

August 29, 2023

## CMS Unveils the First 10 Drugs Subject to Price Negotiation

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On Tuesday (August 29), the Centers for Medicare & Medicaid Services (CMS) published the first list of 10 Medicare Part D drugs that will be subject to the Medicare Drug Price Negotiation Program created under the Inflation Reduction Act (IRA).

During a White House event announcing the selected drugs, HHS Secretary Xavier Becerra called the Medicare Drug Price Negotiation Program a “gamechanger.” He said, “We have never been closer than we are right now to everyone being closer to having health care that they need and can afford.”

Neera Tanden, domestic policy advisor to President Biden, said, “The practice where pharmaceutical companies can charge any price to seniors is ending.” She added that the administration hopes these negotiated prices will have a broader impact, noting, “any insurer can use these” negotiated drug prices.

As CMS moves ahead with its implementation of the Medicare Drug Price Negotiation Program, several drugmakers, as well as the U.S. Chamber of Commerce, PhRMA, the National Infusion Center Association, and the Global Colon Cancer Association, have filed lawsuits to halt the program, with several lawsuits challenging the constitutionality of the program.

- [HHS press release](#), [CMS press release](#), [Fact sheet](#), [Details on Drug Price Negotiation Program](#)

### Details on the 10 Selected Medicare Part D Drugs

CMS in the fact sheet said the 10 drugs were selected from a list of 7,400. The selected drugs had to meet certain criteria, established in the IRA by Congress, including being single source drugs that have been on the market for at least seven years, or at least 11 years for biologics. CMS said the drugs were selected based on total gross covered prescription drug costs under Medicare Part D from June 1, 2022 through May 31, 2023. As part of the selection process, the IRS mandated that CMS exclude certain drug types, including certain orphan drugs, plasma-derived products, and small biotech drugs.

The selected drugs account for roughly \$50.5 billion in total Part D gross covered prescription drug costs, or nearly 20% of all Medicare prescription drug costs. CMS said seven of the 10 selected drugs are FDA approved for treatment of chronic conditions, including diabetes, stroke prevention, and cardiovascular disease. Three drugs have smaller patient populations, including those for cancer and autoimmune conditions. In total, CMS said more than 8 million people, or 16.5% of beneficiaries rely on the selected drugs, and that beneficiaries paid a total of \$3.4 billion in out-of-pocket costs in 2022 for these drugs.

The 10 drugs selected, and the total Part D gross covered prescription drug costs, are:

- Eliquis, \$16,482,621,000;
- Jardiance, \$7,057,707,000;
- Xarelto, \$6,031,393,000;
- Januvia, \$4,087,081,000;

- Farxiga, \$3,268,329,000;
- Entresto, \$2,884,877,000;
- Enbrel, \$2,791,105,000;
- Imbruvica, \$2,663,560,000;
- Stelara, \$2,638,929,000;
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill, \$2,576,586,000.

CMS will accept data and information on the accepted drugs from drug companies and the public through October 2, 2023. CMS will then engage individually with drug companies and plans to host patient-focused listening sessions. For more information on the patient-focused listening sessions [click here](#).

CMS will send its initial proposal for the maximum fair price (i.e. negotiated rate) and a justification by February 1, 2024, and companies will have 30 days to respond. If agreement is not reached, CMS will issue a counteroffer, after which CMS will host up to three negotiation meetings with the drug company before the negotiation period concludes on August 1, 2024. The final maximum fair prices negotiated will take effect January 1, 2026, for seniors enrolled in Part D coverage. For a detailed outline of the negotiation timeline [click here](#).

To hear more from EY policy and strategy professionals about the evolving policy landscape and implications to commercializing medicines, join our September 21 [Life Sciences webcast](#), State of pharma market access in the US: The evolving policy landscape and implications for commercializing medicines.

*If you have questions, please contact [Heather Meade](#) or [Heather Bell](#).*

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