

American College of Rheumatology
Position Statement

Subject: Step Therapy

Presented by: Committee on Rheumatologic Care

Presented to: Members of the ACR
State Insurance Commissioners
Pharmacy Benefit Management Companies
Managed Care Entities and Insurance Companies
Pharmaceutical Companies
Members of US Congress
Centers for Medicare Services

BACKGROUND

Step therapy was first introduced by managed care organizations in the 1980s as an attempt to control the costs of prescription drugs (1). Step therapy is also known as step protocol, fail first policy, sequencing, or tiering. The increasing cost of prescription drugs has led managed care organizations and their pharmacy benefits managers to limit their formulary. Under the step therapy programs, the patient is generally required to fail one or more formulary covered drug before allowing the non-formulary (or non-preferred) agent to be used. Frequently, the non-preferred drug is a more expensive medication. The cost of the drug may be based on fair market pricing of the medication or may be based on negotiated pricing between the manufacturer and pharmacy board. Presently, the privately contracted pricing, rather than market cost, on biologics therapies for rheumatic conditions drive step therapy decisions. Often, higher copays for non-preferred drugs are applied to discourage their use which leads to tiering of drugs within a similar class. This specialty tiering (such as Tier 4 or higher) places crucial treatments out of reach for the patient.

PRIOR AUTHORIZATIONS

Step therapy and related programs may reduce use of more expensive alternatives but they have also been shown to delay appropriate therapies for several reasons. First, the biologic agents are medications that require prior authorizations. Unfortunately, there are hundreds of insurance plans that each regulate prior authorizations differently and impose different procedures for drug approval. In addition, each insurance company develops their own formulary and varies in their preferred drugs creating additional confusion. Next, communication between pharmacy boards who review prior authorization and specialty pharmacies also delay the access to care since specialty pharmacies may require their own administrative forms and separate documentation. According to a 2010 AMA Survey, 69% of physicians wait several days for a response to a prior authorization request (2). This step further delays the initiation of treatment. 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 (3). Another study reviewing the restrictive use of COX-2 inhibitors versus regular NSAIDs resulted in more hospitalizations from gastrointestinal bleeds with the increased use of NSAIDs (4).

Since biologics consistently, although not universally, decrease signs and symptoms of rheumatoid arthritis, induce clinical remission, halt radiographic progression of disease, and improve quality of life for these patients, prior authorizations for these drugs should not impede access to treatment. Prior authorizations should optimize affordable, appropriate access to care and ought not lead to poor patient outcomes. Standardized prior authorization forms will improve efficient, quality patient care. Providers, health benefit plan issuers, and pharmacy benefit managers should adopt a single, standard form. The ACR encourages a prior authorization form that follows each state's regulatory guidelines. In addition, this prior authorization should easily interface with electronic health records and reduce the administrative burdens for practices and insurance companies to ensure timely delivery of care. Lastly, response to the prior authorization should occur in a reasonable time frame with a clear explanation of coverage to the patient and their prescribing physician.

COST SAVINGS /REBATES

The cost of biologic therapy for rheumatoid arthritis is expected to increase to approximately one fifth of all health plan drug spending by 2014 (5). Rebate programs from drug manufacturers provide cash incentives to insurance companies to lower the cost of the medication and increase the utilization of their drug. Within a class of medications, this rebate leads to preferred products. Currently, Medicaid participates in a large rebate program with manufacturers, and their program and preferred drug list are available online. On the other hand, private insurance companies do not disclose their privately negotiated contracts and leave stakeholders unaware of why one agent may have been preferred over another, except for cost to the insurer. Undoubtedly, negotiated pricing and contracts with pharmacy boards lead to cost savings. Step therapy results in substantial savings to the insurance company and may lead to overall lowered health care expenses. It is not clear, however, how these cost savings extend to the patient, the greater health care system, or promote decreased spending.

Cost sharing programs should not interfere with proper use of medications. Unregulated step programs for biologics have taken over standard clinical practices and ignore the clinical decision making by the physician and patient. For example, there are four injectable TNF therapy agents routinely used in the treatment of rheumatic diseases. These agents are chosen by the physician based on individual patient considerations, overlapping medical and immune conditions, and safety considerations. While some biologics may have similar effectiveness in large populations, individuals vary according to their responses. In addition, these agents do not confer equivalent adherence, safety, and tolerability profiles. Moreover, these drugs differ in time to remission, need for oral DMARDs, frequency of administration, and injection site pain. They also differ according to FDA indications and usage in various diseases. Step therapy and rebates have resulted in forced drug switching, treatment gaps, and cessation of effective therapy. In addition to the dangers to the patient in lost access to therapy and disease flares, these programs may result in immunogenicity, adverse effects, and secondary nonresponse (6). Downstream effects of this restricted access lead to the complications of uncontrolled disease for the patient, disabilities, and increased health care costs.

EXECUTIVE SUMMARY

Given the safety concerns and medical complexity of biologics, along with the lack of evidence for clinical superiority or safety for large populations, access and coverage for biologics should

remain fair and equal. Standardized prior authorizations will improve efficient health care. Step therapies, fail first policies, tiering, and class switching requirements create unnecessary obstacles for patients and their physicians, delays in appropriate therapy, potentially dangerous outcomes for patients, and undermine the decisions made between the patient and physician. Strategies for affordable, quality care require application of standard, safe clinical practice. The cost savings programs for drugs should promote healthier business practice and healthier patients.

POSITIONS

- Access to treatment should be reasonable and timely without unnecessary barriers to medically necessary care.
- ACR promotes universal prior authorizations compatible with the EHR.
- Mandatory drug switching of stable medical therapy is inappropriate and potentially harmful to patients.
- The ACR opposes step therapies, fail-first policies, and tiering of biologics.
- Pharmacy review committees should include rheumatologists in developing their formulary benefits programs. The ACR welcomes the opportunity to provide expertise to insurers regarding rheumatic therapies.
- All healthcare stakeholders deserve transparency in the formulary decision making processes between manufacturers and payers.
- The ACR supports strategies for lowering the cost of expensive medical therapies but discourages cost savings plans that compromise the standards of quality, safe clinical practice.

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RESOURCES

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

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