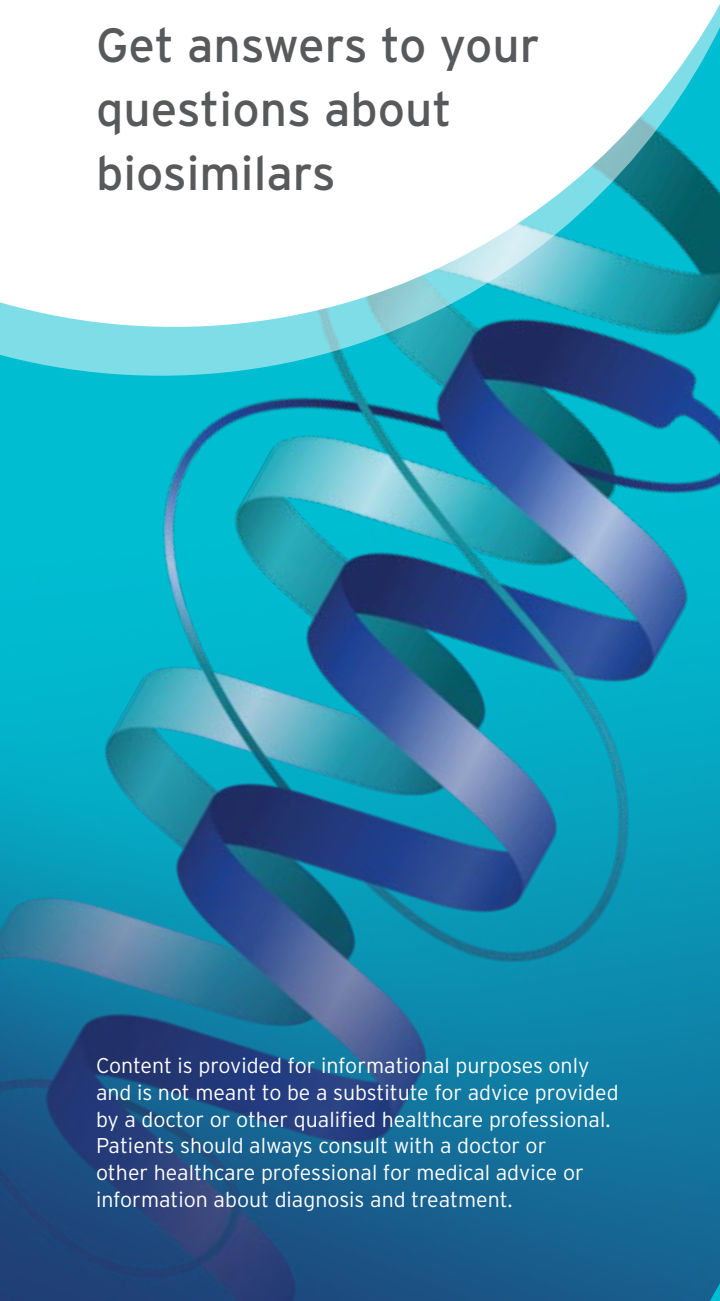
Understanding Biosimilars

Get answers to your questions about biosimilars



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An introduction to biosimilars

Your doctor may want you to begin treatment with a new biosimilar medicine, but if you've never heard of biosimilars before, you may have questions. This brochure may help answer your questions so you can feel more confident taking the next step with your treatment.

What is a biosimilar?

Biosimilars are safe and effective medicines approved by the U.S. Food & Drug Administration (FDA) that are a highly similar version of existing biologic medicines.[1]

What is a reference product? It's the original biologic medicine, already approved by the FDA, to which a proposed biosimilar product is compared.[1]

Biosimilars are used to treat

Rheumatoid arthritis

Cancer

Reference Biologic Medicines[1]

- ✔ FDA-approved
- ✔ Manufactured from living cells such as microorganisms, plant cells, or animal cells
- ✔ Used to diagnose, prevent, treat, and cure serious diseases and medical conditions

Biosimilars[2]

- ✔ FDA-approved
- ✔ Manufactured from living cells such as microorganisms, plant cells, or animal cells
- ✔ Used to diagnose, prevent, treat, and cure serious diseases and medical conditions

many illnesses, including[2]:

Bowel diseases

Other chronic or life-threatening diseases

How do biosimilars work?

