



Drugs are made in different ways. Biologic drugs are made by or from cells or tissue. Many of the drugs used to treat cancer are biologic drugs.

A biosimilar drug is a very similar copy that has the same effect as an already approved biologic drug. This booklet explains:

- How biosimilar drugs are made (p. 2)
- How they are approved by the U.S. Food and Drug Administration (FDA) (p. 3)
- How they are prescribed (p. 5)

You may be considering a biosimilar because your insurance covers it or because the copay is less. This booklet will help you understand more about this treatment option. Knowing what biosimilars are and how they work can help you feel more confident about the cancer care you receive.

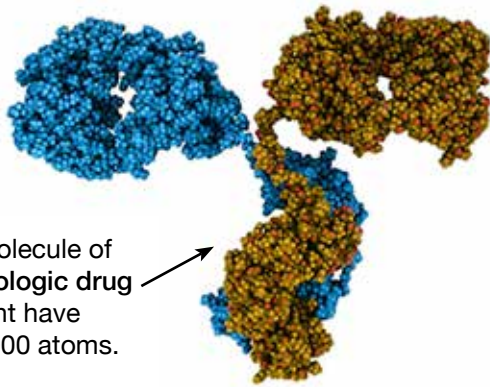
What Is a Biosimilar Drug?

To understand what a biosimilar drug is, you first have to know how drugs are made. You also have to know what a biologic drug is.

Many drugs are made from chemicals. Aspirin and chemotherapy are two types of chemical drugs. A biologic drug is made by or from living cells or tissue. Some of the newest drugs used to treat cancer are biologic drugs. This includes immunotherapies and targeted therapies.

Biologic drugs are much larger and more complex than drugs made from chemicals.

A molecule of aspirin is made of 21 atoms.

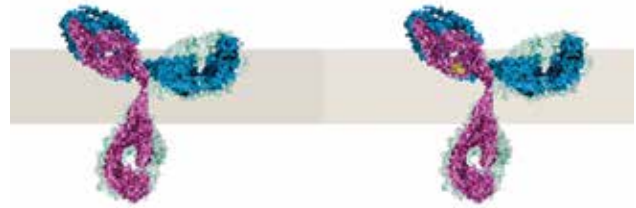


A molecule of a biologic drug might have 25,000 atoms.

Because they are so complex, different batches of the same biologic drug have small differences. These differences do not affect how it works in your body.

When a new manufacturer wants to make a copy of a biologic drug, they make a biosimilar—a very similar copy of the original biologic drug. In the same way that each batch of biologic drugs is very similar to the others, biosimilars are also very similar to the original biologic drug.

Biosimilars work the same way in your body, are just as safe, and have the same potential side effects as their original drug.



A biosimilar drug (on the left) is a copy version of an original biologic drug (on the right).



Biosimilars are not EXACT copies, but are very similar. Any difference has no effect on safety or how well they work.

GLOSSARY OF TERMS

You will hear many words used to talk about biosimilars. Some key ones are:

BIOLOGIC DRUG: A drug that is made by or from a living organism.

BIOSIMILAR: A copy of a biologic drug made by a new manufacturer. It is a very similar copy of the original biologic drug. Biosimilars work the same way in your body, are just as safe, and have the same potential side effects as their original biologic drug.

BIOLOGIC DRUGS THAT TREAT CANCER

Biologic drugs are used to prevent and treat diseases. Many biologic drugs are used to treat cancer and other conditions. These include:

- **bevacizumab (Avastin®)** – Used to treat brain, colorectal, lung, ovarian, and certain other cancers
- **cetuximab (Erbix®)** – Used to treat colorectal and head and neck cancers
- **trastuzumab (Herceptin®)** – Used to treat HER2+ breast and gastric cancers
- **rituximab (Rituxan®)** – Used to treat certain types of blood cancers



Biosimilars for some of these drugs have been approved by the FDA. (See page 7 for a list.)

How Is a Biosimilar Approved?

