Mountain-Pacific Quality Health

# DUR PROGRAM NEWS

**WINTER 2015-2016**


Lisa Sather, RPh
DUR Coordinator
Mountain-Pacific
Quality Health
3404 Cooney Drive
Helena, MT 59602
406-457-5818


The Drug Utilization Reveiw (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 Synagis® Coverage

### Updated for the 2015-2016 RSV (Respiratory Syncytial Virus) 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 and updated periodically as new data has become available. New peer-reviewed, evidence-based data became available in 2014, which has allowed additional clarification and simplification of AAP recommendations to target children at the highest risk of severe disease.

> Per a recommendation from the Medicaid Drug Utilization Review (DUR) Board, Montana Medicaid has adopted the revised American Academy of Pediatrics (AAP) recommendations (released in July 2014) for the use of palivizumab for RSV prophylaxis.

Palivizumab is not a vaccine, but a monoclonal antibody produced by recombinant DNA technology, which works to bind to the RSV virus and effectively neutralizes the virus and inhibits fusion with respiratory epithelial cells. This only occurs if palivizumab encounters RSV in the lower respiratory tract. Clinical studies show that 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, full-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

For Specific Medicaid Coverage Criteria Continue ›

**For drug-specific prior authorization information, please contact the Medicaid Drug Prior Authorization Unit @ Mountain-Pacific 1-800-395-7961**

# MONTANA MEDICAID SYNAGIS® COVERAGE CRITERIA - 2015-2016 RSV SEASON CONT.

- **Coverage dates for Montana Medicaid RSV prophylaxis began December 15, 2015, and will end April 30, 2016.** 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 in Montana officially begins the first of two consecutive weeks with ≥10% of specimens testing positive.
  - ➢The RSV season offset is the last of two consecutive weeks with ≥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.
- Medicaid will allow one 50mg vial (0.5ml) OR one 100mg (1ml) vial. Doses above 100mg will require prior authorization based on patient weight.

| AGE AT ONSET OF RSV SEASON | RISK FACTORS ELIGIBLE FOR APPROVAL |
|---|---|
| **<12 MONTHS (does not include 1st birthday)** | |
| | 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** |
| | Diagnosis of **hemodynamically significant acyanotic congenital heart disease** in the past 12 months AND 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 **AND 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** OR patient is **profoundly immunocompromised** (e.g., stem cell or organ transplant, chemotherapy, etc.) **during RSV season** |
| **<24 MONTHS (does not include 2nd birthday)** | |
| | Diagnosis of **CLD in the past 2 years** WITH **history in past 6 months of O2 supplementation, bronchodilators, diuretics or 3 or more claims for systemic or inhaled corticosteroids** |
| | Patient **undergoing cardiac transplantation** OR 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 diagnosis history. If a request is denied through the SmartPA® system and the patient should meet the above criteria, please contact the Medicaid Drug Prior Authorization Unit @ Mountain-Pacific at 1-800-395-7961 to provide additional supporting documentation for review.**

# MONTANA MEDICAID PRIOR AUTHORIZATION CRITERIA UPDATES


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

**Belsomra®** (suvorexant) - A first-in-class, orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Orexin is a neuropeptide that promotes wakefulness, and inhibition of this neuropeptide is thought to suppress wake drive. It is a controlled substance (C-IV). In an abuse liability study, suvorexant produced similar effects of "drug liking" as zolpidem (Ambien®).

➢**Of note, the clinical trial for the FDA-approved starting dose of 10mg leading to the FDA approval of Belsomra® (vs. placebo) enrolled only 62 non-elderly subjects. This dose was only evaluated for one month.**

Due to significant safety concerns (see below), cost (approximately $315/month AWP) and the availability of numerous alternatives, the Montana DUR board unanimously recommended implementation of the following clinical criteria:

- Patient must be at least 18 years old and have a diagnosis of insomnia with NO history of narcolepsy.
- Patient cannot be concurrently taking opioids or benzodiazepines.
- Patient should not have a history of substance use disorder (drug or alcohol) or a history of suicidal ideation.
- Patient must have had a documented trial on one preferred benzodiazepine (unless contraindicated) in the last 24 months.
- Patient must have a documented inadequate response or contraindication to all of the following molecules: zolpidem, eszopiclone, zaleplon, ramelteon, trazodone, mirtazapine and doxepin within the last 24 months.
- Dosing limitations also apply. An initial approval will be granted for six months to determine efficacy and tolerance.

## Belsomra® Safety Concerns

➲Impaired daytime wakefulness that may persist for several days following a dose

➲Abnormal thinking and behavioral changes (amnesia, anxiety, hallucinations, "sleep driving/eating")

➲Worsening of depression and increase in suicidal ideation

➲Sleep paralysis, including an inability to move or speak for several minutes

➲Vivid/disturbing perceptions

➲Symptoms similar to mild cataplexy

**Luzu®** (luliconazole) - An antifungal indicated for the topical treatment of tinea pedis, tinea cruris and tinea corporis. Due to significant cost (~$425 AWP per 60 gm tube), patient must be 18 and have one of the above diagnoses confirmed by KOH preparation or culture and previously trialed two topical creams (clotrimazole, ketoconazole, etc. – cost around $30-35/month for generics). Quantity limits apply.

**Kerydin®** (tavaborole) - A topical oxaborole antifungal indicated for the treatment of onchomycosis of the toenails. Due to significant cost (~$545/4ml and $1370/10ml), patient must be >18, have a diagnosis of onychomycosis of toenails, have a documented major clinical complication secondary to onychomycosis) and have a contraindication to oral terbinafine. Quantity limits apply.

**Savaysa®** (edoxaban) - A factor Xa inhibitor FDA-indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (A-fib), and for the treatment of deep vein thrombosis and pulmonary embolism (following 5-10 days of therapy with a parenteral agent).

➢**Of note, the use of Savaysa® is not indicated in A-fib patients with normal renal function due to reduced efficacy and increased risk of stroke (stroke risk was increased by 64%). Due to the availability of several alternative newer agents without this restriction**, specific clinical limitations apply and can be obtained by contacting the Drug PA unit at **1-800-395-7961.**

Continued ▸

## Criteria Updates-Continued

**Movantik®** (naloxegol) - An opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. Naloxegol antagonizes mu-opioid receptors at the peripheral level (such as the GI tract) to decrease the constipating effects of opioids. It is a pegylated derivative of naloxone that reduces permeability at the central nervous system level, limiting interference with the intended effect of centrally mediated opioids. Due to significant cost (~$254/month AWP) and availability of other less expensive alternatives (i.e., lactulose), the following clinical criteria will apply:

- Patient must be at least 18 years old with a diagnosis of opioid-induced constipation of chronic, non-cancer pain and is recently receiving opiates (for 4 weeks); patient must have been unsuccessful with documented treatment of appropriate over-the-counter bowel regimen **AND** lactulose; patient must not concurrently be taking a strong CYP3A4 inhibitor (clarithromycin, ketoconazole, protease inhibitors for HIV, etc.). Quantity limits apply.

## References:


Belsomra [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp. 2014.

Movantik [Prescribing Information]. Wilmington, DE 19850: AstraZeneca Pharmaceuticals LP, Inc; January 2015

Savaysa [Prescribing Information]. Parsippany, NJ: Daiichi Sankyo Co.,LTD.; 2015.



Mountain-Pacific Quality Health
3404 Cooney Drive
Helena, MT 59602



Nonprofit Organization
US Postage
PAID
Permit No. 300
Helena, MT