# Medicaid Pharmacology: Step Therapy



Joint Labor, Health and Social Services Committee



April 29th, 2024

## What is "step therapy"?

- → Requiring a trial and failure of one treatment before advancing to a different treatment for the same disease state.
- → Example: Knee pain
  - ◆ Step 1—Physical therapy and simple analgesics
  - ◆ Step 2—Injections into the joint
  - ◆ Step 3—Knee surgery
- → Example: Atopic dermatitis (a form of eczema)
  - ◆ Step 1—Topical corticosteroid
  - ◆ Step 2—Topical immunomodulator
  - ◆ Step 3—Injectable immunomodulator

# Why do payers require "step therapy"?

- → Early steps tend to:
  - ◆ Be more conservative, less invasive, or have fewer side effects and lower risks
  - ♦ Have more robust clinical evidence of effectiveness or clear evidence of clinical superiority.
  - ◆ Be less costly choice in a category where safety and efficacy are essentially equal among all treatment choices.
- → Late step drugs sometimes come to market with an FDA labeled indication that limits them to a later place in therapy (e.g. "treatment resistant depression" or chemotherapy agents that specifically state "for patients previously treated with...")

# Step therapy - Medicaid policy

- → In Medicaid, the cost of a drug is only considered a factor in determining place in step therapy if there is no evidence of a safety or efficacy difference between it and competitors in the same drug class.
  - ◆ Uncommon for drug manufacturers to conduct head to head trials between their drug and competing drugs.
  - Relative safety and efficacy often inferred based on the quantity and quality of clinical evidence
  - ◆ A single drug may be labeled for multiple indications, but may only have superiority data for one of those indications. Therefore, a drug may be Step 1 for one indication but Step 3 for another.

# Medicaid Pharmacology: Opioids



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### Opioid-naive patients and acute pain

- → For opioid naïve patients:
  - ◆ No more than seven (7) day initial supply
- → For acute pain:
  - ◆ Defined as less than six weeks of continuous opioid therapy
  - No dosage limits

#### Patients with chronic pain

- → Defined as more than six weeks of continuous opioid therapy
- → 120 morphine milligram equivalents (MME) per day of long acting opioid; moving toward 90 MME per day limit
- → 4 units per day of short acting opioid (for breakthrough pain)
- → Prohibit use of more than one long acting or more than one short acting opioid concurrently
- → Do not cover and opioid and benzodiazepine concurrently

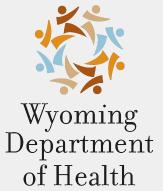
#### Medicaid opioid coverage policy

- → If a Medicaid client pays cash for any prescription, Medicaid is not aware of it and cannot use it in calculating coverage metrics.
- → Medicaid covers drugs used in the treatment of opioid use disorder (e.g., Medication Assisted Therapy).

# Medicaid Pharmacology: Weight Loss Drugs



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### What are they?



- → Glucagon-like Peptide-1 (GLP-1) Drugs
  - Semaglutide (Ozempic—for diabetes; Wegovy—for weight management)
  - ◆ Tirzepatide (Mounjaro—for diabetes; Zepbound—for weight management)
- → Mechanism of action
  - Work for diabetes by stimulating the secretion of insulin and helping keep blood sugars stable
  - Work for weight loss by suppressing appetite and by slowing movement of food from the stomach to the small intestine, so patients feel full longer

## Medicaid coverage policy

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- → Medicaid covers Ozempic and Mounjaro for patients with diabetes (after applicable step therapy has been tried)
- → Medicaid does not currently cover any drugs solely for a diagnosis of obesity or overweight.
  - ◆ Therefore, Medicaid doesn't cover Wegovy or Zepbound at all, and does not cover Ozempic or Mounjaro for patients who do not have a diagnosis of diabetes.