

Complete Patient and Physician information (PLEASE PRINT)

STEP 1	Member Name:	Physician Name:
	Address:	Address:
	Member ID:	Phone #:
	Member DOB:	Fax #:
		Tax ID or NPI #:

If Applicable: Pharmacy Name: _____ Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP 2	Diagnosis	<input type="checkbox"/> Prevention of serious lower respiratory tract disease 2° to respiratory syncytial virus (RSV) in high risk pediatric patients <input type="checkbox"/> Other (please state): _____
	Clinical consideration (please check appropriate box)	<input type="checkbox"/> Child is <2 years old at the start of the RSV season with <u>any</u> of the following (despite not being prematurely born): <ul style="list-style-type: none"> • Chronic lung disease with medical treatment within 6 months of RSV season • Hemodynamically significant cyanotic or acyanotic congenital heart disease • Congenital abnormalities of the airways • Neuromuscular disease affecting airway secretions • Severe immunodeficiency <p style="text-align: center;"><i>OR</i></p> <input type="checkbox"/> Child was born at <32 weeks of gestational age, and <u>either</u> of the following conditions apply at the start of the RSV season: <ul style="list-style-type: none"> • Child is <12 months of age (if born at <29 weeks of gestation) • Child is <6 months of age (if born between 29 and 32 weeks of gestation) <p style="text-align: center;"><i>OR</i></p> <input type="checkbox"/> Child was born ≤35 and ≥32 weeks of gestational age and the following condition applies at the start of the RSV season: <ul style="list-style-type: none"> • Child is <6 months of age and has been deemed to have significant risk (ie. either a sibling younger than 5 or will attend child care outside the home)
	Supporting Documentation	<p><i>Synagis is only approvable during the RSV season (generally October through March) at a maximum of 5 consecutive monthly doses</i></p> <p>Diagnosis: ICD-9/10 Code #/ Description / J Code (required):</p> <p>Please attach a copy of the Rx or provide ALL the following: Synagis® (palivizumab) Strength _____ Sig _____ Qty _____ Refills _____</p> <p style="text-align: center;"><i>*Please attach all relevant medical records and test results*</i></p> <p style="text-align: center;">We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>

STEP 3 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____ Pharmacy Technician Initials: _____ Date Initiated: _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 04/29/11

RMHP Formulary Coverage Policy

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

Palivizumab (Synagis®)

CLASSIFICATION

- Antiviral
- Immunological Agent
- Monoclonal Antibody

DESCRIPTION

- Palivizumab is indicated as prophylaxis against respiratory syncytial virus (RSV) infection in selected high-risk infants and children, such as those with chronic lung disease of prematurity, a history of preterm birth (less than 35 weeks gestation), neuromuscular disease or congenital abnormalities of the airways, or congenital heart disease. Palivizumab is administered once a month during the RSV season (generally beginning of November through April). Generally, infants receive 5 monthly doses (Committee on Infectious Diseases, American Academy of Pediatrics et al, 2009).
- Palivizumab is not effective for the treatment of hospitalized infants and children with severe RSV lower respiratory tract infections.
- 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 has dosing and immunoselective advantages over RespiGam(R).
- The American Academy of Pediatrics Committee on Infectious Diseases (COID) recently published new guidelines in the 2009 Redbook. The major change this revision made over prior guidelines was in regards to babies with gestational ages 32 through 34 weeks, 6 days. The changes are as follows:
 - The age in which this group is recommended to receive Synagis changed from six months to three months
 - The number of injections recommended for this group changed from five (the entire season) to three (90 days)
- The 2009 updated guidelines have proven to be controversial, because of more restrictive recommendations than found in other, earlier algorithms. Due to the lack of consensus regarding these guidelines, RMHP will reimburse for Synagis based on these guidelines in most instances, with 2 exceptions:
 - For the gestational age cohort of 32 through 34 weeks/ 6 days, RMHP finds it acceptable if providers decide to follow the prior 2006 COID guidelines for this cohort.
 - For infants or children with congenital abnormalities of the airway or neuromuscular disease that compromises handling of airway secretions, RMHP finds it acceptable if providers decide to administer Synagis up to 24 months of age, consistent with guidelines such as those distributed by the National Perinatal Association

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Medical benefit

Commercial Formulary: Medical benefit

Medicare Part D coverage:

