Biosimilar drugs underused due to commercial insurance restrictions: Study

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Biosimilars provide the same therapeutic benefits at much less cost than biologic medications, yet slow marketplace acceptance has prevented their advantages from being fully realized.

A new study led by USC Schaeffer Center Fellow Jakub Hlávka finds insurers either excluded or imposed restrictions on biosimilars in 19.4%

of the cases examined. The study, published in the journal *BioDrugs*, is the first to address the drivers of biosimilar coverage.

Coverage limitations may take the form of step-therapy requirements that keep biosimilars away from patients until after other treatments have failed. In traditional pharmaceuticals, such exclusions are usually aimed at more expensive treatment options, however, in the case of biosimilars, their list prices tend to be lower than those of their reference products.

Hlávka worked with James Chambers, associate professor at Tufts Medical Center, and students from the USC Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences and USC Dornsife College of Letters, Arts and Sciences Department of Economics to examine 1,181 coverage decisions made by 17 U.S. commercial plans. The research included 19 commercially available biosimilars that provide alternatives to seven biologic reference products used in treating 28 different conditions.

Five of the plans—or 29.4% of the total—restricted biosimilar use in 30% or more of their decisions.

"These restrictions hamper the potential of biosimilars to increase access to care," says Hlávka. He adds that, "such coverage variations may negatively impact patient access to effective treatments."

The researchers find the following trends related to coverage decisions:

- While plans were more likely to allow biosimilars for cancer patients, they were generally more likely to impose restrictions on biosimilar use for pediatric patients.
- Coverage decisions were also found to be influenced by market competition and budget impacts: the first biosimilars to enter the

market were less likely to have restrictive coverage and biosimilars offering savings of $15,000 or more per patient annually were much less likely to be restricted. Furthermore, the availability of cost-effectiveness evidence correlated significantly with coverage being less constrained.
- Health plan pharmacy benefits managed by the three largest pharmacy benefit managers—CVS Caremark, Express Scripts, and OptumRx—were less likely to impose restrictions on biosimilar coverage relative to plans not managed by the big three.

The researchers note that many competing factors may be driving these trends: plans may be more cautious when it comes to pediatric patients while large PBMs may be leveraging their market power to negotiate higher rebates from biosimilars.

"We know that biosimilars are not being utilized as much as they could be," says Hlávka. "Our study helps to uncover some of the trends in coverage decisions and offers points in the system where more research is warranted."

Although brand biologics and specialty medicines account for just 3% of all prescriptions, they constitute 55% of all drug spending. Therefore, biosimilars have the potential to greatly increase savings while reaching greater numbers of patients with effective therapies for a wide range of diseases, from cancer to rheumatoid arthritis.

"Insurer coverage policies have a determining role in patients' access to biosimilars. This study sheds light on the factors that influence insurer decision-making and provides novel insights into when patients have favorable access to biosimilars," adds Chambers.

While Hlávka and his co-authors acknowledge that more research is

needed, this study takes an important step in uncovering the decisions that result in a slower adoption of lower-cost equivalents of expensive biologic treatments.

More information: Tianzhou Yu et al, Factors Associated with Biosimilar Exclusions and Step Therapy Restrictions Among US Commercial Health Plans, *BioDrugs* (2023). DOI: 10.1007/s40259-023-00593-7

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