Mountain-Pacific Quality Health

DUR PROGRAM NEWS

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

Tony King, RPh, PharmD
Director of
Pharmacy Programs
MT DUR Coodinator
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

FDA Safety Announcement - Gabapentinoids

Serious breathing problems associated with gabapentin/pregabalin

The U.S. Food and Drug Administration (FDA) has reviewed several data sources, including case reports submitted to the FDA, which have shown serious, life-threatening and sometimes fatal respiratory depression can occur when gabapentinoids are taken by patients **with respiratory risk factors**. Gabapentinoids were previously believed to be relatively safe, lacking drug interactions and having a wide therapeutic index.

The FDA is now requiring new safety warnings regarding respiratory depression be added to the prescribing information for gabapentinoids, and requiring manufacturers to conduct clinical drug trials to further evaluate abuse potential of gabapentinoids (especially in combination with opioids due to rising misuse of the products together).

Who is at risk?

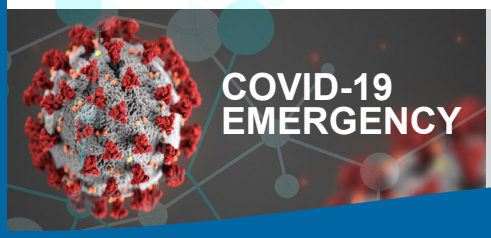
Patients who have respiratory risk factors such as:

- Those who use opioid pain medications or other central nervous system (CNS) depressants (i.e., anxiolytics, antidepressants and antihistamines)
- Those with underlying respiratory impairment, such as chronic obstructive pulmonary disease (COPD)
- Elderly patients

Guidance for Health Care Professionals

- Initiate gabapentinoids at the lowest effective dose, if prescribed with another CNS depressant (especially opioids) or in patients with underlying respiratory impairment.
- Adjust the dose of gabapentinoids in renal impairment or dialysis patients (renally excreted).
- Monitor the patient for symptoms of respiratory depression if co-prescribing in at risk patients.
- Provide patient safety education. Encourage patients to read the MedGuide received with their prescription.

The complete safety update can be accessed at:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin



The Department is closely monitoring this rapidly evolving situation. Please check the Montana Healthcare Programs provider website frequently for updates and provider notices.

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

After a review of the clinical evidence, the Montana Drug Utilization Review (DUR) Board recently recommended implementation of prior authorization criteria for the following medications:

Vumerity DR ™ (diroximel fumarate) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Coverage will be authorized if ALL the following criteria are met:

- Neurologist consult is required
- Diagnosis of relapsing form of multiple sclerosis is required
- Trial/inadequate response to an interferon beta and glatiramer are required
- Maximum of four capsules daily
- Initial approval will be for six months, then a follow-up from the provider is required to assure patient is tolerating and WBC monitoring is being done. Subsequent approvals will be granted for one year.

Dupixent™ (dupilimab) is an interleukin-4 receptor alpha antagonist previously indicated for uncontrolled moderate-severe atopic dermatitis (ages 12+) and add-on maintenance treatment for uncontrolled moderate-severe eosinophilic or oral steroid dependent asthma (ages 12+). Dupixent recently gained approval as add-on treatment for uncontrolled chronic rhinosinusitis with nasal polyposis (CRSwNP) in patients age 18 and older. The following criteria have been approved in addition to previously developed criteria for atopic dermatitis and asthma:

- Patient must be 18 years of age or older
- Medication must be prescribed by or in consultation with an allergist, immunologist or otolaryngologist
- Patient must have clinical documentation of chronic rhinosinusitis with nasal polyps as evidenced by a computed tomography (CT) scan or endoscopy
- Patient must have had an inadequate treatment response, intolerance or contraindication to *both of the following*:
  - » Two different intranasal corticosteroids (must be adherent to each therapy and used at optimized doses for at least 3 months) **AND**
  - » Systemic corticosteroid trial (must be within last year) **AND/OR** sino-nasal surgery
- Patient must concurrently be using an intranasal corticosteroid unless contraindicated

LIMITATIONS:

- Maximum of 2 x 300mg syringes every month
- Initial approval will be for six months
  - » Continuation of therapy approvals will be granted for 12-month intervals if patient has been adherent to therapy and concurrent intranasal corticosteroid AND documentation is provided supporting positive response to therapy as demonstrated by a reduction in severity of sino-nasal symptoms or systemic steroid reduction (if using).

Modafinil/Armodafinil in Pediatrics

The DUR Board recently reviewed information regarding utilization of modafinil/armodafinil in pediatric patients in Montana. The board recommended modification of the existing prior authorization criteria to exclude approval in patients under the age of 18 due to safety/efficacy concerns (previous criteria did not address the pediatric population). Any requests for the use of modafinil/armodafinil in pediatric patients will require individual case review by the DUR Board.

Montana Healthcare Programs Updates

Codeine/Hydrocodone/Tramadol Restrictions in Pediatrics

Based on a review of FDA-required labeling changes and safety concerns in pediatrics, the DUR Board recently recommended implementation of the following prior authorization in pediatrics:

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

For additional educational information, go to our website to see the detailed article in the winter 2019-2020 DUR newsletter: https://www.mpqhf.org/corporate/dur-winter-newsletter-2019/

Zolpidem Prior Authorization Requirements in Women (Effective 3/26/2020)

After a review of safety concerns and updated dosing information recommended by the FDA, the DUR Board recommended implementation of the following prior authorization criteria in women. Preferred drug list requirements also apply.

- Zolpidem IR: Will be limited to a 5mg initial dose in women who have not already been established on the medication. A dose increase to 10mg will be authorized if the 5mg dose has been tolerated but has not been effective.
- Zolpidem ER: Will be limited to a 6.25mg initial dose in women who have not already been established on the medication. A dose increase to 12.5mg will be authorized if the 6.25mg dose has been tolerated but has not been effective.

