

Plain Language Summary

Biosimilar medicines: what are they and how are they used?

Date of summary: November 2022

- This summary talks about article 1 in the supplement *Biosimilars for Immune-Mediated Inflammatory Diseases: 2022 Update*, a collection of articles written for managed care professionals.
- The medicines in this summary are approved to treat many diseases that are mediated by the immune system.



How to say:

Adalimumab = ad-a-lim-moo-mab

Ankylosing spondylitis = an-kee-loh-zing spon-dee-ly-tiss

Biologic = bye-oh-lo-jik

Biosimilar = bye-oh-sim-e-lar

Crohn = crone

Extrapolation = ex-trap-o-lay-shon

Immune = imm-yoon

Inflammatory = in-flam-ah-tor-ee

Insulin glargine = in-suh-lin glar-jeen

Interchangeable = in-ter-change-a-bull

Plaque psoriasis = plak saw-ry-a-siss

Psoriatic = saw-ree-a-tik

Rheumatoid = roo-muh-toyd

Ulcerative colitis = ul-ser-a-tiv col-ly-tiss

What did this article look at?



- This article talks about biosimilars. Biosimilars are a group of biologic medicines that are highly similar to an already approved biologic medicine (also known as the reference biologic or reference product).



The article looks at the biosimilars available for the treatment of immune-mediated inflammatory diseases caused by problems with the immune system.

- Inflammation is a natural process that occurs when areas of the body become damaged or infected. It can cause redness, swelling, pain, and/or a feeling of heat.
- In people with autoimmune diseases, inflammation can occur even in the absence of damage or infection.
- Autoimmune inflammatory diseases include diseases of the joints (eg, rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis), skin disease (eg, plaque psoriasis), and diseases affecting the gut (eg, Crohn disease and ulcerative colitis).



What are biosimilars?

- Biologic medicines (biologics) are made from natural and living sources such as animals and plants, or microorganisms such as bacteria or yeast.
- Biologic medicines are usually more complicated than other medicines and therefore more difficult to make.
- Biologics are usually given by injection or infusion directly into the vein and can be used to treat a range of different diseases.
- To be considered a biosimilar, a biologic must provide the same treatment benefits and be as safe as the reference biologic (ie, the original medication).
- In the United States, biosimilars are approved by the FDA after testing.
- The FDA is the government body responsible for approving all medicines for public use in the United States.
- The approval and use of biosimilars has been quicker to progress in Europe, where many biosimilars are already approved and being used in patients.

How does a biosimilar compare with the reference biologic?



- Made with the same types of natural sources as the reference biologic.



- Works in the same way as the reference biologic.



- Given in the same way as the reference biologic (usually by injection).



