The Biosimilars Council Opposes Efforts to Prohibit Biosimilars From Receiving Pass-Through Status in the Medicare Part B Program

Background

To encourage the use of innovative products and help ensure they would be available to Medicare patients, Congress established pass-through "transitional" reimbursement payments[1] for new medical devices, drugs and biologics in the Medicare Part B program. These payments are designed to support the introduction of new medicines and provide manufacturers of new products an opportunity to familiarize prescribers with their products when they are first brought to market.

The Centers for Medicare and Medicaid Services (CMS) presently provides such payments for qualifying biosimilar products to allow biosimilar manufacturers to create a market for newly launched products and compete on a level playing field with their reference biologic counterparts. These payments are meant to encourage manufacturers to invest in biosimilar development as well as increase education for physicians and patients on the quality and safety of the biosimilar by providing competitive reimbursement.

Payment for biosimilars assigned pass-through status is made at wholesale acquisition cost (WAC) + 6 percent for the first two quarters the product is available, and then at average sales price (ASP) + 6 percent of the reference products ASP when ASP data for the biosimilar becomes available. Products eligible for pass-through status are often exempt from a number or reimbursement deductions created by other payment policies, which provides providers consistency in reimbursement for new products.

The Issue

Despite the importance of biosimilars to reducing the cost of medicine, policymakers recently included a provision in a proposed bill[2] that would have prohibited biosimilars from receiving pass-through status in Medicare Part B. While this provision was ultimately removed from the final legislation, the Biosimilars Council is concerned that it continues to be proffered by certain brand biologic manufacturers as a means to stifle biosimilar competition. The prohibition of biosimilars from receiving pass-through status would reduce patient access to these affordable alternatives to brand biologic medicines, disincentivize manufacturer investment, and significantly weaken the nascent biosimilars market in the United States.

Pass-through payments serve an important purpose in the biosimilars market, just as they do in the brand market. Newly introduced biosimilars will require significant provider education, and manufacturers will likely require sales forces to provide information to local Pharmacy and Therapeutics Committees. Pass-through payments will ensure that there is a reliable market for these new products that can support the development of that infrastructure. Importantly, maintaining pass-through payments for biosimilars also ensures that they are on a level playing field with their branded competitors,

which receive pass-through status and use it as an opportunity to create significant market presence with which biosimilars must contend.

It is the Biosimilars Council's position that Congress established pass-through status to foster innovation and to remove financial barriers to the utilization of new medicines. Prohibiting biosimilars from receiving this designation would inevitably increase patients' out-of-pocket costs and increase costs to the federal government. Congress and other stakeholders should not entertain any proposal that would stifle the development of more affordable, FDA-approved biosimilars.

References

1. Public Law No: 106-113. (link)
2. Roll Call No. 60 on House Resolution 1892 "Further Extension of Continuing Appropriations Act, 2018" (link)