, researchers, and other interested parties to discuss clinical considerations related to all the selected drugs. For additional information or to register, please click [here](#). Participant registration is open until March 19, 2025.
- Send an initial offer for each selected drug with CMS' proposal for the maximum fair price and concise justification no later than June 1, 2025. The participating drug company will have 30 days to respond by accepting the initial 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 related to research and development, production, and distribution of the selected drug. CMS will invite the drug company to a negotiation meeting to take place during the 30-day period after CMS sends the initial offer and before the response from the drug company is due to begin negotiation discussions.
- If agreement on a maximum fair price is not reached through the initial offer or counteroffer, CMS will invite each participating drug company to up to two additional negotiation meetings during Summer and Fall 2025 before the negotiation period ends on November 1, 2025.

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