



Mountain-Pacific Quality Health

DUR PROGRAM NEWS

FALL 2019

Lisa Sather, RPh, Editor,
Director of
Clinical Pharmacy Services
406-457-5818

Tony King, RPh, PharmD
Director of
Pharmacy Programs
MT DUR Coordinator
406-457-5843

Mountain-Pacific
Quality Health
3404 Cooney Drive
Helena, MT 59602
www.mpqhf.org

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

SUPPORT Act Requirements Implemented October 1, 2019

On October 24, 2018, the Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law in response to the nations' opioid epidemic. This legislation is broad in scope and includes many provisions with the over-arching goal of reducing opioid related fraud, misuse and abuse. [The full version of the SUPPORT Act can be referenced here.](#)

For State Medicaid programs, updated retrospective and prospective drug utilization review (DUR) requirements are included within section 1004 of the Act and must be implemented by October 1, 2019. These provisions will supplement existing requirements previously mandated by Section 1927(g) of the Social Security Act. Currently, safety edits for opioids, including but not limited to maximum morphine milligram equivalents and fraud and abuse identification requirements, are addressed by the Montana Healthcare program. These are also specific requirements of the SUPPORT Act. The following new requirements of the SUPPORT Act will be implemented and monitored through an ongoing, retrospective DUR educational process:

Monitoring concurrent use of opioids and benzodiazepines

Clinical rationale: The Food and Drug Administration (FDA) added boxed warnings to opioid analgesics, opioid-containing products used for cough, and benzodiazepines regarding serious risks associated with concurrent use. Risks include extreme sleepiness, respiratory depression, coma and death. It is recommended to thoroughly evaluate the risk/benefit of concurrent use for each patient on a case-by-case basis. Patients who receive these medications in combination may benefit from increased coordination of care between all providers. [The FDA announcement can be referenced here.](#)

Monitoring concurrent use of opioids and antipsychotic agents

(Sedating antipsychotic agents will be targeted, per a recommendation from the DUR Board.)

Clinical rationale: In 2016 the FDA published a safety announcement warning about the increased risk of respiratory and central nervous system (CNS) depression associated with concurrent use of opioids and CNS depressants, including antipsychotic agents. Risks include extreme sleepiness, respiratory depression, unresponsiveness and death. It is recommended to limit prescribing opioids with other CNS depressants (e.g., antipsychotics) only when alternative treatments are inadequate. [The FDA announcement can be referenced here.](#)

Monitoring antipsychotic medication use in children

Background and clinical rationale: In 2012, federal law passed requiring states to develop programs for the appropriate use and monitoring of psychotropic medications for children in foster care. Montana has a robust, pharmacy case management-based foster care oversight program that was implemented in 2012. The SUPPORT Act now requires all states to implement programs that will monitor and manage the appropriate use of antipsychotics in **all** Montana Healthcare Programs children. Pediatric patients may experience more prevalent and severe adverse effects than those experienced in adults (e.g., weight gain, extrapyramidal side effects, insulin resistance).

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

Montana Healthcare Programs Updates

Initial Seven-Day Supply for Opioid-Naive Patients

Effective October 1, 2019, Montana Healthcare Programs will implement a maximum initial seven-day supply for opioid-naive patients. (Opioid-naive is defined as having no opioid claims within the last 90 days.) Claims that exceed this limit will reject at the pharmacy and require prior authorization.

Codeine/Hydrocodone/Tramadol Use in Pediatrics

Following a review of the clinical evidence and new safety warnings (see page 3) for the use of codeine, hydrocodone and tramadol products in pediatrics, the DUR Board has recommended implementation of the following prior authorization criteria:

- Codeine and hydrocodone-containing **cough and cold products** will not be approved for use in children <18 years of age.
- Codeine analgesic products will not be approved to treat pain in children <12 years of age.
- Tramadol products will not be approved to treat pain in children <12 years of age.

Growth Hormones

Existing growth hormone criteria have been updated to include allowing approval for Small for Gestational Age (SGA) with failure to achieve catch-up growth by age two. Approval for a diagnosis of SGA may be authorized according to the following criteria which is in accordance with guidelines and stakeholder consensus.

- Diagnosis of SGA as defined by birth weight and/or length of standard deviation (SD) of 2.0 or more below mean for gestational age AND
- Patient must be at least 2 years old AND
- Patient must not have attained a height above -2 SD by 2 years (failure to catch up)
- Open epiphyses required
- Bone age <14 - 15 years (female); <15 - 16 years (male) required

Gastrointestinal (GI) Motility Agents

After a review of the clinical evidence, the Montana DUR Board recommended implementation of prior authorization criteria (in addition to Preferred Drug List Requirements) for the following medications, which are both selective serotonin type 4 (5-HT₄) receptor agonists.

