

# Considerations in Generic Step Therapy Programs

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# The Pharmacy Benefit Management Institute

The mission of the Pharmacy Benefit Management Institute (PBMI) is to create the industry's premier forum for health care purchasers to exchange ideas, advance best practices, and drive appropriate changes in the pharmacy benefit management marketplace.

# Agenda

- Overview of generics
- Market adoption of step therapy
- Evidence of step therapy outcomes
- Implementation considerations
- Conclusions and questions

# Overview of Generics

## Definition

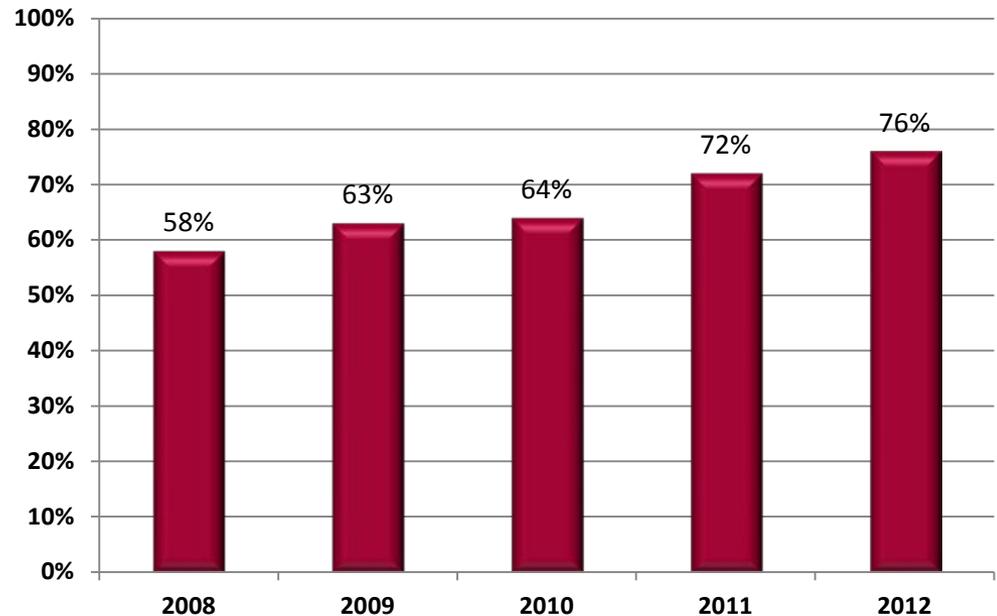
- A generic medication is a chemically equivalent copy designed from a brand-name drug where the patent has expired

## Net Ingredient Cost, 2011

- Generic: \$17.95
- Brand: \$165.33

Source: Prime Therapeutics. *2012 Drug Trend Insights*.

