

What are biosimilars?

Biosimilars are drugs that are highly similar to other biologic drugs already approved by the U.S. Food & Drug Administration (FDA).

To understand more about biosimilars, we will first talk about biologics.

What are biologics?

“Bio” in the word biologic means the study of living things. Biologics are drugs made from biological products, such as antibodies and proteins. They can come from all sorts of living things – animal and plant cells, and even bacteria. Biologics include things like vaccines and insulin. A common biologic used to treat HER2-positive breast cancer is trastuzumab (Herceptin®) which is made from antibodies.

How are biosimilars different from generic drugs?

Biosimilars are “generic-like.” They are not the same as generic drugs because they contain biologics. For example, when a generic drug like ibuprofen is made, the active ingredients (chemicals) are exact copies of the brand-name drug. Many brand-name drugs have generic versions.

Biosimilars are made from living things, so there’s no way to make an exact copy of them. All biologics, including biosimilars, may vary slightly from one batch to the next. These small differences don’t affect how they work in the body.

How are biosimilars tested for safety and effectiveness?

Biosimilars can’t be used unless they’ve been approved by the FDA. Strict manufacturing guidelines are required to get FDA approval. Manufacturers must show biosimilars:

- Are as safe as the original biologic
- Are as effective as the original biologic
- Have similar side effects as the original biologic
- Are made from the same biologic (for example, if the original biologic is made from an antibody, the biosimilar must also be made from an antibody)
- Are given the same way as the original biologic (for example, by injection or by vein (through an IV))
- Are given at the same strength and dosage

Once a biosimilar is approved by the FDA, it’s safe to use.



This fact sheet is intended to be a brief overview. For more information, visit [komen.org](https://www.komen.org) or call the Komen Patient Care Center’s Breast Care Helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Thursday, 9 a.m. to 7 p.m. ET and Friday, 9 a.m. to 6 p.m. ET or email at helpline@komen.org. Se habla español.

Resources

Susan G. Komen®

1-877 GO KOMEN
(1-877-465-6636)
komen.org

U.S. Food & Drug Administration (FDA)

1-888-INFO-FDA
(1-888-463-6332)
For more information on biosimilars, click [here](#).

Related educational resources:

- [Treatment Overview for Breast Cancer](#)
- [Biosimilars: What They Are and What You Need to Know \(video\)](#)
- [HER2-Targeted Therapies for Early Breast Cancer](#)
- [Metastatic Breast Cancer: HER2-Targeted Therapies](#)
- [Questions to Ask Your Doctor: Biosimilars](#)

Are biosimilars available today?

Many biosimilars have been approved in the U.S. The FDA-approved biosimilars for breast cancer treatment are all biosimilars to trastuzumab (Herceptin).

Other biosimilars to trastuzumab as well as biosimilars to other drugs used to treat breast cancer are under study.

How much do biosimilars cost?

Due to the complex manufacturing process, biosimilars are costly to produce.

It's unknown how biosimilar costs affect patient costs.

Talk with your doctor

Your doctor can tell you whether a biosimilar may be part of your breast cancer treatment plan. Below are some questions you can ask your doctor about your treatment.

- Will I be getting a biosimilar as part of my treatment?
- Do biosimilars work the same way as the original biologic?
- How will the biosimilar be given?
- What side effects should I report to you?



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