



Mountain-Pacific Quality Health

# DUR PROGRAM NEWS

**WINTER  
2019 - 2020**

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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 Medicaid Synagis® Coverage Updated for the 2019-2020 Respiratory Syncytial Virus (RSV) Season

Initial guidance from the American Academy of Pediatrics (AAP) for the use of Synagis® (palivizumab) for prophylaxis against RSV was first published in 1998. It 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. It is a monoclonal antibody produced by recombinant DNA technology that works to bind to RSV and effectively neutralize the virus, inhibiting 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.

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

➤ See page 2 for specific Montana Healthcare Programs coverage criteria.

**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 Synagis® Coverage Criteria

### 2019-2020 Respiratory Syncytial Virus (RSV) Season

- Coverage dates for Montana Medicaid and Healthy Montana Kids/Children's Health Insurance Program (CHIP) RSV prophylaxis began December 12, 2019 and will end April 30, 2020. These coverage dates are based on epidemiologic surveillance by the Montana Department of Public Health and Human Services Communicable Disease and Epidemiology Program.
  - » RSV season onset officially begins the first of two consecutive weeks with  $\geq 10\%$  of specimens testing positive.
  - » The RSV season offset is the last of two consecutive weeks with  $\geq 10\%$  of specimens testing positive. Weekly updates can be found at <http://www.dphhs.mt.gov/publichealth/cdepi/diseases/rsv.aspx>.
- Approval will be for one dose per month up to a maximum of five doses during the RSV season coverage dates.
- One 50mg vial (0.5ml) OR one 100mg (1 ml) vial will be allowed. Doses above 100mg will require prior authorization based on the patient's weight.

Age at Onset of RSV Season	Risk Factors Eligible for Approval (any of the following)
<b>&lt;12 MONTHS</b> <i>(does not include 1st birthday)</i>	Estimated gestational age (EGA) <29 weeks
	EGA <32 weeks with a diagnosis of chronic lung disease (CLD) in the past 12 months and history of requirement for 21% oxygen for the first 28 days after birth (CLD of prematurity)
	Diagnosis of hemodynamically significant acyanotic congenital heart disease in the past 12 months <u>AND</u> history of drugs to treat congestive heart failure or moderate to severe pulmonary hypertension in the past 45 days
	Diagnosis of hemodynamically significant cyanotic congenital heart disease in the past 12 months <u>AND</u> prescriber is a pediatric cardiologist
	Diagnosis of severe neuromuscular disease or congenital respiratory abnormalities (does not include cystic fibrosis) in the past 12 months
	Patient undergoing cardiac transplantation <u>OR</u> patient is profoundly immunocompromised (e.g., stem cell or organ transplant, chemotherapy, etc.) during RSV season
<b><math>\geq 12</math> and &lt;24 MONTHS</b> <i>(does not include 2nd birthday)</i>	Diagnosis of CLD of prematurity as defined above in the past 2 years <u>WITH</u> history in past 6 months of O2 supplementation, diuretics or 3 or more claims for systemic or inhaled corticosteroids
	Patient undergoing cardiac transplantation <u>OR</u> patient profoundly immunocompromised during RSV season

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 meets the above criteria, please contact the Medicaid Drug Prior Authorization Unit at  
**1-800-395-7961**  
 to provide additional supporting documentation for review.

## 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:

**Sunosi® (solriamfetol)** is a dopamine and norepinephrine reuptake inhibitor (C-IV) indicated to improve wakefulness in patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Approximate cost is \$700-800/per month. Coverage will be authorized if the following criteria are met:

- Patient must be  $\geq 18$  years old
- Covered diagnoses:
  - » Narcolepsy with excessive daytime sleepiness - Requires an inadequate response, intolerance or contraindication to modafanil or armodafanil AND a central nervous system stimulant (i.e., methylphenidate, dextroamphetamine)
  - » Obstructive Sleep Apnea (OSA) impacting activities of daily living - Requires an inadequate response, intolerance or contraindication to modafanil or armodafinil
- Limitations:
  - » Max 1 tablet daily up to 150mg per day
  - » Initial approval for 6 months with re-authorization granted at 1-year intervals with evidence of clinical improvement

**Wakix® (pitolisant)** is an antagonist/inverse agonist of the histamine-3 (H3) receptor, although its complete mechanism of action is unclear. It is indicated for the treatment of EDS in adults with narcolepsy. Due to place in therapy, significant drug interactions and cost (approximately \$5,700 per month), the following prior authorization criteria have been implemented:

- Patient must be  $> 18$  years old
- Diagnosis of narcolepsy with EDS that impacts activities of daily living required
- Patient must have had an inadequate response, intolerance to or contraindication to ALL of the following:
  - » Central nervous system stimulant (i.e., methylphenidate, dextroamphetamine, etc.) AND
  - » Modafinil OR armodafinil AND
  - » Sunosi®
- Provider must have reviewed clinically significant drug interactions
- Limitations:
  - » Max 35.6mg/daily (dose optimization required)
  - » Initial authorization x 6 months; may be reauthorized at yearly intervals with attestation of clinical improvement

A prior authorization fax-back form for Wakix® can be obtained by contacting the Medicaid Drug Prior Authorization Unit, administered by Mountain-Pacific, at 1-800-395-7961.