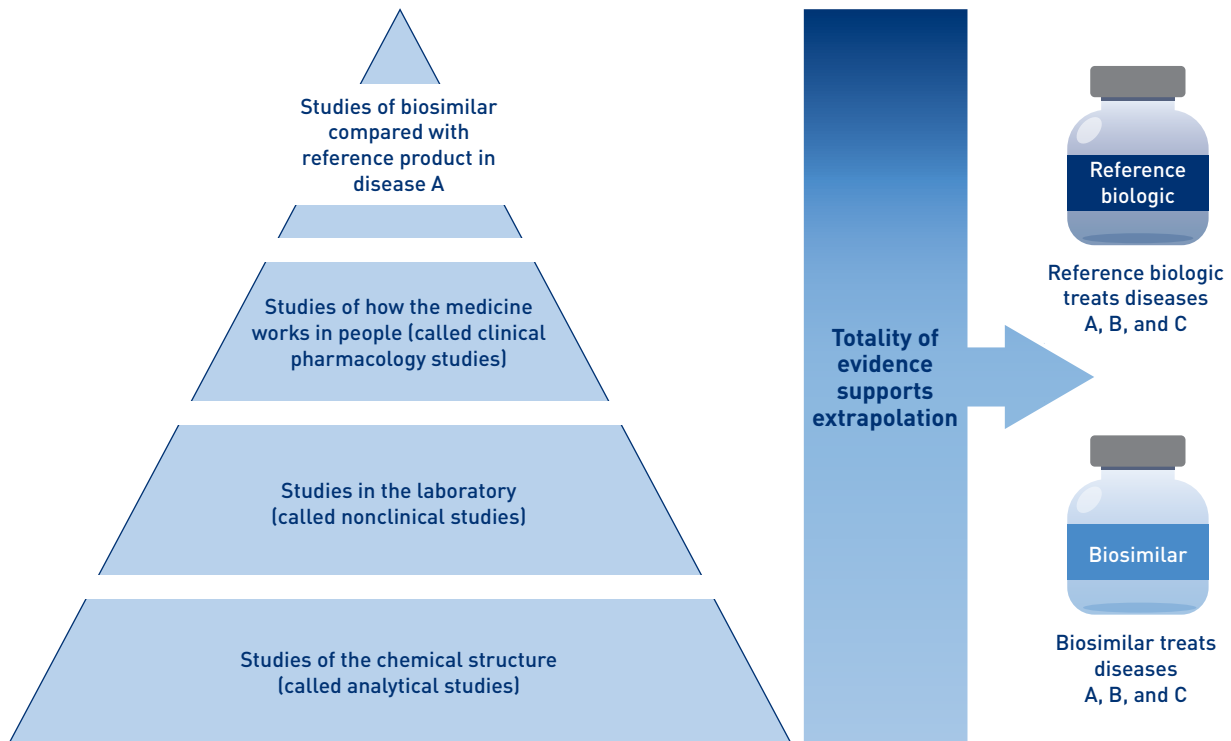
- Provides the same treatment benefits and has the same potential side effects as the reference biologic.



- Has the same strength and dosage as the reference biologic.

What do extrapolation and 'totality of evidence' mean?

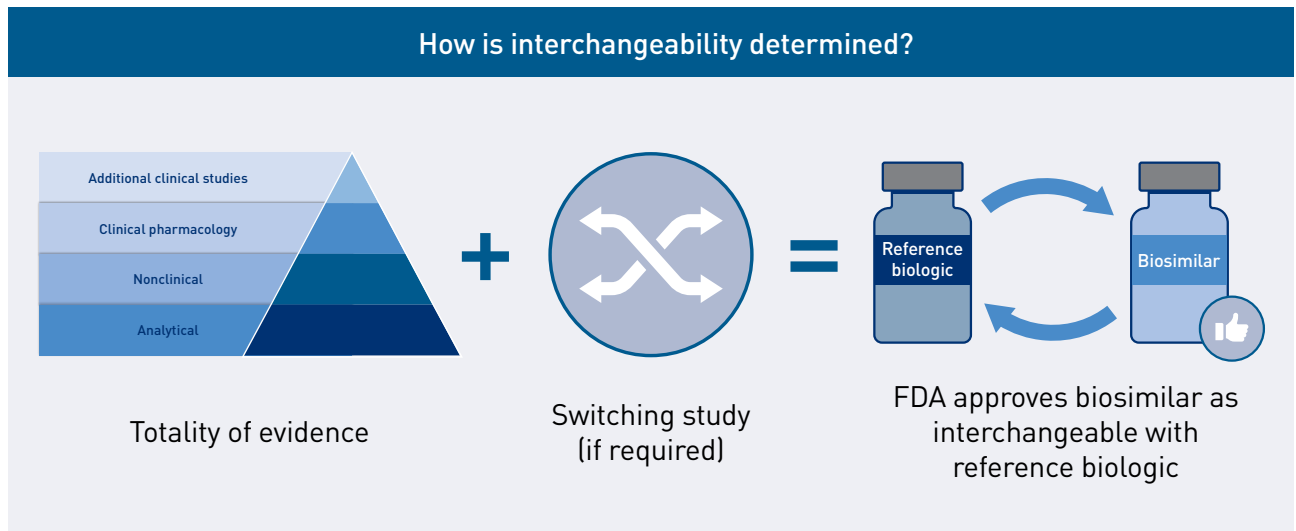
- Extrapolation is a process used to apply existing information about one thing to understand something else.
 - Researchers can use information gathered about how a medicine works in treating one disease to help understand how it might work in patients with a different disease.
- Biosimilars that are approved by the FDA can be considered for use in people with any of the diseases (also known as indications) that the reference biologic is used to treat, even if the biosimilar was not studied in people with that disease.
 - This is called extrapolation of indications.
- The decision to approve a biosimilar is made after the FDA has looked at all the research studies that were carried out during the development of the new biosimilar medicine.
 - This includes studies that look at the chemical structure of the medicine (how the medicine is made) as well as studies of how the medicine works.
 - Additional studies also look at how well the medicine treats people with the disease, and any unwanted effects of treatment (known as side effects) that might occur when taking the biosimilar.
 - Researchers call this approach the 'totality of evidence' and this supports the extrapolation of indications.



