CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Synagis (palivizumab)
BILLING CODE	90378 (1 unit = 50 mg)
BENEFIT TYPE	Medical or Pharmacy
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 or pharmacy** 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.

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

For **initial** authorization:

1. Request must be made during the RSV season (*October 1st through February 29th*) AND initiation of injections should be timed with the onset of laboratory confirmed cases of RSV activity in the community, no earlier than October 1, 2019; AND
2. Member is < 12 months old at the beginning of the RSV season AND meet **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), patent ductus arteriosus (PDA), 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 defect (e.g., coarctation or complete interruption of the aorta, Ebstein anomaly, hypoplastic left heart syndrome, Tetralogy of Fallot (TOF), total anomalous pulmonary venous connection (TAPVC), transposition of the great arteries (TGA), truncus arteriosus, tricuspid atresia, etc.);
      iv) Previous cardiac or cardiopulmonary surgical procedures (e.g., cardiac bypass, at the conclusion of extracorporeal membrane oxygenation (ECMO), 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 meet **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, diuretics, or bronchodilator therapy during 6 months before the 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:** Administer 15 mg/kg intramuscularly prior to beginning of RSV season and continue every month 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 (February 29, 2020), 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 mild cardiomyopathy
- 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 coartation 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.

References:

1. Palivizumab (Synagis) [prescribing information]. Gathersburg, MD: MedImmune, LLC; May 2017.
2. Brady MT, Byington CL, Davies HD, et al. Updated guidance for palivizumab among infants and young children at increased risk of hospitalization for RSV infection. *Pediatrics*. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.

3. Feltes T, Cabalka A, Meissner H, 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.
4. Weinrauch LA. Cyanotic heart disease: MedlinePlus. Verimed Healthcare Network: October 2015. https://medlineplus.gov/ency/article/001104.htm.
5. 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.
6. Kong AM, Krilov LR, Fergie J, et al. The 2014–2015 National Impact of the 2014 American Academy of Pediatrics Guidance for Respiratory Syncytial Virus Immunoprophylaxis on Preterm Infants Born in the United States. Thieme Medical Publishers, Inc. July 26, 2017.
7. Goldstain M, Krilov LR, Fergie J, et al. Respiratory Syncytial Virus Hospitalizations among U.S. Preterm Infants Compared with Term Infants Before and After the 2014 American Academy of Pediatrics Guidance on Immunoprophylaxis: 2012–2016. Thieme Medical Publishers, Inc. April 26, 2018.
8. MARP ID SENTINEL1 ID Week 2016 poster ML-3016-US-0098.
9. 2018 PAS Poster Goldstein et al. RSVHs Before and Two Seasons After 2014 AAP Guidance on RSVIP.
10. Rajah B, Sanchez PJ, Garcia-Maurino C, et al. Impact of the Updated Guidance for Palivizumab Prophylaxis against Respiratory Syncytial Virus Infection: A Single Center Experience. *J Pediatr* 2016. November 15, 2016.

Effective date: 09/26/2019
Revised date: 09/04/2019