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Utilization Management for Medications for Opioid Use Disorder (MOUD) in Medicaid

Findings from Literature Review and Stakeholder Interviews

Sheila Shaheed and Anupama Warrier

Medicaid and CHIP Payment and Access Commission

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Policy and Research Questions

- Do utilization management strategies (i.e., PA, daily dosage limits, refill thresholds) enable states and managed care organizations (MCOs) to ensure appropriate and timely access to MOUD while also managing costs?
- What are state and MCO policies with respect to PA, daily dosage limits, and early refill thresholds? How are these policies developed?
- What are the main concerns associated with the use of PA, daily dosage limits, and early refill thresholds for MOUD?

Methodology

- Contracted with Acumen LLC:
  - Conducted a literature review examining federal, state, and MCO policies; clinical guidelines; and peer-reviewed and gray literature
  - Interviewed 17 stakeholders including state and federal officials, MCOs, provider and pharmacy associations, a patient advocacy group, and an individual with lived experience
  - Conducted a claims analysis to examine effects of utilization management policy changes on utilization and clinical outcomes between fiscal years (FYs) 2019 and 2023

Background

Types of MOUD

- Three forms approved by the U.S. Food and Drug Administration (FDA) for treatment of opioid use disorder (OUD)
  - Buprenorphine (buprenorphine-only monoproduct and buprenorphine/naloxone combination product)
  - Methadone
  - Naltrexone
- MOUD have been shown to reduce the risk of overdose death and address socioeconomic costs associated with the opioid epidemic
- Federal guidance underscores that access to MOUD should not be contingent upon receipt of other services (e.g., counseling)

Utilization of MOUD in Medicaid

- As of FY 2020, state Medicaid programs must cover all forms of FDA-approved MOUD and related counseling and behavioral therapies (Consolidated Appropriations Act 2024; P.L. 118-42)
- In FY 2022, Medicaid enrollees with OUD most commonly received an oral formulation of buprenorphine (57 percent)
  - 28 percent received methadone, 6 percent received extended-release injectable naltrexone, and 3 percent received extended-release injectable buprenorphine
- In FY 2022, less than one-fifth of enrollees receiving MOUD were treated with methadone in 17 states

Utilization Management

- Although state Medicaid programs must cover all forms of MOUD, states and MCOs can apply utilization management strategies
- State and MCO utilization management policies are intended to ensure the delivery of appropriate care and address other goals, such as controlling costs and reducing the potential for fraud, waste, and abuse
- Three types of entities are primarily involved in establishing utilization management policies at the state level:
  - Medicaid Drug Utilization Review (DUR) boards
  - State Boards of Pharmacy (SBOP)
  - Pharmaceutical and Therapeutics (P&T) committees

Utilization Management Strategies

- **PA** is the process by which medical providers request and receive approval for coverage from health care payers
- **Daily dosage limits** are the maximum daily amount of a drug that Medicaid will cover; excess amounts require PA or are not covered
- **Refill thresholds** are the number of days before a prescription runs out that a pharmacy can dispense a refill (typically a percentage of the days' supply that must be used before a refill can be provided)

Review of Key Findings

PA: Findings

- Findings from studies on effects of PA on costs and access to MOUD are mixed
- Evidence suggests that cost savings for total cost of care are limited
- There is some evidence that PA requirements can help ensure MOUD is prescribed appropriately; but some evidence suggests that removing PA requirements for buprenorphine may not markedly change buprenorphine prescribing
- PA may reduce improper use of medications, but it can restrict access to MOUD by denying or delaying care
- PA creates burden for patients and providers

PA: Findings, cont.

- Payer-specific PA processes and clinical criteria for coverage decision making are often not publicly available
  - State DUR reports provide limited information on PA for MOUD
- Based on DUR reports, most states provided at least one oral buprenorphine/naloxone product without PA in FYs 2019 through 2023
- States leverage flexibilities to design PA policies
  - States can limit or prohibit PA for MOUD, based on medication type, inclusion on the state's preferred drug list (PDL), or time period (e.g., prohibited for the first 30 days of treatment)
  - State Medicaid programs' ability to create a PDL and apply PA to specific medications gives them leverage when negotiating supplemental rebates
  - Single PDLs may result in administrative streamlining and easier prescribing for providers

Daily Dosage Limits: Findings

- Daily dosage limits may pose barriers for those seeking OUD treatment by inhibiting patient-centered care and shared decision-making
  - States may impose PA for higher doses of buprenorphine
- Daily dosage limits generally reflect recommended dosages on FDA drug labels and clinical standards
  - Limits may become outdated if changes in clinical needs and emerging evidence for different dosing approaches outpace the FDA's label update process
- The FDA issued a December 2024 notice recommending makers of these products to submit applications to adjust labels accordingly

Daily Dosage Limits: Findings, cont.

- In some states, daily dosage limit policies (e.g., state dose tapering policies) are misaligned with FDA 2024 labeling recommendations
  - Concerns about budgetary considerations, risk of diversion with higher doses
- 35 states had daily dosage limits of 24 mg/day in FY 2023 DUR reports, an increase from 29 states in 2019

Refill Thresholds: Findings

- The federal government determines refill limits and timeframes for Schedule III drugs; state Medicaid agencies and MCOs must set refill thresholds for opioid prescriptions, including MOUD
- Some but not all state Medicaid agencies exclude opioid-based MOUD from pain-related opioid safety edits
- States have the flexibility to define refill thresholds for MOUD that are different from those applicable to opioids used for pain
  - Pharmacies may have the flexibility to set stricter refill thresholds than payers
- In FY 2023, refill thresholds for Schedule III substances in fee-for-service (FFS) ranged from 75 percent to 95 percent

Utilization Management in Medicare

Medicaid and Medicare policies differ

- Part D plan sponsors may not require beneficiaries to receive PA for buprenorphine more than once per plan year
- Buprenorphine for OUD is explicitly excluded from Medicare Part D pain-related opioid safety edits; however, Part D plans can implement separate safety edits, PA, or quantity limits for buprenorphine based on FDA labeling
- Medicare does not require a refill threshold for oral buprenorphine; this difference can be confusing for providers

Next Steps

Next Steps

- We welcome feedback and questions from the Commission about the background and findings presented on utilization management of MOUD in Medicaid
- Commissioners' feedback on the following would be helpful:
  - state policies making just *one* type of MOUD available without PA
  - the misalignment between state-established daily dosage limits and FDA guidance, and confusion among providers about daily dosage limits
  - policy differences between Medicaid and Medicare regarding PA for MOUD, refill thresholds and safety edits for oral buprenorphine
  - data gaps (e.g., about PA processes, limitations of information in CMS DUR reporting)
- We will return in October to present the findings from the claims analysis

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