Biosimilars are just as safe and effective as reference products, and they work the same way in your body.[1]

- ✔ Same benefits[2]
- ✔ Same potential side effects[2]
- ✔ Same strength and dosage[2]
- ✔ Administered in a similar way*[2]

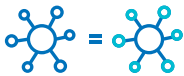
Biosimilars have only minor differences in clinically inactive ingredients as compared to reference products.[1]

Any differences between the proposed biosimilar product and the reference product are carefully evaluated by the FDA to ensure the biosimilar meets its high approval standards.

*Please keep in mind that while the medications are very similar, if your medication is delivered using an advanced device, such as an auto injector, the advanced device appearance and function may differ. Talk to your healthcare team if you have questions.

Are biosimilars the same as generics?

While biosimilars and generic medicines are both versions of brand name drugs, there are important differences between them.[1]

Generic drug[1]

✔ Simple molecule from chemical compounds that are easy to duplicate and manufacture
✔ Identical copy of the brand-name drug
✔ Abbreviated FDA approval process

Biosimilar[1]

✔ A complex molecule from living cells that is harder to duplicate
✔ Highly similar to the reference product
✔ Rigorous FDA approval process

Biosimilars, like generics, may provide patients like you with more affordable access to lifesaving and life-enhancing treatments.[1]

Biologics (including biosimilars) and generics have different manufacturing processes. Generic drugs are considered "simple molecules" which makes it easier to reproduce an exact copy during production. Unlike generics, biologic medicines are made of more complex molecules which requires a different production process to create a highly similar product.[1]

How are biosimilars approved?[1-3]

Biosimilars are approved by the FDA after careful evaluation and thorough testing to confirm that the biosimilar has no clinically meaningful differences in safety or effectiveness.

Biosimilars must:

Meet the FDA's rigorous approval standards

Be manufactured in an FDA-licensed facility

Be checked for medication quality during production

The FDA continues to monitor the safety and effectiveness of biosimilars even after their approval.[2]

Why are biosimilars important?

Biosimilar medicines can help **drive down prices** by introducing **competition**, creating **more options**, and making **medications more accessible** to patients, including those who previously may not have been able to afford them.[2]

By enabling **more patients to have access** to biologics, the availability of biosimilars could result in **improved health outcomes** for patients.[4]

Biosimilars are projected to save the healthcare system $54 billion over a period of 10 years.[5]

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Getting started with biosimilars[1-3]

You can feel more confident in your treatment if your doctor or pharmacist substitutes your biologic medicine for an FDA-approved biosimilar.

Myth: Biosimilars are less safe and effective than reference biologics.
Fact: FDA-approved biosimilars are rigorously tested, reviewed and monitored to demonstrate they are as safe and effective as the reference biologic product.
Myth: Biosimilars don't actually save money.
Fact: Biosimilars offer more choices and may provide significant savings to patients, providers, and the healthcare system.
Myth: Patient support programs only exist for reference biologics.
Fact: Many biosimilar manufacturers offer patient support and financial assistance programs.

Talk with your doctor or healthcare team to get more information about FDA-approved biosimilars.

References:
1. Biological product definitions - Food and Drug Administration. FDA.gov. https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf. Accessed September 7, 2022. **2.** Biosimilar Basics - Food and Drug Administration. FDA.gov. https://www.fda.gov/media/130918/download. Accessed September 7, 2022. **3.** What is a biosimilar? - Food and Drug Administration. FDA.gov. https://www.fda.gov/media/108905/download. Accessed September 7, 2022. **4.** Boccia R, Jacobs I, Popovian R, de Lima Lopes G Jr. Can biosimilars help achieve the goals of US health care reform?. *Cancer Manag Res.* 2017;9:197-205. Published 2017 Jun 1. doi:10.2147/CMAR.S133442. **5.** Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case, Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html.

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