IRA Drug Price Negotiation

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The Inflation Reduction Act (IRA) of 2022 (the Act) enables the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices with manufacturers, while also implementing an inflation cap on drug prices and reducing out-of-pocket expenses on prescription medications for Medicare recipients. This article will explore the new Drug Price Negotiation Program framework, the Medicare Part B and Part D inflation rebates and their calculation methods and the potential impact of these changes on pharmaceutical manufacturers as various provisions of the Act take effect.

Drug Price Negotiation Program

Key takeaways:

- Manufacturers need to understand the criteria for drug selection under the Medicare Drug Price Negotiation Program, including the eligibility requirements and exemptions. This will help them assess the potential impact of the program on their specific drugs and adjust their commercial strategies accordingly.
- Manufacturers should be prepared to provide detailed data on research and development (R&D) costs, production and distribution costs, federal financial support, patent applications and approvals, market data and evidence for alternative treatments. This data will be crucial to the negotiation process and will influence manufacturers' calculation of the "maximum fair price" (MFP) for their drugs. It is important for manufacturers to gather and organize this information to effectively participate in the negotiation process and advocate for fair pricing.

The IRA directs the CMS to implement the Medicare Drug Price Negotiation Program for 2026, 2027 and 2028 by program instruction or other forms of program guidance. The CMS released guidance in June 2023 to address the more than 7,500 comment letters it received. The secretary of Health and Human Services (HHS) will negotiate prices with manufacturers for certain drugs covered under Medicare Part D (starting in 2026) and Part B (starting in 2028).

In May 2025, CMS released updated draft guidance for the third negotiation cycle — which includes Part B drugs for the first time (effective in 2028) and introduces a process for renegotiating previously selected drugs. The draft guidance builds on the 2023 framework and includes key clarifications for manufacturers preparing for future program applicability years. Public comments were open through 26 June 2025, and final guidance is expected later in the year.

For Medicare Part D, negotiation-eligible drugs are limited to the 50 qualifying single-source drugs with highest total expenditures under Part D during a specified 12-month lookback period (beginning June 1, 2022, and ending May 31, 2023, for prices applicable in 2026). Total expenditure for Part D drugs is defined as the total gross covered prescription drug costs incurred under a Part D/Medicare Advantage-Part D (MA-PD) plan, excluding administrative costs but including costs directly related to the dispensing of covered Part D drugs during the year and costs relating to the deductible, whether paid by the enrollee or under the plan. Similarly, for Medicare Part B drugs, negotiation-eligible drugs are limited to the 50 qualifying single-source drugs with highest total expenditures under Part B during a specified 12-month lookback period. For Part B total expenditures, the CMS will use the Part B claims data to calculate the total allowed charges, inclusive of beneficiary cost sharing under Part B. For both Part D and Part B, the total expenditure is calculated by aggregating across dosage forms and strengths of the drug, including new formulations such as extended release, and not based on a specific formulation, package size or package type of the drug.

Single-source drugs that meet the following criteria may be subject to negotiation:

- Drugs or biologics approved or licensed by the Food and Drug Administration (FDA)
  - Drugs must be at least seven years post-approval by the selection date.
  - Biologics must be at least 11 years post-licensure by the selection date (with no generic or biosimilar on the market).
  - An "authorized generic drug" does not count as a separate single-source drug.

However, certain drugs will not be subject to negotiation:

- Drugs or biologics designated as an orphan drug (i.e., it is the only approved drug for, and only prescribed for, a single rare disease or condition)
- Drugs or biologics for which total Parts B and D expenditures during a specified lookback period are less than $200 million (increased over time by an inflation factor)
- Biologics derived from human whole blood or plasma
- "Small biotech drugs" are ineligible for selection during the initial program applicability years (2026–28)[1]

The number of drugs selected for negotiation each year will increase over time. Starting in 2026, the Secretary must cumulatively select a specified number of negotiation-eligible drugs for the Drug Price Negotiation Program:

- 2026: 10 Part D drugs
- 2027: 15 Part D drugs
- 2028: 15 Part B or D drugs
- 2029 and thereafter: 20 Part B or D drugs each year

For 2026 and 2027, the drugs selected must be the 10th- and 15th-highest-spend drugs, respectively, on the list of the 50-highest-spend Part D drugs. For years 2028 and beyond, the drugs selected must be the 15th- and 20th-highest-spend drugs, respectively, on a combined list of the 50-highest-spend Part B drugs and the 50-highest-spend Part D drugs. The CMS must publish the list of selected drugs by February 1 of the selection year (two years before the initial price applicability year). For 2026, the first 10 Part D drugs were selected on September 1, 2023. Drugs selected for negotiation are still subject to the standard Part B and Part D inflation rebate calculations.[2]

