

Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027



In August 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) (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

that now have negotiated prices, which the statute refers to as maximum fair prices (MFPs), that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies in 2024. The savings realized through the negotiation process are expected to lower out-of-pocket costs for Medicare enrollees by an estimated \$1.5 billion in 2026 under the projected defined standard benefit design.

On January 17, 2025, CMS announced the selection of the below list of 15 drugs covered under Medicare Part D for the second cycle of negotiations (initial price applicability year 2027), 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 November 2023-October 2024	Number of Medicare Part D Enrollees Who Used the Drug from November 2023 - October 2024
Ozempic; Rybelsus; Wegovy	Type 2 diabetes; Type 2 diabetes and cardiovascular disease; Obesity/overweight and cardiovascular disease	\$14,426,566,000	2,287,000
Trelegy Ellipta	Asthma; Chronic obstructive pulmonary disease	\$5,138,107,000	1,252,000
Xtandi	Prostate cancer	\$3,159,055,000	35,000
Pomalyst	Kaposi sarcoma; Multiple myeloma	\$2,069,147,000	14,000
Ibrance	Breast cancer	\$1,984,624,000	16,000
Ofev	Idiopathic pulmonary fibrosis	\$1,961,060,000	24,000
Linzess	Chronic idiopathic constipation; Irritable bowel syndrome with constipation	\$1,937,912,000	627,000
Calquence	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma	\$1,614,250,000	15,000
Austedo; Austedo XR	Chorea in Huntington's disease; Tardive dyskinesia	\$1,531,855,000	26,000
Breo Ellipta	Asthma; Chronic obstructive pulmonary disease	\$1,420,971,000	634,000
Tradjenta	Type 2 diabetes	\$1,148,977,000	278,000
Xifaxan	Hepatic encephalopathy; Irritable bowel syndrome with diarrhea	\$1,128,314,000	104,000
Vraylar	Bipolar I disorder; Major depressive disorder; Schizophrenia	\$1,085,788,000	116,000
Janumet; Janumet XR	Type 2 diabetes	\$1,082,464,000	243,000
Otezla	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis	\$994,001,000	31,000

Note: Numbers are rounded to the nearest thousands.

* The commonly treated conditions are limited to conditions for which prescription drug coverage is currently available under the Medicare Part D program.

For the time period between November 1, 2023 and October 31, 2024, which is the time period used to determine which drugs were eligible for negotiation for this second cycle, about 5,258,000 people with Medicare Part D coverage used these drugs to treat a variety of conditions, such as type 2 diabetes, prostate cancer, and chronic obstructive pulmonary disease. These selected drugs accounted for \$40.7 billion in total gross covered prescription drug costs under Medicare Part D, or about 14% of total gross covered prescription drug costs under Medicare Part D during that time period. When combined with the total gross covered prescription drug costs under Medicare Part D of the 10 drugs selected for the first cycle of negotiations (which were about \$60 billion during the same time period of November 1, 2023 through October 31, 2024), this represents 36% of total gross covered prescription drug costs under Medicare Part D during that time period.

Q: How did CMS select the 15 drugs for the second cycle of negotiations?

The IRA specified that CMS select drugs by:

1. Identifying potential qualifying single-source drugs — that is, drugs for which at least 7 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 gross covered prescription drug costs under Medicare Part D, except for drugs granted a Small Biotech Exception and drugs already selected during the first cycle of negotiations.
4. Ranking the negotiation-eligible drugs according to highest total gross covered prescription drug costs under Medicare Part D.
5. Selecting the 15 drugs with the highest total gross covered prescription drug costs under Medicare Part D 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 to determine 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 the second cycle of negotiations was November 1, 2023, through October 31, 2024.

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

For the second cycle of negotiations, drug companies submitted requests and information to CMS for four drugs that were determined to qualify for the Small Biotech Exception.

Q: How many drugs would have been selected drugs for initial price applicability in the year 2027, absent the Biosimilar Delay?

All 15 drugs would have been selected drugs for initial price applicability year 2027 absent the Biosimilar Delay.

Q: How can the public engage with CMS during the negotiation process?

In the **final guidance** for the second cycle of negotiations CMS outlined opportunities for the public to engage with CMS during the negotiation process. These include patient-focused and clinical-focused public engagement events for the selected drugs, as well as an information collection request to submit written feedback.

CMS will host up to 15 patient-focused roundtable events that will aggregate selected drugs by condition when appropriate and 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.

CMS will also host one town hall meeting focused on clinical considerations related to the selected drugs. CMS encourages practicing clinicians, researchers, and other interested parties to register to participate in the town hall meeting.

