Interchangeable Biosimilars

Pharmacist's Guide to Frequently Asked Questions

What are biologic medications?

» Biologic medications, commonly referred to as biologics, belong to a class of medications cultivated and purified from large-scale cell cultures of microorganisms, plants, animals, or human cells, using cutting-edge biotechnology methods. Biologics include a diverse range of products, including vaccines, gene therapies, tissues, recombinant therapeutic proteins, monoclonal antibodies, and derivatives from human blood and plasma.

How are biologics different from other types of medications?

» Biologics originate from living sources, in contrast to other types of medications categorized as "small molecules," which are typically synthesized chemically or purified from plants. Because of the unique nature of their development and production, small molecular medications have identifiable structures, whereas biologics often consist of complex mixtures that are challenging to identify or characterize.

What conditions are treated with biologics?

» Biologics offer effective treatment options for a broad spectrum of both common and rare health conditions. These include various types of cancer, rheumatoid arthritis, chronic kidney disease, psoriasis, and inflammatory bowel diseases such as Crohn's disease. Additionally, it is important to mention insulins, which are vital in managing different types of diabetes, and vaccines, which play a crucial role in preventive care, as notable examples of biologic treatments.

Are biologics safe and effective to use?

» FDA plays a crucial role in overseeing the quality, safety, and efficacy of biologics through a stringent testing process.

» Common potential adverse effects of biologics include injection or infusion reactions, such as redness, itching, swelling, or pain. While most adverse effects are mild to moderate in severity, there is a possibility of serious and rare reactions, including difficulty breathing, severe allergic reactions, chest pain, fluctuations in blood pressure, and fever.

» Similar to other medications, the likelihood of experiencing adverse effects varies depending on factors such as the type of biologic, duration of therapy, individual medical history, and individual response to treatment. However, clinical research indicates that there is generally not a significant difference in the occurrence of adverse effects between biologics and the use of a placebo.

What are biosimilar medications?

» Biosimilar medications, commonly referred to as biosimilars, are a subset of biologics that are highly similar to the reference biologics with no clinically meaningful differences. Both biologics and biosimilars are derived from highly similar sources, such as living organisms or their byproducts.

How do biologics and biosimilars compare?

» Biosimilars undergo a thorough evaluation by FDA to ensure their safety and efficacy, which must be comparable to that of reference biologics. Both types of medications undergo a rigorous regulatory assessment process before approval and continuous compliance assessments post-approval; however, biosimilars are developed based on existing reference biologics, resulting in a shorter development period and reduced costs.

» The availability of biosimilars can enhance patient access to essential medications and contribute to reducing health care expenses by fostering healthy economic competition among biologics companies. A study from IQVIA revealed that use of biosimilars can generate significant savings, with average sales price reductions of $2,526 to $4,913. Savings from using biosimilars are projected to exceed $180 billion in the U.S. over the next 5 years. Furthermore, according to the June 2023 report from the Medicare Payment Advisory Commission, biosimilars launch at significantly lower prices relative to their brand biologics.

What are interchangeable biosimilars?

» Interchangeable biosimilars are biosimilars that have the same scientific characteristics, but pharmaceutical companies voluntarily undergo additional requirements to allow for pharmacy-level substitution. Depending on state law, pharmacists are permitted to substitute an interchangeable biosimilar without prescriber consultation, similar to generic medications substituting for brand-name drugs. This practice, known as pharmacy-level substitution, is governed by state pharmacy laws.

What are regulations for interchangeable biosimilars by state?

» Interchangeable biosimilars may generally be substituted for the reference product at the pharmacy level without the prescribing physician's authorization. However, regulations differ among states. Therefore, it is crucial for pharmacists to adhere to state-specific laws and regulations. Of note, Alabama, Indiana, South Carolina, Washington, and Puerto Rico do not allow automatic substitution by the pharmacist.

