Pharmacy Medical Necessity Guidelines: Synagis® (palivizumab)

Effective: September 12, 2017

Prior Authorization Required ✓ Type of Review – Care Management ✓
Not Covered Type of Review – Clinical Review
Pharmacy (RX) or Medical (MED) Benefit MED / RX Department to Review PRECERT / MM

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
☑ Tufts Health Plan Commercial Plans – large group plans
☑ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
☑ Tufts Health Direct – Health Connector
☑ Tufts Health Together – A MassHealth Plan
☑ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☑ Tufts Health Freedom Plan - large group plans
☑ Tufts Health Freedom Plan - small group plans

Fax Numbers:
All plans except Tufts Health Public Plans:
PRECERT: 617.972.9409
Tufts Health Public Plans:
MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION (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 (palivizumab) have not been established for treatment of RSV disease.

Synagis (palivizumab) was approved in June 1998 by the FDA 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 (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.

COVERAGE GUIDELINES

The plan 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. The beginning of the RSV season is defined as November 1st. The first dose must be administered after October 15th and the last dose before March 31st. The plan will begin approving requests for Synagis beginning October 1st.
**Pharmacy Medical Necessity Guidelines:**

**Synagis® (palivizumab)**

**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:  
  - gestational age ≤ 31 weeks, 6 days  
  **AND**  
  - requirement for > 21% oxygen for at least the first 28 days after birth  
  - For the second RSV season during the second year of life: Preterm infants who:  
  - satisfy the above definition of CLD of prematurity  
  **AND**  
  - continue to require supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy or bronchodilator therapy within 6 months of the start of the second RSV season |
|---|---|
| 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 Food and Drug Administration.
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:

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

REFERENCES

APPROVAL HISTORY
November 1998: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- June 14, 2005: Under Coverage Criteria, the total number of monthly injection covered by Tufts Health Plan during the RSV season is changed from 6 to 5.
- May 9, 2006: No changes
- March 13, 2007: No changes
- March 4, 2008: No changes
- March 10, 2009: No changes
- September 08, 2009: Added maximum number of doses to criteria for children with Chronic Lung disease. Updated criteria for Prematurity to define premature infants born before 32 weeks gestation (31 weeks, 6 days or less). Added criteria to Prematurity for infants less than 35 weeks gestation with congenital abnormalities of the airway or neuromuscular disease. Added maximum number of doses to criteria for Prematurity. Changed criteria for Risk Factors: infants will require one risk factor (previously two or more). Removed Risk Factors of: severe neuromuscular disease, school-aged siblings, congenital abnormalities of the airways, and exposure to environmental air pollutants including tobacco smoke. Added risk factor of "Siblings less than 5 years of age.” Added maximum number of doses to criteria for Risk Factors
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- September 13, 2011: Added note that 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.
- August 14, 2012: No changes
- July 9, 2013: No changes
• May 13, 2014: Extended approval interval for last dose through March 31st.
• September 9, 2014: Effective September 1, 2015: Updated criteria to define Chronic Lung Disease: Members during first year of life with a gestational age ≤ 31 weeks, 6 days and require >21% Oxygen for at least the first 28 days after birth. For the second RSV season during the second year of life Member must meet the aforementioned definition and continue to require medical support: Congenital Heart Disease limited to Members who are < 12 months unless Member <24 months of age who undergo cardiac transplantation during the RSV season: Congenital Abnormality of the Airway/ Neuromuscular Condition: removed limitation of being born before 35 weeks of gestation. 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: Added the diagnoses and criteria for Immunocompromised and Cardiac Transplant.
• May 12, 2015: No changes
• January 1, 2016: Administrative change to rebranded template.
• May 10, 2016: Moved Tufts Health Together to Commercial Medical Necessity Guidelines, for Tufts Health Together, first dose administration changed from after October 31st to October 15th. Added note that the plan will begin approving requests for Synagis beginning October 1st.
• September 12, 2017: No changes
• September 18, 2018: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity 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 service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.