Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Synagis® (palivizumab)

Effective: September 10, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season,
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season,
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season.

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.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage up to a maximum of five (5) doses of Synagis per RSV season for the prevention of serious lower respiratory tract disease caused by RSV per the coverage criteria outlined below. For Members who qualify to receive five (5) doses, the first dose is typically administered at the beginning of November and the last dose at the beginning of March to provide protection in April.

The Plan will begin approving requests for Synagis beginning October 1. Note: Slight variations to the RSV season may be announced by the state's Department of Health and/or the Centers for Disease Control and Prevention (CDC) or based on RSV activity indicating a 3% or higher positive RSV PCR test date and will be taken into consideration when determining when the plan will begin approving requests for a given year.

Chronic Lung Disease of Prematurity (formerly bronchopulmonary dysplasia)	1. Documentation of **all** of the following: a. The patient is less than 12 months of age at the start of the RSV season b. Documentation of Chronic Lung Disease of Prematurity defined as both of the following: i. Gestational age ≤ 31 weeks, 6 days ii. Requirement for supplemental oxygen for at least the first 28 days after birth c. Documentation the member has not received a dose of Beyfortus in the current RSV season **OR** 2. Documentation of **all** of the following: a. The patient is less than 24 months of age at the start of the RSV season b. Documentation of Chronic Lung Disease of Prematurity defined by both of the following: i. Gestational age ≤ 31 weeks, 6 days ii. Requirement for supplemental oxygen for at least the first 28 days after birth c. Documentation the patient required supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy or bronchodilator therapy within 6 months of the start of the second RSV season d. Documentation the patient has not received a dose of Beyfortus in the current RSV season
Congenital Heart Disease (CHD)	1. The patient is 12 months of age or younger at the start of the RSV season **AND** 2. Documentation of hemodynamically significant congenital heart disease (e.g., atrial or ventricular septal defect, patent ductus arteriosus, coarctation of aorta, tetralogy of Fallot, pulmonary or aortic valve stenosis, D-Transposition of great arteries, tricuspid atresia, Ebstein's anomaly, pulmonary atresia, transposition of great arteries, truncus arteriosus, hypoplastic left/right ventricle, single ventricle, double-outlet right ventricle, total anomalous pulmonary venous return) **AND** 3. Documentation of **one (1)** of the following: a. Moderate to severe pulmonary hypertension b. Acyanotic heart disease and receiving medication to control congestive

	heart failure and will require cardiac surgical procedures **AND** 4. Documentation the patient has not received a dose of Beyfortus in the current RSV season
Cardiac Transplant	1. The patient is less than 24 months of age at the start of the RSV season **AND** 2. The patient is scheduled to undergo cardiac transplantation during the RSV season **AND** 3. Documentation the patient has not received a dose of Beyfortus in the current RSV season
Congenital Abnormality of the Airway/ Neuromuscular Condition	1. 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 **AND** 2. Documentation the patient has not received a dose of Beyfortus in the current RSV season
Prematurity	1. 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 **AND** 2. Documentation the patient has not received a dose of Beyfortus in the current RSV season
Immunocompromised	1. The patient is 24 months of age or younger at the start of the RSV season **AND** 2. Documentation the patient is profoundly immunocompromised during the RSV season **AND** 3. Documentation the patient has not received a dose of Beyfortus in the current RSV season

Limitations

- Synagis will be authorized for a maximum of five (5) seasonal doses. Additional doses within a given season will be reviewed on a case-by-case basis based on medical necessity.
- Synagis will not be authorized in members who have already received Beyfortus for the current RSV season.
- Authorization of Synagis for use in months outside of the regional RSV season for a given year will be reviewed on a case-by-case basis.

Codes

The following code(s) require prior authorization:

Table 1: CPT Codes

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

References

1. Barr EF, et al. Respiratory syncytial virus infection: Prevention in infants and children. UpToDate. Wolter Kluwers. Updated Mar 19, 2024. Accessed online July 16, 2024 at https://www.uptodate.com/contents/respiratory-syncytial-virus-infection-prevention-in-infants-and-children.
2. 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.
3. 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.

4. Grindeland CJ, Mauriello CT, Leedahl DD, Richter LM, Meyer AC. Association Between Updated Guideline-Based Palivizumab Administration and Hospitalizations for Respiratory Syncytial Virus Infections. *Pediatr Infect Dis J*. 2016 Apr 13. [Epub ahead of print].
5. 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.
6. Joffe, S., et al. (1999). Cost-effectiveness of respiratory syncytial virus prophylaxis among preterm infants. *Pediatrics*.104(3): 419-427.
7. 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.
8. Respiratory Syncytial Virus Infection (RSV). Centers for Disease Control and Prevention (CDC). Accessed online March 1,2022 at https://www.cdc.gov/rsv/index.html.
9. 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.
10. Synagis (palivizumab) [package insert]. Gaithersburg, MD: MedImmune, LLC; November 2020.
11. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2021-2022 RSV Season. American Academy of Pediatrics. December 17, 2021 accessed online February 28, 2021 at https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Minor wording updates throughout to clarify coverage. Updated ">21% oxygen" to be "supplemental oxygen." Removed the Limitations Use of Synagis in the absence of chronic lung disease of prematurity, congenital heart disease, congenital abnormality of the airway/neuromuscular condition, immunocompromised status or pre-maturity (pre-term birth) as defined above; The safety and efficacy of Synagis have not been established for treatment of RSV treatment; and Infants with mild cardiomyopathy who are not receiving medical therapy. Added "Documentation the member has not received a dose of Beyfortus in the current RSV season" and the Limitation Synagis will not be authorized in members who have already received Beyfortus for the current RSV season (effective 10/1/2023).
- September 10, 2024: No changes (eff 9/10/24).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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