See p. 4 of this newsletter for additional zolpidem educational information.

Eszopiclone Prior Authorization Requirements (Effective 3/26/2020)

Due to safety concerns, the FDA has recommended initial dosing limitations for eszopiclone for both men and women due to the potential for next-day impairment of driving and other activities that require alertness. An initial dose of 1mg will be required for men and women not previously established on this medication. A dose increase to 2mg or 3mg will be authorized if the medication has been tolerated but not effective. Preferred drug list requirements also apply.

Changes to Hepatitis C Treatment Criteria

Per a recent provider notice, effective February 3, 2020, Montana Healthcare Programs expanded Hepatitis C treatment coverage to individuals with all stages of liver fibrosis. The Montana Department of Public Health and Human Services also eliminated the provider specialty restriction and readiness criteria. Prior authorization is still required to ensure the treatment prescribed is for an FDA-approved indication and duration of treatment. In addition, providers must attest they have educated the patient regarding treatment goals and expectations and have assessed the patient's psychosocial readiness. The patient must also attest they have discussed their treatment with their provider and understand retreatment may not be possible if a cure is not achieved.

The complete prior authorization form can be obtained by calling the Drug Prior Authorization Unit at 1-800-395-7961.

Mavyret™ is Montana Healthcare Programs' preferred Hepatitis C treatment for most individuals, as it is appropriate for all genotypes, most stages of liver disease and usually requires only eight weeks of treatment. However, there are currently no FDA-approved direct-acting antiviral Hepatitis C treatments for retreatment in individuals who have failed Mavyret™. Before beginning treatment with Mavyret™, it is imperative providers ensure their patients are fully engaged in all aspects of their health care, including their ability to follow up and complete treatment. Providers must perform psychosocial readiness evaluations and work with members to identify and eliminate barriers to successful treatment.

The complete provider notice can be accessed here: https://medicaidprovider.mt.gov/Portals/68/docs/providernotices/2020PN/provnoticchangestohepatitisctreatmentcriteria01032020.pdf

Prior authorization and attestation forms can be accessed here:
https://medicaidprovider.mt.gov/Portals/68/docs/forms/HepCPAForm01102020.pdf

FDA Recommends Lower Zolpidem Doses to Reduce Morning Somnolence

In January 2013, the U.S. Food and Drug Administration (FDA) notified the public of new recommended doses for zolpidem, a widely prescribed insomnia drug available generically, and the active ingredient in the branded products Ambien®, Ambien CR®, Edluar® and Zolpimist®. The FDA recommends the dose be lowered, because new data show blood levels in some patients may be high enough in the morning after use to impair activities that require alertness, including driving.

Driving Simulation Studies:

Recent driving simulation and laboratory studies indicate that blood levels above 50ng/ml appear capable of impairing driving to a degree that increases the risk of a motor vehicle accident. In pharmacokinetic trials of 250 men and 250 women, zolpidem concentrations that exceeded 50ng/ml eight hours after use were found:

- In trials of *immediate-release 10mg zolpidem*, in about *15% of women* and *3% of men*.
- In trials of *extended-release 6.25mg zolpidem*, in about *15% of women* and *5% of men*.
- In trials of *extended-release 12.5mg zolpidem*, in about *33% of women* and *25% of men*.

*New guidelines suggest reducing the dose of certain zolpidem containing products **by 50% in women** to avoid residual morning effects.*

New Zolpidem Dosing Recommendations:

As a result of these studies, the FDA informed manufacturers the recommended doses for women and men should be adjusted due to decreased elimination rate of zolpidem in women. *The FDA is recommending the doses for immediate-release products (Ambien®, Edluar®, Zolpimist® and generics) be lowered from 10mg to 5mg, and from 12.5mg to 6.25mg for extended-release products (Ambien CR® and generics) in women*. The FDA is also encouraging manufacturers to change labeling to indicate lower doses should also be considered in men, especially with extended-release zolpidem, as next-morning impairment is highest for patients taking the extended-release forms.

Zolpidem Dosing Recommendations for Adults (Non-Elderly):

Zolpidem Dosage Form	Previous FDA Approved Dosing Recommendations	New FDA Dosing Recommendations
Ambien® (tablet) Edluar® (sublingual tablet) Zolpimist® (oral solution)	**Men and Women**: 10mg once daily, immediately before bedtime	**Women:** 5mg once daily, immediately before bedtime **Men:** 5 or 10mg once daily, immediately before bedtime
Ambien CR® (extended- release tablet)	**Men and Women:** 12.5mg once daily, immediately before bedtime	**Women:** 6.25mg once daily, immediately before bedtime **Men:** 6.25 or 12.5mg once daily, immediately before bedtime

- Lower doses of immediate-release and extended-release zolpidem are recommended for elderly patients (men and women), debilitated patients, and for those with hepatic impairment.
- The recommended doses of Intermezzo®, a lower dose zolpidem product (1.75mg and 3.5mg) approved for middle-of-the-night awakenings, are not changing since the label already recommends a lower dosage for women than for men.
- Patients already prescribed zolpidem should contact their healthcare provider prior to adjusting their dose.

References:

1. http://www.fda.gov/Drugs/DrugSafety/ucm334041.htm (Accessed March 3, 2020).
2. https://www.fda.gov/media/84992/download (Accessed March 3, 2020).
3. PL Detail-Document, FDA Recommends Lower Doses for Zolpidem-Containing Products. Pharmacist's Letter/Prescriber's Letter. February 2013.

Montana Medicaid Top Therapeutic Classes YTD 2020