

## 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 an exact copy of the brand named drug. Many brand name drugs have generic versions.

Biosimilars are made in or from living things so there’s not a 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 are 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 given the same way as the original biologic (for example, by injection or by vein (through an IV))



## Resources

**Susan G. Komen®**  
1-877 GO KOMEN  
(1-877-465-6636)  
[komen.org](http://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:

- [Patients' Access to Treatments Webinar-Biosimilars](#)
- [Making Breast Cancer Treatment Decisions](#)
- [Targeted Therapies for HER2-Positive Breast Cancer](#)
- [Questions to Ask Your Doctor: Biosimilars](#)

## Are biosimilars available today?

Many biosimilars have been approved in the U.S., and others are in development. The first FDA-approved biosimilar in the U.S. was a drug to boost white blood cell counts. The FDA-approved biosimilars for breast cancer treatment are all biosimilars to trastuzumab (Herceptin).

## How much do biosimilars cost?

Due to the complex manufacturing process, biosimilars are costly to produce. As more enter the market, competition may bring costs down over time.

It's unknown how biosimilar costs will affect patients.

## 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.

- Am I getting a biosimilar? If so, why?
- Do biosimilars work the same way as the original biologic?
- Why am I being given a biosimilar?
- How will the biosimilar be given? How many treatments will I have?
- What side effects I should report to you?

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