

Clinically Speaking: What Are Biosimilars?

Biosimilars are more affordable than the drugs they're modeled after — and they work just as well. Could they be an option for you? Here's some basic information to help you decide whether biosimilars might be an option for you.

In order to understand biosimilars, you need to first understand biologics.

1. What is a biologic?

Biologics are drugs that are produced from living sources, such as plant cells, animal cells, human cells and even bacteria. They can be composed of sugars, proteins, DNA or whole cells or tissues. In other words, they come from a natural source.

Biologics are used to treat a wide variety of conditions, including autoimmune disorders and diseases such as [rheumatoid arthritis](#), [psoriasis](#), breast cancer and [Crohn's disease](#). Some vaccines are also biologics. Their high price, however, may make them inaccessible. Medications called biosimilars can be used in place of some biologics, offering equally effective treatment at a potentially lower price.

2. What is a biosimilar?

The [U.S. Food and Drug Administration \(FDA\)](#) defines a biosimilar as “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.”

Biosimilars are almost the same as the biologics they're modeled after in terms of safety and function. They aren't considered identical to their biologic counterparts because the complex manufacturing process of biologics means each batch is unique, but they work in the same way. The biggest difference? Biosimilars can be much cheaper than their biologic counterparts.

3. Are biosimilars the same as generic drugs?

[Generic drugs](#) are exact chemical copies that are the same in dosage, safety, effectiveness, strength and quality as brand-name medications. This means a doctor or pharmacist can automatically substitute a generic drug for a brand-name one.

Because of the complex way biosimilars are made, they're very close to the biologic medications they're modeled after — but they're not exactly the same. Therefore, they're not considered to be generic versions of biologics.

4. Are biosimilars as safe and effective as biologics?

Biosimilars are just as safe and effective as biologics. For a biosimilar to be approved by the FDA, it must be shown to have no clinically meaningful differences from its biologic counterpart. “These are drugs that are going to work,” said Lisa Kennedy Sheldon, clinical and scientific affairs liaison at the Oncology Nursing Society. “That's why the FDA has approved them and why we choose them for our patients.”

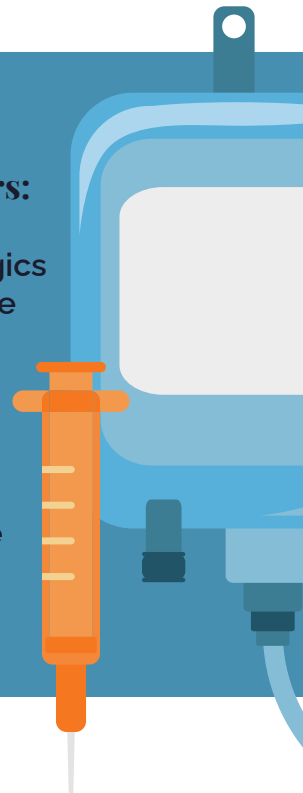
5. How do biosimilars benefit consumers?

Biologics are among the most expensive medications in the world because of the costs associated with their development. Biologics that are used to treat rheumatoid arthritis, for example, can cost [between \\$9,000 and \\$22,000 a year](#).

Because biosimilars are cheaper to produce, they're usually much more affordable for consumers. In 2017, biosimilars were found to be [27% cheaper](#) on average than their biologic counterparts. “The great hope has always been that the production of biosimilars will decrease the cost to the patient,” Kennedy Sheldon said.

Benefits of Using Biosimilars:

- More affordable than biologics but just as safe and effective
- Helpful in treating a variety of conditions, including breast cancer
- Can be used safely at home instead of in the hospital



Breast cancer is one example where biosimilars could be useful. “We now have five biosimilars for trastuzumab (Herceptin), which is used to treat HER2-positive breast cancers, Kennedy Sheldon said. “That’s remarkable.” If you or someone you know has been diagnosed with breast cancer, it’s well worth talking to the care team about biosimilars.

“We also have biosimilars for cancer support that can be subcutaneously [under the skin] injected at home by a trained professional, so women with breast cancer don’t have to come to the hospital and risk COVID-19 or other infections,” Kennedy Sheldon said.

6. Are biosimilars readily available in the United States?

In 2010, the Biologics Price Competition and Innovation Act (BPCIA) was signed into law as part of the Affordable Care Act. The BPCIA makes it easier and cheaper for companies to get their biosimilars approved by the FDA as long as they can prove that the drugs aren’t clinically different from the biologic it’s modeled after.

Still, the United States is lagging behind in biosimilar availability compared to Europe, where around twice as many of these medications are approved for use. This may be due in part to actions taken by some biologics manufacturers to block the availability of biosimilars, including patent-related lawsuits and rebates meant to entice patients to use their brand-name products.

7. Can I safely switch to a biosimilar from a biologic?

This is perhaps the most important question to ask your healthcare provider about biosimilars. If you’re taking a biologic that has an available biosimilar counterpart, you may be able switch with professional guidance.

In a 2018 review, a large majority of publications did not report differences in safety or efficacy between biologics and biosimilars.

8. Are there risks and side effects associated with biosimilars?

Just as with biologics or any drug, the risks and side effects of biosimilars vary depending on the medication and the person, but overall, biosimilars have been proven to be safe, just as biologics have. Your healthcare provider can provide you with information specific to you.

The power of information (and hope)

Information is a powerful tool when it comes to being proactive about your health care. When you know what to ask your provider about biosimilars, you can work together to determine whether they’re an option for you.

Kennedy Sheldon is optimistic about the promise biosimilars hold. “To be able to increase accessibility to care while decreasing cost, along with the potential for home treatment — these are messages of great hope.”



Ask your healthcare provider if biosimilars are right for you.