
Inappropriate Use of Step Therapy “Fail First” Policies by Health Insurers Can Lead to: Disease Progression, Poor Health Outcomes and Increased Costs

Carlton, R.I.; Bramley, T.J.; Nightengale, B.; Conner, T.M. & Zacker, C. (2010) Review of outcomes associated with formulary restrictions: Focus on step therapy. *The American Journal of Pharmacy Benefits* 2(1). 50-58.

- “Step edits may lead to scenarios where patients do not fill prescriptions or underutilize medication.”
- “...less than half of patients who initially face a step edit actually start on the first-line medication as intended.”
- “...several studies have demonstrated that total healthcare costs remained the same or increased.”
- Yokoyama et al (2007) looked at the impact of step therapy on Anti-hypertensives and found that 69.5% of patients received the restricted drug within 12 months after failing initial edit and nearly 7% of patients received no antihypertensive drug.
- Motherel et al (2004) looked at the impact of step therapy on PPIs, SSRIs, and NSAIDs and found that 17% of patients received no drug and 16% paid out of pocket for the needed drug.
- Panzer et al (2005) looked at the impact of step therapy on Anti-depressants and total Medicaid costs, drug costs and drug utilization. The study found that total Medicaid costs increased by \$0.32 per member per month (PMPM) while drug costs decreased by \$0.26 PMPM (an overall increased spend of \$.06 PMPM). The same study also found that due to step therapy requirements, more patients switched medications within 6 months and fewer patients received continuous therapy at 6 months.

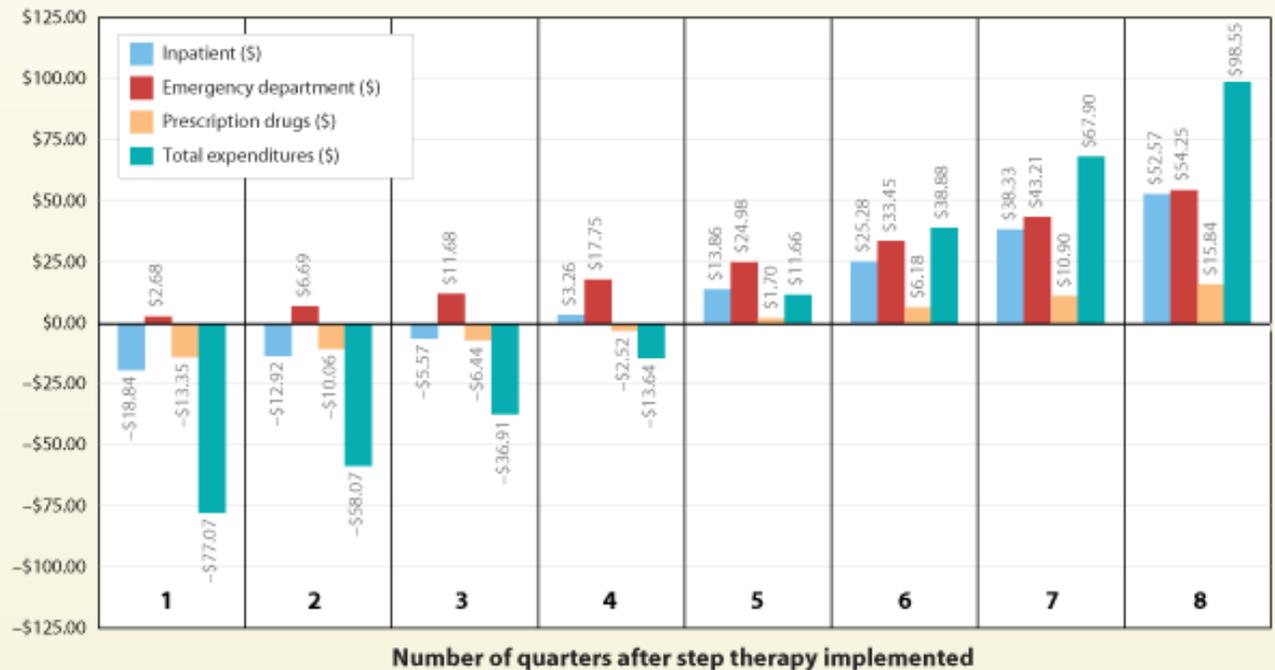
Motherel, B.R. (2011). Pharmaceutical step-therapy interventions: A critical review of the literature. *Journal of Managed Care Pharmacy*, 17(2). 143-155.

- “Nearly 60% of commercial payers reported having one or more step-therapy (ST) programs in 2010, making it one of the most popular pharmacy benefit management tools.”
- “...the hazard rate of treatment discontinuation [in bipolar patients subjected to step therapy] was 2.28 times as high in the post-policy period than in the pre-policy period, suggesting that the savings resulted from treatment discontinuation rather than switching to lower-cost alternatives.”
- “Also looking at antidepressants, Mark et al. (2010) reported an initial savings of 1.7% across total prescription drug costs (not just antidepressant spend) but *found that the savings diminished over time.*”

Mark TL, Gibson TB, McGuigan KA (2009). The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditures. *American Journal of Managed Care*, 15(2): 123-131.

Effects of step therapy on expenditures

Difference between step therapy plans and comparison plans in each quarter after start of step therapy



Source: Mark TL, Gibson TB, McGuigan KA. The effects of antihypertensive step-therapy protocols on pharmaceutical and medical utilization and expenditures. *Am J Manag Care*. 2009;15(2):123-131

- This chart highlights one of the major issues of step therapy: that if there are initial financial benefits, they are only short term. In the case of anti-hypertensives, this study found that after three quarters, costs began to increase significantly. The price of drugs may have remained relatively low, but emergency room visits and inpatient expenses surged, causing the total expenditures to heavily outweigh the benefits of the drug savings.
- The researchers found “that patients discontinued their medication more so after step therapy was implemented,” and reported an “initial 7.9% reduction in days of medication supplied.”

