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What is a biosimilar?

Biosimilars are a class of medicines that are based on and may be used instead of biologics.

The market for biologics and biosimilars is expected to grow. This should benefit you and your health care provider by increasing treatment options and improving access to vital drugs at lower costs.

In order for a biosimilar to be approved by the FDA, it must meet strict standards to show that it works the same way as the reference product and produces no meaningful clinical differences in terms of safety and effectiveness from the reference product.

- It must also have the same medical effect, be given the same way, have doses offered in the same form, and have the same strength as the reference product.
- Also, it may only be used for reasons and conditions for which the reference product is approved.

As biosimilars become more available, it is important for you and your health care provider to understand what they are and how they can be used to treat a wide range of diseases.

Health care providers need to know how to prescribe and administer these drugs to you and be ready to answer your questions about their safety, effectiveness, risks and side effects (unintended results of a medicine).

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Biosimilars should not be confused with generic medicines (generics).

- A generic is an exact copy of its chemically-formed reference product.
- The original biologic a biosimilar is measured against is often called the reference product.
- A biosimilar is highly similar to, but not an exact copy of, the biologic reference product, which is already on the market and approved by the U.S. Food and Drug Administration (FDA).
- The process to make a biosimilar is very complex, involving many difficult and specific steps that must be carefully regulated to make sure they are of the highest level of quality.

Who should take a biosimilar?

Biologic and biosimilar medicines can help patients with moderate to severe inflammatory bowel disease (IBD), who have not responded to, or who are not candidates for other treatments. Biologics are an important treatment option for IBD. They work by targeting specific proteins or cells in the immune system (the body's natural defense against illness and germs) involved in the inflammatory process.

IBD most often refers to two conditions — ulcerative colitis and Crohn's disease — which are characterized by inflammation (swelling) of different parts of the digestive tract. The exact cause of IBD is complex, but research shows it may be the result of someone's immune system attacking healthy cells and tissue in the digestive tract by mistake.

> Although IBD cannot be cured by biologics or biosimilars, both can help keep symptoms in remission (when symptoms are less or go away) and improve quality of life for many patients with moderate to severe IBD. They also have an advantage over other medicines used in IBD, because they are more targeted and selective in the body and in their medical effect.

Choosing a biosimilar

Biologics for IBD work by targeting specific proteins or cells in the immune system involved in the inflammatory process.

At this time, there are three types of biologics used to treat IBD

Tumor necrosis factor antagonists

Biologics that block a protein called tumor necrosis factor (TNF) that causes inflammation of the intestine and other body organs or tissues. They are given by injection or infusion into a vein.

Integrin-receptor antagonists

Biologics that block a protein on the surface of immune cells that contribute to inflammation. They are given by infusion into a vein.

Interleukin-12/-23 (IL -12/-23) antagonists

Biologics that block two cytokines (interleukin IL-12 and IL-23) from causing inflammation in Crohn's disease. They are given by infusion or injection.

In 2016, the FDA approved the first two biosimilars to treat IBD. While biosimilars are not yet commonly used for treatment in IBD, it is important to know that they are now an option and to expect that the number of biosimilars available will soon increase. In certain circumstances, biologics and biosimilars may even be appropriate to prescribe along with other commonly used immunosuppressive IBD medicines. This is called combination therapy.

Work with your GI to decide if a biologic or biosimilar is right for you

When considering biologics and biosimilars as a potential treatment, **it is important for you and your health care provider to work closely together and discuss these medicines thoroughly.** This will help ensure you have the information you need to take the medicine safely and effectively.

Some key points to discuss include:

- The type of biologics and biosimilars available and their purpose.
- How the medicines are administered (usually by injection or intravenous [IV] infusion).
- The benefits of taking these medicines (offer targeted and effective treatment with few possible side effects).
- The risks and possible side effects of these medicines (these can be different for each drug).

Sticking to your treatment plan

Biologics and biosimilars are medicines that need to be taken consistently and as directed by your health care provider.

Not following your health care provider's plan for how much of your biologic or biosimilar to take, when to take it and how to take it may cause your body to mount an immune response, making the treatment ineffective and increasing the risk for complications, such as allergic reactions.

The body's production of an antibody that binds to and neutralizes the drug can lead to loss of response. This can occur with both biologics and biosimilars, and often requires an increase in dosage, how often the drug is taken, or a change to another biologic or biosimilar.

Work closely with your health care provider to understand the importance of taking your medicine as prescribed, as well as it being vital to a good result.

You should feel encouraged to actively participate in discussions with your gastroenterologist and other health care providers. This will help you feel like your needs have been put first, which has been linked to staying on a treatment plan, better agreement to treatments, and better clinical outcomes.

Safety of biosimilars

Both biologic reference products and biosimilars have unique and rigorous pathways for FDA approval. These usually involve additional quality assurance testing compared to chemically-formed drugs, as well as clinical and non-clinical data to ensure safety and effectiveness for patients.

Use of these medicines is carefully watched when they enter the market. You can help improve the safety of these drugs by taking your medicine as directed and reporting any side effects or adverse reactions as soon as they occur.

What do biosimilars cost?

Each insurance company covers biologics and biosimilars differently. Before initiating or changing therapy, check your insurance coverage. Manufacturers frequently offer patient-assistance programs to help make treatment more affordable.

If your insurance company requires you to first try and see if another, cheaper biologic or biosimilar does not work for you before agreeing to cover the first therapy prescribed by your health care provider, work with your provider's office to contact your state health department to file an appeal.

Step Therapy

Learn more about step therapy and whether protections are available in your state.