Mountain-Pacific Quality Health

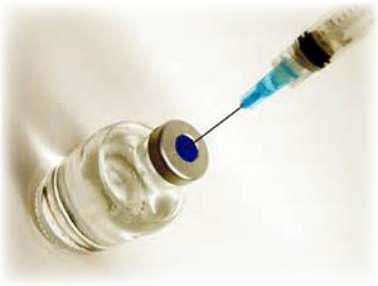
DUR PROGRAM NEWS

WINTER 2016

Mark Eichler, RPh
DUR coordinator
Mountain-Pacific
Quality Health
3404 Cooney Drive
Helena, MT 59602
406-457-5843
Lisa Sather, RPh, editor
406-457-5818

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 Synagis® Coverage~Updated for the 2016-2017 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.

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

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

Medicaid Coverage Criteria Continued Page 2 ›

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MONTANA MEDICAID SYNAGIS® COVERAGE CRITERIA 2016-2017 RSV SEASON

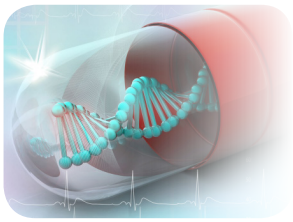
- **Coverage dates for Montana Medicaid RSV prophylaxis began December 15, 2016 and will end April 30, 2017.** These coverage dates are based on epidemiologic surveillance by the Montana Department of Public Health and Human Services Communicable Disease and Epidemiology Program.
  - » RSV season onset officially begins the first of two consecutive weeks with ≥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 1 dose per month, up to a **maximum** of 5 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 (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**
	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 **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.

Testosterone Products to Require Labeling Updates Regarding Risk of Abuse and Dependence



Why is the FDA requiring labeling changes?

In October 2016, the FDA approved a class-wide labeling change for all prescription testosterone products after completing a review of the published literature and numerous case reports regarding the risks associated with abuse and dependence of testosterone.

Prescription testosterone products are FDA-approved for use in men with documented low testosterone. The abuse of testosterone (C-III) containing products, typically at doses higher than prescribed, and usually in conjunction with other anabolic androgenic steroids, is associated with serious safety risks.

What has been updated?

Abuse and Dependence Section

- New safety information is now included from published literature and case reports regarding the risks associated with the abuse and dependence of testosterone and other anabolic androgenic steroids.

Warnings and Precautions Section

- **New Warning Added** –Testosterone is subject to abuse typically at doses higher than recommended for testosterone replacement and also in combination with other anabolic steroids. Serious cardiovascular and psychiatric adverse reactions may occur.
- **Recommendations for Provider Monitoring Added**
  - » If testosterone abuse is suspected, it is recommended to check serum testosterone concentrations to assure concentrations are within the normal therapeutic range.
  - » If serious cardiovascular or psychiatric adverse events occur, providers should consider the possibility of testosterone abuse.
  - » In men abusing synthetic testosterone derivatives, testosterone levels may be in the normal or subnormal range.
  - » Patients should be counseled regarding serious adverse reactions associated with abuse.

The complete safety update can be accessed at http://www.fda.gov/Drugs/DrugSafety/ucm526206.htm

REMINDER

METHADONE NOW REQUIRES PRIOR AUTHORIZATION

Effective December 21, 2016, methadone requires prior authorization for use in non-malignant pain. Criteria have been implemented based on a recommendation by the Medicaid Drug Utilization Review Board, after review of the currently available safety evidence and Montana utilization data.

Montana Medicaid recipients who are currently stable on methadone therapy, or those with a cancer diagnosis, will not require prior authorization. Concurrent other long-acting opioids or benzodiazepines will not be allowed with methadone regardless of diagnosis or stable therapy indicator.

Please contact the Montana Medicaid Drug Prior Authorization Unit at 1-800-395-7961 to obtain a Prior Authorization Form outlining the specific clinical requirements.

Mountain-Pacific Quality Health . . . a recognized leader for driving innovation in health care.

