

Step Therapy and Fail First Policies Backgrounder

Pfizer believes that step therapy is not in the best interest of patients or the health care system because it undermines providers' medical judgment and the relationship between health care providers and patients. It is often driven by cost considerations rather than appropriate pharmaceutical and patient care and may involve significant unrecognized risks, as the entire patient medical history may not be available. We believe that a provider's prescribing decision is the outcome of a careful and deliberate process between the provider and his/her patient, based on his or her judgment of how best to prevent, treat or cure a disease or medical condition. This process requires the evaluation of a specific individual's condition, needs and a variety of scientific data in order to choose the individualized course of therapy that is right for the patient.

Background

Step therapy requires patients to fail on a less costly medication before he or she can be prescribed a more appropriate medication. Step therapy (also referred to as fail first) is one of many tools employed by payers to manage utilization of health care services. In the case of medications, the process usually requires a patient to try medicines for his or her conditions in a series of steps. The Centers for Medicare & Medicaid Services (CMS), as a part of their explanation of the Medicare Prescription Drug benefit, describes the coverage rule to patients as follows:

*"Some plans may require you to first try a generic prescription drug (if available), then a less expensive brand-name prescription drug on their drug list, before you can get a similar, more expensive brand-name prescription drug covered."*¹

Step therapy is a commonly used cost management tool, and in recent years, health insurers have increased the use of step therapy. In 2010, about 57 % of employer plans used these fail first requirements to control costs of pharmaceuticals, compared with 50 % just two years earlier.² According to a national pharmacy benefit manager, the number of enrollees in plans using step therapy techniques nearly tripled in a three-year period.³

In a study comparing spending on schizophrenia medications in Georgia's and Mississippi's Medicaid programs, a step therapy program saved Georgia \$19.62 per member per month (PMPM) in atypical antipsychotic expenditures. However, the pharmacy savings was "accompanied by a \$31.59 PMPM increase in expenditures for outpatient services."⁴

Research on the use of step therapy in the private insurance market shows similar outcomes: pharmacy savings were generated, but hospital and emergency room admissions increased. As a result, the use of step therapy did not have the intended effect of reducing overall costs but in fact, increased health care costs.⁵

In addition, the use of utilization management tools, such as step therapy, increases the administrative burden on providers and medical staff. Research on medical practices' interactions with insurers show that to administer insurance every year, the average provider's office requires: three weeks of provider's time; 23 weeks of nursing staff time and 44 weeks of clerical staff time.⁶ A recent survey of providers found that more than half of

¹"How Medicare Drug Plans Use Pharmacies, Formularies, and Common Coverage Rules," The Centers for Medicare & Medicaid Services, 2009. Available at: <http://www.medicare.gov/Publications/Pubs/pdf/11136.pdf>

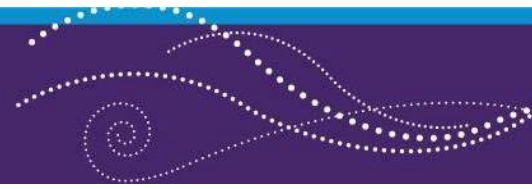
²"Prescription Drug Benefit Cost and Plan Design Report 2010-11 Edition," Pharmacy Benefit Management Institute, Available at: <http://www.benefitdesignreport.com/Home/DownloadFullReport2/tabid/128/e/1/Default.aspx>

³"Pharmacy Benefit Guide," Express Scripts. Available at: <http://www.express-scripts.com/research/studies/drugtrendreport/2004/pharmacyBenefitGuide.pdf>

⁴Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," *Clinical Therapeutics*, 30: 1524-1539, 2008.

⁵Mark, T. et al., "The Effects of Antihypertensive Step-Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures," *American Journal of Managed Care*, 15: 123-131, 2009.

⁶Casalino L, et al. "What Does It Cost Provider Practices To Interact With Health Insurance Plans?" *Health Affairs* 28, no. 4 (2009): w533-w543.



providers experience difficulty obtaining prior approval for prescriptions on 25 % or more of their requests to plans. Most providers report having to wait several days to receive approval.⁷

Key Data Points

- The American Pain Foundation notes that according to the National Center for Health Statistics, 76.5 million Americans report pain lasting at least 24 hours. Once an effective course of therapy for their pain is found, there is often a limitation placed by insurers on the patient's ability to access this treatment or the length of availability of this treatment.⁸
- The Epilepsy Foundation emphasizes that a seizure can involve severe injury to the individual and to others and the possibility for long-term brain injury. Step therapy or fail first policies cause unnecessary harm by not allowing the consumer access to the most appropriate line of treatment for his/her condition.⁹
- According to an AMA survey, 78 percent of physicians believe insurers use preauthorization requirements for an unreasonable list of tests, procedures and drugs.¹⁰
- The administrative burden of maintaining insurer preferred drug lists, time spent requesting prior authorization, and the imposition on the physician's ability to prescribe their first-choice drug is estimated to cost \$1,569 per physician per year for statins and antihypertensives¹¹.
- There is no conclusive evidence that therapeutic substitution reduces long-term health care costs. In addition, it does not account for potentially higher costs from possible adverse reactions and other medical treatment that may be necessary as a result of the unintended consequences of substitution.

Pfizer's Position

Pfizer believes that clinical judgment and patient choice, within the bounds of accepted medical practice, should take precedence over payer cost considerations in decisions about individual care. Health care professionals must retain the ability to address the variability of patient responsiveness and individualize care through access to multiple treatment options. In addition, patients stabilized on specific medications should not be switched to other drugs except when medically indicated. We also support increased transparency regarding plan switching and substitution policies. We believe that patients should be notified of pending changes to medication treatments and provided an opportunity to appeal a change before it occurs.

Impact on Patients and Health Care Professionals

Managing the prescription drug benefit and receiving authorization is the most time-consuming element for providers. This impact is disproportionately experienced by primary care doctors, especially those in small practices, who spend a larger proportion of their time interacting with health plans. In addition, step therapy and fail first policies often require patients to endure monetary, physical and psychological distress. Even when a provider thinks the treatment may not work, these policies can unnecessarily force patients to:

- Pay cost-sharing for the first steps of therapy and for additional medical visits;
- Suffer physically because effective treatment is delayed; and
- Tolerate side effects from inadequate medicines.

7 "AMA Survey Of Providers On Preauthorization Requirements," American Medical Association, Available at: <http://www.ama-assn.org/ama1/pub/upload/mm/399/preauthorization-survey-highlights.pdf>

8 American Pain Foundation. "Position Statement on Step Therapy and Therapeutic Switching." Accessed 02 Oct. 2009.

<http://www.painfoundation.org/newsroom/position-statements/step-therapy-therapeutic-switching.html>

9 Epilepsy Foundation. "Strategies Used to Limit Access to Medications." Accessed 12 Oct. 2009.

<http://www.epilepsyfoundation.org/advocacy/priorities/limitcoverage.cfm>

10 <http://www.ama-assn.org/ama/pub/news/news/survey-insurer-preauthorization.shtml>

11 Ketcham JD, Epstein AJ. Which physicians are affected most by Medicaid preferred drug lists for statins and antihypertensives? *PharmacoEconomics* 2006; 24 (Suppl 3): 27-40.