



Medicare Announced First 10 Drugs for Upcoming Price Negotiations

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Medicare announced the first 10 drugs subject to price negotiations, but there are continued legal challenges to the constitutionality of the process.

In 2024, Medicare will, for the first time, have authority under the Inflation Reduction Act passed in 2022 to negotiate drug prices with pharmaceutical manufacturers. On August 29, the Centers for Medicare and Medicaid Services (CMS) released the first 10 prescription drugs that will be subject to the Medicare price negotiations. The selected drugs accounted for 20% of Medicare Part D spending (i.e., \$50.5 billion) from June 1, 2022 through May 31, 2023.

Additionally, Medicare beneficiaries spent \$3.4 billion out of pocket for these drugs in 2022. CMS stated they chose drugs treating chronic conditions that are prevalent across the Medicare population. The Congressional Budget Office projects the price negotiation process will save approximately \$98.5 billion over a decade for the Medicare program.^[1]

Price Negotiations for 2026

The first round of price negotiations will formally begin in the calendar year 2024, and the new prices will go into effect in the calendar year 2026. The first 10 drugs for this process are:

- Eliquis, used to prevent blood clotting and reduce the risk of stroke

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- Jardiance, used to lower blood sugar for people with Type 2 diabetes
- Xarelto, used to prevent blood clotting and reduce the risk of stroke
- Januvia, used to lower blood sugar for people with Type 2 diabetes
- Farxiga, used to treat Type 2 diabetes, heart failure, and chronic kidney disease
- Entresto, used to treat certain types of heart failure
- Enbrel, used to treat rheumatoid arthritis
- Imbruvica, used to treat different types of blood cancers
- Stelara, used to treat Crohn's disease and psoriasis
- Fiasp and NovoLog, used to treat diabetes

Manufacturers of the selected drugs have until October 1, 2023, to sign voluntary agreements for participation in the maximum fair price (MFP) negotiations. If a manufacturer does not agree to participate, it may be subject to tax penalties unless it removes all of its products from the Medicare and Medicaid programs.

In the fall of 2023, CMS will host meetings with the manufacturers to discuss economic and market data as well as patient-focused listening sessions with patient and consumer groups. By February 1, 2024, CMS must submit a proposed offer for the MFP to each manufacturer to begin the negotiations. CMS must present a final written offer by July 15, 2024, and the final MFP will be published by September 1, 2024.

The Inflation Reduction Act requires CMS to consider various factors when negotiating the MFP, but the statute does not direct CMS on how to weigh each factor. Some of the manufacturer-specific factors include:

- The manufacturer's research and development costs and the extent to which the manufacturer has recouped these costs.
- The current unit costs for production and distribution.
- Federal financial support for novel therapeutic discovery and development related to the drug.
- 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.

Legal Challenges

There are currently eight pending lawsuits challenging the legality of the Medicare price negotiation authority. The Inflation Reduction Act limits judicial review for various components of the Medicare price negotiation process, including the drugs chosen for negotiating, which constrains the types of legal challenges manufacturers can bring.

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Currently, many of the lawsuits argue this process is unconstitutional and in violation of the manufacturer's Fifth Amendment rights against unconstitutional takings, First Amendment free speech rights, and Eighth Amendment rights. It is widely expected that at least one challenge will eventually wind up at the US Supreme Court, and the manufacturers have certainly stated this is their intent.

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[1] Congressional Budget Office, Cost Estimate (Sept. 7, 2022), *available at* https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.