Separately, the public is also invited to submit data to CMS by March 1, 2025, on topics such as patient experiences with the conditions or diseases treated by the selected drugs, as well as experiences taking the selected drugs and therapeutic alternatives to the selected drugs, prescribing information for the selected drugs and therapeutic alternatives, comparative effectiveness data for the selected drugs and therapeutic alternatives, and/or information on the extent to which the selected drugs address unmet medical need. The final information collection request with these questions is available [here](#). Interested parties are encouraged to review this information collection request to prepare for data submission. The data submission portal will open in the days following the publication of the selected drug list.

Q: What are the details of the patient-roundtable events and the town hall meeting?

CMS expects that these events will occur between March and April 2025. CMS anticipates releasing additional information on meeting dates, participant and speaker registration, and other logistical details on the [CMS IRA website](#) in February 2025.

Key Milestones for the Second Cycle of the Negotiation Program

- **May 3, 2024**, CMS issued draft guidance for the second cycle of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements.
- **October 2, 2024**, CMS issued final guidance detailing the requirements and parameters of the Medicare Drug Price Negotiation Program for the second cycle of negotiations, which will occur during 2025 and, for drugs where an agreement on a negotiated price is reached, will result in prices that will be effective beginning in 2027.
- **January 17, 2025** — CMS published the list of 15 drugs covered under Part D selected for the second cycle of negotiations.
- **February 28, 2025** — Deadline for participating drug companies for the second cycle of negotiations to sign agreements to participate in the Negotiation Program.
- **March 1, 2025** — Deadline for participating drug companies to submit manufacturer-specific data to CMS for consideration in the negotiation of an MFP. In addition, this is the deadline for the public to submit data on selected drugs and their therapeutic alternatives, if any, data related to unmet medical needs, and data on impacts to specific populations, among other considerations.
- **March and April 2025** — CMS will host patient-focused and clinical-focused public engagement sessions. CMS will host up to 15 patient-focused roundtable events that will aggregate selected drugs by condition when appropriate and will be open to patients, patient advocacy organizations, and caregivers to share patient-focused input. CMS will also host one town hall meeting focused on clinical considerations related to the selected drugs. Additional information about these public engagement sessions will be shared in the future. CMS also will provide an optional opportunity for participating drug companies to meet with CMS to discuss their data submission.
- **June 1, 2025** — Deadline for CMS to send an initial offer of an MFP for a selected drug with a concise justification to each drug company participating in the Negotiation Program.
- **June 2025** — CMS will offer each participating drug company up to one optional negotiation meeting, which would occur after the initial offer is issued and before the deadline to accept the initial offer or to propose a statutory written counteroffer.
- **July 1, 2025** — Deadline for participating drug companies to accept CMS' initial offer or propose a statutory written counteroffer if desired. Participating drug companies have 30 days from receiving CMS' initial offer to respond.
- **Summer 2025** — CMS will respond to any statutory written counteroffers from participating drug companies within 30 days after receipt of a counteroffer or within 60 days of sharing the initial offer, whichever is later. CMS and participating drug companies may engage in up to two additional optional negotiation meetings, as well as additional written price exchanges.
- **September 30, 2025** — Last day for negotiation meetings to take place.
- **October 8, 2025** — Last date by which CMS and participating drug companies may exchange additional written offers or counteroffers.
- **October 15, 2025** — Deadline for CMS to send a final MFP offer to participating drug companies if the agreement was not reached during the negotiation meetings or the additional price exchange process.
- **October 31, 2025** — Deadline for participating drug companies to accept or reject a final MFP offer from CMS.
- **November 1, 2025** — The negotiation period ends.

- **November 30, 2025** — Deadline for CMS to publish any agreed-upon MFPs resulting from the second cycle of negotiations.
- **March 1, 2026** — Deadline for CMS to publish an explanation of any agreed-upon MFPs resulting from the initial price applicability year 2027 negotiation process. In the interest of balancing transparency and confidentiality, as part of the public explanation of an agreed-upon MFP, CMS will publish a narrative explanation of the negotiation process and certain additional information. Any information submitted by participating drug companies during the negotiation process that constitutes confidential commercial or financial information will be considered proprietary and will be redacted.
- **January 1, 2027** — Any agreed-upon MFPs negotiated for selected drugs from the second cycle of negotiations become effective.

Key Policymaking Milestones for Future Cycles of Negotiations:

- **Spring 2025**— CMS intends to release draft guidance for the third cycle of negotiations (initial price applicability year 2028), including new policies on renegotiation and Part B drugs.
- **Fall/Winter 2025**—CMS intends to release final guidance for the third cycle of negotiations, including new policies on renegotiation and Part B drugs.
- **Spring 2026** – CMS intends to undertake rulemaking to establish policies for future years of the Negotiation Program.