Price negotiation guidance does not prescribe how the maximum fair price will be established; however, it states that the Secretary is required to consider the following criteria:

- Manufacturer's R&D costs and the extent to which the manufacturer has recouped these costs
- Current unit cost of production and distribution
- Prior federal financial support for novel therapeutic discovery and development
- Data on pending and approved patent applications, exclusivities and certain other applications and approvals
- Market data and revenue and sales volume data in the US
- Evidence about alternative treatments, including:
  - The extent to which the drug represents a therapeutic advance over existing therapeutic alternatives and the costs of these alternatives.
  - FDA-approved prescribing information for the drug and its therapeutic alternatives.
  - Comparative effectiveness of the drug and its therapeutic alternatives, including their effects on specific populations (including individuals with disabilities, the elderly, the terminally ill, children and other patient populations).
  - The extent to which the drug and its therapeutic alternatives address unmet medical needs for a condition that is not adequately addressed by available therapy.[3]

[1] A small biotech drug is a drug for which 2021 Part B/Part D expenditures constituted less than 1% of total 2021 expenditures for all Part B/Part D drugs of all manufacturers, and greater than 80% of 2021 Part B/Part D expenditures for all Part B/Part D drugs of the small biotech drug manufacturer.

[2] On August 29, 2023, the CMS announced the first 10 drugs covered under Medicare Part D selected for negotiation for the first price applicability year of 2026: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara and Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill.

[3] "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026," Centers for Medicare & Medicaid Services, June 30, 2023, Sections 50.1 and 50.2.

Once a drug has been selected for the Medicare negotiation program, the manufacturer is expected to submit these data elements, which the CMS will use to determine its initial offer. However, depending on the drugs selected, the requested data may not be readily available, which could make it difficult for the manufacturer to provide it. For example, manufacturers would need to align and quantify historical R&D programs costs used to develop platforms that resulted in multiple successful and unsuccessful drugs. Manufacturers may also need to quantify costs of production and distribution across all stages (i.e., inspection, assembly, maintenance, formulation, clean and prep, filling) to equitably allocate historical costs.

After data submission, the CMS will invite each participating drug company to discuss the data. The CMS will also hold a patient-focused public listening session for each selected drug with patients and other interested parties. The IRA requires the CMS to provide the manufacturer of a selected drug with an initial offer for the MFP and a concise justification for that offer. Companies will have 30 days to respond by accepting the offer or providing a counteroffer, if desired.

For the purposes of determining an initial offer, the CMS will identify therapeutic alternative(s), if any, for the selected drug. Next, the CMS will use the Medicare Part D net price for covered therapeutic alternative(s) and/or the average sales price (ASP) for the Part B therapeutic alternative(s). The CMS will also evaluate the clinical benefits of the selected drug (including comparing it with its therapeutic alternative(s)), such as whether it addresses an unmet medical need or impacts specific populations. Lastly, the CMS will further adjust the preliminary price by the negotiation factors outlined in CMS IRA guidance to determine the initial offer price and begin the negotiation process with the manufacturer.

The law also establishes an upper limit for the MFP. For the Part D initial applicability year (2026), the limit is the lower of:

- The drug's enrollment-weighted net Part D negotiated price (net of all price concessions) under each Part D/MA-PD plan for the most recent year for which data are available (calendar year 2022 data) for the Part D drug
- A percentage (based on monopoly type of the drug) of the drug's average non-federal average manufacturer price (non-FAMP) for 2021 (overall package sizes of the drug), increased by an inflation factor based on the difference between September 2021 and September 2022 consumer price index for all urban consumers (CPI-U)

For Part B the upper limit is the lower of:

- The ASP of the drug for the year before the selection year
- A percentage (based on monopoly type) of average non-FAMP for 2021, increased by an inflation factor based on September 2021 and September of the year before the selection year CPI-U
- A percentage (based on monopoly type) of average non-FAMP for the year before the selection year[4]

The MFP offer will include a single drug price, even for multiple dosage forms and strengths. Once the sides have agreed on the MFP, the Act directs the CMS to establish procedures to compute and apply the MFP across the drug's dosages and strengths. The CMS will base the single price on the cost of the selected drug per 30-day-equivalent supply (rather than per unit: such as tablet, capsule, injection — or per volume or weight-based metric), weighted across dosage forms and strengths. The methodology that the CMS will use to translate the MFP back into the dosage and strength per-unit prices at the National Drug Code (NDC)-9 and NDC-11 levels will be provided to manufacturers during the negotiation process.

[4] The percentage based on monopoly type of the drug is 75% for small-molecule drugs and vaccines more than nine years but less than 12 years beyond approval, and 40% for drugs more than 16 years beyond approval or licensure.

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