Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028

Under the Medicare Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) directly negotiates the prices of certain high expenditure, single source drugs without generic or biosimilar competition.

CMS selected 10 and 15 drugs covered under Medicare Part D for the first and second cycle of negotiations, respectively, that now have negotiated prices, which the statute refers to as maximum fair prices (MFPs). These prices are effective beginning January 1, 2026 for the first cycle and January 1, 2027 for the second cycle, based on negotiations and agreements reached between CMS and participating drug companies.

For the second cycle of negotiations, if the prices agreed upon between CMS and participating drug companies under the Negotiation Program had been in effect during 2024, the negotiated prices would have saved an estimated $12 billion in net covered prescription drug costs or about $8.5 billion if Coverage Gap Discount Program spending were included.

On January 27, 2026, CMS announced the selection of the below list of 15 drugs payable under Medicare Part B and/or covered under Medicare Part D for the third cycle of negotiations (initial price applicability year 2028), based on total expenditures for drugs payable under Part B and/or covered under Part D and other criteria as required by the law.

Drug Name	Commonly Treated Conditions	Total Medicare Part B and Part D Prescription Drug Expenditures from November 2024-October 2025	Number of Medicare Enrollees Who Used the Drug from November 2024–October 2025
Trulicity	Type 2 diabetes; Type 2 diabetes and cardiovascular disease or multiple cardiovascular risk factors	$4,898,378,000	617,000
Biktarvy	Human immunodeficiency virus type 1 infection	$3,904,486,000	101,000
Orencia	Psoriatic arthritis; Rheumatoid arthritis	$2,450,065,000	72,000
Cosentyx	Plaque psoriasis; Psoriatic arthritis	$2,327,442,000	40,000
Erleada	Prostate cancer	$1,947,504,000	19,000
Kisqali	Breast cancer	$1,578,679,000	17,000
Entyvio	Crohn’s disease; Ulcerative colitis	$1,483,348,000	37,000
Verzenio	Breast cancer	$1,428,714,000	15,000
Botox; Botox Cosmetic*	Chronic migraine; Overactive bladder; Spasticity; Other movement disorders	$1,143,070,000	390,000
Lenvima	Thyroid cancer; Endometrial cancer; Liver cancer; Kidney cancer	$1,088,498,000	10,000
Xolair	Asthma; Chronic spontaneous urticaria	$1,077,271,000	40,000
Rexulti	Major depressive disorder; Schizophrenia; Agitation associated with dementia due to Alzheimer’s disease	$1,075,274,000	119,000
Xeljanz; Xeljanz XR	Psoriatic arthritis; Rheumatoid arthritis; Ulcerative colitis	$1,013,332,000	22,000
Anoro Ellipta	Chronic obstructive pulmonary disease	$812,772,000	281,000
Cimzia	Crohn’s disease; Plaque psoriasis; Psoriatic arthritis; Rheumatoid arthritis	$786,790,000	38,000

Note: Numbers are rounded to the nearest thousands. Conditions listed under commonly treated conditions are limited to conditions for which prescription drug coverage or payment is currently available under the Medicare Part B and/or D program and is not intended to be exhaustive.

**The selected drug name reflects the manufacturer’s naming convention, and use of the manufacturer’s assigned name when describing the selected drug is not indicative of any change in Medicare coverage or payment for this selected drug when used for cosmetic purposes.*

For the time period between November 1, 2024 and October 31, 2025, which is the time period used to determine which drugs were eligible for negotiation for this third cycle, about 1,777,000 people with Medicare Part B and/or Part D coverage used these drugs to treat a variety of conditions, such as cancer, psoriatic arthritis, and human immunodeficiency virus type 1 infection. These selected drugs accounted for $27.0 billion in Total Expenditures under Medicare Part B and Part D, or about 6% of Total Expenditures under Medicare Part B and Part D during that period.

Also, on January 27, 2026, CMS announced the selection of one drug for renegotiation during the third cycle of negotiations (initial price applicability year 2028), based on criteria required by the law.

