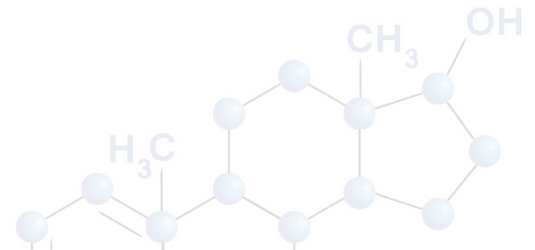




Mountain-Pacific Quality Health

DUR PROGRAM NEWS



WINTER 2017-2018

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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 2017-2018 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 last became available in 2014. This has allowed additional clarification and simplification of the AAP recommendations in order to target children at the highest risk of severe disease.

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, 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>

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



Continued ▶

Montana Healthcare Pharmacy Programs Link

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

Montana Medicaid Synagis® Coverage~Updated for the 2017-2018 RSV (Respiratory Syncytial Virus) Season, continued

Montana Healthcare Programs Synagis® Coverage Criteria

2017-2018 RSV Season

- **Coverage dates for Montana Medicaid and Healthy Montana Kids/CHIP RSV prophylaxis began December 13, 2017 and will end April 30, 2018.** 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 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.

| AGE AT ONSET OF RSV SEASON | RISK FACTORS ELIGIBLE FOR APPROVAL (any of following) | |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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 (CLD of prematurity) | |
| | 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 | |
| | ≥ 12 and <24 MONTHS (does not include 2nd birthday) | Diagnosis of CLD or prematurity as defined above in the past 2 years WITH history in past 6 months of O2 supplementation, 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 at 1-800-395-7961 to provide additional supporting documentation for review.

New illicit Fentanyl Formulation (acrylfentanyl) Causing Spike in Fatal Overdoses - May Be Naloxone-Resistant

The chemical entity acryl fentanyl was first noted in the scientific literature in 1981, but it has never been approved by the FDA for human consumption. It is a close analogue of the synthetic opioid fentanyl, a schedule II controlled substance available by prescription. DEA (Drug Enforcement Administration) officials suspect that it is being manufactured by drug labs in China and Mexico and being imported illegally in the US. Acrylfentanyl and other fentanyl analogues, carfentanyl and furanylfentanyl are commonly advertised on commercial “dark” web-based marketplaces for transactions involving drugs and other substances. These analogues are appearing in combination with other illicit drugs such as heroin and cocaine. The DEA has received reports of at least 83 confirmed fatalities associated with acrylfentanyl since September, 2016. Although the deaths occurred in Midwest and Eastern states, its use is likely to spread due to the regional nature of how drugs are distributed. Further toxicologic analyses from the unintentional overdose deaths in Ohio from the beginning of 2017 indicated a predominant presence of illicitly manufactured fentanyl analogues and the decline of prescription opioids. Approximately 90% of the deaths which occurred in early 2017 involved fentanyl, fentanyl analogues or both. 32% of decedents did not test positive for norfentanyl, the major metabolite for fentanyl, suggesting a very rapid death.

Fentanyl analogues including acrylfentanyl are not included in most illicit drug screens so may go undetected if overdose by these drugs are suspected. Preliminary reports suggest that acrylfentanyl may be resistant to the opioid reversal agent naloxone, but this has yet to be confirmed by laboratory science. In some case reports, as many as 4 doses of naloxone was required for a patient to be stabilized.

Pharmaceutical fentanyl is 50-100 times more potent than morphine, however illicitly manufactured fentanyl analogues can be up to 10,000 times more potent (i.e., carfentanyl).

In June 2017 the DEA issued a notice of intent to classify acrylfentanyl as a Schedule I controlled substance to avoid an imminent hazard to public safety. Currently, illicitly manufactured fentanyl analogues are not distinguished from pharmaceutical fentanyl in toxicology panels and have been responsible for most fentanyl-related overdoses in the US. This highlights a need to make illicitly manufacturer fentanyl analogue testing a part of standard toxicology panels.

Co-Prescribing Naloxone with Opioids in High-Risk Patients

Naloxone is a prescription opioid antagonist indicated for the emergency treatment of severe respiratory depression associated with known or suspected opioid overdose. The 2016 U.S. Centers for Disease Control and Prevention (CDC) “Guideline for Prescribing Opioids for Chronic Pain” recommends evaluating patients for risk factors for opioid-related harms before starting opioid therapy, and during therapy continuation. **It is recommended not to initiate opioids when factors that increase opioid-related harms are present.** However, if the decision is made to prescribe an opiate in the presence of certain risk factors, the CDC recommends considering offering naloxone as part of an overall strategy to help mitigate patient risk. Re-evaluating patients more frequently and referral to pain and/or behavioral health specialists is also recommended.

