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FIVE THINGS TO KNOW ABOUT BIOSIMILARS

… from Premera Blue Cross

Access to affordable, quality care is the cornerstone for a healthy community. Here are the five things you need to know about biosimilars, which can help you understand the challenges around defining a biosimilar strategy.

What are biologic medications and biosimilars?

Biologic medications are different than the "traditional" medications we typically think of. Those traditional medications are chemically based, easily reproduced, and manufactured. For example, generics that are now available for acetaminophen and ibuprofen are created from chemicals and are easy to duplicate and manufacture. On the other hand, a biologic medication is made from natural and living sources such as proteins, living cells, and/or tissues[i]. Biologic medications are more complex to manufacture. Because of this, a biologic medication cannot be copied exactly but is highly similar.

A biosimilar is a biologic medication that is highly similar to an existing FDA-approved, branded biologic medication (sometimes, called the reference product or innovator product)[ii]. A biosimilar is not considered a generic but rather an alternative version of the innovator product. The original innovator product is the first branded biologic medication released and has patent protection for a specified length of time[i]. A biosimilar is comparable, but not identical, to the original innovator product. Similar to how we substitute generic medications as alternatives to brand medications today, biosimilars offer an alternative to an innovator product. The Food and Drug Administration (FDA) allows for the substitution of a biosimilar for the innovator product; however, state pharmacy laws may require pharmacists to receive permission from the prescriber[iii]. For more information, watch Premera's Healthcare Asks video about biosimilars.

Why are biosimilars a big topic right now?

The introduction of widely available biosimilars marks a shift in healthcare economics, representing an opportunity to create competition and reduce costs, transforming the pharmacy landscape like generics did. The biosimilar marketplace is dynamic and competitive. Adoption and access to biosimilars is essential to lower specialty drug costs, increase competition and improve affordability. Whenever new biosimilars or other emerging medications, services, or products are released into the market, Premera's focus will continue to be ensuring members and customers have access to quality healthcare at an affordable price.

What's the impact?

Rising prescription drug costs are a public health concern and biologic medications are often associated with high costs, which presents a challenge for patients who need them. A recent study shows that almost 13 million individuals delayed filling a prescription, or didn't fill the prescription, due to costs[iv]. Biosimilars are positioned to have a significant impact on healthcare by driving competition, leading to improved affordability and access for members and cost savings for employers.

The biosimilar market continues to grow. The average sales price for a biosimilar is 40% lower than the innovator (reference) product at the time of the biosimilar launch[v]. Savings from biosimilars increased by more than 30% to $12.4 billion in 2023; however, biosimilars achieved only a third of the market compared to brand biologic medications[v].

How is the industry responding?

In the U.S., the utilization of biosimilars has been slow. Reasons for this include higher than expected costs, deeper contracts offered by the innovator product manufacturers, lack of interchangeability, lack of education in the healthcare community, and less aggressive marketing for the biosimilar agents[vi]. There are variations in biosimilar list costs at launch, but the list costs have improved as more biosimilars (for an innovator product) are launched. Biosimilar manufacturers understand that contracts/rebates will be needed to remain competitive to drive utilization (of biosimilars) over innovator products.

Improving biosimilar interchangeability will also be crucial to increasing utilization. The distinction between biosimilars and interchangeable biosimilars has led to confusion and misunderstanding about their safety and effectiveness, similar to when generics were introduced. The FDA's 2025 budget includes a legislative proposal to deem all approved biosimilars to be interchangeable with their respective innovator product. If approved, this proposal is expected to increase the utilization of biosimilars further.

The overall utilization of biosimilars is increasing as providers become more comfortable prescribing them. Since 2015, almost 2.7 billion days of patient therapy with biosimilars have been used with no meaningful differences in safety or clinical outcomes[v]. However, there is variation amongst physician specialties. Education to patients and providers is needed to increase utilization of biosimilars further.

What is Premera's strategy?

Premera understands that our clients demand options in addressing high-cost specialty trends and sees biosimilars as an option to address these.

Our experience in managing biosimilars has taught us that it is easy to create unneeded and unwanted disruption for both patients and providers where preferred products are switched often due to release of a new biosimilar option and/or payer/total product cost strategy. Premera's approach continues to be a thoughtful, clinical approach to the clinical evidence, specific product features (i.e., dosage forms & strengths, interchangeability), and net cost (pre- and post-manufacturer rebates) to ensure we reduce disruptive effects while making best efforts to manage cost trends.

Premera will continue to monitor and evaluate each biosimilar and its innovator (reference) product to ensure members and customers have access to quality healthcare at an affordable price. Premera's biosimilar strategy will continue to evolve with the market and client needs.

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[i] Biosimilar Basics for Patients | FDA. https//www.fda.gov/drugs/biosimilars/biosimilar-basics-patients

[ii] Review and Approval | FDA. https://www.fda.gov/drugs/biosimilars/review-and-approval

[iii] Biologics and Biosimilar Drug Products: Pharmacist Guide to Patients' Frequently Asked Questions. https://www.pharmacist.com/Advocacy/Issues/Biosimilars/Biologics-and-Biosimilar-Drug-Products-Pharmacist-Guide-to-Patients-Frequently-Asked-Questions

[iv] In the Years Before COVID-19 Pandemic, 13 Million Adults Delayed or Did Not Get Prescription Drugs Because of Cost. https://www.rwjf.org/en/insights/our-research/2021/11/in-the-years-before-the-covid-19-pandemic-nearly-13-million-adults-delayed-or-did-not-get-needed-prescription-drugs-because-of-cost.html

[v] The U.S. Generic & Biosimilar Medicines Report – September 2024. https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf

[vi] IPD Analytics Drug Management: Biosimilar Medications. November 2024.