# Palivizumab (Synagis®)

EOCCO POLICY

## Policy Type: PA/SP  Pharmacy Coverage Policy: EOCCO051

### Description

Palivizumab (Synagis) is a humanized monoclonal antibody directed against the fusion protein of respiratory syncytial virus (RSV).

### Length of Authorization

- Initial: Five months
- Renewal: N/A

### Quantity limits

| Product Name | Dosage Form | Indication | Quantity Limit | DDID |
|---|---|---|---|---|
| palivizumab (Synagis) | 100 mg/1mL | Respiratory syncytial virus (RSV) prophylaxis | 15 mg/kg (1 dose) per 28 days | 095334 |
| | 50 mg/0.5mL | | | 095335 |

### Initial Evaluation

I. Palivizumab (Synagis) may be considered medically necessary when the following criteria below are met:
   A. Therapy is given during the current RSV season, **AND**
   B. Member is being managed by or in consultation with a pulmonologist or cardiologist; **AND**
   C. A diagnosis of one of the following:
      1. **Preterm Infants WITHOUT Chronic Lung Disease of Prematurity or Congenital Heart Disease**; **AND**
         i. Member was born before 29 weeks, 0 days of gestation; **AND**
         ii. Member is less than 12 months of age; **OR**
      2. **Preterm Infants WITH Chronic Lung Disease**; **AND**
         i. Member was born before 32 weeks, 0 days; **AND**
         ii. Member required greater than 21% oxygen for at least the first 28 days after birth; **AND**
         iii. Member is less than 12 months of age; **OR**
         iv. Member is less than 24 months of age; **AND**
         v. Continues to require medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of second RSV season; **OR**

3. **Infants and Children with Hemodynamically Significant Chronic Heart Disease (CHD)**; **AND**
   - **i.** Member is less than 12 months of age; **AND**
   - **ii.** Member has moderate to severe pulmonary hypertension; **OR**
   - **iii.** Member has acyanotic heart disease; **AND**
     - **a.** Member is receiving medication to control congestive heart failure; **AND**
     - **b.** Member will require cardiac surgical procedures; **OR**
4. **Children undergoing cardiac transplantation during RSV season**; **AND**
   - **i.** Member is less than 24 months of age; **OR**
5. **Infants with Anatomic Pulmonary Abnormalities or Neuromuscular disorder**; **AND**
   - **i.** Member is less than 12 months of age; **AND**
   - **ii.** Member has an impaired ability to clear secretions from the upper airway; **OR**
6. **Immunocompromised Children**; **AND**
   - **i.** Member is less than 24 months of age; **AND**
   - **ii.** Member is profoundly immunocompromised (e.g. undergoing chemotherapy, HIV, SCID, DiGeorge, IgA deficiency, Hypergammaglobulinemia etc.); **OR**
7. **Children with Cystic Fibrosis, Primary Ciliary Dyskinesia, or other rare lung disease**; **AND**
   - **i.** Member is less than 12 months of age; **AND**
     - a. Member has clinical evidence of chronic lung disease (CLD); **OR**
     - **b.** Member has clinical evidence of nutritional compromise; **OR**
   - **ii.** Member is less than 24 months of age; **AND**
     - **a.** Member has previous hospitalization for pulmonary exacerbation in the first year of life; **OR**
     - **b.** Member has abnormalities on chest radiography/chest computed tomography that persist when stable; **OR**
     - c. Member has a weight for length less than the 10th percentile

II. Palivizumab (Synagis) is considered <u>not medically necessary</u> when criteria above are not met and/or when used for:

- A. Infants or children who were born after 32 weeks
- B. Infants and children with hemodynamically insignificant heart disease such as:
  1. Secundum atrial septal defect
  2. Small ventricular septal defect
  3. Pulmonic stenosis

4. Uncomplicated aortic stenosis
5. Mild coarctation of the aorta
6. Patent ductus arteriosus

C. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
D. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
E. Children in the second year (≥24 months) of life
F. Children with Down syndrome without other comorbid conditions listed in the Initial Evaluation (section I) portion of this policy.

III. Palivizumab (Synagis) is considered investigational when used for all other conditions, including but not limited to:
   A. For the treatment of RSV

**Supporting Evidence**

I. For current RSV trends, refer to: http://www.cdc.gov/surveillance/nrevss/rsv/index.html. CDC utilized the past year's surveillance season data to predict the timing of the next year's outbreak; this information is updated annually.

