

August 29, 2023

Top 10 Drug List for Negotiation

Some Surprises for '26 & Next Steps As Legal Challenges Mount

Relevant Companies



This morning, CMS released its top 10 list of drugs that will be negotiated starting January 2026. The due date for release is September 1, 2023 ([here](#)).

»» Our Take & Next Up

The list appears largely as expected with a handful of medicines not on our list. We note that the 2027/28 list will be harder to predict. Manufacturers listed below now have until October 1 to sign negotiation agreements to start the process with CMS. A preliminary injunction request from the Dayton Chamber of Commerce has asked the OH District Court to halt the negotiation process entirely at this time, allowing selected manufacturers to avoid starting the negotiation process. A legal roundup is provided below. The 2026 list was notably more well known based on the IRA requirements, however, 2027/2028 impact is harder to predict.

»» Key Points

The list includes treatments for cardiovascular disease, diabetes, rheumatoid arthritis, psoriasis, and hematologic cancer. CMS's 2026 list includes the following Eliquis (PFE, BMY) for the treatment of blood clots, Xarelto (Bayer, JNJ) for the treatment of blood clots, Januvia (MRK) for the treatment of diabetes, Imbruvica (ABBV, JNJ) for the treatment of blood cancers, Enbrel (AMGN) for the treatment of rheumatoid arthritis and psoriasis, Jardiance (Boehringer Ingelheim, LLY) for the treatment of diabetes, Farxiga (AZN) for the treatment of diabetes, Stelara (JNJ) for the treatment of psoriasis, and Fiasp/NovoLog/FlexPen (NVO) for the treatment of diabetes, and Entresto (NVS) for heart failure.

We do not think that CMS will negotiate the lowest possible price as Medicare gains a new superpower. Instead, we expect prices closer to the ceiling to be the norm. The new prices will be announced on Sept. 1, 2024, and will go into effect on

Jan. 1, 2026. We provide legal challenges to the IRA below and note that we are at 30% odds of a preliminary injunction halting the law.

Our Top Ten list is here, and the CMS list differs by four including Fiasp (Novo), Farxiga (AZN), and Stelara (JNJ) along with NVS's Entresto. Our list expected Eliquis (PFE, BMY), Xarelto (Bayer, JNJ), Januvia (MRK), Imbruvica (ABBV, JNJ), Enbrel (AMGN), Jardiance (Boehringer Ingelheim, LLY), Ibrance (PFE), Symbicort (AZN), Xtandi (Astellas, PFE), Breo Ellipta (GSK), Myrbetriq (Astellas). Notably, Stelara (JNJ) and Farxiga (AZN) were surprises as other predicted lists largely failed to list these two medicines. Stelara (JNJ) faces LOE in 2025. Fiasp (NVO) was also a surprise. Predicted drugs that are noticeably missing include Xtandi (Astellas, PFE), Ibrance (PFE), and respiratory med, Symbicort (AZN).

BACKGROUND

As a reminder, CMS used gross price (2022-23) to determine eligibility for 2026 negotiations. Gross covered prescription drug costs mean total spending for a prescription claim including Medicare, plan, and beneficiary payments. Part D spending between June 1, 2022, and May 31, 2023, determined the top 10 eligible drug drugs (as outlined in the IRA). Net price will factor into the initial offer. Drugs with more than one rare disease designation will not qualify even if the drug has not been approved for any indication in the additional designations. Once a drug loses its orphan exclusion, CMS will use the initial FDA approval date not the loss of eligibility date. Combination drugs with two or more active ingredients are treated as 1 distinct active ingredient, separate from products containing only 1 (but not both) active ingredients and will not be included in negotiations. For 2026 through 2028, "small biotech" drugs will be exempt from negotiation.

To date, eight lawsuits have been filed against the negotiation program. They include MRK's [lawsuit](#) filed in the District Court for DC, BMY's [lawsuit](#) filed in New Jersey, JNJ's [lawsuit](#) also filed in New Jersey (and combined with BMY), the Chamber of Commerce's [lawsuit](#) filed in Ohio, PhRMA's [lawsuit](#) filed in Western District of Texas, Boehringer Ingelheim's [lawsuit](#) filed in Connecticut, AstraZeneca's [lawsuit](#) filed in Delaware, and Astellas' [lawsuit](#) filed in Illinois. Note all the filings have been in different states with different regional Circuits for appeals. The number of cases in different Circuit courts increases odds of Supreme Court review as the high court may step in to harmonize conflicting decisions.

Preliminary injunction is unlikely by Oct 1 (30% odds in our view) while summary judgment requests would remove trial proceedings and rule in company/plaintiff's favor. The Dayton Chamber of Commerce has requested a preliminary injunction by October 1 which is the deadline by which manufacturers must agree to negotiation terms (for 2026). MRK, PhRMA, JNJ & BMY have all requested a summary judgement which is a decision made by a judge based on statements and evidence without going to trial. If granted, the lawsuits would be ruled in the companies' favor. We believe a summary judgement/preliminary injunction is unlikely to occur, but the increasing number of summary judgements indicates the plaintiff's confidence in the legal arguments knocking down the negotiation program.

For 2027, CMS will select up to 15 incremental Part D drugs for negotiation; Part B is included in 2028. This will increase to up to 15 more Part B or Part D drugs for 2028, and up to 20 more Part B or Part D drugs for each year after that. The count is 10 Part D drugs in 2026, 15 more Part D drugs in 2027, 15 more Part B&D drugs in 2028, 20 more Part B&D drugs in 2029 and each year after.

CMS timeline for Drug negotiation.

- Data for 2026 selection: June 1, 2022, and ending on May 31, 2023
- Deadline for companies to sign agreements to participate: October 1, 2023.
- Negotiation period: October 2, 2023- August 1, 2024
- Company specific data deadline: October 2, 2023.
- Written initial offer deadline: February 1, 2024

- Negotiated Price publication date: September 1, 2024
- Deadline for explanation of the negotiated price: March 1, 2025.
- Negotiated Price effective date: January 1, 2026.

Ipsita Smolinski

Managing Director | Capitol Street

ipsita@capitol-street.com

900 19th Street, NW 6th Fl
Washington DC 20006

202.250.3741

www.capitol-street.com

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