

# Step Therapy or Fail-First Protocol

Bruce Kozlowski

Director

Center for Quality Measurement & Reporting

# Background

- ▶ Step Therapy – is a process under which medications/services are provided using an effective, but more affordable medication/service (Step 1) before a more costly (Step 2) medication/service is authorized by a payer.
- ▶ Used by private carriers, self-insured employers, public payers who content....
  - Step Therapy allows safer lower cost services/medications to be provided first
  - Step Therapy allows payers to negotiate most favorable prices for most effective services/medications
- ▶ Scope of Step Therapy varies across payers
- Providers generally accept principles of Step Therapy programs, but express frustration...
  - No consistency in implementation
  - Limited flexibility to override
- ▶ Patients accept principle, but worry about getting access to the most appropriate medication or service
- ▶ Providers and patients sometimes confuse prior authorization and step therapy requirements

# 2013 Legislation

- ▶ Senate Bill 746/House Bill 1015– Step Therapy or Fail–First Protocol
  - Limits the duration of step therapy protocol to
    - 30 days or
    - the period deemed necessary by the prescriber to determine clinical effectiveness of the prescription drug or device preferred by the carrier
  - Requires immediate access to an override process
  - Override process must allow prescriber to override the protocol if in professional judgment
    - The prescription drug preferred by the carrier has been ineffective or
    - Based on sound clinical, medical, and scientific evidence the known relevant physical or mental characteristics of the patient, and the known characteristics of the treatment regimen, the preferred treatment would either
      - be ineffective or adversely affect the compliance with the treatment regiment or
      - has caused or is likely to cause an adverse reaction or other harm to the patient

# MHCC Process

- ▶ MHCC Staff held individual meetings with Providers, Payers and Patient Advocacy groups
- ▶ Discussed areas of concern, magnitude of problems, and suggestions for process improvement
- ▶ MHCC is conducting an examination of drugs subject to Step Therapy
  - Limited to drug programs of major carriers
  - Focuses on overlap in Step Therapy Drugs among carriers
- ▶ Engaged Mercer to assist in report development
- ▶ Sent draft report to stakeholders November 5<sup>th</sup> for review and comment

# Current Areas Where Consensus Could Be Developed

- ▶ Duration of Step Therapy before a preferred pharmaceutical can be used
- ▶ Maximum number of Step Protocols that could imposed before a preferred pharmaceutical can be used
- ▶ Exemption process for a Step Therapy
  - Grandfathering of existing services or pharmaceuticals
  - Patients with multiple complex conditions
- ▶ Emergency exemption process and duration

# Possible Technical Solutions

- ▶ Practices and Payers agree that prior authorization systems could play a role in simplifying Step Therapy
- ▶ Payers contend..
  - Step Therapy is a variant of broader prior authorization processes
  - Automated prior authorization needs to take deeper root before Step Therapy is added
- ▶ Long-term approach that would most benefit physicians is integration in EHR systems, alert provider to Step Therapy requirements at the time the order is written.

# Next Steps

- ▶ Add results of MHCC's study on consistency of Step Therapy
- ▶ Finalize report with Stakeholder input where appropriate
- ▶ Present Final report to Commission in December
- ▶ Report to the Senate Finance and House Health and Government Operations Committees