

Biosimilars

Position Statement

The Crohn's & Colitis Foundation advocates on behalf of the 1.6 million Americans who are affected by Crohn's disease and ulcerative colitis, which are collectively known as inflammatory bowel diseases (IBD). The Foundation is also the professional organization for those physicians, nurses, scientists and other healthcare providers who care for patients with IBD. We believe that treatment decisions should be shared between the healthcare provider and the patient. We want to ensure patient safety is paramount as the Food & Drug Administration (FDA) creates and implements the approval standards for biosimilars. The Foundation also advocates that the healthcare provider and patient relationship be deemed a priority in determining the most appropriate treatment options.

To enhance and to safeguard shared-decision making between the healthcare provider and patient, the Foundation supports the principles below:

Safety and Effectiveness:

The Foundation encourages the FDA to ensure that all biologics and biosimilars undergo thorough human testing and meet the highest safety standards. Consideration should be given to the application of the biosimilar in pediatric patients.

The Foundation urges the FDA, when considering interchangeability, to provide reasonable proof that switching from the originator to the biosimilar would not incur immunogenicity or loss of response to the originator (and vice versa).

The Foundation is not opposed to single transitions of stable patients from an originator to a biosimilar (or vice versa) by third parties (payers or pharmacies), but is opposed to multiple switches if the agents involved have not been designated as interchangeable by the FDA.

When any transitions or switches occur, the patient and providers should be informed of the exact agent the patient is receiving and whether it has received an interchangeable designation.

Each biosimilar should have a unique identification number, name, or else use international non-proprietary naming standards to eliminate patient and provider confusion.

Records of substitution should be tracked by the pharmacist in a manner that can be accessed by the provider and provided upon request to the provider. Communications should be made within 5 days and can include making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology or a pharmacy record; or by using facsimile, electronic transmission or telephone.

Shared-Decision Making and Transparency:

The prescribing provider should have the following rights:

- Be notified of a substitution of the originator agent with a biosimilar (or vice versa).
- Be able to prevent substitution by indicating “dispense as written.”

When not otherwise specified in the prescription of these agents, patients, or their designated caregivers, as well as the treating providers, should be notified of the substitution of an originator agent with a biosimilar.

Patients who utilize biosimilars should share in the cost-savings, such as through lower co-pays or other mechanisms to lower their out of pocket costs. Switches to biosimilars should not result in more out-of-pocket expenses for patients.

We encourage the FDA, state legislatures, and insurers to incorporate these policies.

Inquiries can be addressed to the Irwin M. and Suzanne R. Rosenthal IBD Resource Center (IBD Help Center), Monday thru Friday, 9:00 am to 5:00 pm ET at 888-MY-GUT-PAIN (888-694-8872).