COVERAGE CRITERIA

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

- Infants or children ≤ 24 months old at the start of RSV season with any of the following:
 - Chronic lung disease requiring medical care within 6 months of the anticipated start of RSV season.
 - Hemodynamically significant cyanotic or acyanotic congenital heart disease with either symptomatic congestive heart failure or moderate-to-severe pulmonary hypertension
 - Congenital abnormalities of the airway
 - Neuromuscular disease (e.g. Cerebral palsy, muscular dystrophy, or neurological diseases of the brain and spinal chord) that compromise the handling of respiratory secretions
 - Severe immunodeficiency
- Infants that were premature (gestational age younger than 35 6/7 weeks), *in the following conditions*:
 - For gestational age of 31 6/7 weeks or earlier *in either of the following conditions*:
 - Child is ≤ 12 months of age at the start of RSV season (if born at ≤ 28 6/7 weeks of gestation)
 - Child is ≤ 6 months of age at the start of RSV season (if born between 29 and 32 weeks of gestation)

OR

- For gestational age of ≤ 35 6/7 weeks and ≥ 32 0/7 weeks of gestational age and the following condition applies:
 - Child is < 6 months of age at the start of the RSV season and has been deemed to have significant risk (ie. either a sibling younger than 5 or will attend child care outside the home)

NOTE: Synagis is approvable only during the RSV season (generally October through April) and at a maximum of 5 consecutive doses for all patients

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 younger than 24 months of age with mild cardiomyopathy that does not require medical treatment
- RSV prophylaxis in individuals younger than 24 months of age with congestive heart failure that does not require medical treatment
- RSV prophylaxis in individuals younger than 24 months of age with hemodynamically insignificant heart disease (e.g. atrial septal defect, pulmonary stenosis, uncomplicated aortic stenosis, patent ductus arteriosus, etc.)
- RSV prophylaxis in individuals who were born prematurely, but now exceed above stated age limits

Required Provider Specialty:

- None required

DOSAGE/ADMINISTRATION:

- Respiratory syncytial virus infection, High risk patients; Prophylaxis
 - For prevention of serious respiratory syncytial virus (RSV) disease in high-risk infants, the usual dose of palivizumab is 15 milligrams/kilogram 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.

PRECAUTIONS:

- Acute hypersensitivity reactions, some severe, including anaphylaxis; have been reported on initial exposure or re-exposure; permanently discontinue if a severe hypersensitivity reaction occurs

Billing/Coding information

Associated HCPCS Codes:

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Associated CPT Coding:

90378	
96372	
87252	
87420	

Associated ICD-9 Coding:

279.00 - 279.9	Disorders involving the immune mechanism [severe immunodeficiencies]
358.0 - 358.9	Myoneural disorders [severe neuromuscular disease]
416.0 - 416.9	Chronic pulmonary heart disease [chronic lung disease]
428.0	Congestive heart failure, unspecified [infants receiving medication for control]
491.0 - 491.9	Chronic bronchitis [chronic lung disease]
493.20 - 493.22	Chronic obstructive asthma [chronic lung disease]
496	Chronic airway obstruction, not elsewhere classified [chronic lung disease]
745.0 - 747.5	Bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other anomalies of circulatory system [congenital heart disease]
748.5	Agenesis, hypoplasia, and dysplasia of lung [congenital anomaly of airways]
748.60 - 748.69	Other anomalies of lung [congenital anomaly of airways]
765.21	Less than 24 completed weeks of gestation [see criteria]
765.22	24 completed weeks of gestation [see criteria]
765.23	25 - 26 completed weeks of gestation [see criteria]
765.24	27 - 28 completed weeks of gestation [see criteria]
765.25	29 - 30 completed weeks of gestation [see criteria]
765.26	31 - 32 completed weeks of gestation [when a risk factor is present - see criteria]
765.27	33 - 34 completed weeks of gestation [when a risk factor is present - see criteria]
765.28	35 - 36 completed weeks of gestation [with congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions during the first year of life]
770.7	Chronic respiratory disease arising in the perinatal period [bronchopulmonary dysplasia]
987.8	Toxic effect of other specified gases, fumes, or vapors [exposure to indoor air pollutants]
V04.82	Need for prophylactic vaccination and inoculation, respiratory syncytial virus (RSV) [must meet criteria]

COST

- AWP (October 2010): 100mg/ml vial (1): \$2,433.36

COMMITTEE APPROVAL:

November 2010	
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GUIDELINE UPDATE INFORMATION:

October 2010	Policy created
November 2010	Policy reviewed/approved at P&T

REFERENCES:

- DRUGDEX®, accessed 10/20/2010
- Product Information: Synagis(R), palivizumab. MedImmune, Inc., Gaithersburg, MD, 2003.
- American Academy of Pediatrics. Policy Statement- Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections. Pediatrics 2009; 124: 1694-1701.
- National Perinatal Association Guideline Statement: Respiratory Syncytial Virus (RSV) Prevention 2010. Available at www.nationalperinatal.org. Accessed November 1, 2010.