PRECISION value & health®

Medicare Drug Price Negotiation: First 10 Drugs Announced

Andrew Cournoyer, Ryan Cox, and Sejal Jonas
Access Experience Team | Precision Value & Health

Andrew Cournoyer

Ryan Cox

Sejal Jonas

Overview

The Centers for Medicare & Medicaid Services (CMS) released the first 10 drugs that will be subject to Medicare Part D price negotiations in 2026. According to CMS, these drugs accounted for $50.5 billion in Medicare Part D spending from June 2022 to May 2023:

Drug	Therapeutic Area	Manufacturer	Total Cost to Medicare	Medicare Enrollees Treated
Eliquis	Blood thinner	Bristol Myers Squibb	$16.5B	3.7M
Jardiance	Diabetes	Boehringer Ingelheim/Eli Lilly	$7.2B	1.6M
Xarelto	Blood thinner	Johnson & Johnson	$6B	1.3M
Januvia	Diabetes	Merck	$4.1B	869K
Farxiga	Diabetes	AstraZeneca	$3.3B	799K
Entresto	Heart failure	Novartis	$2.9B	587K
Enbrel	Rheumatoid arthritis	Amgen	$2.8B	48K
Imbruvica	Cancer	Johnson & Johnson/AbbVie	$2.7B	20K
Stelara	Anti-inflammatory/Crohn disease	Johnson & Johnson	$2.6B	22K
NovoLog/Novo-Log 70/30/Fiasp	Diabetes	Novo Nordisk	$2.6B	777K

Timeline

Announcing the drugs to be negotiated was the first step in the process.

- Pharmaceutical manufacturers have until October 1, 2023, to decide if they will participate in negotiations.
- CMS will meet with manufacturers in the fall of 2023.
- CMS will send an initial offer for each drug's maximum price by February 1, 2024. Offers will be made based on CMS's analysis of the market basket, evaluating multiple factors, such as net costs, comparative effectiveness data, the impact on specific populations, and the ability to meet an unmet need. Manufacturers have 30 days to either accept an offer or submit a counteroffer.

- Companies will get up to 3 negotiation meetings with CMS through the period ending August 1, 2024.
- The new prices will be announced on September 1, 2024.
- The negotiated prices are planned to go into effect January 1, 2026.

CMS said discounts will range from 25% to 60%, depending on how long the drugs have been on the market. If a manufacturer refuses to negotiate, they will be subject to a substantial nationwide sales excise tax. Based on negotiations, a drug company can either accept the deal or withdraw from Medicare and Medicaid coverage. The program has evoked a battle to be settled in the courts. Six pharmaceutical companies, the US Chamber of Commerce, and trade groups have taken the conversations to the courtroom, calling the program unconstitutional. If the program proceeds as intended, CMS will extend the program over time by negotiating an additional 15 Part D drugs in 2027, another 15 Part D and Part B drugs in 2028, another 20 Part D and Part B drugs in 2029, and up to 20 more drugs each subsequent year.

Impact to payers

Many payers have been using the speculative drug lists put forth by industry analysts as a proxy to determine the impact to their rebate guarantees, trend calculations, and future premiums. Some of the targets, such as Eliquis, were not surprising because they represent the largest expenditure and volume for Medicare Part D claims. However, some targets gave pause because they are expected to have generic competition in the near future (Stelara in 2025 and Januvia in 2026), potentially limiting the ability to maximize savings. In any event, given that payers are incurring higher liabilities resulting from the Part D redesign components of the Inflation Reduction Act (IRA), it is anticipated that payers will push to offset this liability through benefit design, drug preferencing on formularies, and utilization management programs.

Regarding formulary access impacts, payers may be challenged to reconsider their preferred drug strategies. Per IRA regulations, payers will be required to cover CMS-negotiated drugs and, although not explicitly stated, it is likely they will have to be covered in a preferred position (or at least not disadvantaged to non-negotiated drugs). As a result, if these drugs were not already preferred, it could impact contractual arrangements with existing preferred products; especially those that limit the number of preferred products within a therapeutic category a plan can have on its formulary. In these situations, payers may negotiate with drug manufacturers to maintain existing contracting rates despite the potential new preferred additions resulting from CMS's negotiation drug list.

In some cases, a CMS-negotiated price may be advantageous for the payer, particularly in categories where steeper discounts are not already obtained, such as oncology. On the other hand, payers have already negotiated steep discounts for many categories and it remains to be seen if CMS will be able to negotiate a price that is steeper than the net price payers have already obtained. The added layer of transparency will support negotiation leverage for payers, especially when negotiating with manufacturers whose drugs compete in the same or similar therapeutic categories as the CMS-negotiated drugs.

Impact to Manufacturers

Releasing the first drugs subject to price negotiation was step one, with the White House marking the announcement as a momentous occasion. However, many uncertainties still exist. We don't know if the outcomes of the litigation will maintain the program's status quo, refine the program, or terminate the program. We don't know how deep the discounts will be. We also don't know what will be done with the savings CMS will achieve (ie, if and how it will be passed on to the beneficiaries).

Opponents argue that this will deter research investments and negatively impact quality of care. The most immediate impact is to those manufacturers of the targeted brands. However, there are inconsistencies in the level of impact as several brands were set to lose exclusivity prior to 2026, so the financial implications may be minimal. For example, some manufacturers may be less concerned because of the pending loss of exclusivity limiting the impact to their earnings. The greater risk is if this will bleed into commercial segments and have an incremental impact on their financial solvency.

Targeted Considerations:

Manufacturers With Drugs Selected for CMS Negotiations

Manufacturers of a drug that has been selected for price negotiation will have to determine their baseline (or starting) point, which CMS will set as the maximum fair price (MFP). This will be determined by the number of years the drug has been on the market (25% for >9 and <12 years, 35% for >12 and <16 years, 60% for >16 years). From this point, they will need to defend their price from additional discounts by preparing to share results from evidence-generation activities, including Health Economics and Outcomes Research (HEOR) and real-world evidence (RWE) studies. Additionally, scenario-based financial modeling exercises will be needed to determine gross-to-net exposure as well as impacts to prescription volume, which, in some cases, could be positive if access is improved as a result of being selected.

Manufacturers Who Compete Against Selected Drugs

These manufacturers will need to consider the spillover effect. Selected drugs are likely to be positioned in cost advantageous formulary positions and coupled with public awareness. CMS-negotiated drugs may drive additional prescription volume above drugs competing in a similar therapeutic category. Payer demand for steeper discounts has been forecasted by many industry watchdogs, including our own research into payer response strategies stemming from the IRA. As a result, we expect payer demand for steeper discounts to impact manufacturers who are competing against negotiated drugs—not only for maintaining access but also as an offset to increased payer liabilities resulting from Part D benefit redesign.

Beyond the First Round

- Drug manufacturers will need to monitor formulary access impacts resulting from the initial selection as these drugs span several critical macro drug categories, including specialty drugs, biosimilars, oncology, and high-prevalence disease. Although this is a small sample of drugs impacting a relatively small number of Medicare beneficiaries, these insights are important for preparing for the next round of 15 drugs to be selected on February 1, 2025.
- Published pricing resulting from CMS negotiations of these first 10 drugs will be announced on September 1, 2024. At this point, manufacturers will have their first line of sight to compare list prices to negotiated CMS prices as well as to determine how successful (or not) CMS was in negotiating additional discounts beyond the baseline MFP.

Spillover effect is also likely to carry into the commercial space. Payers will have some level of knowledge of or insight into the types of discounts being negotiated for Part D and will push for similar discounts into the commercial benefit, if not already there.