3404 Cooney Drive, Helena, MT 59602 • Phone 406.443.6002 • Toll Free 800.395.7961 • Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

Montana Medicaid Drug Prior Authorization
Key Contacts

In order to expedite Drug Prior Authorization requests and related issues, please see list below and direct inquiries to the appropriate contact

Drug Prior Authorization
For drug prior authorization requests and related questions (i.e., clinical criteria requirements, Preferred Drug List options, prior authorization status). *Note: Medication denials for eligibility/billing issues are processed by POS Help Desk or Provider Relations.*

800.395.7961 or **406.443.6002** (Helena)
8:00 am to 5:00 pm Monday–Friday (MST)

Fax back-up documentation to:

800.294.1350 or **406.513.1928** (Helena)

Provider Relations
For questions about **eligibility**, other **primary insurance information**, **member co-pay amounts**, **pharmacy unlocks** (press option 4 when prompted), and **provider enrollment issues**:

800.624.3958 or **406.442.1837** (Helena)
8:00 am to 5:00 pm Monday–Friday (MST)

Drug Prior Authorization Program Policy
For all other questions regarding Montana Medicaid drug prior authorization policy **(i.e., low pay/reimbursement questions,** other general policy questions, etc):

Medicaid Pharmacy Program Officer
(406) 444-2738 (Helena)
8:00am to 5:00pm Monday – Friday (MST)

Point-of-Sale (POS) Help Desk
For assistance with online **POS claims adjudication** (i.e., **manual claim reversals**, coordination of benefits **(COB)** billing, etc.):

Xerox, Atlanta
Technical POS Help Desk
800.365.4944

6:00 am to midnight, Monday–Saturday
10:00 am to 9:00 pm Sunday (EST)

Medicaid Client Help Line
Clients who have Medicaid or Passport questions, client complaints, or client requests for new lock-in pharmacy:

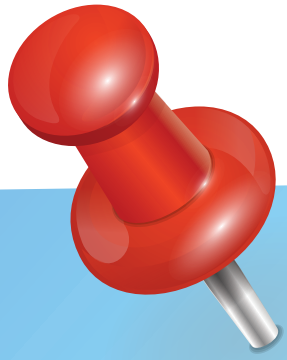
Passport To Health
800.362.8312

8:00 am to 5:00 pm Monday–Friday (MST)

Key Websites
Drug and Pharmacy News, including DUR Board Information and Preferred Drug List (PDL)*
https://medicaidprovider.mt.gov/19
*PDL located under **"Additional Resources"** left column

Montana Access to Health (MATH) Web Portal
https://mtaccesstohealth.acs-shc.com/mt/general/home.do

A reminder to pharmacies and providers



DRUG PRIOR AUTHORIZATION REQUESTS IN AN EMERGENCY, AFTER HOURS, ON HOLIDAYS & ON WEEKENDS

If a medication rejects for prior authorization, an emergency, 72-hour supply of medication may be dispensed by the pharmacy after-hours, on weekends, holidays and in emergency situations when the Drug Prior Authorization Unit is closed. This override is to only be used when appropriate and is auditable by the Department of Public Health and Human Services.

➲ Payment is authorized by the pharmacy inputting a "3" in the Day Supply field and a Medical Certification Code of "8" in the PA/MC Code field.

Montana Medicaid Top 20 Drugs for YTD 2016 by Generic Name*

Drug Name	By Dollars	# of Patients	Drug Name	By Rx Count
Aripiprazole	9,483,844	2,322	Hydrocodone/Acetaminophen	53,631
Methylphenidate	3,917,583	3,897	Albuterol	44,117
Lurasidone	3,406,870	836	Amoxicillin	31,818
Insulin Aspart	2,893,419	1,341	Gabapentin	30,709
Lisdexamfetamine	2,715,836	2,121	Omeprazole	30,045
Insulin glargine	2,647,233	1,479	Levothyroxine	29,560
Fluticasone/salmeterol	2,643,928	2,180	Methylphenidate	24,734
Albuterol sulfate	2,619,819	18,500	Lisinopril	24,460
Atomoxetine	2,533,332	1,253	Fluoxetine	24,034
Dextroamphetamine/amphet	2,525,848	3,027	Sertraline	23,442
Pregabalin	2,430,215	1,356	Azithromycin	19,809
Paliperidone palmitate	2,280,021	175	Bupropion	18,728
Ombitasvir/paritaprevir/ritonavir; Dasabuvir	1,714,944	19	Clonazepam	18,020
Insulin Detemir	1,390,612	806	Dextroamphetamine/amphet	18,008
Quetiapine	1,337,793	2,840	Metformin	17,733
Sofosbuvir	1,273,041	15	Quetiapine	17,257
Oxycodone	1,222,418	4,067	Montelukast	17,242
Dexmethylphenidate	1,209,687	681	Oxycodone	16,907
Sofusbuvir/velpatasvir	1,196,409	23	Lamotrigine	16,664
Fluticasone propionate	1,144,654	6,747	Citalopram	16,660

*excludes injectable drugs except insulins (Note: the brand product is preferred in some instances; dollars are pre-rebate).

Mountain-Pacific Quality Health
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