CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Synagis (palivizumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

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 certain high-risk groups of qualifying pediatric patients. The safety and efficacy of Synagis have not been established for treatment of RSV disease. The safety and effectiveness of Synagis in children older than 24 months of age at the start of dosing have not been established. Synagis is not a vaccine; it delivers antibodies to fight RSV. Synagis is administered by intramuscular injection once monthly for up to 5 consecutive months during RSV season, providing 6 months of protection.

Synagis (palivizumab) will be considered for coverage when the following criteria are met:

Respiratory Syncytial Virus (RSV): Prevention of serious respiratory disease

For **initial** authorization:

1. Medication will be administered during the RSV season (*October 1st through March 3rd*) AND initiation of injections should be timed with the onset of laboratory confirmed cases of RSV activity inthe community, no earlier than October 1; AND
2. Member is < 12 months of age at the beginning of the RSV season AND meets **one** of the following (chart notes must be provided as supporting 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 of age at the beginning of the RSV season AND meets **one** of the

following (chart notes must be provided as supporting 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 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; AND

4. Member is unable to use Beyfortus; AND
5. Synagis is NOT being prescribed for any of the following:
    a) Treatment of RSV infection
    b) RSV prophylaxis for children who were previously infected with RSV in the current season
    c) RSV prophylaxis for children with Down syndrome
    d) RSV prophylaxis for health care-associated RSV disease
    e) RSV prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing
    f) 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); AND
6. Member has not received RSV monoclonal antibodies (ex. Synagis or Beyfortus) or RSV vaccinations including maternal vaccinations (ex. Abrysvo) in the current RSV season.

Dosage allowed/Quantity limit: 15 mg/kg once monthly for a total of 5 doses or until the end of the RSV season.Limits: Two 1 mL (100 mg) vials per 30 days OR three 0.5 mL (50 mg) vials per 30 days

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 3), whichever comes first.

For **reauthorization**:

1. Synagis will not be reauthorized.*

* Requests may be reviewed on a case-by-case basis outside of the typical RSV season window when increased interseasonal RSV activity is present. This will follow guidance from the American Academy of Pediatrics (AAP) and CDC trend data. State specific rules may also apply.

CareSource considers Synagis (palivizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
08/25/2021	RSV season time limits updated for 2021-2022.
08/23/2022	Transferred to new template. Updated references. Removed specific years. Added reauth section with statement about case-by-case interseasonal review. Revised exclusions and moved up to criteria section.
08/18/2023	Added inability to use Beyfortus; added that member has not received other monoclonal antibodies or maternal vaccine in the current RSV season.

References:

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Effective date: 12/01/2023
Revised date: 08/18/2023