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Arthritis Foundation Position Statement on Biosimilar Substitution

ISSUE

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

BACKGROUND

Biologic medical products have offered significant therapeutic benefit to thousands of patients with arthritis and have also helped many others living with complex chronic diseases. This new class of biosimilars is expected to enter the market place in the near term. These complex genetically engineered products offer new treatment opportunities for people with forms of inflammatory autoimmune arthritis and other chronic diseases. Through special review processes conducted by the FDA some of these biosimilar products may be deemed to be therapeutically equivalent or interchangeable with an original biologic or reference product. In the future, interchangeable biosimilars recognized by the FDA may be substituted for an approved biologic. However, as both biologics and biosimilars are complex treatments requiring careful therapeutic monitoring, pathways for substitution require communication and transparency in all pharmacy transactions.

ARTHRITIS FOUNDATION POSITION

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

- Communication to the patient upon substitution.
- Communication to the prescriber within 48 hours of the substitution.
- Retention of substitution records for a minimum of 5 years.
- Permit a physician override to substitution where patients are stable on a prescribed biologic.
- Biosimilar medications must be approved by the FDA as therapeutically equivalent and interchangeable to the original biologic.
- Biosimilar medications must have an individualized and unique name noticeably different than the reference biologic.

October, 2014