Mountain-Pacific Quality Health

DUR PROGRAM NEWS

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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 Drug Prior
Authorization Unit
1-800-395-7961

Montana Health Care Programs and Preferred Drug List Updates

A trial of two preferred agents is now required for the **Serotonin Reuptake Inhibitor (SSRI)** and **Novel Antidepressant classes** on the Montana Medicaid Preferred Drug List. Of note, trazodone is excluded from applying to the two-trial requirement for the novel class. Following clinical review, the Montana Drug Utilization Review (DUR) Board unanimously recommended this change due to the availability of numerous preferred therapeutic options.

Long-Acting Narcotic Analgesics

Due to safety concerns, the DUR board recommended **fentanyl patches be moved to non-preferred status for the treatment of non-malignant pain**. This requirement was effective January 24, 2019.

Anti-Migraine Treatments

Effective June 12, 2019, Emgality® (galcanezumab) became the preferred CGRP-inhibitor (calcitonin gene-related peptide) migraine agent. Approval for Aimovig® (erenunumab) or Ajovy® (fremanezumab), the other available CGRP-inhibitor agents, will require a clinical rationale why Emgality® cannot be utilized. Additional clinical criteria also apply to the CGRP-inhibitor class. Please contact the Drug Prior Authorization (PA) unit for the detailed PA form.

Support Act Requirements

In October 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act received presidential approval. The SUPPORT Act is a federal law that creates new DUR requirements for all state Medicaid programs that must be implemented by October 1, 2019. One component of this requirement is a claims review process that monitors when a Medicaid recipient is concurrently prescribed opioids and antipsychotic agents. Guidance from the Centers for Medicare & Medicaid Services (CMS) regarding the scope of this particular requirement was unclear, leaving states to determine specific oversight.

The Montana Medicaid DUR board recommended addressing those specific antipsychotic agents, which are sedating in nature, when used in combination with opioids. As a result, Montana Medicaid will be identifying those recipients who are receiving sedating antipsychotic agents in combination with opioid medications and informing providers through an educational process.

Montana Healthcare Pharmacy Programs Link
(Current Montana Medicaid Preferred Drug List, Provider Notices, DUR Board/Meeting Information, Resources)
http://medicaidprovider.mt.gov/19

Montana Medicaid Further Announces Dosage Restrictions for All Opioids Based on Maximum Morphine Milligram Equivalents (MME)

Effective June 3, 2019

Morphine Milligram Equivalents (MME)

Also described as MEDD (Morphine Equivalent Daily Dose) or MED (Morphine Equivalent Dose)

- MME are used to assess comparative potency to morphine but not to convert from a particular opioid dosage to another.
- The calculation to determine morphine equivalent daily dosing includes drug strength, quantity, day's supply and a defined conversion factor unique to each drug. Dose conversions to MME are estimated and do not account for incomplete cross-tolerance or individual differences in pharmacokinetics and therefore should not be used to convert from one opioid to another.
- By converting the dose of an opioid to a morphine equivalent dose, a clinician can determine whether a cumulative daily dose of opioids approaches an amount associated with an increased risk.

Rationale for Requiring Prior Authorization

- The benefits of high-dose opioids for chronic pain have not been established.
- The U.S. Centers for Disease Control and Prevention (CDC) "Guideline for Prescribing Opioids for Chronic Pain" recommends close follow-up for patients receiving >50 MME per day and **avoiding >90 MME per day unless cautiously justified**.
- Recent clinical studies demonstrate that a patient's cumulative daily MME can be utilized as an indicator of potential dose-related risk for serious harms such as motor vehicle injury, opioid use disorder and overdose.
- The clinical evidence suggests a patient receiving > 100 mg MME daily is up to nine times more likely to overdose than a patient on a lower dose.

Prior Authorization Requirements

The Montana Department of Public Health and Human Services (DPHHS), in conjunction with a review of the clinical evidence from the Montana Medicaid Drug Utilization Review Board, has recommended implementation of a daily MME dose for all opioids for the treatment of non-malignant pain.

Effective June 3, 2019, a maximum limit of 120 MME will be allowed per day for existing patients. Individual claims or multiple claims that exceed this average daily limit will reject at the pharmacy and will require a prior authorization from the prescriber. New starts are limited to a maximum of 90 MME. Please see the DPHHS provider notice for further information:

https://medicaidprovider.mt.gov/Portals/68/docs/providernotices/2019PN/provnotice192744dosagerestrictionsfor%20opiodsMME05012019.pdf?ver=2019-05-01-105810-417

No standard opioid tapering schedule is available, and a patient-specific plan should be developed to avoid withdrawal symptoms (see also FDA Safety Announcement, next page). As one example, the CDC Guideline for Prescribing Opioids for Chronic Pain recommends the dose of an opioid tapered by 10% weekly to 10% monthly (see Section 7 in the guideline for further information).

