# AMERICAN COLLEGE OF RHEUMATOLOGY

# POSITION STATEMENT

**SUBJECT:** Therapeutic Substitution

**PRESENTED BY:** Committee on Rheumatologic Care

**FOR DISTRIBUTION TO:** Members of the American College of Rheumatology
Pharmaceutical Councils/Representatives
Professional Pharmacists' Associations
Medical Review Organizations, e.g., AMCRA
Medicare Carriers/Private Insurers
State Insurance Commissioners
Other interested parties

## POSITION

- The American College of Rheumatology opposes legislation or regulation that would permit prescription therapeutic substitution by hospitals, pharmacies or other entities.

BACKGROUND

Therapeutic substitution is the dispensing of a different chemical entity from the same therapeutic class instead of the drug prescribed by the licensed provider. Therapeutic substitution is different from generic substitution. Generic substitution is the selection of an alternate brand of the same chemical entity as the originally prescribed medication.

An important aspect of rheumatologic practice is the careful selection of medication for disease management. Rheumatologists, rheumatology nurse practitioners, and physician assistants prescribe drugs from diverse categories including nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, immunosuppressive agents, and other disease modifying anti-rheumatic drugs (DMARDs) based on knowledge of the patient's individual disease status from personal observation and assessment as well as input from the patient. In many cases, current practice involves combinations of drugs from two or more categories. Each therapeutic class has many drugs, some chemically similar and some very unique. Chemically similar drugs can have vastly different benefits, allergic reactions and toxic side effects. Individual patient response is not predictable.

Patients who are stable on a particular combination of DMARDs, traditional or biologic, should not have their medications changed by anyone except their prescribing provider. Safety and efficacy are not comparable between DMARDS even when they are of the same class.

Therapeutic substitution is especially relevant regarding biologic medications and biosimilars. Biosimilars are similar to the innovator biologic product but do not have the same biochemical structure (see biosimilar position paper for more details) [1]. Biologics are highly complex medications created in living cells and each product within a class of biologics has unique properties as well as varied safety and efficacy profiles. Biosimilars differ from the original comparator biologic due to the complexity of these medications and unpredictability in the manufacturing process which may lead to substantial differences in safety and efficacy. The treating provider is best capable of determining when a substitution between biologic drugs is clinically appropriate based on individual patient and disease characteristics as well as comorbid conditions. Allowing other entities to make therapeutic substitutions between biologics and biosimilars carries a significant risk of disease flares, organ damage and adverse drug reactions.

The treating provider has the clinical experience, knowledge of disease, and access to relevant patient-specific data to make informed decisions regarding appropriate pharmacologic agents for their patients. Accordingly, the decision to substitute medications should only be made by the prescribing provider.

REFERENCES

1. https://www.rheumatology.org/Portals/0/Files/Biosimilars-Position-Statement.pdf

Approved by Board of Directors: 05/00, 03/04, 08/08, 08/11, 08/15, 05/19