Arthritis Foundation Position Statement on Interchangeable Biosimilar Substitution

Issue

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

Biosimilars have now started to enter the marketplace and many more are on the way. These complex products offer potentially more affordable treatment opportunities for people with forms of inflammatory 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.

The Arthritis Foundation conducted a survey of adults with rheumatoid arthritis to determine their current state of awareness about biosimilars. Over 90 percent of respondents expressed a preference to receive a communication if a substitution for a biosimilar occurs. As both biologics and biosimilars are complex treatments requiring careful therapeutic monitoring, pathways for substitution should require communication and transparency in all pharmacy transactions.

Our Position

The Arthritis Foundation supports state legislation that provides a pathway for biosimilar substitution that includes the following:

- Permission for a physician to prevent substitution (with “dispense as written”) for patients who are stable on a prescribed biologic.
- 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 via electronic health record or other means if an electronic health record system is not available.
- Retention of substitution records for a minimum of five years.
- An individualized and unique name for the biosimilar medication that is noticeably different from the name-brand innovator biologic.