

Can the Government's New Ability to Negotiate Drug Prices Eliminate Blockbuster Price Tags?

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The drug companies want \$26,500 per year for the newest Alzheimer's drug; negotiations might take it to \$20,000.

The potential for full Food and Drug Administration approval of the new Biogen-Esai Alzheimer's drug (Leqembi) means that Medicare may make the drug available to beneficiaries. The \$26,500 annual price tag associated with Leqembi will wreak havoc with Medicare finances, raise part B premiums, and place **an enormous financial burden on afflicted families** through the required copays.

The question is how does the nation deal with a potentially valuable medical treatment – be it Leqembi or future more effective drugs – that come with a blockbuster price tag. Clearly, Congress views this issue as important and, in **the Inflation Reduction Act of 2022**, gave the federal government the power to negotiate for some drugs covered under Medicare Parts B and D. How would negotiations work in the case of Leqembi?

The general process is summarized nicely in **a recent piece from the Kaiser Family Foundation**. Let's start with how things work currently. Under Part D, which covers retail prescription drugs, Medicare contracts with private plans to provide a drug benefit, but the law that established the Part D benefit included a **"noninterference"** clause. This clause says explicitly that the Secretary of Health and Human Services cannot interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors. In terms of Part B, negotiations also do not take place; Medicare simply pays providers 106 percent of the average price to all non-federal purchasers in the United States.

The Inflation Reduction Act adds an exception to the noninterference clause that requires the Secretary to negotiate prices for a small number of drugs without competitors. The drugs subject to price negotiation will be selected from the 50 drugs with the highest total Part D spending and the highest total Part B spending. The number will start with 10 Part D drugs and 15 Part B drugs and will accumulate over time.

The timeline for the negotiation process spans roughly two years. For Part D, the list of 10 drugs selected for negotiation will be published on September 1, 2023; the period of negotiation will occur between October 1, 2023 and August 1, 2024; and the negotiated "maximum fair prices" will be published no later than September 1, 2024. For Part B, the initial period of drug price negotiation will take place between February 28, 2026 and November 1, 2026. Negotiated prices for the first set of selected drugs covered under Part D will be available in 2026 and under Part B in 2028.

The maximum price for a given drug will be the lower of: 1) the drug's negotiated price for a Part D drug; 2) the average sales price for a Part B drug; or 3) a percentage of a drug's average non-federal average

manufacturer price that ranges from 75 percent to 40 percent based on years from approval. Medicare's payment to providers for Part B drugs with negotiated prices will be 106 percent of the maximum price (rather than the current payment based on the average sales price).

The legislation gives the government real leverage in that if companies don't comply, they will face an excise tax, which starts at 65 percent of U.S. sales and increases rapidly to a maximum of 95 percent. In addition, manufacturers that refuse to negotiate will pay a civil penalty equal to 10 times the difference between the price charged and the maximum fair price. Alternatively, the company can choose to withdraw all of their drugs from coverage under Medicare and Medicaid. So, what does all this mean for Leqembi or subsequent drugs that target amyloid? These drugs would be covered under Part B, because they must be administered by physicians. They are also classified as biologic drugs, which are not eligible for price negotiation until they are 13 years away from FDA approval. Hence, negotiated prices will not be available until 2036 at the earliest. And, even then, my hunch is that drug manufacturers will find some way to ensure that any negotiated discount is relatively modest, meaning that these drugs will still cost a lot of money for the program and beneficiaries.