BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Synagis

Policy Number: 9.405
Version Number: 2.0
Version Effective Date: 2021-2022 RSV Season

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Synagis (palivizumab)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	• Medically accepted indications
Exclusion Criteria	Synagis is not recommended for the following CHD infants: • Hemodynamically insignificant heart disease (such as secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) • With lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure • With mild cardiomyopathy and without requirement of medical therapy for this

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	condition • Children in the second year of life
Required Medical Information	Documentation of the following: 1. Infants less than 12 months of age at onset of the current RSV (respiratory syncytial virus) season and one of the following: a. Gestational age is less than 29 weeks, 0 days; **OR** b. Diagnosis of chronic lung disease (CLD*) of prematurityor bronchopulmonary dysplasia (BPD); **OR** c. Diagnosis of hemodynamically significant congenital heart disease (CHD) as evidenced by: i. Documented acyanotic heart disease, on medication to control congestive heart failure, and who will require cardiac surgical procedures; or ii. Documented moderate to severe pulmonary hypertension; or iii. Documented cyanotic heart defects and the medication is prescribed by, or in consultation with a pediatric cardiologist; **OR** d. Presence of neuromuscular disease or anatomic pulmonary abnormalities that impairs the ability to clear secretions from the upper airways; **OR** e. Diagnosis of cystic fibrosis with clinical evidence of CLD and/or nutritional compromise; OR 2. Children less than 24 months of age at onset of the current RSV (respiratory syncytial virus) season and one of the following: a. Diagnosis of chronic lung disease (CLD*) of prematurity or bronchopumonary dysplasia and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, bronchodilator therapy or supplemental oxygen) during the 6-month period before the start of the current RSV season; **OR** b. Planned cardiac transplantation during the current RSV season; **OR** c. Being profoundly immunocompromised during the current RSV season; **OR** d. Diagnosis of cystic fibrosis with severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computer tomography that persists when stable) or weight for length less than the 10th percentile * CLD of prematurity is defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least 28 days after birth
Age	Less than 24 months of age

Restrictions	
Prescriber Restriction	None
Coverage Duration	Initial: Up to 5 months
Quantity Limit	Up to 5 monthly doses between November 1st and April 30th will be approved
Other criteria	None

Applicable Coding:

Clinical Background Information and References

1. Synagis® [package insert]. Gaithersburg (MD): MedImmune, LLC; May 2017.

2. Respiratory Syncytial virus. American Academy of Pediatrics. Red Book: 2012 Report of the Committee on Infectious Diseases. Pickering LK, ed. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012

3. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Policy Statement: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2014 Aug; 134(2): 415-420.

4. Feltes TF; Cabalka AK; Meissner HC; Piazza FM; Carlin DA et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. J Pediatr 2003 Oct; 143(4):532-40.

5. Tulloh R; Marsh M; Blackburn M; Casey F; Lenney W et al. Recommendations for the use of palivizumab as prophylaxis against respiratory syncytial virus in infants with congenital cardiac disease. Cardiol Young. 2003 Oct;13(5):420-3.

6. Palivizumab is the only RSV immunoprophylactic agent approved for infants with congenital heart disease. Adapted from: Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics 2003; 112:1442.

7. Drugs at FDA. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed July 26, 2007.

8. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Technical Report: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2014 Aug; 134(2): e620-e633.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.124 Synagis Policy retired, new policy created	1/1/2021	P&T Committee
2/11/2021	P&T Review: Minor language update for children less than 24 months with chronic lung disease	6/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as

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the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.