Consider offering naloxone with opioid therapy if any of the following risk factors which can increase risk of opioid overdose are present:

- A history of prior overdose
- Concurrent benzodiazepines and opioid use
- A history of substance use disorder
- In patients at risk for returning to a high dose to which they are no longer tolerant
- In patients taking higher dosages of opioids (≥ 50 MME /day) which is:
 - ≥ 50 mg of hydrocodone per day
 - ≥ 33 mg of oxycodone per day
 - ≥ 12 mg of methadone per day

The following naloxone products do not require prior authorization by Montana Medicaid when a prescription is provided to your patient:

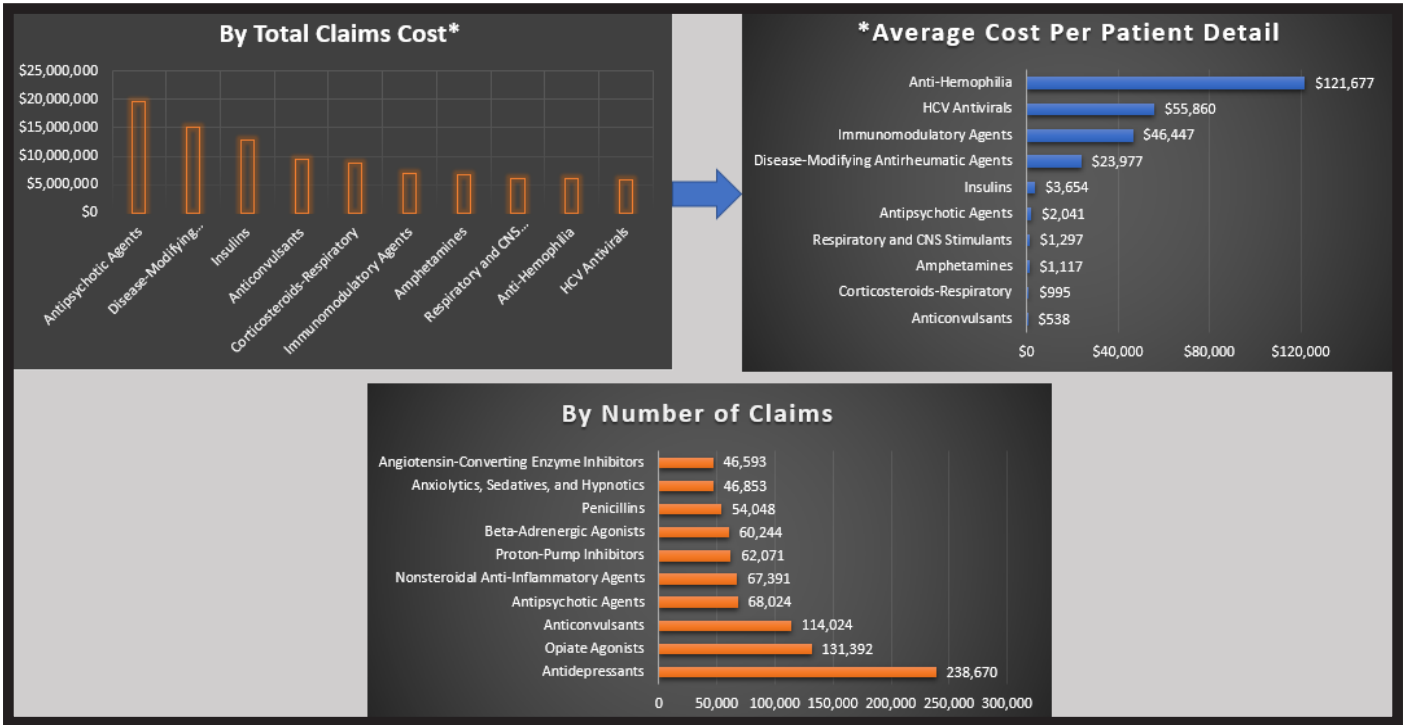
- Naloxone prefilled syringe for injection
- Naloxone vial for injection
- Narcan® nasal spray

The complete CDC guideline can be accessed at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

Resources for prescribing naloxone in primary care can be found through <http://prescribetoprevent.org/>.


Medicaid Drug Prior Authorization and Pharmacy Case Management, administered by Mountain-Pacific: 1-800-395-7961

Montana Medicaid Top Therapeutic Classes YTD 2017



The MT DUR Program News is also available online: <http://mpqhf.com/corporate/montanans-with-medicaid/pharmacy/>

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