



# Presentation Overview

- Value of Rx
- Step therapy defined
- Step therapy in context
- Defining related terms
- Step therapy in depth
- Case studies
- Questions



# Cost and Value of Prescription Drugs

- Prescription drugs make up ~ 10% of overall health care costs
  - But patients pay more out-of-pocket (OOP) for Rx than other services
- Prescription drugs result in lower death rates: cancer 23%  
heart disease 46%
- For every \$1 spent on Rx the system saves \$3 - \$10 for CVD and Diabetes
- Newer drugs treat underlying cause & promote high quality of life to maintain “normal” social roles

# Dept. of Health & Human Services:

*Step therapy is a type of prior authorization. With step therapy, in most cases, you must first try certain less expensive drugs that are also approved for use for your condition before you can move up a “step” to a more expensive drug. For example, your plan may require you to first try a generic prescription drug (if available), then a less expensive brand-name prescription drug on its formulary, before it will cover a similar, more expensive brand-name prescription drug.*

*However, if you’ve already tried the similar, less expensive drugs and they didn’t work, or if your prescriber believes your medical condition makes it medically necessary for you to be on the more expensive step therapy prescription drug, he or she can contact your plan to ask for an exception.*

# Defining Related Terms

- ***Formulary***—a list of approved drugs
- ***Manufacturer discounts/rebates***—money given back to insurer for placement of drug onto a formulary
- ***Tiered cost-sharing***—patients have lower copayments for drugs that are *preferred* by the insurer

# Defining Terms (cont'd)

- ***Generic substitution***—pharmacists dispense a generic drug instead of the brand, innovator drug
- ***Therapeutic interchange***—pharmacists substitute an entirely different drug than the one prescribed
- ***Prior authorization***—physician or pharmacist must seek approval from the insurer prior to dispensing a drug

# Step Therapy in Depth

- A type of prior authorization program
- Requires “fail-first”
- In some cases, patients are required to fail numerous drugs that may be inadequate for their condition<sup>1</sup>

<sup>1</sup>Yosipovich G. Step therapy stalls appropriate treatment. *Dermatology Times*. 2015 Sept:3.

# Step Therapy Implementation and Reaction

- In 2013, 67% of employer-sponsored health plans reported use of step therapy, up from 27% in 2005<sup>2-3</sup>
- Used in many diseases, including cancer, hypertension, mental health, diabetes, pain, and auto-immune diseases<sup>4</sup>
- Some states have enacted laws to limit step therapy policies<sup>5</sup>
- CMS limits its use in Medicare Part D for antidepressants, immunosuppressants, antineoplastics, and other drugs<sup>6</sup>

<sup>2</sup>Hoadley J, Summer L, Hargrave E, Cubanski J. Medicare Part D prescription drug plans: the marketplace in 2013 and key trends. Kaiser Family Foundation.

<sup>4</sup>Pharmacy Benefit Management Institute. 2013-2014 prescription drug benefit cost and plan design report. Plan (TX): PBMI;2013:August.

<sup>4</sup>Express Scripts. 2008 drug trend report (Internet). Maryland Heights (MO): Express Scripts; 2005 Jun. Available from:<http://lab.express-scripts.com>

<sup>5</sup>Conn. Gen. Stat. Set. 38a-492i (2012).

<sup>6</sup>Centers for Medicare and Medicaid Services. Medicare prescription drug benefit manual (Internet). Baltimore, MD: CMS. Chapter 6, Part D drugs and formulary requirements.

# Concerns About Step Therapy

- Physicians compelled or incentivized to prescribe drugs they might know to be less effective, beforehand
- Use of drugs with contraindications for that patient
- Patients' clinical presentation worsening due to delays in receiving optimal treatment<sup>7-8</sup>

<sup>7</sup>Nayak RK, Pearson SD. The ethics of “fail-first”: Guidelines and practical scenarios for step therapy coverage policies. *Health Aff.* 2014;33:1779-1785.

<sup>8</sup>Leukemia and Lymphoma Society. Testimony in favor of MD SB622 (Middleton) health insurance—step therapy or fail-first protocol. Senate Finance Committee (Internet). Washington, DC: LLS;2014 Feb 19. Available from: <http://www.lls.org/content/nationalcontent/pdf/ways/MDSB622StepTherapyTestimony>

# Case Studies

- Pregablin, used for pain associated with diabetic neuropathy, fibromyalgia, and spinal cord injury
  - Increased disease-related pharmacy costs; no difference in total health expenditures<sup>9</sup>
  
- Antidepressant use in employer-sponsored plans<sup>10</sup>
  - Antidepressant days supply and med costs decreased
  - Increase in emergency room utilization, medical care use, and OVERALL expenditures

<sup>9</sup>Suehs BT, et al. Impact of a pregablin step therapy policy among Medicare Advantage beneficiaries. *Pain Practice*. DOI:10.1111/paper.12073

<sup>10</sup>Mark TL, et al. The effects of antidepressant step therapy protocols on pharmaceutical and medical utilization and expenditures. *Am J Psych* 2010;167:1202-1209.

