Mountain-Pacific Quality Health
DUR PROGRAM NEWS
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Montana Healthcare Programs Prior Authorization Criteria Updates

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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 Healthcare Programs members.

Montana Healthcare Programs
Drug Prior Authorization Unit
1-800-395-7961

The Montana Healthcare Programs Drug Utilization Review Board recently recommended the addition or modification of clinical prior authorization criteria as subsequently outlined for the following medications:

Entresto™ (sacubitril/valsartan) – A combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated:

1. To reduce risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
2. For treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes.

Member must meet all the following criteria:

- Have a diagnosis of symptomatic chronic heart failure with reduced ejection fraction (HFrEF): LVEF ≤ 40%
- Concurrently taking an evidence-based beta-blocker (metoprolol succinate, carvedilol or bisoprolol) unless contraindicated
- ACEI or ARB must be discontinued if approved; ACEI must be discontinued at least 36 hours in advance of starting Entresto
- Max daily dose (MDD): 2 tablets

Invega Trinza™ (paliperidone palmitate) – Three-month injection atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna for at least four months.

Member must meet all the following criteria:

- Subject to PDL requirements
- At least 18 years of age or older
- Have a diagnosis of schizophrenia
- Have been treated with Invega Sustenna for **at least 4 months**

Linezolid™ (Zyvox) – An oxazolidinone-class antibacterial indicated in adults and children for treatment of the following infections caused by susceptible Gram-positive bacteria: Nosocomial pneumonia; Community-acquired pneumonia; Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; Uncomplicated skin and skin structure infections; Vancomycin-resistant Enterococcus faecium infections.

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

Montana Health Care Programs Prior Authorization Criteria (cont.)

Growth Hormone Therapy with Turner Syndrome – Member must meet all the following criteria:

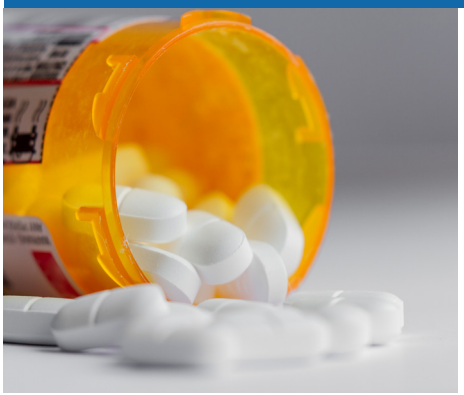
- Must be prescribed by or in consult with an endocrinologist
- Height of female is below 5th percentile for age on the normal female growth chart (Note: This usually occurs between two and five years of age.)
- Open epiphyses required
- Bone age < 14-15 years

The Board also requested that ALL growth hormone therapies be prescribed by or in consult with an endocrinologist. All indications for growth hormone will be updated with this specialist requirement.

For More Information

Overall, the Board reviewed and recommended criteria for 20 medications during the July/September Drug Utilization Review (DUR) Board meetings. To find the DUR Board Meeting Minutes and Agendas please visit https://medicaidprovider.mt.gov/19dur. For current prior authorization criteria, please visit https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/.

Gabapentin Utilization



Gabapentin is approved by the Food and Drug Administration (FDA) for seizures and post-herpetic neuralgia but has a wide variety of off-label uses including fibromyalgia, neuropathic pain, anxiety and insomnia. From 2012 to 2016, gabapentin prescribing increased by 64%, and in 2017, it was the tenth most commonly prescribed medication.[1]

While Lyrica (pregabalin) is classified as a Schedule V controlled substance and reported to the Montana Prescription Drug Registry (MPDR), gabapentin is not controlled and is not currently reported or searchable within the MPDR. While three states currently schedule gabapentin (Kentucky, Michigan, Tennessee), 12 additional states have either mandated reporting to the monitoring program or are pending action to mandate reporting.[2]

There have been several deaths attributed to gabapentin in combination with benzodiazepines, opioids and muscle relaxers due to their combined central nervous system (CNS) depressant effects. Additionally, in 2019 the Food and Drug Administration (FDA) announced a requirement for warnings to be added to gabapentinoids (gabapentin/pregabalin) highlighting the risk for serious breathing problems associated with these medications.[3] There has also been an increase in illicit use of gabapentin as the cutting agent in heroin.