» Furthermore, states vary in terms of requirements related to communication and recordkeeping for pharmacy-level switches from a reference product to an interchangeable biosimilar. Nearly all states mandate that pharmacists communicate back to the prescribing physician when substituting with an interchangeable biosimilar. The time frame for such communication varies among states.

Are biosimilars the same as generic medications?

» Biosimilars and generic medications share similarities but differ in their nature. Both are regulated by FDA to ensure safety and efficacy before and after approval, aiming to provide patients with more affordable treatment options. While generic medications typically have identical chemical structures to their brand-name counterparts, all biologics, including biosimilars, may have slight variations from batch to batch, even from the same brand. However, in accordance with FDA regulations, biologic and biosimilar manufacturers must meticulously monitor these differences to ensure they do not impact safety or efficacy.

Are biosimilars safe and effective to use?

» FDA-approved biosimilars are as safe and effective as their reference biologics. They also share the same benefits and risks as reference biologics. To gain approval from FDA, manufacturers must demonstrate that there are no new or worsening adverse effects in patients treated with biosimilars compared to those treated with the reference biologics.

Will my patients' insurance cover biosimilars?

» Insurance plans typically cover biosimilars. As with all prescription medications, understanding insurance coverage and reimbursement is essential for pharmacists to ensure optimal patient care. Various factors, including type of insurance plan and formulary coverage, significantly impact coverage eligibility. Pharmacists can proactively engage with insurance providers and obtain comprehensive information about their patients' plans.

» For patients covered by Medicare and Medicaid, consulting directly with their plan provider can help gather coverage details. Additionally, pharmacists can empower patients by educating them about manufacturer copay cards and patient assistance programs. These resources can help alleviate the financial burden associated with medication costs, ultimately enhancing medication adherence and improving health outcomes.

References

1. Brand Institute. FDA approves Alymsys® (bevacizumab-maly), a biosimilar of bevacizumab by Amneal Pharmaceuticals, Inc., developed by mAbxience. Chicago, IL: PR Newswire; April 18, 2022. Available at: https://www.prnewswire.com/news-releases/fda-approves-alymsys-bevacizumab-maly-a-biosimilar-of-bevacizumab-by-amneal-pharmaceuticals-inc-developed-by-mabxience-301527266.html. Accessed June 1, 2024.
2. Federal Trade Commission. Are you on a biologic medication? What you need to know about biosimilar treatment options. Washington, DC: FTC; February 2023. Available at: https://consumer.ftc.gov/articles/are-you-biologic-medication-what-you-need-know-about-biosimilar-treatment-options. Accessed February 26, 2024.
3. IQVIA Institute. Biosimilars in the United States 2020-2024. Durham, NC: IQVIA; September 29, 2020. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2020-2024. Accessed March 11, 2024.
4. IQVIA Institute. Biosimilars in the United States 2023-2027. Durham, NC: IQVIA; January 2023. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/biosimilars-in-the-united-states-2023-2027/iqvia-institute-biosimilars-in-the-united-states-2023-usl-orb3393.pdf. Accessed April 3, 2024.
5. Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. Washington, DC: MedPAC; June 2023. Available at: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf. Accessed April 3, 2024.
6. Mulcahy AW, Hlavka JP, Case SR. Biosimilar cost savings in the United States: Initial experience and future potential. Rand Health Q. 2018;7(4):3. PMCID: PMC6075809
7. U.S. Food and Drug Administration. Biosimilar and interchangeable biologics: More treatment choices. Silver Spring, MD: FDA; August 17, 2023. Available at: https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed February 26, 2024.
8. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. What are "Biologics"? Questions and answers. Silver Spring, MD: FDA; February 6, 2018. Available at: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers. Accessed February 26, 2024.
9. World Health Organization. Health Topics: Biologicals. Geneva, Switzerland: WHO. Available at: https://www.who.int/health-topics/biologicals#tab=tab_1. Accessed February 26, 2024.

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