

Biosimilars

What Is a Biologic?

It is a medicine made with cells using advanced technology. Biologics are used in many different diseases, and they are used often in rheumatic diseases. To make a biologic for rheumatic disease (like rheumatoid arthritis), cells are changed so they can decrease inflammation in different parts of the body by interfering with the way cells talk to each other.

What Is a Biosimilar?

It is a biologic medicine that is a close copy, but not an identical copy of a biologic. Biosimilars are tested over many years to make sure they work the same and are as safe as the original medicine. All biosimilars are reviewed by the U.S. Food & Drug Administration (FDA) and are only approved if they are just as safe and helpful as the original biologic.

Biosimilars and the original biologic have the same risks and benefits, and the same strength and dosage.

Are Biosimilars the Same as Generic Drugs?

Biosimilars are not the same as generic drugs because generic drugs are an identical copy of the reference product, sometimes known as a “brand name” product. Biologic drugs, which biosimilars are based on, are designed differently than other drugs, making it impossible to create an identical copy.

Here’s a good example: If you asked two people to build a building from the same set of blueprints, the buildings will look the same, be the same height, and have the same number of rooms. But they might have different paint colors, doorknobs, or other small differences. However, these small differences do not change the function of the building, and it would look the same from the outside. This is the same way the slight differences in biosimilars do not affect the drug’s function.

Are Biosimilars Safe?

Yes. The FDA requires a strict review process to make sure the biosimilar is safe and matches as closely as possible to the biologic it is based upon.

For FDA approval, a biosimilar must be tested and go through many clinical trials with a wide range of patients. When this testing is done, the results must match up to the original drug to make sure they are safe and effective, with no significant differences from the original.

Do All Biologics Have a Biosimilar Option?

No. For rheumatic diseases, there are a few biologic drugs with biosimilar options available. These drugs treat diseases such as rheumatoid arthritis, lupus, certain forms of vasculitis, inflammatory muscle diseases, psoriatic arthritis, juvenile idiopathic arthritis, Crohn’s disease, ulcerative colitis, and ankylosing spondylitis. However, biosimilars are a growing part of treatment as more options become available.

How Do You Take It?

Biosimilars can be given by intravenous (IV) infusion (usually given in a hospital or clinic by a nurse) or by an injection under the skin. The injection can be given at home or in a clinic depending on the medication. The frequency and dose depend on the specific biosimilar drug prescribed and should be taken under the direction of a rheumatology healthcare provider.

When Should a Patient Start or Switch to a Biosimilar?

The decision to start or switch to a biosimilar should be made with a rheumatology healthcare provider so that you can discuss if it is right for you. The biosimilar and the original biologic may have different prices. Patients should talk to their rheumatologist and insurance provider for cost details.

Additional Resources

- [ACR Biosimilars Position Statement](#)
- [ACR on Air Podcast, Episode 48: Biosimilars](#)

Sources:

- [Arthritis Foundation Drug Guide: Biosimilars](#)
- [GoodRx Health: What Are Biologics and Biosimilars? Definitions and Examples](#)
- [U.S. Food & Drug Administration: Biosimilar Basics for Patients](#)

Written July 2023 by the American College of Rheumatology Committee on Rheumatologic Care and reviewed by the American College of Rheumatology Communications and Marketing Committee.

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