II. Palivizumab (Synagis) was evaluated in two randomized, double-blind, placebo-controlled trials of prophylaxis against RSV infection in children at high risk of an RSV-related hospitalization.
   - Trial 1 was conducted during a single RSV season with 1502 children who were less than or equal to 24 months of age with bronchopulmonary dysplasia (BPD) or infants with premature birth (less than or equal to 36 weeks of gestation) who were less than or equal to 6 months of age at study entry.
     i. Results of Trial 1: 4.8% (49/1002) participants were hospitalized in the palivizumab (Synagis) group compared to 10.6% (52/500) participants were hospitalized in the placebo group.
   - Trial 2 was conducted over four consecutive RSV seasons with 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease.
     i. Results of Trial 2: 5.3% (34/639) participants were hospitalized in the palivizumab (Synagis) group compared to 9.7% (63/648) participants were hospitalized in the placebo group.

III. A technical review by the American Academy of Pediatrics (AAP) was completed in 2014 and the recommendation was palivizumab (Synagis) for RSV prophylaxis "cannot be considered as high-value health care for any group of infants" because its high cost is associated with minimal benefit. From that technical review, AAP published the following guidance in 2014: Palivizumab

(Synagis) Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection.

- The AAP states available data for infants born at 29 weeks, 0 days' gestation or later do not identify a clear gestational age cutoff for which the benefits of prophylaxis are clear. For this reason, infants born at 29 weeks, 0 days' gestation or later are not universally recommended to receive palivizumab (Synagis) prophylaxis. Infants 29 weeks, 0 days' gestation or later may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.

IV. Although the National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: An Evidence-Based Interdisciplinary Collaboration published additional guidance and new information as it relates to RSV, after reviewing the new information, the AAP still recommended their guidelines from 2014 as the new evidence did not change the cost-benefit analysis that was done.

V. The indications and criteria associated are directly from the guidance provided by AAP 2014 RSV guidance.

## Investigational or Not Medically Necessary Uses

I. The above listed diagnoses under the section of not medically necessary were called out in the APP 2014 RSV Guidance as not medically necessary for immunoprophylaxis with palivizumab (Synagis).

II. Treatment of RSV

A. Safety and efficacy has not been established for the use of palicizumab (Synagis) for the treatment of RSV.

## References

1. Synagis [Prescribing Information]. Gaithersburg, MD: MedImmune, LLC. March 2014.
2. Wegzyn C, Toh LK, Biguenet S, et al. Safety and Effectiveness of Palivizumab in Children at High Risk of Serious Disease Due to Respiratory Syncytial Virus Infection: A Systematic Review. Infect Dis Ther. 2014 Dec; 3(2): 133–158.
3. American Academy of Pediatrics: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Available at: https://pediatrics.aappublications.org/content/134/2/415
4. American Academy of Pediatrics: RSV recommendations unchanged after review of new data. Available at: https://www.aappublications.org/news/2017/10/19/RSV101917
5. Goldstein M, Phillips R, DeVincenzo J, et al. The National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: An Evidence-Based Interdisciplinary Collaboration. October 2017.
6. Center for Disease Control and Prevention: Respiratory Syncytial Virus Infection (RSV). Available at: https://www.cdc.gov/rsv/clinical/index.html

## Policy Implementation/Update:

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|---|---|
| Date Created | September 2008 |
| Date Effective | October 2008 |
| Last Updated | August 2012 |
| Last Reviewed | 12/2008, 07/2012, 05/2013, 09/2019 |

| Action and Summary of Changes | Date |
|---|---|
| Transitioned criteria into policy with supporting evidence, and incorporated the updated AAP RSV prophylaxis guidelines that details the specific coverage recommendations for: chronic lung disease in patients less than 24 months, patients less than 12 months with hemodynamically significant chronic heart disease, cardiac transplantation in patients less than 24 months, anatomic pulmonary abnormalities/neuromuscular disorder in patients less than 12 months, immunocompromised children, children with rare lung disease. Additionally, incorporated the recommendations from the updated AAP RSV prophylaxis guidelines to detail what diagnoses are not medically necessary for RSV prophylaxis/Synagis. | 09/2019 |
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