Biosimilar Drugs

Biosimilars are medicines that are very similar in structure and function to biologics, which are medicines made in living systems (such as yeast, bacteria, or animal cells). Biologics and their biosimilars can be used to treat some diseases, including certain types of cancer. Learn more about them here.

- What Are Biosimilar Drugs?
- List of Biosimilars Used in Cancer Treatment
- Biosimilar Drug Safety

What Are Biosimilar Drugs?

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

A *biologic,* or *biologic drug,* is a medicine made in a living system, such as yeast, bacteria, or animal cells.

Biologics used in the treatment of cancer can work in many ways. For example, they might:

- Help the body's immune system recognize and kill cancer cells more effectively
- Work against certain proteins in or on cancer cells to stop their growth
- Help the body make more blood cells to replace the ones lost because of other cancer treatments

Immunotherapy[1] and some targeted therapy[2] drugs are examples of biologics used in cancer treatment.

For some brand name biologics, one or more biosimilarsare available. A biosimilar has a structure that is highly similar to, but not exactly the same, as a brand name biologic. 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 is also considered as safe and effective as the biologic. Both come from living systems.

Are biosimilars the same as generic drugs?

You've probably heard about generic drugs. A generic drug is an exact 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 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 studies.
- The brand name drugs they are tested against have already been approved by the US 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, while a generic drug is made from chemicals.
- A biosimilar is the same in many 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 biologic.
- 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, while a generic drug can be automatically substituted for its brand name drug. (This is discussed below.)

All of these differences are due to the way biologics (and biosimilars) 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* of its brand name drug (that is, it has the exact same chemical makeup). This is possible because the active ingredients in drugs are made from chemicals that have a specific structure that can be copied.

However, a biologic comes from a biologic (natural) source that cannot be copied exactly. These medicines come from very complex, living systems whose environments can change. So, while a **biosimilar** is the same in the most important ways, it cannot be exactly the same in its structure.A biosimilar is *highly similar* to its brand name drug, but not 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** gets its initial FDA approval, it's *not* automatically interchangeable with its brand name biologic. While biosimilars can be used to treat a disease once they get initial approval, they need another, special FDA approval to be considered interchangeable before they can be substituted automatically for a brand name biologic. If a biosimilar is not approved as interchangeable, it needs a prescription to be written specifically for the biosimilar to be used instead of its brand name biologic.

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

Are biosimilars safe?

Like other medicines, a biosimilar needs to be tested in clinical trials[4] 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, 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. Clinical trials are then needed to test if the biosimilar is as safe and effective in treating the same disease as the brand name biologic.

The clinical trials that test all drugs and biologics 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 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 biologic in certain ways. Testing needs to show that both medicines:

- 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 biologic.

If a biosimilar is approved by the FDA, this means it has met the strict standards for being safe.

Learn more in Biosimilar Drug Safety.

Why are biosimilars being developed?

Biologics are often very expensive because they cost a lot to study and make. And unlike the case with drugs, where generic versions can lead to increased competition and lower prices, until fairly recently there were no alternate versions of biologics.

The high cost of biologics can sometimes make it hard for a person to get 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 let the FDA create a shortened approval process for biosimilars.

Some experts have estimated that biosimilars could reduce the cost of biologics over time by many billions of dollars. But this depends on how many biosimilars are approved and become available. It also depends on what types of diseases can be treated with biosimilars and how much these medicines are used.

How are biosimilars being used in cancer treatment?

There are many biologic medicines, such as immunotherapy drugs, now being used to treat cancer, and some have biosimilar versions available. Some biosimilars have been approved to treat certain types of cancer, and some have been approved to help manage side effects. To find out more, see the List of Biosimilars Used in Cancer Treatment.

You can also learn more about how different types of cancer are treated in Cancer A to Z[5] and by talking to your cancer care team.

Are biosimilars covered by insurance?

Some insurance companies will cover the cost, or part of the cost, of a biosimilar. Others might not. If a biosimilar 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
2. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy.html
3. www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
4. www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html

5. www.cancer.org/cancer.html

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Comprehensive Cancer Network. 2011;9(S4).

Last Revised: April 27, 2022

List of Biosimilars Used in Cancer Treatment

A **biologic** is a medicine that is made in a living system, such as yeast, bacteria, or animal cells. A **biosimilar** is a medicine that is very close in structure and function to a specific biologic medicine (also known as the *reference product*). The biosimilar has a structure that is highly similar to, but not exactly the same as, the brand name biologic. A biosimilar behaves in much the same way, so that there are "no meaningful differences" between it and the original biologic. To learn more, see What Are Biosimilar Drugs?

Biosimilars used in cancer treatment

For some brand name biologics used in the treatment of cancer, one or more biosimilars are now approved for use by the US Food and Drug Administration (FDA).

Biosimilars for the biologic medicine **bevacizumab (Avastin):**

- Mvasi
- Zirabev
- Alymsys

Biosimilars for the biologic medicine **rituximab (Rituxan):**

- Truxima
- Ruxience
- Riabni

Biosimilars for the biologic medicine **trastuzumab (Herceptin):**

- Ogivri
- Herzuma
- Ontruzant
- Trazimera
- Kanjinti

Biosimilars for the biologic medicine **filgrastim (Neupogen):**

- Zarxio
- Nivestym
- Releuko

Biosimilars for the biologic medicine **pegfilgrastim (Neulasta):**

- Fulphila
- Udenyca
- Ziextenzo
- Nyvepria

Biosimilar for the biologic medicine **epoetin alfa (Epogen):**

- Retacrit

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Last Revised: April 27, 2022

Biosimilar Drug Safety

A biosimilar drug is a type of biologic drug — a medicine made from a biological or natural source. A biosimilar drug is a safe and effective, high-quality treatment that is "highly similar with no meaningful clinical differences" to a brand name biologic drug that's used to treat a certain disease.

Are biosimilar drugs safe?

There are strict rules about how a biosimilar drug is tested for its safety, and what that testing needs to show. Just like any drug, a biosimilar drug is tested in clinical trials to make sure it is safe to use in people. The data from the clinical trials are carefully reviewed by the Food and Drug Administration (FDA) to be sure the biosimilar drug is just as safe and effective as its brand name biologic drug. If a biosimilar drug is approved by the FDA, this means it has met the strict standards for being safe. Learn more about how a biosimilar drug is tested in What Are Biosimilar Drugs?

After a drug gets FDA approval to treat a certain type of cancer and is "on the market," doctors can start using it. Doctors and other members of the cancer care team often give the FDA feedback about how they're using drugs to treat people with cancer. This data is called *post-marketing information.* This information helps the drug companies and the FDA make sure drugs are still safe, meaning they are doing what they're supposed to do and aren't causing more side effects than what clinical trials showed. Just like for other drugs used to treat cancer, post-marketing information is collected for biosimilar drugs.

Are special precautions needed for biosimilar drugs?

Much is known about the need to protect others from exposure to chemotherapy (chemo) because it can be dangerous. This is why there are safety rules and recommendations for people who handle chemo drugs. However, because biologic (and biosimilar) drugs are newer, there is not as much information about long-term effects of exposure. To be safe, many experts recommend treating biologic drugs, including biosimilars, as hazardous and taking the same precautions as when handling chemotherapy. This is especially true because many biologic drugs are given along with other drugs that are known to be hazardous, so your cancer care team will take precautions to protect themselves and others from exposure to them. You can read more in Targeted Therapy Safety[1].

Hyperlinks

1. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-

therapy/safety.html

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Last Revised: March 9, 2020

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