Fortrea

Inflation Reduction Act (IRA): Assessing the implications of Medicare drug price negotiations for drug development sponsors

Manufacturers should consider the impact of IRA price negotiations as they set priorities, plan their clinical development programs and prepare for market access

Author

John Carlsen, MHA, Vice President, Reimbursement Strategy & Payer Insights, Market Access Consulting & HEOR, Fortrea

The Centers for Medicare and Medicaid Services' (CMS's) recent announcement of the first Medicare-negotiated drug prices marks a significant milestone for the Inflation Reduction Act of 2022 (IRA), which includes several provisions that impact the U.S. healthcare system. To help drug development sponsors understand how the IRA may affect drug development decisions and how to navigate uncertainty, this white paper explains the mechanics of the Medicare drug price negotiation program and details where things stand with the first round of drugs selected for negotiation.

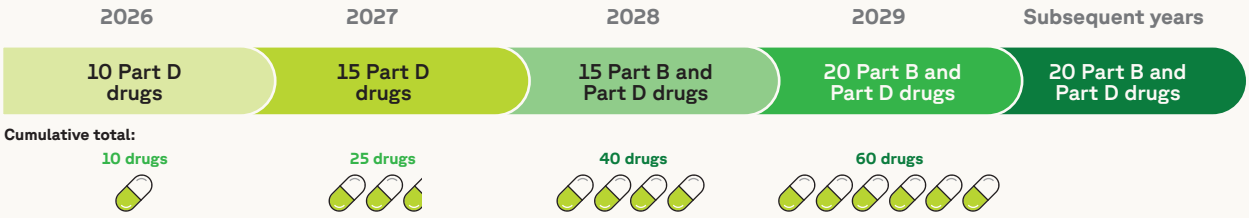
How drugs are selected for Medicare drug price negotiation

The IRA requires that CMS select drugs for negotiation from among the products with the highest Medicare spending. CMS must negotiate Medicare prices for a specified number of drugs each year, with 10 drugs selected for the first year of negotiations (see Figure 1). The negotiated prices for the first 10 drugs will take effect in 2026.

For the first two years of the program, only Part D drugs will be selected. Part D coverage applies to drugs dispensed by a pharmacy, such as oral medications and self-administered injectables. Beginning with the third year (for prices taking effect in 2028), both Part B and Part D drugs will be selected. Drugs covered under Part B are typically products administered in a physician's office or hospital outpatient department, such as intravenous infusions or provider-administered injections.

The number of drugs selected for negotiations each year is cumulative from the previous year(s). For example, the 15 drugs selected for negotiation for the second year of the program will be in addition to the 10 drugs selected for the first year, meaning that a total of 25 drugs will have negotiated prices in 2027.

Figure 1. Timeline of Medicare drug price negotiations



The IRA states that CMS will select "up to" the specified number of drugs for each year (e.g., up to 10 drugs for 2026, up to 15 drugs for 2027, etc.). For this white paper, we have assumed that CMS will select the maximum number of drugs for each year.

Drugs excluded from price negotiation

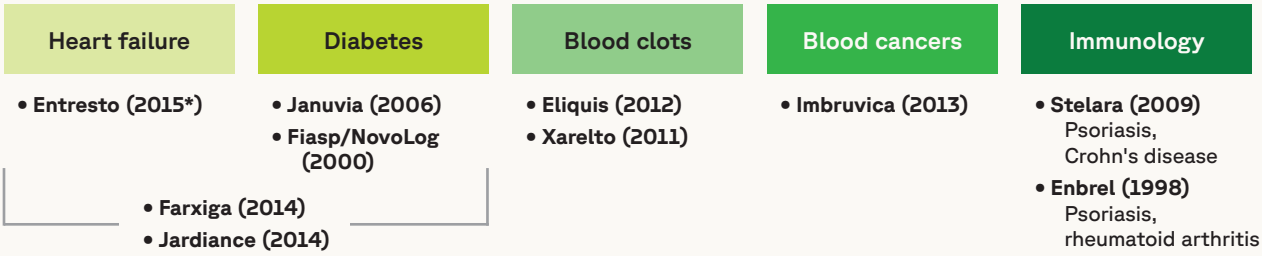
As defined in the legislation, certain drugs are excluded from drug price negotiation or will be excluded for a specific period:

- New drugs and new biologicals cannot be selected for negotiation until 7 years and 11 years, respectively, after FDA approval
- Any products that have generic or biosimilar versions available are excluded from negotiation
- Price negotiation can be delayed for biologicals for which there is a "high likelihood" of FDA approval of a biosimilar version within two years (biosimilar manufacturers in this situation must submit a delay request to CMS)
- Drugs with an orphan designation are excluded from price negotiation, but only if they are approved for only one rare disease. If a drug is approved for other indications (orphan or non-orphan), the orphan drug exclusion would not apply
- Plasma-derived products are exempt from negotiation
- Drugs that account for less than $200 million in total Medicare spending are excluded from negotiation
- Certain "small biotech drugs" are not eligible for drug price negotiation for 2026 through 2028 (manufacturers must submit a small biotech exception request to CMS)

Year 1 of negotiations: timing and key milestones

On August 20, 2023, CMS selected the first 10 drugs to be subject to Medicare price negotiations (see Figure 2). In late 2023, manufacturers and other stakeholders had the opportunity to provide input on the selected drugs to CMS.

Figure 2. 10 drugs selected by CMS for year one of Medicare price negotiations (effective 2026)



*Year in parentheses represents year of initial FDA approval

In February 2024, CMS made its initial confidential price offers to the manufacturers of the selected drugs. All of the manufacturers rejected those initial offers, and, in turn, CMS then rejected all of the counteroffers made by the manufacturers. Because all of the counteroffers were rejected, the price negotiations continued, with each manufacturer being allowed up to three meetings with CMS during the first half of 2024. CMS made its final price offers by July 15, 2024, at which point the manufacturers had until July 31 to either accept or reject those offers.

On August 15, 2024, CMS announced the final negotiated prices for the first 10 drugs. The negotiated prices, which are called Maximum Fair Prices (MFPs), reflect discounts ranging from 38% to 79% off published list prices.[1] The average discount across all 10 drugs is 63%.

Table 1. Negotiated discounts (based on 2023 list prices) for the first 10 selected drugs

Imbruvica 38%	Entresto 53%	Eliquis 56%	Xarelto 62%	Stelara 66%
Jardiance 66%	Enbrel 67%	Farxiga 68%	Fiasp/NovoLog 76%	Januvia 79%

For now, CMS has only provided the dollar amounts of the MFPs. However, by March 1, 2025, CMS is required to publish a "public explanation" of the MFPs. CMS has said that the public explanation will include a narrative explanation of the negotiation process, as well as information (subject to redactions) regarding the data received for each drug, the exchange of offers and counteroffers, and the negotiation meetings, if applicable. Finally, the negotiated prices for the first 10 drugs will take effect on January 1, 2026.

How CMS determines the price offered to manufacturers

For each year of the Medicare drug price negotiation program, CMS publishes draft guidance and final guidance on the parameters of negotiations. The final guidance document for the first year of negotiations (for prices taking effect in 2026) was published in June 2023.[2] This guidance outlines the various steps of the negotiation process and explains the factors that CMS considers in developing price offers. These factors include:

- **Therapeutic alternatives:** The June 2023 guidance states that CMS will first look at the net prices of "therapeutic alternatives" as a starting point for determining an initial price offer. CMS has significant discretion in its interpretation of what constitutes a therapeutic alternative and how many therapeutic alternatives will be considered for a selected drug. As a result, there is substantial uncertainty surrounding therapeutic alternatives, because no one knows how broadly or narrowly CMS will define the therapeutic alternatives for each drug. This uncertainty is compounded by CMS's focus on net prices, since these are not publicly available for products covered under Part D.
- **Clinical benefit:** After CMS develops a starting point for an initial offer by looking at the net prices of therapeutic alternatives, it will adjust the starting point based on a review of the clinical evidence. As with therapeutic alternatives, clinical benefit is an area where CMS has significant discretion; the agency has said that it will use a qualitative approach to analyzing clinical benefit "to preserve flexibility in negotiation" and will adjust the starting point "based on the totality of the information and evidence."[2] In its June 2023 guidance, CMS provides numerous examples of sources of information that might inform its evaluation of clinical benefit, including data submissions from the public, literature reviews, claims datasets, peer-reviewed research, expert reports, white papers, clinician expertise, real-world evidence, patient experience and consultations with various stakeholders, such as the FDA, patient organizations, clinicians, and academic experts.
- **Manufacturer-specific data:** By law, CMS must also consider five specific data elements reported by the manufacturer of each selected drug: (1) research and development (R&D) costs, including the extent to which R&D costs have been recouped; (2) unit costs of production and distribution; (3) prior federal financial support for the drug; (4) information related to patents, exclusivities recognized by the FDA and authorized generics; and (5) market, revenue and sales data for the drug. CMS will consider these five data elements in totality and adjust its price offer accordingly.

Prohibition on quality-adjusted life years (QALYs)

Although CMS seemingly has the flexibility to consider nearly all types of information when developing a price offer, there is one important exception: The statute prohibits CMS from using quality-adjusted life years (QALYs) or similar measures that place more value on extending the life of an individual who is not elderly, not disabled, or not terminally ill, as compared to an individual who falls into one of those categories. This prohibition is significant because many other countries use QALYs in their health economic analyses when making pricing or reimbursement decisions for drugs.

Using data to help sponsors navigate uncertainty

Regardless of whether a drug has been commercialized or is still in development, manufacturers will need to consider the implications of Medicare drug price negotiations. The implications will be more straightforward for drugs that have been on the market for several years, as these products could face an imminent risk of being selected for price negotiation. But even for drugs that are early in the development process, the impact of Medicare drug price negotiations will still be significant, because the future economic outlook for a drug will vary depending on whether it will be competing with drugs that have been selected for negotiations. This, in turn, could affect drug development decisions such as which indications to pursue and in what sequence. In addition, it will be important for all manufacturers to understand the different exclusions from drug price negotiations (discussed above) and determine whether one or more of the exclusions might apply to their products.

Although there is a great deal of uncertainty surrounding Medicare drug price negotiations (especially in the early years of the program), several sources of available information and data can help manufacturers incorporate price negotiations into their product planning. These include:

- CMS guidance documents on drug price negotiations
- Reports from other governmental agencies, such as the Assistant Secretary for Planning and Evaluation (ASPE)
- Third-party analyses, such as assessments from the Institute for Clinical and Economic Review (ICER)
- Academic articles and other published studies on the potential impact of drug price negotiations
- Clinical guidelines, compendia recommendations and peer-review studies on the clinical benefit of a drug
- Publicly available dashboards and subscription-based information services to examine published list prices for drugs and gather data on Medicare spending and utilization for individual drugs
- Medicare policies that specify coverage and reimbursement requirements for new drugs

Fortrea specializes in partnering with clients to help synthesize this information and plan for Medicare price negotiations in the context of a particular product and situation.

Looking ahead

Knowing Medicare drug price negotiations will be an ongoing process, our team at Fortrea is analyzing the final negotiated prices for the first 10 selected drugs and is looking forward to reviewing CMS's public explanation of the prices (due by March 1, 2025). In parallel with this, we are closely tracking developments related to the second year of drug price negotiations; CMS published draft guidance for year two in May 2024, with final guidance expected this fall, and is required to announce the next 15 selected drugs by February 1, 2025.

As more data and information become available, we will continue to help manufacturers make informed decisions for their products to navigate uncertainty and optimize planning for the future.

Enable a more efficient, agile development process through
Fortrea Consulting Services

References

1. Centers for Medicare & Medicaid Services. New Lower Drug Prices Under the Medicare Drug Price Negotiation Program. https://www.cms.gov/files/document/infographic-negotiated-prices-maximum-fair-prices.pdf. Accessed Aug. 20, 2024.
2. Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf. Accessed Aug. 20, 2024.

LEARN MORE at fortrea.com

Fortrea

WP_0063_Inflation Reduction_0924