### Prior Authorization Criteria and Informed Consent for Atypical Antipsychotics Expanded for Children

Effective January 16, 2020, prior authorization requirements for atypical antipsychotics prescribed for children will be expanded to include age 7 and younger (previously 6 and under). Antipsychotic medication can cause significant metabolic side effects. In 2003, the Food and Drug Administration (FDA) required a warning on diabetes risk to be added to the prescribing information for all second-generation antipsychotics. In 2004, the American Psychiatric Association and the American Diabetes Association issued a consensus statement guideline recommending baseline and follow-up fasting glucose testing. Research indicates children, especially those who are antipsychotic naïve, are more vulnerable to metabolic effects than adults. Required documentation for prior authorization approval may include but is not limited to:

- Atypical antipsychotic medication dose/frequency
- Indication for use (diagnosis/target symptoms)
- Safety monitoring information (fasting blood sugar, lipids)
- Medication regimen history
- Informed consent signed by legal guardian and prescriber
- Provider specialty designation

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

# Montana Medicaid Announces Further Dosage Restrictions for All Opioids Based on Maximum Morphine Milligram Equivalents (MME) - Effective January 9

## Morphine Milligram Equivalent (MME)

- Also described as MEDD (Morphine Equivalent Daily Dose) or MED (Morphine Equivalent Dose)
- 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 an opioid dose 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 a patient's cumulative daily MME can be used 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 >100mg 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 DUR Board, has recommended implementation of a daily maximum MME dose for all opioids for the treatment of non-malignant pain.

Effective January 9, 2020, a maximum limit of 90 MME will be allowed per day for existing patients. New starts are also limited to a maximum of 90 MME. Individual claims or multiple claims that exceed this average daily limit will reject at the pharmacy and require prior authorization from the prescriber.

Please see the DPHHS provider notice for further information: <https://medicaidprovider.mt.gov/Portals/68/docs/providernotices/2019PN/provnoticedoseagerestrictionsOpiodsonMME12042019.pdf>

This information is being provided in advance of the limit implementation to allow prescribers to collaborate with existing patients on an individualized tapering plan and reduce to the current allowed maximum dose of <90 MME per day. No standard opioid tapering schedule is available, and a patient-specific plan should be developed to avoid withdrawal symptoms. 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:

90 MME/day = 90mg hydrocodone = 60mg oxycodone = 20mg oxymorphone = 22.5mg 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:

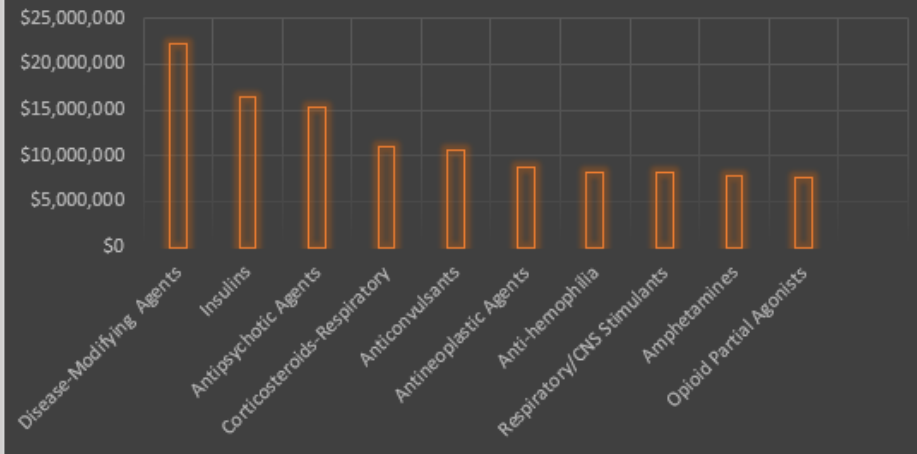
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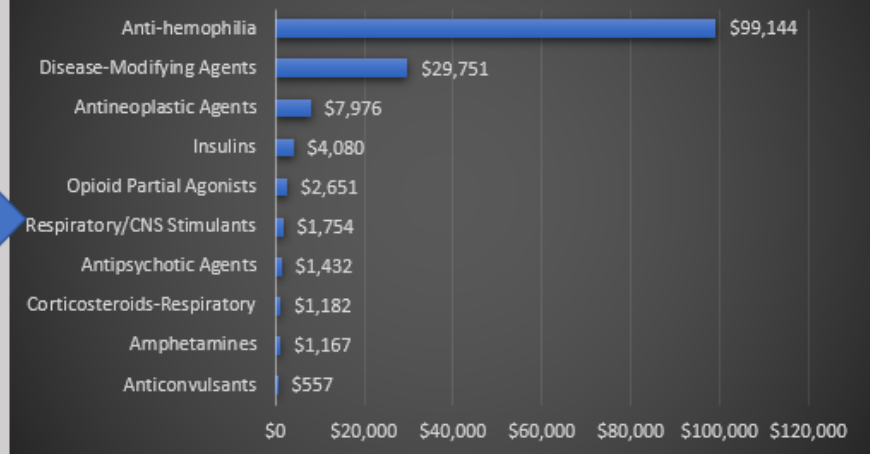
# Montana Medicaid Top Therapeutic Classes YTD 2019

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**By Total Claims Cost\***



**\* Average Cost Per Patient Detail**



**By Number of Claims**