Drug Name	Commonly Treated Conditions	Initial price applicability year for which the drug was originally negotiated
Tradjenta	Type 2 diabetes	2027

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

The law specifies 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, under certain circumstances, there is no generic or biosimilar competition.
2. Excluding certain orphan drugs, as amended by the "Working Families Tax Cuts" legislation, (P.L. 119-21), low-spend Medicare drugs, and plasma-derived products.
3. Determining the negotiation-eligible drugs — that is, up to 50 qualifying single source drugs with the highest total expenditures for drugs payable under Medicare Part B and up to 50 qualifying single source drugs with the highest total expenditures for drugs covered under Medicare Part D, except for drugs granted a Small Biotech Exception and selected drugs for the first and second cycle of negotiations.
4. Ranking the negotiation-eligible drugs according to highest total expenditures for drugs payable under Medicare Part B and/or covered under Medicare Part D.
5. Selecting the 15 drugs with the highest Total Expenditures under Medicare Part B and Part D after excluding from the ranked list of 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 Expenditures under Medicare Part B and Part D that was used to determine negotiation-eligible drugs for the third cycle of negotiations was November 1, 2024, through October 31, 2025.

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

For the third cycle of negotiations, drug companies submitted requests and information to CMS for five 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 2028, absent the Biosimilar Delay?

All 15 drugs would have been selected for initial price applicability year 2028 absent the Biosimilar Delay.

Q: How did CMS select the drugs for renegotiation?

The law specifies that CMS select drugs for renegotiation by:

1. Identifying all selected drugs from prior rounds of negotiation for which CMS has not determined that a generic or biosimilar product for the selected drug is approved or licensed and is marketed.

2. Identifying which such drugs are renegotiation-eligible based on whether:
    a. The monopoly status, based on how many years have elapsed since the drug's first approval, has changed to long monopoly since the original negotiation; or
    b. A new indication has been added; or
    c. A material change in one of the statutory negotiation factors has occurred.

3. Among the renegotiation-eligible drugs, selecting any drugs for renegotiation for which:
    a. The monopoly status has changed to long monopoly since the original negotiation; or
    b. CMS believes renegotiation is likely to result in a significant change in the MFP.

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

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

CMS will host patient-focused roundtable events that will aggregate drugs selected for negotiation and renegotiation 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 drugs selected for negotiation and renegotiation. 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, 2026, on topics such as patient experiences with the conditions or diseases treated by the selected drugs, 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 approved collection of information under OMB control number 0938-1452 with these questions is available **here**. Interested parties are encouraged to review this collection of information 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 in April 2026. CMS anticipates releasing additional information on meeting dates, participant and speaker registration, and other logistical details on the CMS Medicare Drug Price Negotiation Program website in February 2026.

Key Milestones for the Third Cycle of the Negotiation Program for Drugs Selected for Negotiation and Renegotiation

May 12, 2025 — CMS issued draft guidance for the third cycle of the Medicare Drug Price Negotiation Program, including requests for public comment on key elements.

September 30, 2025 — CMS issued final guidance detailing the requirements and parameters of the Medicare Drug Price Negotiation Program for the third cycle of negotiations, which will occur during 2026 and, for drugs where an agreement on a negotiated price is reached, will result in prices that will be effective beginning in 2028.

January 27, 2026 —CMS published the list of 15 drugs payable under Part B and/or covered under Part D selected for the third cycle of negotiations, along with the drug selected for renegotiation.

February 28, 2026 — Deadline for participating drug companies for the third cycle of negotiations to sign agreements to participate in the Negotiation Program. Drugs selected for renegotiation have existing Agreements that remain in effect and include provisions related to renegotiation, therefore an additional agreement is not required.

March 1, 2026 — 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.

April 2026 — CMS will host patient-focused and clinical-focused public engagement sessions. CMS will host 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, 2026 — 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 2026 — CMS will offer each participating drug company 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, 2026 — 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 2026 — 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 11, 2026 — Last day for negotiation meetings to take place.

September 18, 2026 — Last date by which CMS and participating drug companies may exchange additional written offers or counter offers.

September 30, 2026 — 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, 2026 — Deadline for participating drug companies to accept or reject a final MFP offer from CMS.

- **November 1, 2026** — The negotiation and renegotiation period ends.
- **November 30, 2026** — Deadline for CMS to publish any agreed-upon MFPs resulting from the third cycle of negotiations and renegotiation.
- **March 1, 2027** — Deadline for CMS to publish an explanation of any agreed-upon MFPs resulting from the initial price applicability year 2028 negotiation and renegotiation 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 and renegotiation 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, 2028** — Any agreed-upon MFPs negotiated for selected drugs from the third cycle of negotiations and drugs selected for renegotiation become effective.