

US CMS Announces Initial Prices for Medicare Drug Price Negotiation Program

September 5, 2024

On August 15, 2024, the Centers for Medicare & Medicaid Services (CMS) released the first set of negotiated prices for the Medicare Drug Price Negotiation Program for 2026. Authorized under the Inflation Reduction Act of 2022, this drug-pricing program marks a significant shift in Medicare’s ability to negotiate directly with drug manufacturers for select high-cost prescription drugs. The program has announced the initial 10 drugs that represent significant Medicare expenditures and lack generic or biosimilar competition. The negotiation process began in January 2024 and concluded August 1, 2024, and negotiation factors included information from manufacturers, such as drug unit revenue and sale data, research and development costs, and costs for production and distribution.

Negotiation highlights

Reimbursement reduction

The negotiated prices are 38% to 79% less than the current list prices.

Projected savings

CMS estimates that, had these prices been in place for 2023, Medicare would have saved approximately \$6 billion. For beneficiaries, these changes are expected to reduce out-of-pocket expenses by around \$1.5 billion in 2026.

Implementation timeline

These negotiated prices will be effective starting January 1, 2026. This represents the first time Medicare will directly negotiate drug prices, with future negotiations expanding to additional drugs covered under Medicare Part D and, eventually, Part B.

Chart of first 10 drugs

Below, we’ve reproduced a chart from a CMS fact sheet listing negotiated prices for the initial 10 drugs covered under Medicare Part D that will go into effect January 1, 2026.

Drug name	Participating drug company	Commonly treated conditions	Negotiated price for 30-day supply for calendar year (CY) 2026	List price for 30-day supply, CY 2023	Discount of negotiated price from 2023 list price	Total Part D gross covered prescription drug costs, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	\$113	\$527	79%	\$4,091,399,000

Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk	Diabetes	\$119	\$495	76%	\$2,612,7 19,000
Farxiga	AstraZen eca	Diabetes; heart failure; chronic kidney disease	\$178.50	\$556	68%	\$4,342,5 94,000
Enbrel	Immunex	Rheumat oid arthritis; psoriasis; psoriatic arthritis	\$2,355	\$7,106	67%	\$2,951,7 78,000
Jardiance	Boehring er Ingelhei m	Diabetes; heart failure; chronic kidney disease	\$197	\$573	66%	\$8,840,5 47,000
Stelara	Janssen Biotech	Psoriasis; psoriatic arthritis; Crohn's disease; ulcerative colitis	\$4,695	\$13,836	66%	\$2,988,5 60,000
Xarelto	Janssen Pharma	Preventio n and treatment of blood clots;	\$197	\$517	62%	\$6,309,7 66,000

		reduction of risk for patients with coronary or peripheral artery disease				
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	\$231	\$521	56%	\$18,275,108,000
Entresto	Novartis Pharms	Heart failure	\$295	\$628	53%	\$3,430,753,000
Imbruvica	Pharmaceuticals	Blood cancers	\$9,319	\$14,934	38%	\$2,371,858,000

Notes from the CMS: “Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies’ participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.”

What happens next?

The CMS will publish an explanation of the negotiated prices for the first 10 selected drugs by March 1, 2025, based on the negotiation factors. In February 2025, the CMS will publish the next set of 15 drugs covered under Medicare Part D for negotiation for 2027 price applicability.

Life sciences considerations

The release of pricing for 2026 and the manufacturers’ and industry stakeholders’ lack of success in challenging the drug-pricing program in court, underscores the growing role of federal intervention in drug pricing. Companies must understand not only the result of the negotiated prices, but the factors the CMS is using – and take those into consideration when developing pricing structures. Additionally, because the drug-pricing program will continue to identify drugs covered by Medicare Part D and eventually Part B, companies should anticipate engagement with the CMS and plan compliance strategies accordingly.

Strategic takeaways

1. **Proactive engagement:** Companies with drugs under review should prepare for the negotiation process well in advance, and understanding the CMS criteria and the nuances of the Inflation Reduction Act will be critical.
2. **Regulatory compliance:** Ensuring compliance with the CMS’ new requirements is essential, particularly as the agency likely will focus on transparency in pricing models.

3. **Impact on innovation:** The long-term effects on R&D investment may be substantial as the industry adapts to negotiated prices, and companies should evaluate the potential impact on their innovation pipelines and pricing strategies for high-cost drugs.

This first round of price negotiations may provide insight into how the CMS and the pharmaceutical industry will interact in the future, making it essential for life sciences companies to stay informed and adaptive to this evolving landscape.

For more information or legal assistance in navigating health reform trends, please contact Cooley's [global life sciences and healthcare regulatory \(LHR\)](#) team or one of the lawyers below.

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