# Pharmacy Medical Necessity Guidelines: Synagis® (palivizumab)

*Effective: September 15, 2020*

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| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX for Tufts Health Together / MB for all others | Department to Review | PRECERT/ MM / RxUM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**

Commercial Products:
PRECERT: 617.972.9409

Tufts Health Direct and Tufts Health RITogether:
MM: 888.415.9055

Tufts Health Together:
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## 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 15 and the last dose before March 31. The plan will begin approving requests for Synagis beginning October 1.

**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.

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| Chronic Lung Disease of Prematurity (formerly bronchopulmonary dysplasia) | • For the first RSV season during the first year of life:<br>Preterm infants who develop CLD of prematurity defined as:<br>– gestational age ≤ 31 weeks, 6 days<br>**AND**<br>– requirement for > 21% oxygen for at least the first 28 days after birth<br>• For the second RSV season during the second year of life:<br>Preterm infants who:<br>– satisfy the above definition of CLD of prematurity<br>**AND**<br>– 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<br>• Those most likely to benefit from prophylaxis include:<br>– Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures<br>**OR**<br>– Infants with moderate to severe pulmonary hypertension<br>• 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:

| Code | Description |
|---|---|
| 90378 | Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each |

**Note:** Medical billing codes may not be used for Tufts Health Together. Synagis must be obtained via the Member's pharmacy benefit.

## REFERENCES


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2. American Academy of Pediatrics. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics.* Published online July 28, 2014. aapredbook.aappublications.org. Accessed August 7, 2014.
3. Bernstein D. Epidemiology and genetic basis of congenital heart disease. In: Kliegman RM, Stanton B, St. Geme J, Schor N, and Behrman RE, editors. Nelson Textbook of Pediatrics, 19th ed. Online, chap. 418. nelsonpediatrics.com/default.cfm. Accessed May 21, 2014.
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6. Drysdale SB, Green CA, Sande C1. Best practice in the prevention and management of paediatric respiratory syncytial virus infection. *Ther Adv Infect Dis*. 2016 Apr;3(2):63-71.
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8. Hussman JM, Li A, Paes B, Lanctôt KL. A review of cost-effectiveness of palivizumab for respiratory syncytial virus. *Expert Rev Pharmacoecon Outcomes Res*. 2012 Oct; 12(5):553-67.
9. Joffe, S., et al. (1999). Cost-effectiveness of respiratory syncytial virus prophylaxis among preterm infants. *Pediatrics*.104(3): 419-427.
10. Meissner, HC, Long SS and Committee on Infectious Diseases and Committee on Fetus and Newborn, "Revised Indications for Use of Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prevention of Respiratory Syncytial Virus Infections" Pediatrics 2003, December 6;112 (6):1447-1452.
11. Shadman KA, Wald ER. A review of palivizumab and emerging therapies for respiratory syncytial virus*. Expert Opin Biol Ther*. 2011 Nov; 11(11):1455-67.
12. Synagis (palivizumab) [package insert]. Gaithersburg, MD: MedImmune, LLC; May 2017.


## APPROVAL HISTORY

November 1998: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. 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.
2. May 9, 2006: No changes
3. March 13, 2007: No changes
4. March 4, 2008: No changes
5. March 10, 2009: No changes
6. 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
7. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
8. September 14, 2010: No changes
9. 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.
10. August 14, 2012: No changes
11. July 9, 2013: No changes
12. May 13, 2014: Extended approval interval for last dose through March 31st.
13. 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.
14. May 12, 2015: No changes
15. January 1, 2016: Administrative change to rebranded template.
16. 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.
17. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
18. September 12, 2017: No changes
19. September 18, 2018: No changes
20. September 10, 2019: No changes
21. September 15, 2020: 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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.

Provider Services