In the United States, the FDA must approve a drug before it can be prescribed by a doctor. Drug makers conduct laboratory studies to develop new drugs. Then, the drugs are studied in humans (in clinical studies) to learn

if they are safe and effective. A generic drug is an exact copy of a brand name chemical drug that has already been approved by the FDA. Since it is an exact copy, the FDA requires fewer clinical studies for the generic drug to get approved. This is one reason why generic drugs cost less than brand-name drugs.

Before the FDA approves a biosimilar, the drug must undergo a series of tests, including clinical studies to show that the biosimilar is:

	Meets FDA's rigorous approval standards	Safe option for patients	Effective option for patients
Original Biological	✓	✓	✓
Biosimilar	✓	✓	✓

- As safe as the original (reference) drug
- As effective (works as well) as the original drug
- Used in the same way
- Made at the same dose and strength
- Used to treat some of the same diseases
- Have the same potential side effects

Drug Names

All chemical drugs have two names—a brand name and a “generic” name. For example, Tylenol® is the brand name for the drug acetaminophen. You take the exact same drug whether you buy the brand Tylenol or a generic copy of the drug sold as acetaminophen.

Biologic drugs also have brand names and core or “generic” names. Neupogen® is the brand name for the biologic drug filgrastim.

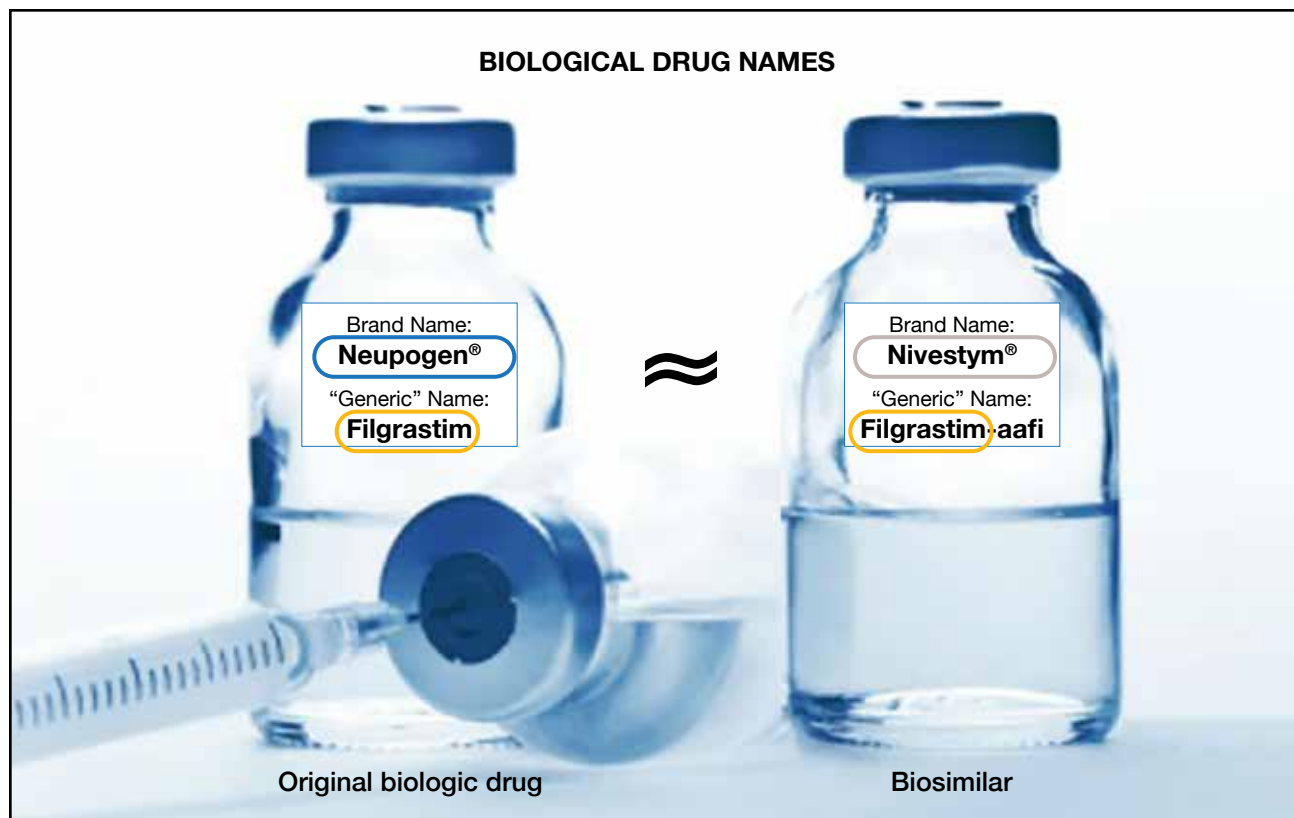
A biosimilar will have a different brand name than its original biologic drug. But it will have the same “generic” name as the original drug, followed by a dash and four letters selected by the FDA at random.

