ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Synagis® (palivizumab)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Synagis® (palivizumab)

Diagnosis (documentation supportive of diagnosis is required)

☐ Prevention of serious lower respiratory tract disease 2° to respiratory syncytial virus (RSV) in high risk pediatric patients
☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ *Child is < 12 months of age at the start of RSV season and born at < 29 weeks and 0 days of gestation.*

Child's current age: _____

Child's gestational age:_____weeks and _____days

OR

Child is < 12 months of age at the start of the RSV season and one of the following conditions apply:

☐ Child has Chronic Lung Disease of Prematurity (defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth).
☐ Child has neuromuscular disease or anatomic pulmonary abnormalities affecting clearance of airway secretions.
☐ Child has hemodynamically significant cyanotic or acyanotic congenital heart disease.
☐ Child is a Navajo or White Mountain Apache infant.

OR

Child is < 24 months of age at the start of the RSV season and one of the following conditions apply:

☐ Child was born at <32 weeks, 0 days' gestation *and* required at least 28 days of oxygen after birth *and* required medical intervention (supplemental oxygen, chronic corticosteroid, or bronchodilator therapy) within 6 months of the start of the second RSV season.
☐ Child has severe immunodeficiency/is profoundly immunocompromised.
☐ Child will undergo cardiac transplantation during the RSV season.

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Synagis® (palivizumab)

CLASSIFICATION

- Antiviral
- Immunological Agent
- Monoclonal Antibody

DESCRIPTION

- Palivizumab is a human monoclonal antibody directed against the fusion protein (F protein) of respiratory syncytial virus (RSV). Its activity encompasses numerous A- and B- subtype clinical isolates of RSV; in vitro studies (cotton-rat model) suggest substantially greater potency (up to 100-fold) than polyclonal RSV immune globulin.
- Palivizumab is FDA approved for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. "High risk" was not defined by the FDA; therefore, the American Academy of Pediatrics (AAP) has issued policy statements to provide more precise guidance for determining who is at increased risk and who should receive palivizumab prophylaxis.
- The American Academy of Pediatrics Committee on Infectious Diseases (COID) recently published new guidelines in Pediatrics on July 28, 2014. The updated guidance is driven by the limited clinical benefit derived from Synagis prophylaxis. "Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality and a minimal effect on subsequent wheezing."
- The 2014 guidelines are more restrictive than the 2009 AAP guidelines and the recommendations in the 2012 Red Book. Other countries have use the same aggregate of date and are even more restrictive than the AAP 2014 guidelines which will replace the recommendations in the 2012 Red Book.
- Financial stewardship was reviewed in the technical update. An independently conducted cost analyses demonstrated a high cost versus limited benefit from Synagis prophylaxis.

Preterm without Chronic Lung Disease (CLD) of prematurity or Congenital Heart Disease (CHD):

- Prophylaxis is recommended for infants born before 29 weeks, 0 days' gestation who are younger than 12 months at the start of RSV season. Prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation.
- *Hospitalization rates are 2 to 4 times higher for preterm before 29 weeks than later pre-term infants.*

Preterm with CLD of prematurity:

- Prophylaxis is recommended for preterm infants with CLD of prematurity in their first year of life.
- CLD of prematurity is defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
- Prophylaxis in the 2nd year of life may be considered only for infants who satisfy the definition of CLD of prematurity AND continue to require medical support during the 6-month period before the start of the second RSV season.

Hemodynamically significant CHD:

- Children ≤ 12 months with hemodynamically significant CHD may benefit from prophylaxis.
  Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension are most likely to benefit.
- Prophylaxis is no longer recommended during the 2nd year of life.

- Exception: prophylaxis may be considered for children <2 years who undergo cardiac transplantation during the RSV season.

Anatomic Pulmonary Abnormalities and Neuromuscular Disorders:

- Prophylaxis may be considered for these children when < 12 months of age.
- There is no data that defines the risk of RSV hospitalization in this population; however, the impaired ability to clear secretions from the upper airway because of ineffective cough is a known risk factor for prolonged hospitalization related to lower respiratory tract infections (LRTI).

Immunocompromised Infants and Children:

- Prophylaxis may be considered for children < 24 months who are profoundly immunocompromised during the RSV season.
- Severe respiratory failure and death attributable to RSV is recognized in children receiving chemotherapy or who are immunocompromised due to other conditions; however, there is no data available to suggest benefit from immunoprophylaxis among immunocompromised patients.

Down Syndrome and Cystic Fibrosis:

- Routine use of prophylaxis is not recommended unless the infant has other qualifying condition (e.g. CLD of prematurity, CHD).

American Indian Infants:

- Limited data about burden of disease; however, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life due to possibly more severe disease.

Breakthrough RSV Hospitalization:

- Discontinue monthly prophylaxis in any child who is hospitalized for RSV due to extremely low likelihood of a 2nd RSV hospitalization in the same season.

