# Medicare Drug Price Negotiation Program: Negotiated Prices 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** 15 drugs (including 14 drugs selected for negotiation and one drug selected for renegotiation) payable under Medicare Part B and/or covered under Medicare Part D for the third cycle of negotiations, i.e., for initial price applicability year 2028, and engaged in voluntary negotiations with participating drug companies for the selected drugs.[1] Below is the list of negotiated prices, which the statute refers to as maximum fair prices (MFPs), for the selected drugs payable under Medicare Part B and/or covered under Medicare Part D that will go into effect beginning Jan. 1, 2028, based on negotiations and agreements reached between CMS and participating drug companies.[2]

CMS negotiated in good faith consistent with the requirements of the law on behalf of people with Medicare and the Medicare program. Throughout the negotiation process, CMS took into account the factors outlined in the law when negotiating these prices, which support the need for innovation and drug development as well as better prices for people with Medicare and the Medicare program.

CMS developed an initial offer for each drug, consistent with the process described in the statute and the agency's guidance, and each participating drug company responded with a counteroffer. CMS held up to three meetings with each participating drug company to discuss the offers and counteroffers, discuss evidence, and attempt to arrive at a mutually acceptable price for the drug. During the negotiation process, CMS revised its offers for each of the drugs upward in response to these discussions. Likewise, each participating drug company revised their counteroffers for their drugs downward, based on the discussions with CMS. For nine of the selected drugs, this process of exchanging revised offers and counteroffers resulted in CMS and the participating drug company reaching an agreement on a negotiated price for the drug offered in a negotiation meeting or via additional price exchanges outside of a negotiation meeting. In five of these nine cases, CMS accepted a revised counteroffer proposed by the participating drug company. For the remaining four selected drugs, CMS sent a written final offer to those participating drug companies, consistent with the process described in its guidance, and in each instance, the participating drug company accepted CMS' written final offer on or before the statutory deadline.

## Impact of the Negotiated Prices

### Overall Medicare Spending and Out-of-Pocket Spending in 2025

For the time period between Jan. 1, 2025, and Dec. 31, 2025, about 1.4 million of the 59 million people with Medicare Part D coverage were dispensed the 13 selected drugs that are covered under Medicare Part D and for which an MFP will apply to treat a variety of conditions, such as cancer, immunologic conditions, and diabetes. These selected drugs accounted for $22.3 billion in total Part D gross covered prescription drug costs, or about 6% of total Part D gross covered prescription drug costs during 2025. During that same time period, people with Medicare Part D prescription drug coverage spent $522 million out-of-pocket for these 13 selected drugs.

For the same time period, about 120,000 of the 67 million people with Medicare Part B coverage (including Original Medicare and Medicare Advantage) were furnished or administered the four selected drugs that are payable under Medicare Part B and for which an MFP will apply to treat a variety of conditions, such as immunologic conditions. These selected drugs accounted for $3.3 billion in total Part B drug costs, or about 2% of total Part B drug costs during 2025.[3] During that same time period, people with Medicare Part B spent $785 million out-of-pocket for these four selected drugs.

[1]Botox; Botox Cosmetic is currently not being treated as a selected drug, consistent with the court order in AbbVie v. HHS, 1:26-cv-00431 (D.D.C.). That litigation remains ongoing.
[2]Only 13 prices are listed below. No MFP will apply for Xeljanz; Xeljanz XR or Xolair since CMS determined, before the end of or during the negotiation period, that at least one generic drug approved under section 505(j) of the Federal Food Drug & Cosmetics Act that identifies Xeljanz; Xeljanz XR as its listed drug and that at least one biosimilar biological product licensed under section 351(k) of the Public Health Service Act that identifies Xolair as its reference product are subject to bona fide marketing pursuant to such approval or licensure (respectively).
[3]Total allowed charges for Part B Medicare Advantage drug costs were calculated by multiplying the total units administered in each quarter by the published payment limit for the quarter.

**Estimated Medicare Net Savings in 2025**

Compared to the 2025 Medicare spending net of all rebates and certain fees and payments, if the prices agreed to between CMS and participating drug companies under the Negotiation Program had been in effect during 2025, the negotiated prices would have saved an estimated $9.2 billion in prescription drug costs, which would have amounted to approximately 45% lower net spending in aggregate.[4] This estimate does not account for Manufacturer Discount Program (MDP) spending for drugs covered under Part D. If MDP spending were included, the estimated savings would be about $5.5 billion and about 33% in lower net aggregate spending.

**Projected Savings for People with Medicare Coverage**

When the negotiated prices go into effect in 2028, people enrolled in Medicare prescription drug coverage (i.e., Medicare Part D) would save under the defined standard benefit design an estimated $69 million in out-of-pocket costs. People with Medicare Part B coverage would save an estimated $395 million in out-of-pocket costs.

A file demonstrating the application of MFP across dosage forms and strengths of each selected drug is available on the CMS website: **https://www.cms.gov/files/zip/selected-drug-list-mfp-data-file.zip**.

