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## What Are Biosimilar Drugs?

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

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.

Biologic drugs work in many ways. Depending on the drug, it might:

- Stimulate the body's immune system to recognize and kill cancer cells more effectively
- Work against certain proteins in or on cancer cells to stop their growth.
- Stimulate the immune system so it becomes stronger.

[Immunotherapy](#)<sup>1</sup> and [targeted therapy](#)<sup>2</sup> drugs are examples of biologic drugs used in cancer treatment.

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.

### Are biosimilars the same as generic drugs?

You've probably heard about generic drugs. A generic drug is a copy of a brand name drug. Generic drugs work the same way and can be used in the same ways as their

brand name drugs. In other words, a generic drug is an equal substitute for its brand name drug and can be used to treat the same disease.

A biosimilar drug is a little like a generic version of a biologic drug, but there are important differences. For example, unlike a generic drug, a biosimilar is not an exact copy of its brand name drug.

Here are ways biosimilar and generic drugs are alike:

- Both are tested and compared to a brand name drug in clinical trials.
- The brand name drugs they are tested against have already been approved by the Food and Drug Administration (FDA).
- 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.
- Both might be less expensive treatment options than their brand name drugs.

Here are ways biosimilar and generic drugs are different:

- A biosimilar is made from a biologic (natural) source, and a generic is made from chemicals.
- 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.
- The FDA often needs more information from studies comparing a biosimilar to its original biologic than it needs from studies done on a generic drug. This is because a biosimilar comes from a natural source and cannot be made as an exact copy of its brand name drug.
- Biosimilars and generic drugs go through different paths for FDA approval.
- Once approved, a biosimilar needs to have special approval to be considered interchangeable with its brand name biologic drug, while a generic drug can be automatically substituted for its brand name drug.

All of these important differences are due to the way biologic (and biosimilar) drugs are made in the lab using a natural source (a living system such as yeast, bacteria, or animal cells).

### **A biosimilar has a biologic (natural) source**

A generic drug is an *exact* copy (exactly the same in chemical make-up) of its brand name drug. This is possible because the active ingredients in many brand name drugs are made from chemicals that have a specific structure that can be copied. However, a biologic drug comes from a biologic (natural) source that cannot be copied exactly. These drugs come from very complex, living systems whose environments can change. So, while a biosimilar drug actually comes from the same natural source as its brand name drug and is the same in certain ways, it cannot be exactly the same in its structure. Unlike a generic drug, a biosimilar drug is highly *similar* to its brand name drug, but not be an exact copy of it.

### **A biosimilar needs extra FDA approval to be used interchangeably**

When a *generic* drug is approved by the FDA, it's usually automatically *interchangeable* with its brand name drug. 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. Because its active ingredient has the exact same chemical structure, a prescription written for a brand name drug can usually be filled using a generic drug instead. So, a patient who is taking a generic drug can expect the same outcome as if they were taking its brand name drug, and can go back and forth between them (if needed) without seeing a difference.

When a *biosimilar* drug gets its initial FDA approval, it may *not* be automatically interchangeable with its brand name drug. So, while all biosimilar drugs go through the same initial FDA approval process, and they can be used to treat a disease once they get initial approval, it needs another, special FDA approval to be considered interchangeable before it can be substituted automatically for its brand name drug. If a biosimilar drug is not approved as interchangeable, it can still be used but is not considered a substitute for its brand name drug. A biosimilar drug that is not approved as interchangeable needs a prescription to be written specifically for the biosimilar to be used instead of its brand name drug.

There are strict FDA rules that need to be met for a biosimilar drug to be approved as interchangeable. Any biosimilar drug that's approved for use has been shown in data from clinical trials to have be as safe and effective in treating a certain disease as its brand name drug. The company that makes or sponsors the biosimilar drug may decide to only submit data to the FDA for this initial approval. But if the company wants their biosimilar drug to be considered interchangeable (and therefore able to be automatically substituted for its brand name drug), they must submit more information from the clinical trials to the FDA. You can read more about this on the [FDA website](#)<sup>3</sup>.

### **Are biosimilars safe?**

Like other drugs, a biosimilar needs to be tested in [clinical trials](#)<sup>4</sup> and approved by the FDA before it can be used to treat a disease. In clinical trials, the biosimilar is compared to its original biologic drug, which was developed first. The original biologic is a *brand name drug* that has already gone through clinical trials, has been approved, and is being used to treat a disease. The clinical trials are required to test if the biosimilar is safe and effective to treat the same disease as the brand name biologic drug.

The clinical trials that test all drugs are thorough and strict. But the clinical trials that test a biosimilar can move along faster than the clinical trials that were required of the brand name biologic drug when it was being tested. During the studies on the biosimilar, testing is done to be sure it is the same as the brand name drug in certain ways. Testing needs to show that both drugs:

- Are made from the same source
- Have the same dose and strength
- Are given to patients in the same way (for example, by mouth)
- Have the same benefits in treating a disease
- Have the same possible side effects

The data from the studies are carefully reviewed by the FDA to be sure the biosimilar is just as safe and effective as the brand name drug.

A biosimilar drug is tested in clinical trials to make sure it is safe to use in people. If a biosimilar drug is approved by the FDA, this means it has met the strict standards for being safe.

Learn more in [Biosimilar Drug Safety](#)<sup>5</sup>.

## Why are biosimilar drugs being developed?

Biologic drugs are often very expensive because they cost a lot to study and make. Their high cost can often make it hard for a person to use them, even if they might be the best treatment for a disease. To make biologic drugs more affordable and available to more people, Congress passed the Biologics Price Competition and Innovation Act (BPCIA). This act lets the FDA shorten the approval process for biosimilar drugs.

Researchers and Congress think one benefit to biosimilar drugs is that they might lead to lower drug costs by offering patients more options for treatment. Some experts have estimated that biosimilar drugs could reduce the cost of biologics over time by many billions of dollars. But this depends on how many biosimilar drugs are tested, approved,

and become available. It also depends on what types of diseases are able to be treated with biosimilar drugs and how much the approved drugs are used.

## How are biosimilars being used in cancer treatment?

There are many biologic drugs, such as targeted or immunotherapy drugs, now being used to treat cancer, and some have biosimilar versions available. Some biosimilar drugs have been approved to treat certain types of cancer, and some have also been approved to help manage side effects. You can learn more about how different types of cancer are treated in [Cancer A to Z<sup>6</sup>](#) and by talking to your cancer care team.

In the next several years, the number of biosimilar drugs approved to treat cancer is expected to go up. Many experts believe having more biosimilar drugs available can lower the cost of treating some cancers.

Some insurance companies will cover the cost, or part of the cost, of a biosimilar drug. Others might not. If a biosimilar drug is a treatment option for you, it's important to talk to your insurance company about coverage.

## Hyperlinks

1. [www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy.html](http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy.html)
2. [www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy.html](http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy.html)
3. [www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars](http://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars)
4. [www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html](http://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html)
5. [www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/safety.html](http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/safety.html)
6. [www.cancer.org/cancer.html](http://www.cancer.org/cancer.html)

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