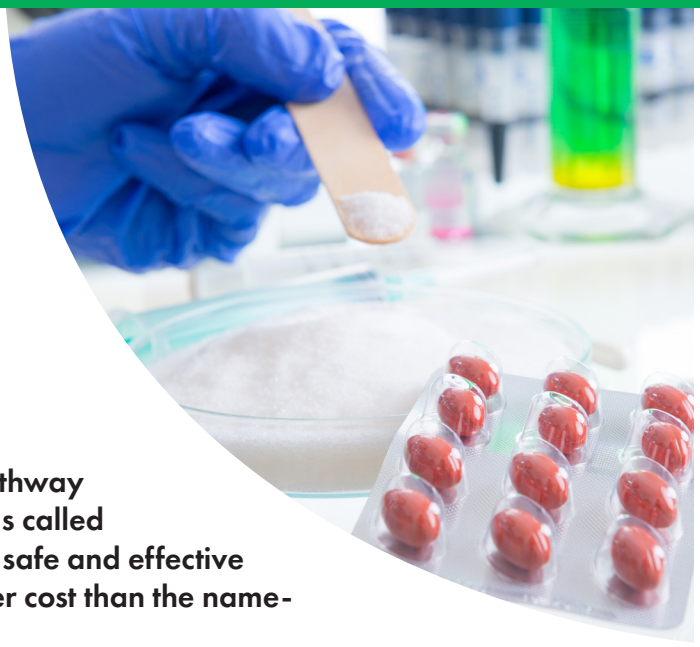
Arthritis Foundation℠

Arthritis Foundation Position Statement on Biosimilar Substitution



Issue

The Affordable Care Act (ACA) creates a regulatory pathway for approving a new generation of biologic medications called "biosimilars." Biosimilars have the potential to provide safe and effective treatment to people with arthritis at a significantly lower cost than the name-brand biologic medications.

Background

For years, biologic medical products have offered tremendous therapeutic benefits to thousands of people with arthritis and have also helped many others living with complex chronic diseases.

This new class of biosimilars has now started to enter the marketplace and will only increase over the near-term. These complex, innovative products offer new, and potentially more affordable, treatment opportunities for people with forms of inflammatory autoimmune arthritis. Through special review processes conducted by the Food and Drug Administration (FDA), some of these biosimilar products may be deemed therapeutically equivalent or "interchangeable" with an original biologic or reference product.

As both biologics and biosimilars are complex treatments requiring careful therapeutic monitoring, pathways for substitution require communication and transparency in all pharmacy transactions.

Our Position

The Arthritis Foundation supports legislation that provides a pathway for biosimilar substitution and should provide the following:

- Communication to the patient prior to or when substitution occurs.
- Entry of the substitution into an electronic health record that may be accessed by the physician.
- Communication to the prescriber within 48 hours of the substitution, if electronic records are not available.
- Retention of substitution records for a minimum of five years.
- Permission for a physician to override substitution when patients are stable on a prescribed biologic.
- An individualized and unique name for the biosimilar medication that is noticeably different than the name-brand innovator biologic.