

THE BASICS OF BIOSIMILARS

Biosimilars are FDA-approved biologic medications that are safe and effective for treating many illnesses.

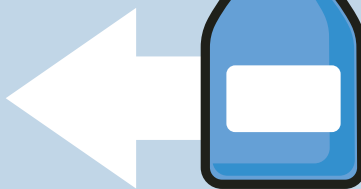
What is a biosimilar?

▶ A biosimilar is a biologic medicine that is

HIGHLY SIMILAR

to a brand name biologic medicine.

Brand name biologic, a.k.a
reference product or originator

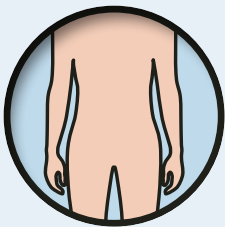


A biologic drug, or biologic, is a drug made from proteins or pieces of proteins (either natural or artificial). Unlike other drugs, biologic drugs must be made in a living system, such as yeast, bacteria, or animal cells.

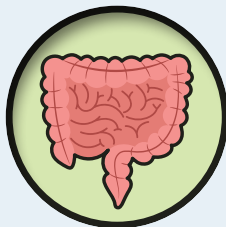
A biosimilar drug, or biosimilar, is a medicine that is very close in structure and function to a biologic drug.

For some brand name biologic drugs, one or more biosimilars are available. A biosimilar drug has a structure that is highly similar to, but not exactly the same, as a brand name biologic drug. A biosimilar behaves in much the same way so that there are “no meaningful differences” between it and its brand name biologic. This means that the biosimilar drug is also considered both safe and effective as the biologic drug. Both come from living systems.

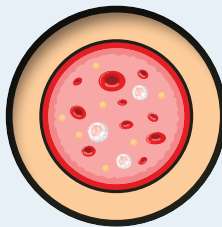
As of October 2021, **31 biosimilars** have received FDA-approval for several indications, including:



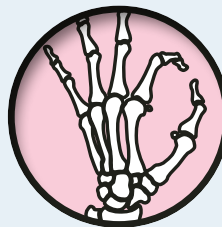
Psoriasis



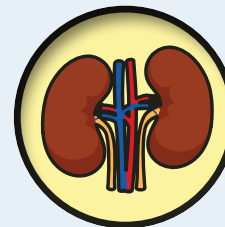
Inflammatory
Bowel Disease



Diabetes



Rheumatoid
Arthritis



Kidney
Conditions



Cancer

Sources: American Cancer Society. (2020). What Are Biosimilar Drugs? Retrieved from <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/what-are-biosimilars.html>. Biosimilars Council. (2021). BIOSIMILARS: A Safe & Effective Option for Patients. Retrieved from <https://biosimilarscouncil.org/wp-content/uploads/2021/10/Biosimilars-Council-Infographic-2021.pdf>. US Food and Drug Administration (FDA). (2021). Biosimilar Product Information. Retrieved from <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>.

Is a biosimilar the same as a generic drug?



A biosimilar drug is a little like a generic version of a biologic drug.

Both are tested and compared in clinical trials to a brand name drug that's already FDA approved. Both go through a thorough but shortened FDA review process compared to their brand name drugs. Both are as safe and effective as their brand name drugs, and both might be less expensive treatment options than their brand name drugs.

However, there are important differences.

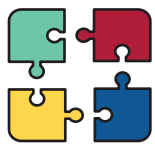
A biosimilar comes from the same natural source and is the same in certain ways as its brand name biologic drug, while a generic is an exact chemical copy of its brand name drug.

Unlike a generic drug, a biosimilar drug is highly similar to its brand name drug, but not be an exact copy of it. Therefore, the FDA often needs more information from biosimilar studies than it needs from studies done on a generic drug.

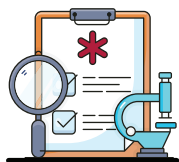
BIOSIMILARS



Have the same safety and efficacy as the brand name biologic



Have the same mechanism of action as the brand name biologic



Undergo rigorous FDA testing and review



Cost less to patients and the health system



Provide the same treatment effects (including side effects) as the brand name biologic

What is an interchangeable biosimilar?

When a generic drug is approved by the FDA, it's usually automatically interchangeable with its brand name drug. Because it is an exact chemical copy, there is no additional information needed by the FDA to show a generic drug is a safe and effective substitute for its brand name drug. This means a prescription written for a brand name drug can usually be filled using a generic drug without notifying the provider who wrote the prescription.

While all biosimilars go through the same initial FDA approval process, and they can be used to treat a disease once they get initial approval, a biosimilar needs another, special FDA approval before it is considered interchangeable and can be substituted automatically for its brand name drug.



Where can I learn more?

Speak to your healthcare provider and/or pharmacist. Additional information is available at: <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>

Sources: American Cancer Society. (2020). What Are Biosimilar Drugs? Retrieved from <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/what-are-biosimilars.html>. Biosimilars Council. (2021). BIOSIMILARS: A Safe & Effective Option for Patients. Retrieved from <https://biosimilarscouncil.org/wp-content/uploads/2021/10/Biosimilars-Council-Infographic-2021.pdf>. US Food and Drug Administration (FDA). (2021). Biosimilar Product Information. Retrieved from <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>.