For example, filgrastim-aafi (Nivestym®) is a biosimilar for the original biologic drug filgrastim (Neupogen). Both drugs are used in the same way at the same dose. Both work equally well.

CHEMICAL DRUG NAMES



BIOLOGICAL DRUG NAMES



Changing a Prescription

A doctor writes a prescription for a specific drug. If it is a chemical drug, the pharmacist can give you the brand-name drug or the generic drug without talking to your doctor. (This is often done for cost or insurance reasons.) That's because the brand-name drug and the generic drugs are the exact same chemical. If you are prescribed a biologic drug, your pharmacist may need to talk to your doctor before they can give you a biosimilar instead of the original drug.

Your insurance may cover the original biologic drug your doctor prescribed. They may cover the biosimilar. Or, they may cover both.

Both the original biologic drug and the biosimilar will be used in the same way, at the same dose, have the same potential side effects, and be equally effective. The retail price for a biosimilar may be about 15% to 30% less than the original drug. The cost to you for either the original biologic or the biosimilar may vary. Talk to an oncology social worker, financial navigator, or another member of your cancer care team to see if you qualify for a patient assistance program that may be able to help you afford the original biologic or the biosimilar.

If you need your prescription changed to a biosimilar for insurance purposes, your pharmacist may need to notify your doctor and you before they can switch. Laws vary by state. Check with your pharmacist if you need your prescription changed.

Q&A: BIOSIMILARS AND THE FDA

How does the FDA make sure a biosimilar drug is as effective as the original biologic drug? The Cancer Support Community asked the FDA to tell us.

Q: WHAT DOES THE FDA DO?

A: The FDA is responsible for promoting and protecting the public health. We oversee the approval of drugs, biological products, and medical devices.

Q: HOW ARE BIOSIMILARS MADE?

A: The manufacturer of a biosimilar product is trying to make a copy version of a biological product. They take apart the reference (original) product and look at its structure and how it works. Then they develop a product that will be a copy version of that product. The copy version must have the same safety and effectiveness as the reference product.

Q: ARE BIOSIMILARS SAFE?

A: Yes. A patient who is treated with a biosimilar drug can expect the same results. The FDA will not approve a biosimilar if it does not meet our standards.

Biosimilar Drugs Used in Cancer

Biosimilars were first approved for use in Europe in 2006. They have been used in the United States since 2015. On page 7 are the biosimilars that have been approved in the United States to treat cancer or manage treatment-related side effects. This table

lists FDA-approved biosimilars for drugs used in cancer care as of January 2021. If you are interested, check with your doctor to see which, if any, are available and approved for your type of cancer. You can find the most recent list of approved biosimilar drugs on our website at www.CancerSupportCommunity.org/biosimilars.