For reference:

120 MME/day = **120** mg hydrocodone = **80** mg oxycodone = **40** mg oxymorphone = **30** mg hydromorphone

Online MME calculators available at:

CDC Opioid Guideline App with MME calculator: https://www.cdc.gov/drugoverdose/prescribing/app.html

Washington Agency Medical Director's Group: http://www.agencymeddirectors.wa.gov/opioiddosing.asp

References: Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

FAQ Corner

What is the mechanism to obtain a drug prior authorization approval in an emergency, after hours or on holidays and weekends?

If a medication rejects for prior authorization, an emergency, 72-hour supply of medication may be dispensed by the pharmacy after hours, on weekends, on holidays and for emergency situations when the Drug Prior Authorization Unit is closed. This override is to only be used when clinically appropriate and is auditable by DPHHS.

Payment is authorized by the pharmacy entering a "3" in the Days Supply field and a Medical Certification Code of "8" in the PA/MC Code Field and changing the quantity dispensed to equal a three-day supply.

FDA Safety Announcement

Why is the FDA requiring labeling changes?

The U.S. Food and Drug Administration (FDA) has received reports of serious harm to patients physically dependent on opioids, whose medications were abruptly discontinued or had an inappropriate rapid reduction in dose. Harms have included uncontrolled pain, psychological distress and suicide. In April 2019, the FDA approved changes to the prescribing information for these medications when used in the outpatient setting. Guidance for health care professionals includes:

FDA requires labeling changes for opioids to guide individualized tapering. Avoid sudden discontinuation or rapid dose reduction.

- Avoid abrupt or rapid dose discontinuation in physically dependent patients; gradually taper.
- Unintended consequences have also included attempts to find additional opioids, including illicit.
- Ensure ongoing care of the patient and reasonable expectations.
- In developing a tapering plan, consider duration of previous treatment, current dose, type of pain and physical/psychological attributes of the patient.
- No standard tapering schedule exists. General rule of thumb = Don't exceed 10-25% every 2 to 4 weeks.
- Consider pause of taper or increasing to previous dose for period of time if increased pain or serious withdrawal occur.
- Ensure a multi-modal approach to pain management is in place prior to taper initiation.
- Monitor patients for suicidal thoughts.
- If taper initiated due to suspected opioid use disorder, evaluate, refer, or treat patient for the disorder.
- Report any adverse events to the FDA MedWatch Program.

The complete safety update can be accessed at https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

What Is Kratom and Why Is Increasing Use of Concern?

Kratom is an herbal preparation made from the leaves of the Mytragyna speciosa tree (native to Southeast Asia). It is currently unapproved by the FDA, unregulated and is listed on the U.S. Drug Enforcement Agency (DEA) list of drugs and chemicals of concern. The DEA has previously sought to ban its use due to public safety concerns (this has been withdrawn as of October 2016 to allow for a public comment period).

Kratom has been promoted as an opioid replacement, analgesic, and anxiolytic as well as treatment for various other ailments. Although commonly ingested in capsule form, it is also available in other forms such as leaf, powders and tablets. Over 25 alkaloids have been isolated from Kratom, with the main psychoactive and analgesic properties produced by its mitragynine and 7-hydroxymitragynine components. Mitragynine does exhibit mu-opioid receptor agonism, but with less affinity than morphine. It has been described as having sedative/opioid properties at higher doses and stimulant effects at lower doses. Due to these pharmacologic properties, **Kratom use can lead to withdrawal symptoms and the potential for addiction**. The presence of 7-hydroxymitragynine and mitragynine can be tested by ordering a Kratom-specific urine drug screen.

There have been at least 44 deaths linked to Kratom use (many included other substances) reported in the U.S. in 2017, and several states have now banned its use. Multiple FDA warning advisories have also been issued. In an October 2017 letter to the DEA, the FDA recommended that Kratom be controlled in Schedule 1 of the Controlled Substance Act (like heroin and other Schedule 1 substances). The National Institute on Drug Abuse (NIDA) concurred.

https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-advisory-about-deadly-risks-associated-kratom. Accessed 6/6/2019.
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https://www.drugabuse.gov/publications/drugfacts/kratom. Accessed 6/6/2019.
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Montana Medicaid Top Therapeutic Classes YTD 2019