Synagis® (palivizumab)  
Effective: 9/1/15

Clinical documentation and prior authorization required ✓  Type of review – case management
Not covered Type of review – clinical review
Fax: 617-673-0988 ✓
Pharmacy (RX) or medical (MED) benefit RX  Department to review RxUM

OVERVIEW
FDA-APPROVED INDICATIONS
Synagis (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), infants with a history of premature birth, and children with hemodynamically significant congenital heart disease. The safety and efficacy of Synagis have not been established for treatment of RSV disease.

Synagis (palivizumab) was approved in June 1998 by the Food and Drug Administration for use in the prevention of severe RSV lower respiratory tract infections in selected patients. It is a monoclonal antibody preparation that is administered intramuscularly on a monthly basis. Given the lack of proven effective antiviral therapy for RSV infections, prevention of disease through the use of passive immunoprophylaxis in selected high-risk infants should be considered. Palivizumab prophylaxis should be initiated at the onset of the RSV season and terminated at the end of the RSV season. The doses should be timed to provide immunologic coverage for the season. The initial dose must be administered in a controlled setting where the patient can be monitored closely for any reaction.

For premature infants about to be discharged from hospitals during the RSV season, physicians may consider administering RSV-IGIV for the first month of prophylaxis. Patients with more severe chronic lung disease, especially those, who require medical therapy, may benefit clinically from prophylaxis for two RSV seasons, whereas those with less severe underlying disease may benefit only for the first season.

Prophylaxis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing. Routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is not recommended unless other indications are present. Currently, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome.

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan– Network Health may authorize coverage of Synagis (palivizumab) for chronic lung disease, pre-maturity, immunodeficiency, or congenital heart disease. Injections are administered monthly for a maximum of 5 doses during the RSV season. Network Health will begin approving requests for Synagis beginning October 1st. The beginning of the RSV season is defined as November 1st. The first dose must be administered after October 31st and the last dose before March 31st. Shipment of the medication will not commence until November 1st.

Note: Slight variations to the RSV season may be announced by the Massachusetts Department of Health and/or the Centers for Disease Control and Prevention (CDC) and will be taken into consideration.

| Chronic Lung Disease of Prematurity (formerly bronchopulmonary dysplasia) | • For the first RSV season during the first year of life: Preterm infants who develop CLD of prematurity defined as:  
  o gestational age ≤ 31 weeks, 6 days AND  
  o requirement for > 21% oxygen for at least the first 28 days after birth  
• For the second RSV season during the second year of life: |
| Congenital Heart Disease | Infants and children ≤ 12 months of age with hemodynamically significant CHD  
| Those most likely to benefit from prophylaxis include:  
| Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures  
| OR  
| Infants with moderate to severe pulmonary hypertension  
| Infants and children < 24 months of age who undergo cardiac transplantation during the RSV season |
| Congenital Abnormality of the Airway/ Neuromuscular Condition | Infants who have either a significant congenital abnormality of the airway or a neuromuscular condition that compromises handling of respiratory secretions for the first year of life |
| Prematurity | Preterm infants born at 28 weeks, 6 days of gestation or earlier, for the first RSV season that occurs during the first 12 months of life |
| Immunocompromised | Children younger than 24 months of age who are profoundly immunocompromised during the RSV season |
| Cardiac Transplant | Children younger than 2 years who undergo cardiac transplantation during the RSV season |

**LIMITATIONS**

1. Use in the absence of chronic lung disease, heart disease or pre-maturity as defined above.
2. Experimental uses not approved by the FDA.
3. Use in months outside of the specified regional RSV season.
4. Children with hemodynamically insignificant heart disease:
   - Secundum atrial septal defect
   - Pulmonic stenosis
   - Patent ductus arteriosus
   - Small ventricular septal defect
   - Uncomplicated aortic stenosis
   - Mild aortic coarctation
   - S/P corrective surgery unless continued treatment of congestive heart failure is required.
5. Infants with mild cardiomyopathy who are not receiving medical therapy.
6. Duration of coverage authorization limited to a maximum of 5 doses.

**CODES**

The following HCPCS/CPT code(s) are:

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>90378</td>
<td>Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each</td>
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**REFERENCES**


**APPROVAL HISTORY**
- September 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.