Whether abused alone or with other agents, gabapentin overdose can result in excessive altered mental status, nausea, vomiting, ataxia, and coma. Additionally, studies have shown an increased risk for diversion for patients taking higher doses of gabapentin. Studies have shown the use patterns for gabapentin are similar to those of other abusable medications.[4]

After a review of the clinical evidence, the Montana DUR Board recently recommended implementation of limits on gabapentin. As there is no clinical evidence showing benefit above 3600mg per day, all patients not currently at that limit will be allowed a maximum of 3600mg per day in the near future.

A provider notice will be sent out from the Montana Department of Public Health and Human Services, and Mountain-Pacific's case management team will work with providers who have patients exceeding that limit on plans to manage those patients. Mountain-Pacific staff will engage in outreach to providers and will be available to assist with any questions/issues for this initiative.

[1] https://www.practicalpainmanagement.com/treatments/pharmacological/non-opioids/special-report-abuse-potential-gabapentin-pregabalin
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6103607/
[3] https://www.deadiversion.usdoj.gov/drug_chem_info/gabapentin.pdf
[4] https://pubmed.ncbi.nlm.nih.gov/28451875/

Montana Healthcare Programs Synagis® Coverage Criteria

Updated for the 2021-2022 RSV (Respiratory Syncytial Virus) Season

Per a recommendation from the Montana Healthcare Programs Drug Utilization Review (DUR) Board, Montana Healthcare Programs has adopted the revised American Academy of Pediatrics (AAP) recommendations for the use of palivizumab for RSV prophylaxis.

Initial guidance from the American Academy of Pediatrics (AAP) for the use of Synagis® (palivizumab) for prophylaxis against RSV was first published in 1998 and is updated periodically as new data becomes available.

In 2014, new peer-reviewed, evidence-based data allowed additional clarification and simplification of the AAP recommendations to target children at the highest risk of severe disease. These decisions were reaffirmed again in 2019.

Palivizumab is not a vaccine, but a monoclonal antibody produced by recombinant DNA technology, which works to bind to the RSV and effectively neutralizes it and inhibits fusion with respiratory epithelial cells. This only occurs if palivizumab encounters RSV in the lower respiratory tract. Clinical studies show immunoprophylaxis has a **limited effect on reducing RSV hospitalizations** on a population basis. Additionally, **no prospective, randomized clinical trial has demonstrated a significant decrease in the rate of mortality associated** with RSV **or in the rate of recurrent wheezing after RSV infection** among infants who receive prophylaxis.

The majority of RSV hospitalizations occur in healthy, term infants. Updated AAP guidance targets infants at the greatest risk for severe disease with risk factors that are the most consistent and predictive of benefit from prophylaxis. This is based on the evaluation of currently published evidence.

It should be noted that 21 AAP sections and committees and also groups outside the AAP have contributed to and concur with the updated guidance.

Please see the following links for the complete AAP reports:
Policy Statement - http://pediatrics.aappublications.org/content/134/2/415
Technical Report - http://pediatrics.aappublications.org/content/pediatrics/early/2014/07/23/peds.2014-1666.full.pdf

Coverage dates for Montana Healthcare Programs and Healthy Montana Kids/CHIP RSV prophylaxis began August 25, 2021, and will end April 30, 2022, unless the data of positive cases shows other trends. It is important to note that, although the monitoring statistics did not indicate a true RSV season for 2020-2021, the utilization of this medication was higher than in years past.

At the September 22, 2021 DUR Board meeting, the Board approved the opening and closing of the RSV season outside the normal date ranges. **Therefore, the Montana Department of Public Health and Human Services (DPHHS) has the ability to alter the date ranges using data trends.** The coverage dates are based on epidemiologic surveillance as reported by the Centers for Disease Control and Prevention (CDC). Visit https://www.cdc.gov/surveillance/nrevss/rsv/state.html.

- Approval will be for 1 dose per month, up to a **maximum** of 5 doses during the RSV season coverage dates.
- One 50mg vial (0.5ml) **OR** one 100mg (1ml) vial will be allowed. Doses above 100mg will require prior authorization based on patient weight.
- Criteria for the use of Synagis can be found at https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/.

Synagis® authorization is granted electronically through the SmartPA® Point-of-Sale Prior Authorization system, which evaluates prescription claims against available diagnosis history.

If a request is denied through the SmartPA® system and the patient should meet the criteria, please contact the Montana Healthcare Programs Drug Prior Authorization Unit at 1-800-395-7961 to provide additional supporting documentation for review.