

Defining the TERMS

Biological therapies (Biologics)

Lab-grown antibodies that **stop specific proteins involved in IBD from causing inflammation**. A number of biologics are approved for the treatment of inflammatory bowel diseases (IBD), including Crohn's disease and ulcerative colitis.



Biosimilar

Biological therapies designed to be **similar to originator biologics**, or reference products. A biosimilar is a drug that acts just like a reference product, having the **same effectiveness and safety** in the patient population that it treats.



Reference product

An FDA-approved **biological drug**. Biosimilars are highly comparable to the reference product.



Food and Drug Administration (FDA)

US government agency that **regulates** consumer products and devices as well as **prescription drugs (including biological therapies) and non-prescription drugs**. *Click here for more information on product categories regulated by the FDA.*



Interchangeable

The FDA determines if a drug is interchangeable based on whether or not a patient can be switched between a **reference product** and a **biosimilar** (or even between two biosimilars) back and forth with **no expected loss of effectiveness or change in safety**. *Click here to learn more about interchangeability.*



Substitution

When an insurance company and/or pharmacy **automatically switches a patient's current biological therapy** for the biosimilar, or vice versa. Many states have already passed laws on substitution of biologics and biosimilars. *To learn about the substitution laws in your area, click here.*



Extrapolation

Extrapolation is when the **research results** on the **safety and effectiveness** of a biosimilar in one disease are then applied to other diseases, such as Crohn's disease and ulcerative colitis for FDA approval. *Click here to find out more about clinical studies for currently approved biosimilars.*



Appeal

A request to **contest or reverse the decision** of an insurance company about your medical coverage when the insurance company makes a decision on your medical coverage that might not meet your needs for the management of your IBD. As biosimilars enter the US market, it is important for patients to know that they have a right to appeal. *Your doctor can help! See CCFA's listing of appeal letters* that can be customized to your needs. You can also learn more about navigating the appeals process by visiting the **Patient Advocate Foundation**.

