Biosimilars

Biosimilar medicines (or biosimilars) are a type of biologic drug. All biologics, including biosimilars, are medicines made from living sources such as human, animal or bacterial cells.

Biologics (including biosimilars) work to suppress or lower the function of the overactive immune system. The immune system normally works to protect the body from illness and infections. With psoriasis and psoriatic arthritis (together called psoriatic disease), the immune system is overactive with increased inflammation. These treatments reduce symptoms of psoriatic disease by bringing the immune system activity back to a normal level.

How are biosimilars approved?

Biosimilars are modeled after an already FDA-approved biologic medicine or biologic (also called the “reference product”). There is a different approval process for biosimilars compared to other medicines. The FDA can approve a treatment as a biosimilar or an interchangeable biosimilar. FDA standards ensure that biosimilars and interchangeable biosimilars are just as safe and effective as their biologic reference product. Biosimilars are highly similar to their biologic reference product in many ways. All biologics, including biosimilars:

- Target specific parts of the immune system rather than impacting the entire immune system
- Are given as an injection (shot) or by intravenous (IV) infusion (a slow drip of medicine into your vein)

To be approved as a biosimilar for a particular reference biologic, the biosimilar must be:

- Highly similar to the reference product and cannot have any clinically meaningful differences in terms of safety or efficacy
- Approved for the indication(s) and condition(s) for which the reference product is approved
- Be given the same form and in the same dosage as the reference product
- Have the same mechanism of action as the reference product, which means it works the same way in the body

An interchangeable biosimilar must meet the biosimilar standard plus an additional standard that the treatment will produce the same clinical result as the reference product in any given patient. If a biosimilar is approved as interchangeable, a pharmacist may substitute (replace or switch) it without letting your prescribing health care provider know, in some states.

Are biosimilars generic versions of biologics?

A generic is a product that is exactly the same as a brand name product, but is not made or sold under a brand name. State pharmacy laws allow for a generic to be substituted for a brand name medicine by a pharmacist without informing your prescribing health care provider, in some states.

Although very similar, biosimilars are not considered generic forms of biologics. This is because biosimilars are not exact copies of biologics. Biologics are large and complex molecules from living sources that cannot be exactly copied. There cannot be the possibility of a generic biologic.

Biosimilars are like biologics in how they treat psoriasis or psoriatic arthritis. Biologics and biosimilars act on cytokines, which are specific proteins released by the immune system that can cause inflammation. They suppress the function of the overactive immune system. Biosimilars are also highly similar to their biologic reference product in their effectiveness, safety and potential side effects or risks. But they are not generic biologics.
Are there biosimilars approved for psoriatic disease?

As of November 2016, three biosimilars were approved for the treatment of psoriasis and psoriatic arthritis by the FDA:

- **Amjevita** (adalimumab-atto) is a biosimilar to Humira (adalimumab). Amjevita is as an injection that you give yourself.
- **Erelzi** (etanercept-szsz) is a biosimilar to Enbrel (etanercept). Erelzi is as an injection that you give yourself.
- **Inflectra** (infliximab-dyyb) is a biosimilar to Remicade (infliximab). Inflectra is given by a health care provider as an IV infusion.

Although these biosimilars have been approved, they are not yet available for your health care provider to prescribe. There are other biosimilars currently being developed and tested. These may also be approved and available in the future.

Why biosimilars?

Biologics are some of the most effective treatments if you have moderate to severe psoriasis or psoriatic arthritis. It is important that people with psoriatic disease are able to access safe and affordable treatments. The development of biosimilars—medications that are highly similar to existing biologics—increases the treatment options available and can help to ease the burden of health care costs and improve access to treatments.

Many considerations go into making a treatment decision. You will work with your health care provider and discuss the benefits and potential side effects or risks. Together, you and your health care provider should agree on the treatment option that is the most appropriate for treating your disease.

Will a biologic be substituted with an interchangeable biosimilar without my knowledge?

The National Psoriasis Foundation (NPF) wants to ensure that that the patient-provider relationship remain at the center of all treatment planning. The NPF Medical Board has a position statement on interchangeable biosimilar substitution. This explains the minimum requirements that should be met for biosimilar substitution to occur, including:

1. The biosimilar has been designated by the FDA as interchangeable with the prescribed biologic for treating the specific disease or condition;
2. The biosimilar has a unique name to avoid confusion with the reference product;
3. The biosimilar follows the same method of delivery (such as injection or IV) and dosage as the reference product;
4. The pharmacist notifies the prescribing provider in writing or electronic communication of the intention to substitute within 48 hours of the substitution;
5. The prescribing provider has not notified the pharmacist that the patient must be treated with the prescribed reference product;
6. The patient (or patient's authorized representative) must be informed and educated about a biosimilar substitution at the point of sale; and
7. A permanent record in the patient's medical record is kept by the pharmacy and prescribing provider about the biosimilar substitution.

NPF works to improve the health of our community. This includes advocating for new treatments to come to market, encouraging health insurance providers to expand access to already approved therapies, and working to ensure that treatment decisions remain between the patient and provider.

For more information, contact the Patient Navigation Center at 800-723-9166 or www.psoriasis.org/navigationcenter.