# Case Studies (cont'd)

- Guanfacine XR for ADHD<sup>11</sup>
  - Greater delay in receiving meds, fewer days covered, less drug spend, yet no overall difference in health care costs
- Orphan drugs used to treat rare diseases<sup>12</sup>
  - Drugs used in Huntington's, hydatid disease, sickle cell, hypercalcemia secondary to carcinoma, hemolytic uremic syndrome, soft tissue sarcoma, Gaucher disease
  - Lower access, lower coverage, fewer days supplied

<sup>11</sup>Suehs et al. Impact of a step-therapy for guanfacine extended release on medication utilization and health care expenditures among individuals receiving treatment for ADHD. *J Manage Care Pharm* 2015;21:793-802.

<sup>12</sup>An early examination of access to select orphan drugs treating rare diseases in health insurance exchange plans. *J Manage Care Pharm* 2014;20:997-1004.

# Case Studies (cont'd)

- Angiotensin-receptor blockers (ARBs) & ACE inhibitors used for hypertension<sup>13</sup>
  - 130-day trial with preferred ACE
  - Higher patient discontinuation of therapy, higher all-cause inpatient, ER, & outpatient visits in step therapy group
- Protein pump inhibitors prior to use of COX-2 inhibitor<sup>14</sup>
  - 44% received different drug than prescribed; 32% received medication at a later date
  - Many patients discontinued therapy

<sup>13</sup>Mark TL, Gibson TB, McGuigan RA. The effects of antihypertensive step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy. *J Manage Care Pharm* 2007;13(235-244).

<sup>14</sup>Cox ER, Henderson R, Motheral RR. Health plan member experience with point-of-service prescription step therapy. *J Manage Care Pharm* 2004;10:291-298.

# Step Therapy Use In Medicaid Populations

- Two-state (Maine & New Jersey) comparator trial of step therapy for bipolar disorder<sup>15</sup>
  - Discontinuation of therapy over twice as high in step therapy group
  - Drug savings of \$27 per patient over 8 months resulted from treatment discontinuation rather than switches
- Two-state (Georgia & Mississippi) comparator trial of step therapy for atypical antipsychotics<sup>16</sup>
  - 29% greater risk of gap in coverage
  - No change in overall drug spend

<sup>15</sup>Zhang Y, et al. Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. *Psych Serv* 2009;60:520-527.

<sup>16</sup>Soumerai SB, et al. Use of atypical antipsychotic drugs for schizophrenia following a Medicaid policy change. *Health Aff (Millwood)* 2008;27:w195-w205.

# Case Study Summary

- Evaluations thus far mostly have looked at drug cost savings and gaps in coverage
- Some studies have examined medication adherence and overall medical expenditures
  - Results suggest poorer adherence and greater utilization of emergency and other medical services
- Studies come from a range of disease/treatment areas
  - Many important treatments not yet studied, as the therapies are too new
  - Results will likely even more problematic
- There is certainly a need to examine clinical outcomes

# Ethical Considerations in Step Therapy

- Help the sick
- Protect the worst off
- Respect autonomy
- Sustain trust
- Promote inclusive decision-making

# Solutions

- Weigh cost savings against long-term outcomes<sup>18</sup>
- Ensure that first-step drugs are clinically appropriate
- Give patient an excellent chance to meet clinical goals
- First-step failure should not cause long-term harm
- Opting out on clinical grounds should be quick and easy

<sup>18</sup>Nayak RK, Pearson SD, op cit.

# Solutions (cont'd)

- Rapidly review new evidence<sup>19</sup>
- Rationale and rules for step therapy and other coverage decisions should be explicit, transparent, and publicly accessible<sup>18</sup>
- Do not disrupt the doctor-patient relationship
- Involve the pharmacist and the point-of-care (writing the prescription)

<sup>19</sup>Teagarden JR, Daniels N, Sabin JE. A proposed ethical framework for prescription drug benefit allocation policy. *J Am Pharm Assoc* 2003;43:69-74.

# Acknowledgements

- \* Helen Berhane, B.S., PharmD Candidate
- \* Jonathan Khakshooy, B.S., PharmD Candidate
- \* Yewande Samuel, B.S., PharmD Candidate
- \* Trang Tran, B.S., PharmD Candidate



# Questions?



APPLIED  
PHARMACY  
SOLUTIONS