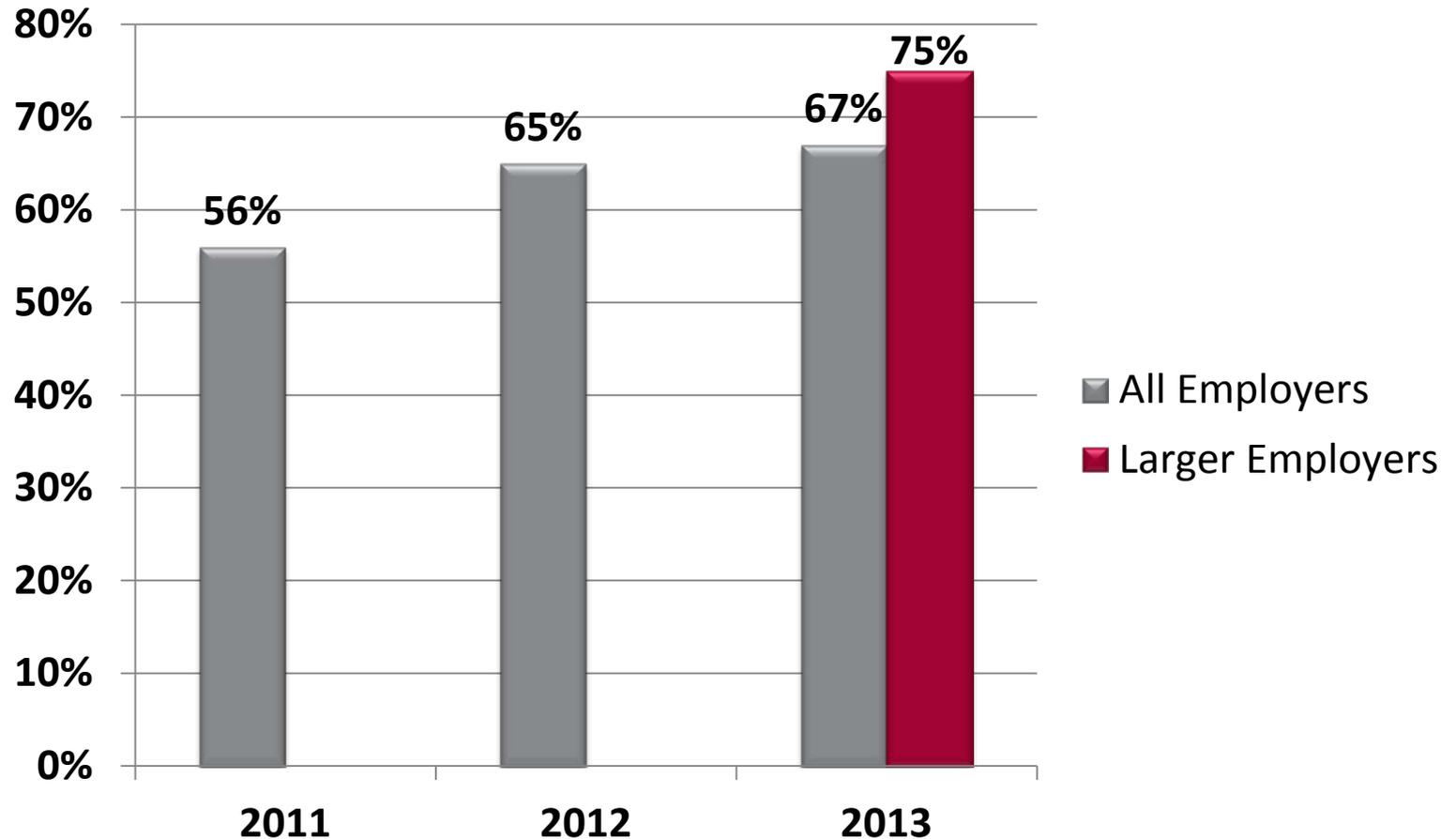
## Generic Fill Rate



2008-2011: PBMI survey data weighted for retail and mail volume per IMS data for each year.

2012: PBMI survey data.

# Step Therapy Adoption



Source: 2012 PBMI survey data

# Evidence on Step Therapy

- Reviewed 14 evaluations of step therapy programs
- Covering 5 therapy classes—antidepressants, antihypertensives, antipsychotics, NSAIDs, and PPIs
- Most studies addressed financial savings and clinical outcomes

**CONTEMPORARY SUBJECT**

## Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature

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**ABSTRACT**

**BACKGROUND:** Adoption of step therapy (ST) is quickly outpacing the market's understanding of its clinical, humanistic, and economic outcomes. The broad scope of previous reviews of drug management programs has prohibited an in-depth discussion of the ST literature specifically.

**OBJECTIVE:** To conduct a critical review of ST program evaluations, discuss their policy implications, and provide recommendations for future research.

**METHODS:** PubMed was searched for relevant English-language articles, and references of relevant articles were examined. The ST policy under evaluation had to require use of a first-line agent prior to coverage of a second-line agent.

**RESULTS:** Fourteen evaluations of ST programs have been published, 7 in commercial populations and 7 in Medicaid. Twelve of the studies empirically examined claims data; 1 was a model; and 1 was limited to patient surveys. Five therapy classes, including antidepressants, antihypertensives, antipsychotics, nonsteroidal anti-inflammatory drugs (NSAIDs), and proton pump inhibitors (PPIs), have been evaluated. The research has consistently found statistically significant drug cost savings with the exception of antipsychotics, where rebates have frequently been excluded. Savings result from greater use of first-line medications and from reduced medication initiation, with the magnitude of noninitiation varying across therapy classes. Three studies have examined medication adherence, producing mixed results. Five studies have empirically examined the effect of ST on hospitalization and emergency room utilization and costs, with none finding statistically significantly higher disease-related utilization or spend, outside of higher outpatient expenditures but not higher outpatient utilization in 1 study.