[4]As above, total allowed charges for Part B Medicare Advantage drug costs were calculated by multiplying the total units administered in each quarter by the published payment limit for the quarter.

| Drug Name | Participating Drug Company | Commonly Treated Conditions | Agreed to Negotiated Price for 30-day Supply for CY 2028 | Medicare Gross Cost for 30-day Supply, CY 2025 | Discount of Negotiated Price from 2025 Medicare Gross Cost | Total Medicare Part B and Part D Prescription Drug Expenditures, CY 2025 | Number of Medicare Enrollees Who Used the Drug, CY 2025 |
|---|---|---|---|---|---|---|---|
| Trulicity | Eli Lilly and Company | Type 2 diabetes; Type 2 diabetes and cardiovascular disease or multiple cardiovascular risk factors | $150 | $965 | -84% | $4,830,883,000 | 582,000 |
| Biktarvy | Gilead Sciences Inc | Human immunodeficiency virus type 1 infection | $2,600 | $4,141 | -37% | $4,012,497,000 | 102,000 |
| Orencia | Bristol-Myers Squibb Company | Psoriatic arthritis; Rheumatoid arthritis | $1,750 | $4,052 | -57% | $2,543,755,000 | 72,000 |
| Cosentyx | Novartis Pharmaceuticals Corporation | Plaque Psoriasis; Psoriatic arthritis | $2,600 | $7,835 | -67% | $2,475,788,000 | 40,000 |
| Erleada | Janssen Biotech, Inc. | Prostate cancer | $7,004 | $14,253 | -51% | $2,076,066,000 | 19,000 |
| Kisqali | Novartis Pharmaceuticals Corporation | Breast cancer | $8,650 | $15,120 | -43% | $1,757,622,000 | 17,000 |
| Entyvio | Takeda Pharmaceuticals U.S.A., Inc. | Crohn's disease; Ulcerative colitis | $2,645 | $4,035 | -34% | $1,514,109,000 | 37,000 |
| Verzenio | Eli Lilly and Company | Breast cancer | $8,650 | $15,423 | -44% | $1,506,509,000 | 15,000 |
| Lenvima | Eisai Inc | Thyroid cancer; Endometrial cancer; Liver cancer; Kidney cancer | $12,985 | $23,878 | -46% | $1,135,195,000 | 10,000 |
| Rexulti | Otsuka Pharmaceutical Company, Ltd. | Major depressive disorder; Schizophrenia; Agitation associated with dementia due to Alzheimer's disease | $780 | $1,320 | -41% | $1,128,501,000 | 121,000 |
| Tradjenta (renegotiation) | Boehringer Ingelheim Pharmaceuticals, Inc. | Type 2 diabetes | $81 | $469 | -83% | $1,039,189,000 | 248,000 |
| Anoro Ellipta | GlaxoSmithKline Intellectual Property Development Ltd. England | Chronic obstructive pulmonary disease | $130 | $465 | -72% | $815,069,000 | 273,000 |
| Cimzia | UCB, Inc. | Crohn's disease; Plaque Psoriasis; Psoriatic arthritis; Rheumatoid arthritis | $1,375 | $2,195 | -37% | $767,597,000 | 38,000 |

**Note:** Numbers other than prices are rounded to the nearest thousands. Gross costs are rounded to the nearest dollar and represent the total Medicare Part B and Part D prescription drug expenditures for the selected drugs based on a 30-day supply using CY 2025 Medicare prescription fills and administrations. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

## Key Milestones for the Third Cycle of Negotiations

- **By June 1, 2026** — CMS sent an initial offer for each selected drug, with a concise justification for the initial offer, to each respective participating drug company.
- **By July 1, 2026** — Each participating drug company responded to the initial offer for a negotiated price with a counteroffer.
- **Summer/Fall 2026** — CMS and participating drug companies conducted in-person and hybrid negotiation meetings and had the ability to exchange prices through the additional price exchange functionality; agreement for a negotiated price was reached for nine selected drugs during this period.
- **By Sept. 30, 2026** — CMS sent final offers to the four participating drug companies where an agreement was not reached in connection with the negotiation meetings.
- **By Oct. 31, 2026** — Participating drug companies where an agreement was not reached in connection with the negotiation meetings or additional price exchange functionality had the opportunity to review CMS' final offers and respond to CMS.
- **November 1, 2026** — The negotiation period ended with agreement reached for negotiated prices between CMS and participating drug companies for 13 selected drugs.

