American College of Rheumatology
Position Statement

SUBJECT: Step Therapy

PRESENTED BY: Committee on Rheumatologic Care

PRESENTED TO: Members of the American College of Rheumatology
State Insurance Commissioners
Pharmacy Benefit Management Companies
Managed Care Entities and Insurance Companies
Pharmaceutical Companies
Members of US Congress
Centers for Medicare Services

POSITIONS

1. The American College of Rheumatology (ACR) supports strategies for lowering the cost of expensive therapies but opposes cost savings plans that compromise quality of care or safe clinical practices.
2. The ACR does not support step therapy, fail-first policies or tiering of medications based solely on cost.
3. Access to medically necessary treatment should be timely and not impeded or delayed by unnecessary barriers.
4. All healthcare stakeholders deserve transparency in formulary decision making processes.
5. Pharmacy review committees should involve rheumatologists when developing formulary benefits programs. The ACR welcomes the opportunity to provide expertise regarding rheumatic therapies to insurers.
6. Non-medical switching between branded products and across therapeutic classes in a medically stable patient solely for cost savings and without the consent of the patient and his/her provider is inappropriate and potentially harmful to patients' health.

STEP THERAPY

Step therapy was first introduced by managed care organizations in the 1980s in an attempt to control the costs of prescription drugs (1). Step therapy policies are also known as step protocols, fail-first policies, sequencing, and tiering. The increasing cost of prescription drugs has led managed care organizations and their pharmacy benefits managers to limit their formularies. Under step therapy programs, the patient is generally required to fail one or more formulary covered drug before the non-formulary (or non-preferred) agent is allowed.

There are several commonly employed categories of step therapy implementation. In some instances, insurers may require a patient try one or more preferred agents within a therapeutic class before approving others. An example in Rheumatology would be the required trial of one anti-TNF biologic medication for rheumatoid arthritis prior to approving the use of another anti-TNF biologic medication. In other instances, insurers may require a patient to try a medication from one immunologic class before

approving one from a different class without consideration of the medical situation. An example would be use of an anti-TNF biologic medication for rheumatoid arthritis prior to approving the use of a non anti-TNF biologic medication. For some conditions, insurers may require the use of certain medications in sequence. An example would be the required use of methotrexate for rheumatoid arthritis prior to approval of a biologic medication.

Frequently, the non-preferred drug is more expensive. In Rheumatology, these often include specialty medications such as biologic agents. The cost of the preferred drug may be based on fair market pricing of the medication or may be based on negotiated pricing. Presently, the privately contracted pricing, rather than market cost of specialty medications, drives step therapy decisions for rheumatic conditions. In addition, higher copays are applied to non-preferred drugs to discourage their use; this leads to tiering of agents within a similar class. This specialty tiering (such as Tier 4 or higher) places crucial treatments out of financial reach for all but the wealthiest patients.

Step therapy and related programs may reduce the use of more expensive alternatives but they have also been shown to delay appropriate therapy. In a survey conducted by Cox et al, up to 11% of patients who tried to fill a non-preferred drug (either a proton pump inhibitor or an NSAID) never obtained treatment (2).

Step therapy programs often apply to Targeted Immune Modulating Agents (TIMs) such as biologics. Since TIMs consistently, although not universally, decrease signs and symptoms of rheumatoid arthritis, induce clinical remission, halt radiographic progression of disease and improve quality of life, step therapy for these drugs should not impede patient access to treatment. Utilization management tools should optimize affordable, appropriate access to care and ought not worsen patient outcomes. Commonly encountered, problematic aspects of step therapy include how step therapy can interrupt a treatment regimen when insurance status changes, such as change in job or employer-provided coverage. Changes in formulary for patients with stable insurance also occur frequently and result in adverse effects on treatment. In these situations, patients may unexpectedly be subjected to new step therapy requirements, forcing them to switch from their current medication to whatever agent is “preferred.” The process of appealing these decisions may take 4 to 8 weeks and require numerous communications between the provider and the insurer. This allows for disease progression and physical damage to occur.

Step therapy and related formulary decisions are often not made in a transparent fashion. Criteria for coverage of a given medication may not be clear to patients and prescribers, and the process for submitting information related to the process, known as prior authorization, is time consuming and burdensome. Provisions allowing prescribers to obtain permission to override step therapy algorithms often require several levels of appeals and not uncommonly require providers to schedule one-on-one telephone calls with insurance personnel. The ACR has approved a separate position statement on prior authorizations specific to these issues.

IMPACT ON CLINICAL CARE

Step therapy programs should not interfere with medically appropriate use of drugs. Unregulated step therapy policies for TIMs have hijacked the otherwise thoughtful and highly complex process that patients and their providers navigate when choosing appropriate therapy. While TIMs within a class may have similar effectiveness in large populations, responses by individual patients vary dramatically.

For example, several distinct TNF inhibitors are routinely used in the treatment of rheumatic diseases. These agents are not equivalent at the level of an individual patient in terms of efficacy, adherence, safety or tolerability (including injection site pain). In addition, these drugs differ in time to remission, FDA indication, requirement for concurrent oral DMARDs and frequency of administration. Particular agents are recommended by the provider based on these considerations keeping in mind a particular patient's circumstances and overlapping medical and immune co-morbidities.

Step therapy has resulted in forced drug switching, treatment gaps, and cessation of effective therapy. In addition to the dangers to the patient related to loss of access to therapy and disease flares, these programs may result in immunogenicity, adverse effects, and secondary non-response (4). Downstream effects of restricted access can lead to complications such as uncontrolled disease for the patient, disabilities, and increased health care costs.

REFERENCES

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2. Cox ER, Henderson R, Motheral BR. Health plan member experience with point-of-service prescription step therapy. JMCP. 2004;10(4):291-298
3. Medco. 2011 Drug Trend Report: Healthcare 2020. Franklin Lakes, NJ: Medco;2011.www.drugtrendreport.com/Medco-2011-Drug-Trend-Report-Executive-Summary.pdf
4. Fefferman et al. Immunogenicity of Biological agents in inflammatory bowel disease. 2005 May 11(5): 497-503

ADDITIONAL RESOURCES

- Under member guidelines of Step Therapy Program; Medical Associate Health Plans page 1: effective 6/15/12.
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results from eight years of surveillance of clinical practice in the nationwide Danish DANBIO registry. Arthritis Rheum. 2010;62:22-32.

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