ISSUE BRIEF #2

Medicare Coverage of Drugs That Receive FDA Accelerated Approval

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August 2022

Part B drugs include a mix of products, some inexpensive (e.g., vaccines, corticosteroids, vitamin B-12) and some very expensive (e.g., biologics, cancer medications).[8,9] As a result, spending is concentrated in a small number of expensive products. In 2019, the top ten drugs accounted for more than 40 percent of total Part B spending on drugs.[10] Expensive Part B drugs cost tens or hundreds of thousands of dollars a year per patient.[11] This expense affects the Medicare program, beneficiaries, and other insurance that provides secondary coverage. Medicare beneficiaries without supplemental coverage that covers cost-sharing must pay cost sharing of 20 percent for most Part B drugs.[12] Medicare beneficiaries with additional coverage do not bear this financial burden directly, but the costs are passed along to these other payers. For

Proposed Policy

One option to encourage the timely completion of confirmatory trials for drugs that have received FDA's accelerated approval is for Congress to enact legislation requiring that these drug manufacturers provide Medicare a 25% of ASP rebate until a confirmatory trial is completed. Congress could opt to apply this policy for all indications of Part B drugs that receive accelerated approval from the FDA or just for those indications that received the accelerated approval. This requirement for Medicare coverage of drugs under Part B would be similar to a recent MACPAC recommendation for Medicaid drug coverage that calls for an increase the minimum rebate percentage on drugs that receive accelerated approval from the FDA and share some similarities with a MedPAC recommendation from 2017 that, among other changes, would require manufacturers to pay Medicare a rebate, in this case when the ASP for their product exceeds an inflation benchmark.[25,26] Such a policy could share this price reduction with beneficiaries by calculating the 20% Part B drug cost sharing based on the reduced price

Medicare could require that manufacturers of drugs that receive an accelerated approval from the FDA offer a 25% rebate off of the average sales price to be covered under Medicare Part B until confirmatory trials are completed and the drug has received full FDA approval.

including the new rebate. Physicians and suppliers could essentially be held harmless if Medicare continued to pay them their 6% add-on based on the price excluding the new rebate.

Based on our analysis of data on the drugs that Medicare currently covers under Part B that received only accelerated approvals, we anticipate that requiring a 25% rebate off of ASP for drugs that are approved by the FDA under accelerated approval as proposed, beginning in 2025 would yield savings of more than $12 billion over 10 years. This is designed to be a conservative estimate as Congress could opt to include additional drugs in a 25%-of-ASP-rebate policy, such as those where only some of the drugs' indications received accelerated approval. These estimated savings do not reflect a behavioral response on the part of drug manufacturers in terms of price setting. Affected drug manufacturers might respond to the policy differently from what we have projected, for example by raising prices for other purchasers, thus increasing ASP. Manufacturer responses other than those included in the model could affect the estimated savings.

[25] Addressing High-Cost Specialty Drugs, MACPAC (June 2021)
[26] Report to the Congress: Medicare and the Health Care Delivery System, MedPAC (June 2017)

Appendix

Fabrazyme	Genzyme	Apr-2003	Apr-2003 Converted	Mar-2021	217.7
Doxil	Janssen Products LP				

Source: HMA analysis of data from the Center for Drug Evaluation and Research (CDER), the FDA Orange Book, and the FDA Purple Book