## Q: How did CMS structure the negotiation process with the participating drug companies of selected drugs?

CMS is implementing the Negotiation Program with the goal of promoting transparency and engagement. As discussed in detail in the **final guidance for initial price applicability year 2028**, CMS set out a process for the third cycle of negotiations that engaged participating drug companies and the public throughout. The process included several steps, such as:

- Participating drug companies and the public had an opportunity to submit data and information on the selected drugs to CMS by March 1, 2026.
- During spring 2026, CMS invited each participating drug company to engage in a meeting on its data submission. Additionally, CMS held patient-focused roundtable events for each selected drug with patients, patient advocacy organizations, and caregivers and one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs.
- CMS sent an initial offer to the participating drug company reflecting CMS' proposal for a negotiated price and a concise justification of the initial offer by June 1, 2026. In developing an initial offer, CMS considered the factors set out by the statute, including evidence related to therapeutic alternatives as well as other factors, such as unit costs of production and distribution of the selected drug.
- Participating drug companies had 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired.
- After receiving initial offers from CMS, each participating drug company and CMS conducted up to three negotiation meetings during summer/fall 2026.
- The negotiation period ended on Nov. 1, 2026.

## Q: How did the process differ for the one drug selected for renegotiation?

In accordance with the Inflation Reduction Act of 2022, the renegotiation process was consistent with the negotiation process to the extent practicable. Both processes consisted of an initial offer provided by CMS by June 1, 2026, followed by, as applicable, a counteroffer from participating manufacturers, up to three negotiation meetings, the ability to exchange prices through the additional price exchange functionality, and, if agreement was not already reached, a final offer from CMS by Sept. 30, 2026.

## Q: What information did CMS consider during the negotiations with participating drug companies?

In accordance with the Inflation Reduction Act of 2022, CMS considered the statutory factors listed at section 1194(e) of the Social Security Act in determining its initial offers, revised offers, and final offers.

Specifically, for the factors listed at section 1194(e)(1), CMS considered information reported by participating drug companies. This included manufacturer-submitted data on research and development costs and the extent to which such costs were recouped; prior federal financial support; unit costs of production and distribution; market/revenue/sales data; and information on patents, FDA exclusivities, and FDA applications and approvals. For the factors listed at section 1194(e)(2) related to evidence about alternative treatments (including therapeutic advances and costs of therapeutic alternatives, prescribing information, comparative effectiveness, and unmet medical need), CMS considered information from a wide variety of sources, including: information submitted by participating drug companies, people with Medicare, academic experts, clinicians, caregivers, and other interested parties in response to Information Collection Requests issued for the Negotiation Program; information provided at the patient-focused roundtable events and the town hall meeting hosted by CMS in the spring 2026; information shared by participating drug companies during meetings with CMS; and information CMS identified from its own literature searches, including from clinical guidelines and published studies.

## Q: How will people with Medicare get access to these prices? When will these prices be effective?

These negotiated prices will become effective on Jan. 1, 2028. A participating drug company with a selected drug is required to ensure the negotiated price is made available to eligible individuals and to the pharmacies, mail-order services, and other entities that dispense the selected drug under Part D, and to the hospitals, physicians, and other providers of services and suppliers that furnish or administer the selected drug payable under Part B with respect to such individuals.

As required by law, Medicare prescription drug plans, including standalone Part D plans and Medicare Advantage-prescription drug plans, must include in their formularies the selected drugs for which CMS and the participating drug company have agreed to a negotiated price. CMS will use its comprehensive formulary review process for Medicare prescription drug plans to assess any practices that may undermine access to selected drugs for people with Medicare.

CMS will make public an explanation of the agreed-upon negotiated prices for the initial price applicability year 2028 by March 2027.

## Q: How long do these negotiated prices apply? Are they adjusted over time?

In accordance with the Inflation Reduction Act of 2022, the negotiated price will apply to a selected drug until it is deselected pursuant to the timelines and situations provided for by the statute and explained in section 70 of the final guidance. Section 70 of the final guidance explains the distinct timeframes under which a drug would be deselected and an MFP would no longer apply due to a determination that a generic or biosimilar is approved or licensed and is subject to bona fide marketing. For example, if CMS makes a determination that a generic or biosimilar is approved

or licensed and is subject to bona fide marketing as of Nov. 2, 2026, through March 31, 2028, for a drug selected for initial price applicability year 2028, then the drug will cease to be a selected drug on Jan. 1, 2029, the MFP will apply for 2028, and the MFP would cease to apply on Jan. 1, 2029. For each year after the first initial price applicability year, CMS will publish an updated negotiated price for each selected drug. The updated price will be equal to the negotiated price that was published for such drug for the previous year, increased by the annual percentage increase in the Consumer Price Index for all urban consumers (United States city average) (CPI-U). The negotiated price of a selected drug would also be updated should CMS and the Primary Manufacturer renegotiate the negotiated price of the selected drug.

## Q: How do the negotiated prices for a 30-day supply translate into prices paid under Medicare Part D or Medicare Part B?

As noted above, a file demonstrating how the MFP applies across dosage forms and strengths of each selected drug is available on the CMS website: **https://www.cms.gov/files/zip/selected-drug-list-mfp-data-file.zip**. For a given dosage form and strength of a selected drug dispensed under Medicare Part D, the MFP for the package would be the "NDC-9 per Unit Price" multiplied by the number of units per package. For a given dosage form and strength of a selected drug payable under Medicare Part B, the MFP for the package would be the "HCPCS Code Dosage Price."