- This means that the development process for a biosimilar is often simpler than the process for a reference biologic because it does not need to be tested in every single disease that it could potentially treat.

What is an interchangeable biosimilar?

- Not all biosimilars are interchangeable.
 - In addition to the totality of evidence, extra research studies called switching studies may be needed for the FDA to consider a biosimilar for approval as an interchangeable biosimilar.
 - In switching studies, people with a condition who are receiving the reference biologic are 'switched' to and from treatment with the biosimilar 2 or more times.
 - Researchers look at any differences in effectiveness or side effects that might happen with this switch in treatment.



- Usually, biosimilars can be used instead of the reference biologic only if it has been specifically written on the original prescription.
- In all but 4 US states, an interchangeable biosimilar can be switched for the reference biologic by the pharmacist dispensing the medicine without permission from the doctor who prescribed it (this is called auto-substitution).
 - State laws in Alabama, Indiana, South Carolina, and Washington require approval from the prescriber before a pharmacist can make a substitution, even for an interchangeable biologic.
- As of August 2022, the FDA has authorized 3 biosimilars to be interchangeable.
 - The first was Semglee, a biosimilar of a type of insulin (insulin glargine), which is used in the treatment of diabetes and was approved as an interchangeable in July 2021.
 - The second is BI 695501, a biosimilar of Humira (also known as adalimumab), used in the treatment of people with certain conditions that affect the joints (such as rheumatoid arthritis), some diseases of the gut (Crohn disease and ulcerative colitis), and a type of skin disease (chronic plaque psoriasis), approved as interchangeable in October 2021.
 - The third is Cimerli, a biosimilar of Lucentis (also known as ranibizumab), used in the treatment of people with certain conditions that affect the eyes (such as wet age-related macular degeneration and diabetic retinopathy).

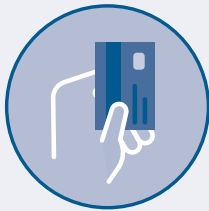
What are barriers to biosimilar use in the United States?

Possible reasons for low use of biosimilars in the United States



Legal issues

- Companies that make the reference biologics sometimes try to stop or slow down the progress of a biosimilar medicine.



Payment issues

- There can be cost benefits to health care systems to use a reference biologic instead of a biosimilar, but these cost benefits are not always passed on to the patient.



Rules and regulations

- The rules and regulations for biosimilars can make it difficult for biosimilars to become available for health care professionals to prescribe.



Health care provider preference

- Some health care providers do not fully understand biosimilars.
- This means that they might prefer to keep using the reference biologic.



Preferences of people receiving treatment

- Some people who need treatment might not understand that a biosimilar is as safe and effective as the reference biologic.
- This means that they might not want to have a biosimilar medicine.

What are the key take-home points?

- Biosimilars are a group of medicines that are highly similar to already approved biologic medicines.
- The use of biosimilars has the potential to make it easier for patients to get the treatment they need and could also help to reduce the costs of treatment.
- Improved education of health care providers and patients about biosimilars could lead to increased use of these medicines.

Where can I find more information about biosimilars?

- FDA, Biosimilars, Patient materials: <https://www.fda.gov/drugs/biosimilars/patient-materials>
- A Patient's Guide to Understanding Biosimilars: https://creakyjoints.org/wp-content/uploads/2018/12/GHLF_Biosimilars_Patient_Guidelines_2018.pdf

The full title of the article is: Overview of Biosimilars for Immune-Mediated Inflammatory Diseases: Summary of Current Evidence. You can find the full article here: <https://www.ajmc.com/view/BiosimilarsSuppl-CurrentEvidence>

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