

**ALERT**

# Medicare Drug Price Negotiation Program: Selected Drugs for 2026

August 30, 2023

On Tuesday, August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) released the first ten prescription drugs selected for price negotiation with manufacturers (Selected Drugs) under the Inflation Reduction Act of 2022 (IRA) Medicare Drug Price Negotiation Program (Price Negotiation Program). As explained in Wiley's prior alert, the Price Negotiation Program allows CMS to directly negotiate drug prices for certain high expenditure, single source Medicare Part B and Part D drugs on an escalating scale, beginning with the August 29 list of ten Part D Selected Drugs. Revised pricing for these Selected Drugs is scheduled to go into effect for the Medicare Part D program in 2026.

CMS's actions indicate it is undaunted by the growing number of lawsuits brought by manufacturers and trade associations against CMS challenging the constitutionality of the Price Negotiation Program. Plaintiffs' arguments include, but are not limited to, Fifth Amendment takings violations, Eighth Amendment excessive fine violations, and First Amendment violations against government-compelled speech. Many of the cases have pending motions for preliminary injunctions which could threaten to impede CMS's implementation of the Price Negotiation Program.

**CMS-Selected Drugs.** The ten Selected Drugs for initial price applicability year 2026 are listed below, along with their commonly treated conditions.

1. Eliquis (blood thinner)
2. Jardiance (diabetes & heart failure)

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3. Xarelto (blood thinner)
4. Januvia (diabetes)
5. Farxiga (diabetes, heart failure, chronic kidney disease)
6. Entresto (heart failure)
7. Enbrel (arthritis, psoriasis)
8. Imbruvica (blood cancers)
9. Stelara (psoriasis, arthritis, Crohn's disease, ulcerative colitis)
10. Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill (diabetes)

CMS issued a fact sheet providing additional detail about the Selected Drugs and explaining CMS's selection process. According to the fact sheet, the Selected Drugs were chosen primarily on their total gross covered prescription drug costs under Part D between June 2022 and May 2023. Such costs range from \$2,576,586,000 (Fiasp) to \$16,482,621,000 (Eliquis). The number of Part D enrollees who used the drugs during the same time period ranges from 20,000 (Imbruvica) to 3,706,000 (Eliquis).

**Negotiations.** Now that CMS has identified the Selected Drugs, negotiations on the drugs' maximum fair prices are set to begin. Upcoming dates in the negotiation process are set forth below:

- *October 1, 2023:* Deadline for manufacturers of Selected Drugs to sign agreements to participate in the Price Negotiation Program;
- *October 2, 2023:* Deadline for manufacturers to submit information on the Selected Drugs to CMS for consideration in the negotiation of a maximum fair price;
- *February 1, 2024:* CMS will make written initial maximum fair price offers to the manufacturer of each Selected Drug;
- *October 2023-August 2024:* Negotiations on the Selected Drugs will take place;
- *September 1, 2024:* CMS will publish maximum fair prices for the Selected Drugs.

Additional detail about the negotiation process can be found [here](#).

**Listening Sessions.** In connection with its release of the Selected Drugs, CMS also released a schedule of ten livestreamed, patient-focused "Listening Sessions" – one for each Selected Drug. The Listening Sessions, which are scheduled to take place between October 30, 2023 and November 15, 2023, are open to the public and will allow registered stakeholders the opportunity to share input regarding the Selected Drugs.

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Wiley's multidisciplinary Medicare Drug Pricing team of experienced attorneys and advisors is closely monitoring IRA developments and is available to assist with speaker registration for the Listening Sessions or any other questions. For more information about the Medicare Drug Price Negotiation Program or the IRA generally, please contact one of the attorneys listed on this alert.