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 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. Biosimilar-related switching issues are covered in the ACR's position statement on biosimilars.[1]
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, 08/22