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 the US Congress
Centers for Medicare and Medicaid Services

POSITIONS

1. The American College of Rheumatology (ACR) supports strategies for lowering the cost of expensive therapies but opposes cost savings plans such as step therapy or fail-first policies that compromise safe clinical practices and delay care.

2. Insurers' step therapy formularies, and requirements for submission for exceptions to step therapy, should be easily accessible and transparent.

3. Patients should be exempt from step therapy if:

    a. The patient has tried at most two plan-required drugs and the treatments failed to be effective.

    b. Delay of effective treatment would lead to severe or irreversible consequences.

    c. The plan-required drug is contraindicated or has caused/ is likely to cause an adverse reaction for the patient.

    d. The patient is already stable on the prescription drug treatment selected by their provider, and that drug has been covered by their previous or current insurance plan.

4. Exemption requests should be processed within 24 hours where the step therapy protocol may seriously jeopardize the life or health of the patient.

5. Pharmacy review committees should involve rheumatologists when developing formularies for rheumatic disease states.

BACKGROUND

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. Under step therapy programs, the patient is generally required to fail sometimes five or more formulary-covered drugs before the non-formulary (or non-preferred) drug is allowed. In the rheumatology subspecialty, step therapy can be especially detrimental since each treatment failure can delay a patient's recovery for months and cause irreparable physical damage.

Impact of Step Therapy on Patients & Clinical Care

Step therapy poses unnecessary risks to patients' health by delaying timely access to care for the financial benefit of insurers and pharmacy benefit managers. Treatment decisions for rheumatology patients are often complex and are carefully tailored to the patient's medical history, pregnancy, comorbidities, and social history. Research supports early aggressive treatment to achieve remission in rheumatic disease. Delayed therapy risks prolongation of pain and sometimes irreversible damage to patient function. This may impede the patient's ability to work, which in turn may affect the patient's, and their families, financial security. Chronic pain and disability carry additional emotional and psychological burdens which may lead to lifelong consequences.

Step therapy disrupts continuity of care, often leading to negative health outcomes. An Arthritis Foundation survey found that most respondents experienced negative health effects from delays in getting the right treatment. Over half of patients reported having to try two or more different drugs prior to getting the one their doctor had originally ordered. Step therapy was stopped in 39% of cases because the drugs were ineffective, and in 20% of cases due to worsening conditions. Respondents also noted changes in coverage exacerbating step therapy requirements. Nearly a quarter of patients who switched insurance providers were required to repeat step therapy with their new carrier (2).

Step therapy programs impede the medically appropriate use of drugs. Unregulated step therapy policies for biologics have impeded the otherwise thoughtful process that patients and their providers navigate when choosing appropriate therapy. In a study among 3,993 rheumatoid arthritis and 1,713 psoriatic arthritis patients, when compared with patients whose plans did not require step therapy, odds of treatment effectiveness were 19% lower for rheumatoid arthritis patients and 27% lower for psoriatic arthritis patients in plans with step therapy (3).

Use of Step Therapy by Payers

While early step therapy protocols were based on drugs' market costs, now the privately contracted price, which is driven by rebates, drives the formation of step therapy algorithms. Rebates are negotiated between drug manufacturers and pharmacy benefit managers (PBMs) acting on behalf of payers. In these agreements, a PBM receives a rebate in exchange for the placement of the manufacturer's drug on a payer's "preferred" formulary. Higher copays are applied to non-preferred drugs to discourage their use.

Problematic aspects of step therapy include the interruption of a treatment regimen due to circumstantial formulary changes. These include changes in insurance status, such as a change in job or employer-provided coverage, and/or changes in formulary by a patient's current payer following PBM negotiation. In these circumstances, patients may unexpectedly be subjected to new step therapy requirements, forcing them to switch from their current medication to whatever agent is "preferred" under a new plan formulary.

Step therapy and related programs have 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 (4). 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.

Need for Transparency

Step therapy and related formulary decisions are often made in a non-transparent fashion. Criteria for coverage of a given medication are not 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 exceptions to 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 (5).

Insurers should implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol. To this end, the ACR supports codifying requirements that step therapy protocols by payers include a clear and transparent process to seek exceptions for step therapy requirements (6). This exceptions process would outline clear criteria regarding treatment effectiveness, patient history of adverse reactions, stability on an existing treatment regimen, and worsening disease state as a consequence of delayed treatment. In addition to transparency, decisions must be streamlined to mitigate undue delays in access to treatment.

Summary

Step therapy protocols interrupt the otherwise nuanced and thoughtful decision-making process undertaken between the rheumatology provider and their patient. They generally prioritize cost savings over evidence-based treatment. The role of rebates negotiated by PBMs, combined with the current scrutiny of their business practices and excess profits, undermines the credibility of such protocols. Step therapy results 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 (7). Downstream effects of restricted access can lead to complications such as uncontrolled disease for the patient, disabilities, and increased health care costs.

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ADDITIONAL RESOURCES

- Under member guidelines of Step Therapy Program; Medical Associate Health Plans page 1: effective 6/15/12.
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