**CONCLUSIONS:** The research demonstrates that ST programs for therapy classes other than antipsychotics can provide significant drug savings through the greater use of lower-cost alternatives and, to a lesser extent, reduced drug utilization. The drug savings and clinical impact of ST for

**What is already known about this subject**

- Nearly 60% of commercial payers reported having 1 or more step-therapy (ST) programs in 2010, making it one of the most popular pharmacy benefit management tools. However, adoption of ST is quickly outpacing understanding of its clinical, humanistic, and economic outcomes.
- Previous reviews of drug cost management tools have reported drug cost savings from ST, highlighted higher discontinuation rates, and identified gaps in the literature related to inclusion of quality of care metrics. Prior critical reviews have focused primarily on the lack of inclusion of a broad range of relevant outcomes rather than on study quality, particularly internal validity.

**What this study adds**

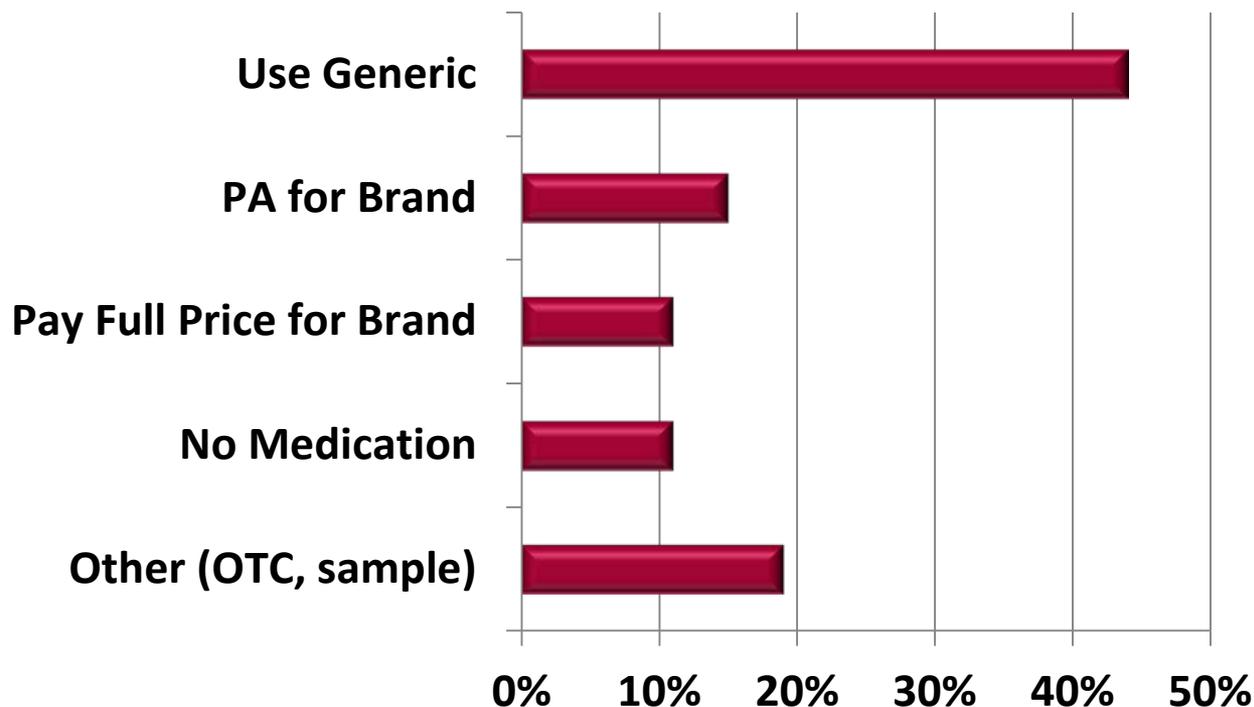
- The research on ST shows gaps in the breadth of evaluation and methodological quality as well as potential study bias.
- Further research on ST is needed for numerous therapy classes where ST is common and for the Medicare Part D population. Research is also needed to better understand the impact of ST on treatment discontinuities, appropriateness of use, other medical costs, and member/provider satisfaction as well as the effect of alternative designs.
- Needed methodological improvements include (a) use of appropriate comparator groups, (b) examination of disease-related medical spending, (c) adjustment for multiple statistical tests, and (d) better causal linkage between program and outcomes.
- To help reduce the potential for study bias, independently funded