Second RSV Season Prophylaxis:

- Prophylaxis recommended ONLY for preterm infants born at <32 weeks, 0 days' gestation who required at least 28 days of oxygen after birth and who continued to need medical intervention (supplemental oxygen, chronic corticosteroid, or bronchodilator therapy) within 6 months of the start of the second RSV season.

Pharmacokinetics of Synagis:

- Serum concentrations of Synagis remain at or above protective levels for most children for at least 6 months when 5 monthly doses are administered.

RSV Mortality:

- A statistically significant reduction in RSV mortality has not been demonstrated in any randomized clinical trial with Synagis.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 6 Medical benefit
Commercial Formulary: Tier 6 Medical benefit
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Synagis (palivizumab) meets the definition of **medical necessity** for the following:

Prevention of serious lower respiratory tract disease 2° to respiratory syncytial virus (RSV) in high risk pediatric patients. One or more of the following must be applicable to meet the definition of medical necessity:

Child is < 12 months of age at the start of RSV season and born at < 29 weeks and 0 days of gestation. Child's current age: Child's gestational age: weeks and days

OR

Child is < 12 months of age at the start of the RSV season and one of the following conditions apply:

- Child has Chronic Lung Disease of Prematurity (defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth).
- Child has neuromuscular disease or anatomic pulmonary abnormalities affecting clearance of airway secretions.
- Child has hemodynamically significant cyanotic or acyanotic congenital heart disease.
- Child is a Navajo or White Mountain Apache infant.

OR

Child is < 24 months of age at the start of the RSV season and one of the following conditions apply:

- Child was born at <32 weeks, 0 days' gestation *and* required at least 28 days of oxygen after birth *and* required medical intervention (supplemental oxygen, chronic corticosteroid, or bronchodilator therapy) within 6 months of the start of the second RSV season.
- Child has severe immunodeficiency/is profoundly immunocompromised.
- Child will undergo cardiac transplantation during the RSV season.

NOTE: Synagis is approvable only during the RSV season (generally between November and April) and at a maximum of 5 consecutive doses for all patients. Five consecutive doses will provide protective levels of Synagis for 6 months.

Synagis (palivizumab) is considered **experimental** for the following:

- Treatment of RSV disease in any patient.
- RSV prophylaxis in individuals older than 24 months of age.
- RSV prophylaxis in individuals with Cystic Fibrosis or Down Syndrome unless other qualifying condition.
- The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:
    - Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
    - Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.
    - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.
    - Children in the second year of life.

Required Provider Specialty:

- None required

DOSAGE/ADMINISTRATION:

- Respiratory syncytial virus infection – Prophylaxis in high risk patients: 15 mg/kg intramuscularly monthly. The first dose should be administered prior to, and continued during the RSV season (typically November through April in the northern hemisphere).
- For infants and children requiring cardiopulmonary bypass and receiving palivizumab, a postoperative dose should be considered; a mean decrease in palivizumab serum concentration of 58% following procedures requiring cardiopulmonary bypass have been reported.
    - The postoperative dose should be given as soon as possible following the procedure, even if this is sooner than a month from the previous dose.
- Not effective for the treatment of RSV and is not approved for this indication.

- Safety and effectiveness in children > 24 months of age at the start of dosing have not been established.

PRECAUTIONS:

- Contraindicated if severe hypersensitivity reaction to palivizumab or other components of this product
- Anaphylaxis and anaphylactic shock have been reported and include fatal cases and other severe acute hypersensitivity reactions. This can occur on initial exposure or re-exposure. Permanently discontinue if a severe hypersensitivity reaction occurs.
- Immunological-based RSV diagnostic tests - interference leading to false-negative RSV test results may occur.
- Thrombocytopenia or any coagulation disorder.

Billing/Coding information

Associated HCPCS Codes:

90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

CPT coding:

96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

COST

- AWP (October 2010): 100mg/ml vial (l): $2,433.36
- AWP (September 2014): 100mg/ml vial (l): $2,962
  50mg/ml vial (l): $1568

COMMITTEE APPROVAL:

- November 2010
- September 2014

GUIDELINE UPDATE INFORMATION:

October 2010	Policy created
November 2010	Policy reviewed/approved at P&T
September 2014	Prior authorization and coverage policy revised

REFERENCES:

- DRUGDEX®, accessed 9/6/2014
- Synagis® Package Insert. Gaithersburg,MD: MedImmune; April 2013. Available at: www.medimmune.com/docs/defaultsource/pdfs/prescribing-informationfor-synagis.pdf. Accessed April 24, 2014
- American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Technical report: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014; originally published online July 28, 2014. Available online at: http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1666.
- American Academy of Pediatrics. Policy statement: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014; originally published online July 28, 2014. Available online at: http://pediatrics.aappublications.org/content/134/2/415.full.html