Mountain-Pacific Quality Health

DUR PROGRAM NEWS

FALL 2016

Mark Eichler, RPh
DUR coordinator
Mountain-Pacific
Quality Health
3404 Cooney Drive
Helena, MT 59602
406-457-5843
Lisa Sather, RPh, editor
406-457-5818

The Drug Utilization Review (DUR) Program, administered by Mountain-Pacific through a contract with the Allied Health Services Bureau of the Montana Department of Public Health and Human Services, is the quality assurance body seeking to assure the quality of pharmaceutical care and to help provide rational, cost-effective medication therapy for Montana's Medicaid recipients.

Montana Medicaid Announces New Restrictions For Methadone Use In Non-Malignant Pain

Rationale for Requiring Prior Authorization

Based on a review of the currently available safety evidence and Montana utilization data, the Medicaid Drug Utilization Review (DUR) board has unanimously recommended implementation of Prior Authorization Criteria for the use of methadone in non-malignant pain.

Historical Information

- A 2012 Centers for Disease Control report found that methadone in pain treatment is associated with a disproportionately high number of overdose deaths compared to other opioid pain relievers (http://www.cdc.gov/vitalsigns/methadoneoverdoses/).

This can be attributed to specific safety concerns related to methadone:

- Narrow therapeutic index, especially in combination with other medications
- Duration of analgesic action is much shorter than elimination half-life
- Steady-state concentrations and full analgesic effects do not occur until at least 3-5 days or longer after therapy initiation
- Cardiac risks: Boxed warning for QTc interval prolongation and serious arrhythmias (torsades de pointes) requiring close monitoring
- Combination use with benzodiazepines or other CNS depressants increases risk of serious side effects including life-threatening respiratory depression

- In October 2015, the president issued a memorandum addressing prescription drug abuse and overdose. A section of the memorandum specifically addresses agencies that facilitate access to health benefits, stating that they shall review and identify any current practices, such as use of methadone as a preferred or first-line pain management drug that are inconsistent with the goals of reducing opioid use disorders and overdoses. (https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin).

Continued ›

Approximately one out of three opioid deaths is associated with methadone ingestion

- In February 2016, the National Council for Behavioral Health convened a meeting with state Medicaid programs to discuss the prescription drug abuse and overdose epidemic. Specific action items addressed regarding methadone included:
  1. Placement of methadone on state Preferred Drug Lists (PDL).
  2. Utilization patterns of methadone and methadone + concomitant benzodiazepine use.
  - As a result, the majority of state Medicaid programs have either moved methadone to non-preferred status, or removed methadone from PDLs and implemented associated clinical criteria.
- Methadone was previously included on the Montana Medicaid PDL as a preferred agent. In April 2016, the DUR board recommended that methadone be removed from the PDL and clinical criteria developed for appropriate use.

Montana Retrospective Methadone Drug Utilization Review Study Information

- A retrospective drug utilization review analysis of Montana Medicaid recipients' methadone use was performed in February 2016.
  - » **For a 6-month period, there were 108 unique Medicaid recipients who received a methadone Rx. Of those individuals, 52 concurrently received a prescription for a benzodiazepine (BZD)**
    - › **Max dose methadone utilized was 110 mg daily**
    - › **Max dose methadone in conjunction w/BZD was 160 mg daily**
    - › **38/52 (73%) of patients received chronic therapy (>3 months) with methadone/BZD concurrently**
      (- Of these patients, 11/38 (29%) had methadone and benzodiazepine prescriptions from different prescribers)

Methadone Prior Authorization Criteria

Note: Exceptions to the criteria requirements below will include utilization for the treatment of cancer pain, and current patients on stable therapy for the treatment of non-malignant pain (>90 days of therapy).

The American Pain Society Methadone Safety Guidelines (update 2014) are available online at www.jpain.org

Initial Review Criteria:

- Patient must be >18 years old AND
- Patient is being prescribed methadone for the treatment of severe, chronic pain and is not being treated with methadone for the treatment of opioid addiction
  - » The diagnosis of chronic non-malignant pain must be supported by progress notes, discharge notes or health conditions AND
  - » The prescriber must provide a copy of the signed pain management agreement documenting ongoing evaluations utilizing monitoring systems such as drug screens, pill counts, the Prescription Drug Registry (PDR), etc
- Medication must be used on a scheduled (and not-as-needed) basis
- Approval requires trial of at least two preferred agents within the past six months.
- PDR report must be attached (last three months)
- Patient must be opioid tolerant as evidenced by recent history (within the past two weeks) of receiving daily opioid analgesics at the following minimum doses for at least one week:
  - » 60 mg oral morphine per day
  - » 25 mcg/hr of transdermal fentanyl
  - » 30 mg oral oxycodone per day
  - » 8 mg oral hydromorphone per day
  - » 25 mg oral oxymorphone per day

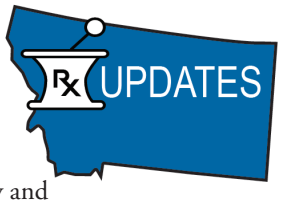
NOTE: A Prior Authorization Request Form can be obtained by contacting the Medicaid Drug Prior Authorization Unit, administered by Mountain-Pacific Quality Health: 1-800-395-7961

