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BIOSIMILARS Q&A

Your patients may come to you with questions about available biologics and biosimilars. Below is some general information that can help you respond to patient questions.

Q: What is a biological product?

A: Biological products, or biologics, are used to treat many illnesses, including chronic skin diseases, such as psoriasis; inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis; arthritis; kidney conditions; diabetes; and cancer. Biologics are generally large, complex molecules that are made from living sources such as bacteria, yeast, and animal cells. Because they generally come from living organisms, biologics inherently contain many slight variations from batch to batch, and their structures are generally more complex than those of other medications. As a result, biologics are often more complicated to purify, process, and manufacture. There are many types of biologics approved for use in the United States, such as monoclonal antibodies, insulin, vaccines, and allergenic products.[1]

Q: What is a biosimilar product?

A: A biosimilar is a biologic medication that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biologic, called a reference product.

Compared with a reference product, biosimilars:

- Are made with the same types of living sources
- Are given to the patient in the same way
- Have the same strength, dosage, potential treatment benefits, and potential side effects

A biosimilar may be used in patients who have previously been treated with the reference product (treatment-experienced), as well as in patients who have not previously received the reference product (treatment-naïve).[1]

Q: Are biosimilars the same as generic drugs?

A: Biosimilars are like generic drugs in some ways, because both are versions of brand-name drugs and may offer patients more affordable treatment options. The main difference between biosimilars and generic drugs is that the active ingredients of generic drugs are generally smaller, simpler, and more straightforward to copy. Biologics generally cannot be copied exactly, because

the products usually contain a mix of many slight variations of a protein, and this mix is never exactly the same in each dose or batch of the product.[1]

Q: What is the difference between a biosimilar and an interchangeable biosimilar?

A: All FDA-approved biosimilars, including interchangeable biosimilars, must be highly similar to and have no clinically meaningful differences from the reference product in terms of safety and effectiveness. An interchangeable biosimilar is a biosimilar that meets additional requirements. A pharmacist may substitute an interchangeable biosimilar for its reference product without consulting the prescriber, depending on state pharmacy laws. FDA does not evaluate or approve a biosimilar as interchangeable unless a company requests it. Learn more about interchangeable biological products.[1]

[1] **Reference:** U.S. Food and Drug Administration. Overview for Health Care Professionals. fda.gov/drugs/biosimilars/overview-health-care-professionals. Reviewed August 1, 2024. Accessed April 23, 2026.

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