Seabury SA, Goldman DP, Kalsekar I, Sheehan J, Laubmeier K, Laubmeier K (2014). *Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients With Schizophrenia and Bipolar Disorder in Medicaid*. *American Journal of Managed Care*, 20 (2), pages e52-e60.

- This study looked at claims level data on inpatient, outpatient, long term care and pharmacy claims for all patients diagnosed with schizophrenia or bipolar disorder for 24 state Medicaid programs including New York from 2001-2008. It focused on the impact of formulary restrictions including prior authorization, quantity limits and step therapy.
- The study found that adherence to medication declined due to formulary restrictions and total costs increased with formulary restrictions due to increased inpatient and medical costs as well as increased pharmacy costs for bipolar disorder.

- The study concluded, “Because the prescriber can individualize a patient’s treatment, our results suggest autonomous prescribers constitute an asset to payers, since these prescribers achieve lower hospitalization rates than prescribers who operate within a restricted payer environment.”

(2008) Implementation of a step therapy protocol for anti-hemophilic medications could be life threatening and will result in higher treatment costs. *Plasma Protein Therapeutics Association*.

- “Since blood clotting factor drugs are not therapeutically equivalent or interchangeable, “step therapy” is not appropriate for this class of drugs”
- “Increased hospitalizations will occur as factor replacement falls below recommended levels when individuals are forced to use a factor product that does not provide them with the best factor recovery levels.”
- “...each time an individual with hemophilia changes therapies at the direction of a payer or pharmacy benefit manager, they must visit the physician in order to determine the proper dosage, administration schedule, and other medical considerations.”

Tanio, C.P. & Steffen, B. (2014) Report and recommendations on fail-first or step therapy. *Maryland Health Care Commission (MHCC)*.

- Recommendations:
 - “Standardize step therapy grandfathering exemptions to permit patients already successfully managed by a drug or service to continue with that treatment without having to restart step therapy protocols.
 - Recommends that all payors use a one year look back period. Currently, look back periods vary from 130 days to 365 days with exceptions based on the treating physician’s documentation.
 - “Require all payors to incorporate step therapy approval and override processes in their automated preauthorization applications beginning July 2015.
- “Drugs assigned to step therapy vary across carriers. Prescribers face considerable uncertainty in identifying which medications are stepped. The variation among drugs subject to step therapy lists presents challenges to patients already well-managed by a medication. When a patient changes payor, the patient’s care could be disrupted because a prescribed medication could potentially be denied because the ‘fail first’ drug may not [have] been previously prescribed.”

Other Studies of Interest:

- One study looked at various drug classes for which health insurers apply step therapy. It found, “With the immunologic agent and biologic therapeutic class, 18 [health insurance] plans, comprising national and regional commercial plans, require a patient to step through one or two branded drugs carrying an FDA ‘boxed warning’ before being prescribed a branded drug that does not carry a boxed warning.”

- Per the FDA, boxed warnings are ordinarily used to highlight for prescribers at least one of the following situations:
 - Adverse reaction associated with the drug is serious in proportion to the potential benefit.
 - Serious adverse reactions can be prevented or reduced in frequency or severity by appropriate use of the drug.
 - The FDA approved the drug with restrictions to ensure safe use because it determined the drug can be safely used only if distribution is restricted.

Branning, G, Schaars R, Horning J, Wick J, Kuznik, Presentation to International Society for Pharmacoeconomics and Outcomes Research, 2015.

- One study found, “after the introduction of step therapy for schizophrenia medications, which initially saved Georgia’s Medicaid program \$19.62 PMPM, the state subsequently spent \$31.59 PMPM- for a net increase of \$11.97 PMPM- on outpatient services- as a result of the utilization of ineffective medications.”

Farley J, Gline R, Schommer J, Hadsall R, Nyman J (2008) Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications. Clinical Therapeutics Vol 30, Issue 8, Pages 1524-1539.

- Another study compared changes in healthcare resource utilization and costs among patients with painful diabetic peripheral neuropathy (pDPN), postherpetic neuralgia (PHN) or fibromyalgia (FM) in a commercial health plan implementing pregabalin step-therapy with members in unrestricted plans. It found that implementation of a pregabalin step-therapy protocol resulted in lower pregabalin utilization, but it was not associated with reductions in total healthcare costs, medical costs or pharmacy costs. While pregabalin utilization was decreased due to step-therapy, the study found an increase in physical therapy and disease-related outpatient utilization as a result.

Udall M, Louder A, Suehs B, Cappelieri J, Joshi A & Patel N (2013) Impact of a step-therapy protocol for pregabalin on healthcare utilization an expenditures in a commercial population. Journal of Medical Economics 16(6):784-92.

- Other studies looked at negative health consequences due to delays in getting correct medications (*Richards et al 1999*) and *Lard et al 2001*). Richards found that breast cancer patients whose treatment was delayed three months or longer had a 12% lower five-year survival rate. Lard found for rheumatoid arthritis patients who had treatment delayed for four months, “experienced significantly more radiologic joint damage after two years.”

S.3419C/A.2834D Regulates Step Therapy Practices in NYS so they are used Appropriately by Improving and Standardizing the “Utilization Review” Appeals Process when such Policies are utilized.

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