KEY CONSIDERATIONS FOR BIOSIMILARS COVERED UNDER THE PHARMACY BENEFIT

The Current State of Biosimilars Under the Pharmacy Benefit

Of the 22 biosimilars currently available in the U.S, none are routinely reimbursed through the pharmacy benefit.[1] Instead, most biosimilars are typically administered by a physician and therefore billed under Medicare Part B, which is Medicare's medical benefit.

Medicare Part D and the pharmacy benefit will play a much larger role in the upcoming years due to the approval and expected launches of biosimilars in more therapeutic areas, such as autoimmune diseases.

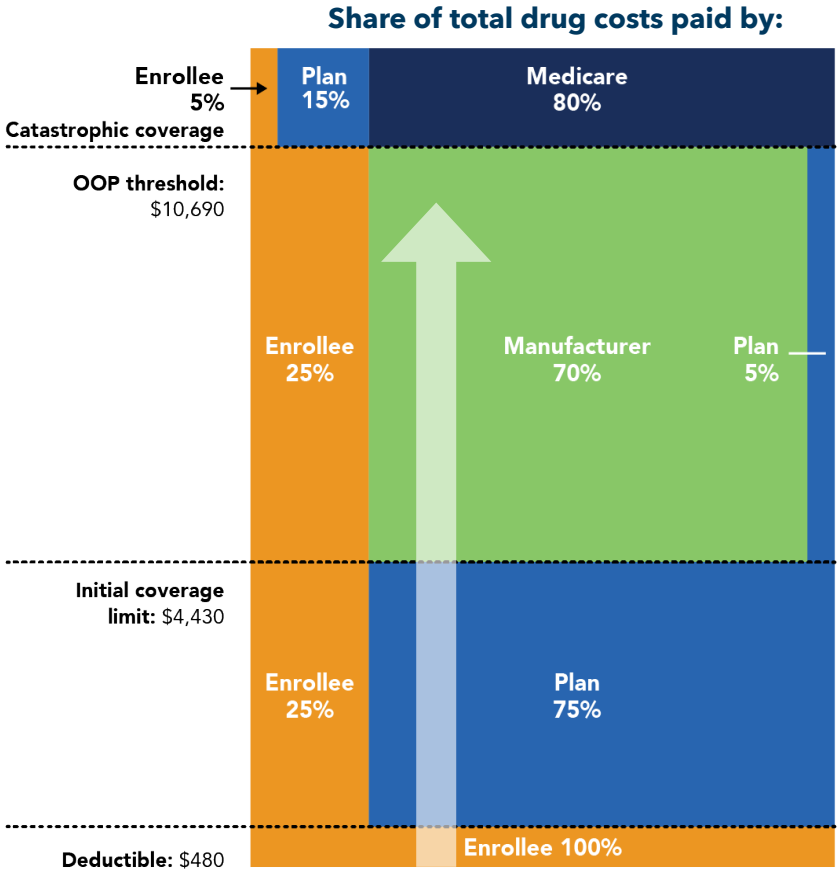
The Pharmacy Benefit Reimbursement Process

In Medicare Part D, biosimilar reimbursement is set through negotiation between plans and pharmaceutical manufacturers. Each plan has a formulary, or a list of covered drugs.

The Medicare Part D standard benefit is divided into 4 phases of coverage: deductible, initial coverage, coverage gap ("donut hole"), and catastrophic coverage. Currently, manufacturers that participate in Medicare's drug discount program cut the price of their medicines by 70% when they are bought by beneficiaries in the coverage gap.[2]

Part D benefit design is the same for innovative products and biosimilars, but the potential for different costs may affect how participants progress through the four phases of coverage.