Motegrity® (prucalopride) is indicated for the treatment of chronic idiopathic constipation (CIC) in adults. The following prior authorization criteria will apply:

- Patient must be 18 years old or older.
- Diagnosis of CIC is required.
- Patient must have been unsuccessful with documented treatment with a stimulant laxative (e.g., senna, bisacodyl) AND lactulose.
- LIMITATIONS: Maximum of 1 tablet daily of either 1mg or 2mg tablet

Zelnorm® (tegaserod) is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in female adults < 65 years of age. Zelnorm® initially received FDA approval in 2002 but was subsequently removed from the market due to cardiac safety concerns. The FDA has issued approval again in 2019 after new cardiac data was presented and restrictions on patient selection were required. The following prior authorization criteria will apply:

- Patient must be a female between 18 and 65 years of age.
- Diagnosis of irritable bowel syndrome with constipation (IBS-C) is required.
- Patient must not have a history of myocardial infarction, stroke, transient ischemic attack or angina.
- Documented trials of a stimulant laxative (e.g., senna, bisacodyl) AND lactulose have been inadequate.
- LIMITATIONS: Maximum of 2 tablets daily



Evidence-Based Prescribing-Medications to Avoid in Children

Codeine, Hydrocodone and Tramadol

Codeine and hydrocodone-containing cough and cold products are no longer indicated to treat cough in children <18 years old following an extensive clinical evidence review by the FDA and advisory committee input (FDA-January 2018).

Codeine products for analgesia are contraindicated in children <12 years old, and in children between 12 and 18 if post-tonsillectomy/adenoidectomy. The American Academy of Pediatrics warns against its use in children < 18 years old for any reason.

Tramadol is contraindicated to treat pain in children <12 years old, not recommended in children between 12 and 18 years old if obese or has obstructive sleep apnea/severe lung disease and contraindicated in children <18 years old to treat pain after surgery to remove tonsils and/or adenoids (FDA-April 2017). (Tramadol is not FDA-approved in children, but may have been used off-label as a codeine alternative).

Serious Risks Outweigh Benefits in Children <18 Years Old

Codeine (3-methylmorphine) is a pro-drug, opioid analgesic with low affinity for opioid receptors within the central nervous system and has been used extensively as an analgesic and antitussive. Although codeine was historically considered safe with a wide therapeutic index, current understanding of pharmacogenetic variations in metabolism warrant closer scrutiny for its use. Codeine must first be metabolized to its active form, morphine, by the CYP2D6 enzyme within the liver to exert its analgesic effect.

- Toxicity and limited efficacy potential: Ultra-rapid metabolizers can produce toxic levels of morphine, resulting in respiratory depression, apnea or death after a therapeutic dose. Slow metabolizers may produce low morphine levels and have little or no analgesic effect.
- Codeine was a factor in 64 cases of severe respiratory depression and 24 deaths in children between 1965 and 2015, according to a FDA review of Adverse Event Reporting System data.

Hydrocodone is a full μ -opioid receptor agonist metabolized by CYP2D6 to the active metabolite, hydromorphone, which can accumulate in ultra-rapid metabolizers (up to 8x higher levels) and may provide inadequate analgesia in slow metabolizers.

Tramadol is a synthetic μ -opioid receptor agonist and weak serotonin/norepinephrine re-uptake inhibitor. It is also metabolized by CYP2D6 to an active metabolite, O-desmethyltramadol. Ultra-rapid metabolizers can produce high levels of the active metabolite, which can lead to toxicity (identified in one case of an ultra-rapid metabolizer that prompted the FDA to update tramadol labeling). Inadequate analgesia may occur in slow metabolizers.

All agents: Addiction potential exists. Alternative agents are available that can reduce unnecessary exposure to opioids in children.

Evidence-based alternatives:

- Mild to moderate pain - Acetaminophen or ibuprofen
- Severe pain - Morphine
- Cough - Vaporizer, humidifier, fluids, honey (if >1 year old), benzonatate (>10 years old if prescription treatment necessary)

Summary

The use of codeine, hydrocodone and tramadol in pediatrics should be avoided due to the potential for limited effectiveness, toxicity and/or future addiction. The use of alternative agents with superior safety and efficacy profiles are strongly recommended in pediatric patients <18 years old.

Sources:

Benzonatate. Drug Facts and Comparisons. Facts & Comparisons eAnswers. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.factsandcomparisons.com>. Accessed August 5/8/2018.

Clinical Resource, Analgesics in Kids: FAQs. Pharmacist's Letter/Prescribers Letter. March 2018.

https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed 8/28/2019.

<https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm>. Accessed 8/28/2019.

<https://www.fda.gov/news-events/press-announcements/fda-acts-protect-kids-serious-risks-opioid-ingredients-contained-some-prescription-cough-and-cold>. Accessed 8/28/2019.

Lexicomp online, Wolters Kluwer Clinical Drug Information, Inc.; Codine: Pediatric Drug Information. Accessed 8/28/2019.

Tobias JD, Green TP, Cote CJ, AAP SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE, APP COMMITTEE ON DRUGS. Codeine: Time to Say "No". Pediatrics. 2016; 138 (4); e20162396.

Montana Medicaid Top Therapeutic Classes YTD 2019

