National Psoriasis Foundation Biosimilar Statement: Frequently Asked Questions

What are biosimilars? Are they generic versions of biologics?

Biologic drugs, or biologics, are protein-based drugs derived from living cells cultured in a laboratory. They are given by injection or intravenous (IV) infusion and target specific parts of the immune system. Biosimilars are treatments that are very similar to an already approved biologic drug. However, biosimilars are not generic versions of biologics because there's no way to precisely copy a drug made from living cells.

Why did the National Psoriasis Foundation develop a biosimilar position statement?

National Psoriasis Foundation (NPF) believes the doctor-patient relationship should be at the center of all treatment decisions for psoriasis and psoriatic arthritis. The NPF Medical Board developed the statement to guide health insurance companies, government agencies, lawmakers, the pharmaceutical industry and the patient community. As we encourage the development of new, safe and effective treatment options, we want to ensure that the treatment decisions remain between doctor and patient, not the pharmacy.

What are the key provisions of the statement?

To keep the patient-provider relationship at the center of all treatment planning, the statement acknowledges that:

- The biosimilar must be designated by the FDA as interchangeable with the prescribed biologic for the specific indicated use.
- The patient must provide written consent for a biosimilar substitution at time of sale.
- NPF recommends that the pharmacy and the prescribing physician retain permanent records of all biosimilar substitutions.
- Pharmacists must notify the physician in writing or electronic communication of the proposed substitution with at least 24 hour notice, and explicit permission must be obtained by the prescribing physician.

Could a pharmacist switch my medication from what my physician prescribed?

Substitutions may be made by pharmacists or health insurance companies under some circumstances without consulting you or your doctor. While biologic products are regulated by the federal government, each state has its own laws to regulate drug and biologic substitution.
Biosimilars sound like a promising new treatment option for my psoriasis and psoriatic arthritis, do you agree?

NPF welcomes new treatment options that will have a positive impact for patients. It’s anticipated that biosimilars may bring drug costs down. We encourage the development of biosimilars, but want to be sure that insurers and other payers do not have the final word on who receives biosimilars versus biologics, especially in cases where the prescribed biologic might be the more appropriate treatment.

How do I know the NPF has not just developed this position to please industry partners?

NPF does work closely and productively with pharmaceutical firms, medical societies and health care professionals to help improve the lives of psoriatic disease patients. We take our role as representatives of patients very seriously and we are aware of, and vigilant about, potential conflicts of interest.

What is the National Psoriasis Foundation doing to address the burden of high out-of-pocket costs?

NPF works to make treatments affordable and accessible to patients. We educate individuals about treatment assistance programs that can reduce the costs of these medications through our Financial Resource Center at www.psoriasis.org/frc. These programs and resources often significantly reduce the out-of-pocket costs for treatments. We actively engage Congress to support access to care with the Patients’ Access to Treatments Act (PATA). PATA would protect access to vital treatments by lowering out-of-pocket costs for specialty drugs, such as biologics, in commercial health plans. Learn more about this legislation at www.psoriasis.org/pata-info.