

15 Aug 2024 | Analysis

Medicare Negotiation Announcement: Discounts From List Price Up To 79%, But Net Savings Unclear

by Cathy Kelly

Net per drug savings achieved by the negotiation process is unclear because many of the products already have significant rebates. The announcement also leaves much of the agency's negotiation process in the dark.

The <u>Medicare negotiated prices</u> for the 10 drugs selected for the first round of the process were released 15 August, but the level of savings achieved for each drug is not clear because the US Centers for Medicare and Medicaid Services compares the new prices to list prices without disclosing rebates, even though most already are subject to them.

As a result, the discounts from list price in the announcement overstate the price reductions produced by the negotiations. The new prices will go into effect in 2026.

The Biden Administration did offer aggregated net pricing data to convey topline savings estimates. Officials claimed that Medicare could have saved \$6bn on a net basis and beneficiary out-of-pocket spending would have been reduced by \$1.5bn if the program had been in place in 2023. The \$6bn would have represented 22% lower net spending in aggregate, according to the agency.

Key Takeaways

- The first round of Medicare negotiated prices were released, but determining the discount the government achieved is difficult because the announcement compares the new prices to 2023 list prices, not net prices after rebates.
- The Biden Administration claims that Medicare could have saved \$6bn on a net basis and beneficiary out-of-pocket

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The list price reductions range from 38% for a 30-day supply of *AbbVie Inc.*'s cancer drug Imbruvica, which lowered the cost to \$9,319, to 79% for a 30-day supply for *Merck & Co., Inc.*'s Januvia for diabetes, which reduced the cost to \$113. *(See chart below.)*

Although the agency does not explain how it approached specific negotiations, the starting point for the Medicare price for Imbruvica may primarily reflect the minimum discount established by the Inflation Reduction Act for drugs of its age.

- spending would have been reduced by \$1.5bn if the program had been in place in 2023.
- The announcement did not have to include a description of how CMS weighed the various factors that went into its price offers. The agency has apparently decided to disclose its approach by the 1 March 2025 statutory deadline.

Imbruvica was first approved in 2013 and so will be 13 years post-approval when the prices are implemented in 2026.

Until 2030, the minimum discounts established by the IRA are: 25% of the non-federal average manufacturer price for drugs that have been approved for nine to 16 years or 60% of the non-FMAP for drugs approved for 16 years or more. From 2030 onward, a minimum 35% discount will be applied to drugs that are 12 to 16 years old.

The IRA directed CMS to set a ceiling for negotiated prices at either a percentage of the non-FMAP or the net price after rebates, whichever is lower. The non-FAMP is the average price paid to manufacturers by wholesalers for drugs distributed to non-federal purchasers and it does not include pharmacy benefit manager and insurer rebates.

The negotiated price for <u>Johnson & Johnson</u>'s immunology treatment Stelara is \$4,695 for a 30-day supply, 66% below its 2023 list price. The price reduction again suggests that CMS started with the minimum discount established by the IRA for the drug. (Also see "<u>Janssen's Stelara May Be Medicare Price Negotiation Savings Star"</u> - Pink Sheet, 9 May, 2024.)

The price for Januvia, on the other hand, may be more reflective of its net price

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because it is highly rebated.

Other negotiated drugs with big rebates include *Novo Nordisk A/S*'s Novolog insulin, the two SGLT2 inhibitors for diabetes, *AstraZeneca PLC*'s Farxiga and *Boehringer Ingelheim GmbH*'s Jardiance, and the two blood thinners, *Bristol Myers Squibb Company*'s Eliquis and Johnson & Johnson's Xarelto.

Will Manufacturers Be Better Prepared For Next Round?

The CMS announcement does not discuss the agency's process for setting maximum fair prices or incorporating information supplied by manufacturers, patients and others on the value of the drugs during the negotiation process.

The IRA does not require the agency to publish an explanation of its approach until 1 March 2025.

That is a disappointment for stakeholders hoping to learn more about the information most important to the agency before the next negotiating round begins. CMS is scheduled to announce the next group of Part D drugs that will be subject

Products

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to negotiation on 1 February. (Also see "<u>Medicare Negotiation Round Two Will Be Dominated By Oral Cancer Drugs, Researchers Predict</u>" - Pink Sheet, 16 Jul, 2024.)

CMS Suggests Process Was Really A Negotiation

The CMS announcement provided an overview of the back-and-forth discussions with manufacturers during the process that suggested actual negotiation occurred. Manufacturers are skeptical that the process would involve real negotiations.

"CMS held three meetings with each participating drug company to discuss the offers and counteroffers, discuss evidence, and attempt to arrive at a mutually acceptable price for the



drug," the agency said. "During the course of the negotiation process, CMS revised its offers for each of the drugs upward in response to these discussions. Likewise, many drug companies revised their counteroffers for their drugs downward, based on the discussions with CMS."

For five of the drugs, "this process of exchanging revised offers and counteroffers resulted in CMS and the drug company reaching an agreement on a negotiated price for the drug in association with a negotiation meeting," CMS said.

In four cases, CMS "accepted a revised counteroffer" proposed by the drug company and "for the remaining five selected drugs, CMS sent a written final offer to those drug companies, consistent with the process described in its guidance, and in each instance, the drug company accepted CMS's offer on or before the statutory deadline."

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