ANTI-CANCER THERAPIES

(As of January 2021)

ORIGINAL BIOLOGIC DRUG	BIOSIMILAR(S)
<ul style="list-style-type: none"> • bevacizumab (Avastin®) <ul style="list-style-type: none"> - Used to treat certain types of brain, cervical, colorectal, kidney, lung, and ovarian/fallopian/peritoneal cancer 	<ul style="list-style-type: none"> • bevacizumab-awwb (Mvasi®) • bevacizumab-bvzr (Zirabev™)
<ul style="list-style-type: none"> • trastuzumab (Herceptin®) <ul style="list-style-type: none"> - Used to treat HER2+ breast and HER2+ metastatic gastric cancers 	<ul style="list-style-type: none"> • trastuzumab-pkrb (Herzuma®) • trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-qyyp (Trazimera™)
<ul style="list-style-type: none"> • rituximab (Rituxan®) <ul style="list-style-type: none"> - Used to treat adults with certain types of B-cell non-Hodgkin's lymphoma and chronic lymphocytic leukemia 	<ul style="list-style-type: none"> • rituximab-arrx (Riabni™) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®)

SUPPORTIVE CARE DURING CANCER TREATMENT

(As of January 2021)

ORIGINAL BIOLOGIC DRUG	BIOSIMILAR(S)
<ul style="list-style-type: none"> • epoetin alfa (Epogen®) <ul style="list-style-type: none"> - Used to stimulate red blood cell growth in patients that develop anemia (a low red blood cell count) while on chemotherapy 	<ul style="list-style-type: none"> • epoetin alfa-epbx (Retacrit®)
<ul style="list-style-type: none"> • pegfilgrastim (Neulasta®) <ul style="list-style-type: none"> - Used to stimulate white blood cell growth to fight infections during cancer treatment 	<ul style="list-style-type: none"> • pegfilgrastim-jmdb (Fulphila®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-bmez (Ziextenzo®)
<ul style="list-style-type: none"> • filgrastim (Neupogen®) <ul style="list-style-type: none"> - Used to stimulate white blood cell growth to fight infections during cancer treatment 	<ul style="list-style-type: none"> • filgrastim-aafi (Nivestym®) • filgrastim-sndz (Zarxio®)

Biosimilar Information and Resources

Cancer Support Community

www.CancerSupportCommunity.org/biosimilars

ACS Cancer Action Network

www.fightcancer.org/policy-resources/understanding-biologic-and-biosimilar-drugs

American Pharmacists Association (APhA)

www.pharmacist.com/biosimilar-basics-patients

U.S. Food and Drug Administration (FDA)

www.fda.gov/biosimilars

Cancer Support Community Resources

Cancer Support Helpline® — Have questions, concerns or looking for resources? Call CSC's toll-free Cancer Support Helpline (888-793-9355), available in 200 languages Mon - Fri 9am - 9pm ET.

Open to Options® — Preparing for your next appointment? Our trained specialists can help you create a list of questions to share with your doctor. Make an appointment by calling 888-793-9355 or by contacting your local CSC or Gilda's Club at www.CancerSupportCommunity.org/FindLocation.

Frankly Speaking about Cancer® — Trusted information for cancer patients and their loved ones is available through publications, online, and in-person programs at www.CancerSupportCommunity.org/FSAC.

Services at Local CSCs and Gilda's Clubs — With the help of 170 locations, CSC and Gilda's Club affiliates provide services free of charge to people touched by cancer. Attend support groups, educational sessions, wellness programs, and more at a location near you.

Cancer Experience Registry® — Help others by sharing your cancer patient or cancer caregiver experience via survey at www.CancerExperienceRegistry.org.

MyLifeLine — CSC's private, online community platform allows patients and caregivers to easily connect with friends and family to receive social, emotional, and practical support throughout the cancer journey and beyond. Sign up at www.MyLifeLine.org.

Grassroots Network — Make sure your voice is heard by federal and state policy makers on issues affecting cancer patients and survivors by joining our Network at www.CancerSupportCommunity.org/become-advocate.

FRANKLY SPEAKING ABOUT CANCER: BIOSIMILARS PROGRAM PARTNERS:



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The Cancer Support Community and its partners provide this information as a service. This publication is not intended to take the place of medical care or the advice of your doctor. We strongly suggest consulting your doctor or other health care professionals to answer questions and learn more.

This booklet is available to download and print yourself at www.CancerSupportCommunity.org/biosimilars. For print copies of this booklet or other information about coping with cancer, visit Orders.CancerSupportCommunity.org.

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