- Duplication with other long-acting narcotic agents or benzodiazepines will not be allowed.
- Limitations:
  - » Initial fill will be authorized for six months.
    - Daily quantity limits will apply:
      - » 5 mg/5 ml solution – 80 ml
      - » 10 mg/5 ml solution – 40 ml
      - » 10 mg/ml solution – 8 ml
      - » 5 mg – 8 units
      - » 10 mg – 8 units
      - » 40 mg dispersible tablet – not allowed (Not FDA indicated for pain, indicated only for the treatment of opioid dependence)

Continuation of Therapy Review Criteria:

- Patient must have been compliant with medication fills AND
- Patient must not have filled any opiates from any other prescriber AND
- No history of behavior indicative of abuse including early refill requests has been noted
- Subsequent authorizations will be granted at one-year intervals

Other Montana Medicaid Prior Authorization Criteria Updates



Initial 15-day supply requirement for atypical antipsychotic agents removed
Effective immediately, atypical antipsychotic medications will no longer require an initial 15-day supply and will process appropriately if written for a 30-day supply of a preferred agent*. Approval may still be subject to dose limits and clinical criteria.

Hepatitis C Updates

- ➤ Hepatitis C treatments will no longer require renewal after the initial four weeks of therapy. If approval is granted, medications will be authorized for the duration of the approved therapy.
- ➤ A **Fibrosure**, **Fibrotest** or **liver biopsy** will be required documentation to support liver fibrosis stage (F0-F4).

The Montana Medicaid DUR board recently recommended the addition of new clinical prior authorization criteria as subsequently outlined for the following medications:

Nucala® (mepolizumab) and **Cinqair**® (reslizumab) are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Both are administered every four weeks, however **Nucala**® is administered subcutaneously and **Cinquair**® is given as an IV infusion. Due to the risk of anaphylaxis, both medications are to be administered in an appropriate health care facility and patients are to be monitored for signs/symptoms of anaphylaxis following the injection or infusion. Due to significant safety concerns and place in therapy, the following prior authorization criteria will apply:

- Medication must be prescribed by an appropriate specialist (allergist, pulmonologist or immunologist) or have an annual consult on file,
- Patient must have a diagnosis of severe asthma with an eosinophilic phenotype (confirmed),
- Patient must be appropriately using inhaled corticosteroids (ICS) and long-acting beta-agonist (LABA) inhalers,
- Patient must meet minimum age requirements (12 years old for **Nucala**® and 18 years old for **Cinqair**®),
- Prior authorization will be granted for one year. For yearly prior authorization updates, patients must have been adherent to the treatment regimen during the previous year (including inhaled corticosteroids and long-acting brochodilators, or the prescriber must provide information regarding extenuating circumstances.

References: Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC. 2015. Cinqair [Prescribing Information]. Frazer, PA: Teva Respiratory, LLC. 2016.

*The current Medicaid PDL can be accessed at: http://medicaidprovider.mt.gov/Portals/68/docs/pharmacy/mtpdl07122016.pdf

Montana Medicaid Top 20 Drugs for YTD 2016 by Generic Name*

Drug Name	By Dollars	# of Patients	Drug Name	By Rx Count
Aripiprazole	8,798,996	2,107	Hydrocodone/Acetaminophen	47,761
Methylphenidate	3,467,937	3,598	Albuterol	38,596
Lurasidone	3,109,032	730	Amoxicillin	28,033
Insulin Aspart	2,570,851	1,220	Gabapentin	27,307
Lisdexamfetamine	2,462,153	1,939	Omeprazole	26,876
Insulin glargine	2,411,667	1,353	Levothyroxine	24,980
Fluticasone/salmeterol	2,377,467	1,975	Methylphenidate	22,015
Atomoxetine	2,295,717	1,149	Lisinopril	21,058
Albuterol sulfate	2,270,610	16,398	Fluoxetine	20,931
Dextroamphetamine/amphet	2,270,116	2,743	Sertraline	20,681
Pregabalin	2,190,544	1,222	Azithromycin	17,103
Ombitasvir/Paritaprevir/Ritonavir;Dasabuvir	1,521,495	16	Bupropion	16,641
Quetiapine	1,219,997	2,542	Clonazepam	16,425
Insulin Detemir	1,181,369	693	Dextroamphetamine/amphet	16,273
Sofosbuvir	1,161,026	14	Montelukast	15,798
Oxycodone	1,124,075	3,623	Quetiapine	15,649
Dexmethylphenidate	1,088,863	637	Metformin	15,483
Fluticasone	1,027,764	6,042	Oxycodone	15,445
Ledipasvir/sofosbuvir	985,163	12	Lamotrigine	15,065
Lipase/protease/amylase	876,603	152	Citalopram	14,591

*excludes injectable drugs except insulins (Note: the brand product is preferred in some instances; dollars are pre-rebate).

Mountain-Pacific Quality Health
3404 Cooney Drive
Helena, MT 59602