# Financial Outcomes

Drug Class	Financial	Clinical
<b>Antidepressants</b>	Increased GFR Financial savings	
<b>Antihypertensives</b>	Increased GFR Financial savings	
<b>Antipsychotics (Medicaid populations)</b>	No savings found	
<b>NSAIDs</b>	Increased GFR Financial savings	
<b>PPIs/H2s</b>	Increased GFR Financial savings	

# Actions Taken Following Step Therapy Edit

## Percent of Patients with Step Therapy Edit

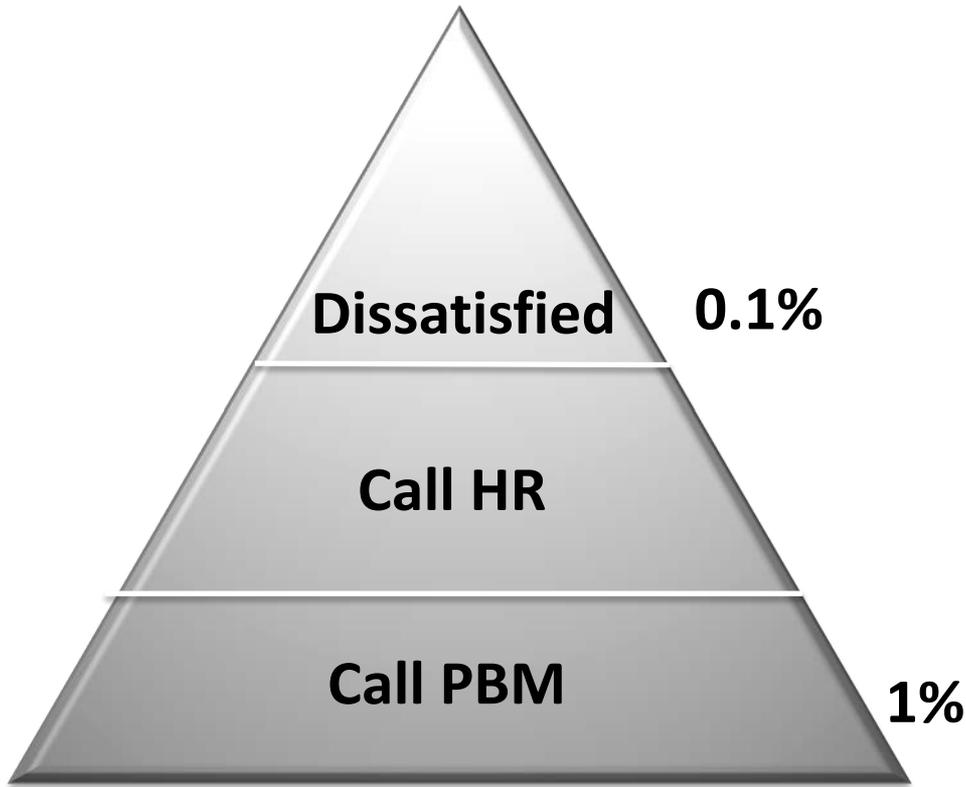


Source: Cox et al. 2004.

# Clinical Outcomes

Drug Class	Financial	Clinical
<b>Antidepressants</b>	Increased GFR Financial savings	No effect on long-term adherence
<b>Antihypertensives</b>	Increased GFR Financial savings	No effect on long-term adherence
<b>Antipsychotics (Medicaid populations)</b>	No savings found	Mixed evidence on adherence and outcomes
<b>NSAIDs</b>	Increased GFR Financial savings	No effect on other medical expenditures
<b>PPIs/H2s</b>	Increased GFR Financial savings	No effect on other medical expenditures

# Member Experience



- Call volume increases for ~3 months
- Paying full price for brand and filling no medication associated with lower satisfaction

# Implementation Considerations

- Prospective member communication is important
- Retrospective outreach is also impactful
  - Members do not always understand the difference between step therapy and prior authorization
  - Targeted letters to members affected by step therapy increase use of generics and reduce the number of patients who pay full price for medication or receive no medication
  - Retrospective physician follow-up impactful as well

# Conclusions

- Promotion of generics provides savings for plan sponsors and members
- Research on step therapy has shown these programs to increase use of generics and provide financial savings without compromising the quality of care for all classes studied (except antipsychotics in Medicaid)
- Careful implementation can maximize satisfaction with a step therapy program