CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Synagis (palivizumab)
BILLING CODE	CPT Code 90378 (1 unit = 50 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 200 mg per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Synagis (palivizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated. CareSource is currently reviewing Synagis requests on a case-by-case basis outside of the typical RSV season window due to the increased interseasonal Respiratory Syncytial Virus (RSV) activity.

PREVENTION OF RESPIRATORY TRACT DISEASE CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

For **initial** authorization:

1. Medication will be administered during the RSV season (*November 1st through March 31st*) AND initiation of injections should be timed with the onset of laboratory confirmed cases of RSV activity in the community, no earlier than November 1, 2021; AND
2. Member is < 12 months old at the beginning of the RSV season AND meets **one** of the following criteria (chart notes must be provided to support evidence):
   a) Member was born < 29 weeks, 0 days' gestation;
   b) Member has Chronic Lung Disease (CLD) of prematurity (defined as gestational age < 32 weeks, 0 days and a requirement for > 21% oxygen for at least the first 28 days after birth);
   c) Member has hemodynamically significant Congenital Heart Disease (CHD) with **one** or more of the following:
      i) Acyanotic heart disease (e.g., atrial septal defect (ASD), ventricular septal defect (VSD), etc.), AND member is receiving medication to control congestive heart failure (CHF) AND will require cardiac surgical procedures;
      ii) Moderate to severe pulmonary hypertension;
      iii) Cyanotic heart disease and referred by a pediatric cardiologist (e.g., coarctation of aorta, Ebstein's anomaly, hypoplastic left heart syndrome, Tetralogy of Fallot (TOF), total anomalous pulmonary venous connection (TAPVC), etc.);
   d) Member has pulmonary abnormalities or neuromuscular disorder that impairs the ability to clear secretions from the upper airways;
   e) Member is profoundly immunocompromised during the RSV season (e.g., concurrent chemotherapy, stem cell transplantation, organ transplantation, etc.);
   f) Member undergoes cardiac transplantation during the RSV season;
   g) Member has Cystic Fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life; OR
3. Member is 12 – 24 months old at the beginning of the RSV season AND meets **one** of the following criteria (chart notes must be provided to support evidence):
   a) Member was born < 32 weeks, 0 days' gestation **and** has CLD of prematurity that required at least 28 days of oxygen after birth and who continues to require supplemental oxygen, chronic systemic

corticosteroid therapy, or diuretic therapy during the 6 month period before the start of the second RSV season;
   b) Member is profoundly immunocompromised during the RSV season (e.g., concurrent chemotherapy, stem cell transplantation, organ transplantation, etc.);
   c) Member undergoes cardiac transplantation during the RSV season;
   d) Member has Cystic Fibrosis with **one** of the following:
      i) Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, or abnormalities on chest radiography or chest computed tomography that persist when stable);
      ii) Weight for length less than the 10th percentile on a pediatric growth chart.
4. **Dosage allowed:** 15 mg/kg once monthly for a total of 5 doses or until the end of the RSV season.

If member meets all the requirements listed above, the medication will be approved for 5 months or until the end of the RSV season (March 31, 2022), whichever comes first.

CareSource considers Synagis (palivizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Prophylaxis of Health Care-Associated RSV Disease
- RSV prophylaxis for children with Down syndrome
- RSV prophylaxis for children who were previously infected with RSV in the current season
- RSV prophylaxis for infants and children with hemodynamically insignificant heart disease (e.g. Secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children with CHD in the second year of life
- Treatment of RSV Disease

DATE	ACTION/DESCRIPTION
09/01/2017	New policy for Synagis created. Criteria divided by age groups. Cystic Fibrosis coverage was added. Cardiac transplantation category was added.
08/07/2018	RSV season time limits updated for 2018-2019.
09/04/2019	RSV season time limits updated for 2019-2020.
08/24/2020	RSV season time limits updated for 2020-2021. Changed “request must be made during RSV season” to “Medication will be administered during RSV season”. Removed previous cardiac or cardiopulmonary procedure under CHD because of inconsistency with guidelines. Added pediatric cardiologist referral to cyanotic heart defect. Removed bronchodilator as an option under 3a.
8/25/2021	RSV season time limits updated for 2021-2022

References:

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6. Anderson EJ, Krilov LR, DeVincenzo JP, et al. SENTINEL1: An Observational Study of Respiratory Syncytial Virus Hospitalizations among U.S. Infants Born at 29 to 35 Weeks' Gestational Age Not Receiving Immunoprophylaxis. Thieme Medical Publishers, Inc. May 27, 2016.
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