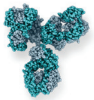
Biosimilars:
An Introduction for Patients

Brought to you by Pfizer Biosimilars

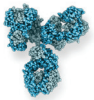
What are biosimilars?

Biosimilars are FDA-approved medicines that are highly similar to existing biologic medicines

Biologic medicines are drugs that are made from living cells. This is in contrast to small-molecule drugs like aspirin, which are made using a chemical process. Biologic medicines have revolutionized the treatment of a wide range of different life-threatening and chronic diseases, including cancer, rheumatoid arthritis, inflammatory bowel disease, diabetes, and cardiovascular diseases.



Biosimilars are highly similar versions of existing biologic medicines.



Reference products are FDA-approved biologic medicines that biosimilars are compared to.

An FDA-approved biosimilar product can be prescribed in place of its reference product

Biosimilars are not generic drugs

Generic medicines are exact copies of small-molecule drugs manufactured by a chemical process, whereas biosimilars are highly similar versions of biologics. Because biologics come from living cells, it is impossible to create exact copies of them. Therefore, they are not considered generics.

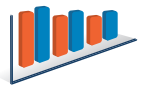
Even though biosimilars are not exact copies, they are designed to have no meaningful differences in safety and effectiveness from the reference product

Biosimilars must meet strict standards established by the FDA

Evaluated by the FDA to assure patients of effectiveness, safety, and quality of biosimilars

The FDA evaluates biosimilars through a unique and thorough process. This process helps ensure the development and approval of high-quality biosimilar medicines that have no meaningful differences in safety and effectiveness from the reference products.

To gain FDA approval, when compared to its reference medicine, a biosimilar must



Scientifically demonstrate safety and effectiveness

Show no clinically meaningful differences

Work the same way in the body

Have the same dosage form and route of administration

Biosimilars must be manufactured according to the same standards as other FDA-approved biologics

The manufacturing of biologics, including biosimilars, is strictly regulated by the FDA. This means that biosimilar manufacturers must demonstrate consistency and control over the manufacturing process in the same way the makers of reference products do.

Comparable safety and effectiveness to the reference biologic medicine

Biosimilar medicines have been prescribed outside the US for over 10 years

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Biosimilars in patient care

Biosimilars are designed to have no meaningful differences from their reference products in terms of safety and effectiveness

Biosimilars must demonstrate that they have no clinically meaningful differences from their reference products in terms of safety and effectiveness. They would be expected to work the same way as the original medicines.

Biosimilars are given the same way as their reference medicines

Biosimilars are dosed and taken the same way as their reference products.

For more information on biosimilars, please visit PfizerBiosimilars.com

Whether you are starting on or switching to a biosimilar medicine, remember that biosimilars are

- FDA-approved
- Highly similar to their reference products and have been shown in studies to have no meaningful differences in safety and effectiveness
- Taken and dosed the same way as their reference products
- A potential way to make biologic medicines more available and lower out-of-pocket costs for certain patients with cost-sharing requirements

Questions? Ask your doctor

Your doctor or healthcare provider may be able to answer your questions or direct you to helpful resources and educational materials about biosimilars. Based on your medical history and diagnosis, your doctor will determine if a biosimilar is the most appropriate option to help treat your condition and manage your symptoms, whether you are new to therapy or currently taking a biologic.

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How biosimilars may help bring value to patients

Biosimilars may improve access to biologics

Biosimilars have the potential to make a positive impact on patients by offering additional treatment choices to patients, physicians, and payers at a lower cost to the healthcare system. These savings to the healthcare system may enable more patients to have access to biologics, which could result in improved health outcomes for patients.

Biosimilars may help reduce the out-of-pocket costs of biologic medicines

One of the main reasons biosimilars were introduced in the United States was to potentially lower healthcare costs. As such, it is expected that healthcare providers, such as clinics or hospitals, will be able to acquire biosimilars at a lower wholesale cost than their reference products. Because of this, biosimilars may have the potential to lower out-of-pocket costs for patients with cost-sharing requirements, such as coinsurance and co-payments.

For example, **patients who may pay less in the form of coinsurance include**

- **Patients covered by Medicare Part B who don't have supplemental insurance** and typically pay 20% of the Medicare-approved amount for most outpatient therapies
- **Patients with private insurance who are required to pay coinsurance** for specialty drugs, including biologics

Even **patients who don't have a cost-sharing requirement** may benefit from biosimilars, as savings to the healthcare system could potentially be reinvested in other areas of patient care.

Check with your healthcare provider or insurance company about your coverage details.

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Glossary

Biologic medicines
Highly complex medicines that are made from living cells. Biologic medicines are used to treat a wide range of diseases.

Biosimilars
Biosimilars are highly similar to the original biologics. Although it is impossible to produce an identical copy of any biologic medicine, a biosimilar must be proven to show no clinically meaningful differences from a reference product.

No clinically meaningful differences
Any differences between a biosimilar and the reference product would not be expected to have a noticeable impact on efficacy or safety.

Effectiveness
The ability of a medicine to produce the desired effect.

Generic drug
A generic drug is the same as a brand-name drug in terms of dosage, safety, strength, route of administration, quality, performance, and intended use. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand-name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference from the brand-name product.

Reference product
An FDA-approved biologic medicine that a biosimilar is compared to.

Small-molecule drugs
Medicines of a relatively small size that are made using a chemical process. Aspirin and many other common medicines are small-molecule drugs.

Biosimilars are approved based on studies showing no meaningful differences to existing reference medicines and are

- FDA-approved
- Rigorously studied and analyzed
- Made to work the same way as their reference products
- Highly similar in terms of safety and effectiveness
- Used to treat a wide range of life-threatening and chronic diseases

Biosimilars have the potential to make biologic medicines more available and lower out-of-pocket costs for certain patients with cost-sharing requirements

Talk with your doctor if you have questions about biosimilars

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