Figure 1: 2022 Part D Standard Benefit Design[2]



For more information on the role biosimilars may play in helping reduce health system costs, including in Medicare Part D, you can view Amgen's 2022 Biosimilar Trends Report here:

www.AmgenBiosimilars.com

The Cost Savings Biosimilars May Create for Medicare Part D

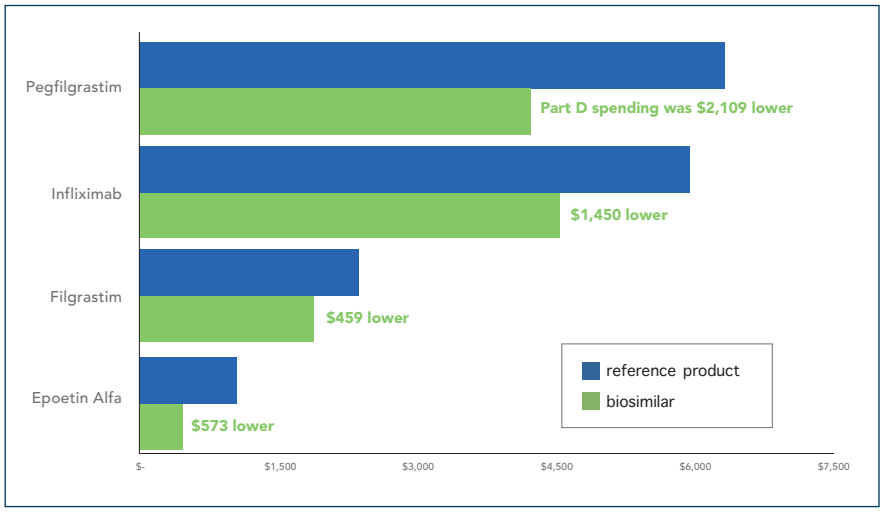
Biosimilars have the potential to reduce costs for the Part D program and its beneficiaries, both now and in the future, especially as biosimilars for blockbuster medicines become available in the coming years.[3]

However, **several factors may limit the use of biosimilars in Part D,** such as formulary exclusion, unfavorable formulary tier placement, and rebates for preferential formulary treatment of reference products.[3]

On average, Part D beneficiaries paid less for most biosimilars that have launched compared with their reference products, according to a report from the U.S. Department of Health and Human Services.

Additionally, Part D spending could have been reduced between 18%-31% if biosimilars were used at a higher rate.[3]

Figure 2: Medicare Part D Spending for Typical Prescriptions was Lower for Biosimilars than for the Corresponding Reference Products[3]



Future Considerations to Improve Uptake of Biosimilars Under Medicare Part D

To take advantage of the savings biosimilars can offer, stakeholders should consider several ways to improve biosimilar uptake.

Payers can ensure coverage of biosimilars at an appropriate tier level and implement incentives to encourage adoption.[3]

Integrated delivery networks can also help promote the use of biosimilars through improved selection and ordering tools to ease provider selection of a lower-cost biosimilar.[4]

Patient understanding of biosimilar products, including their safety and efficacy, will also be key to the utilization of these products. Education on what biosimilars are and the potential for cost savings will be of paramount importance.[5]

Retail pharmacists have had very little exposure to biosimilars to date and will likely need education to become more knowledgeable and comfortable discussing biosimilars with patients.

**As of September 2022*

[1] Xcenda. Biosimilar approval and launch status in US. April 2022. Accessed August 29, 2022. https://www.xcenda.com/biosimilars-trends-report.

[2] Kaiser Family Foundation. An Overview of the Medicare Part D Prescription Drug Benefit. October 2021. Accessed September 16, 2022. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.

[3] U.S. Department of Health and Human Services, Office of Inspector General. "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use." March 2022. https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf.

[4] Generics and Biosimilars Initiative. "Successful increase of biosimilar adoption in a large integrated health delivery network." March 2022. Accessed August 16, 2022. https://www.gabionline.net/biosimilars/research/successful-increase-of-biosimilar-adoption-in-a-large-integrated-health-delivery-network.

[5] Rifkin RM, Peck SR. Biosimilars: implications for clinical practice. J Oncol Pract. 2017;13(9):24s-31s.