



Crohn's & Colitis Foundation

Biosimilars Position Statement

The Crohn's & Colitis Foundation advocates on behalf of the millions of Americans who are affected by Crohn's disease and ulcerative colitis, which are collectively known as inflammatory bowel disease (IBD). The Foundation is also a leading professional organization providing education, resources, and advocacy on behalf of physicians, nurses, scientists, and other healthcare professionals who care for patients with IBD.

To assure safety and to safeguard shared decision making between the healthcare professional and the patient, the Foundation supports these principles:

- Treatment decisions should be shared between the healthcare professional and the patient, and that relationship should be deemed a priority in determining the most appropriate treatment options.
- FDA-approved biosimilars are safe and effective for patients. The Foundation supports the FDA in its role in ensuring the safety of patients, and we support ongoing research in both the adult and pediatric patient populations.
- The Foundation recognizes that additional studies addressing biosimilar interchangeability in the pediatric population are needed, and we strongly encourage the FDA and pharmaceutical industry to produce those studies in order to maximize the treatment options available.
- Health plans that change their coverage or "share of cost" to incentivize patients to switch to a biosimilar, or who otherwise mandate such a switch, should provide timely notifications that include disease and drug-specific education to the patient and the prescriber so there is adequate opportunity for the patient and medical professional to discuss the change.
- When notifying a patient of a switch, communications should include information specific to the product:
 - Cost to the patient of the new medication
 - If the new medication is citrate-free
 - A description of how the new medication is administered, as well as training for any new device
 - Information on where to learn more and who to contact with questions

- Switches to biosimilars should not result in any additional out-of-pocket expenses for patients, and should not be subject to utilization management protocols, which create barriers to timely medication access.
- Patients who utilize biosimilars should have full benefit of any copay assistance provided to them.
- The Foundation, along with the entire health care community shares in the responsibility of educating patients and caregivers about biosimilars.

Patients who wish to share stories about biosimilar use or challenges with the process of switching may use this [link](#).

If you have questions about biosimilars, you can contact 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)

This statement was last updated on January 10, 2024