

**PRIOR AUTHORIZATION CRITERIA**

Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis®) **may be considered medically necessary** in the following infants and children **to a maximum of five monthly doses:**

**1. Prematurity**

Preterm infants less than 12 months of age at the start of RSV season and who were born at or before **28 weeks and 6 days** gestation.

**2. Chronic Lung Disease (CLD)**

- a. Preterm infants less than 12 months of age at the start of RSV season who develop Chronic Lung Disease of Prematurity (CLDP) defined as gestational age  $\leq 31$  weeks and 6 days who required  $>21\%$  oxygen for at least the first 28 days after birth.
- b. Infants less than 24 months of age at the start of RSV season who developed CLD of prematurity as defined in (2.a.) above and who continue to require medical support (supplemental oxygen, chronic corticosteroid, diuretic or bronchodilator therapy) during the 6 month period before the start of RSV season.

**3. Hemodynamically Significant Congenital Heart Disease (CHD)**

- a. Infants who are less than 12 months of age at the start of RSV season with a diagnosis of at least one of the following:
  - Acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures
  - Moderate to severe pulmonary hypertension
  - Cyanotic heart defects and referred by a pediatric cardiologist
- b. Additionally, children less than 24 months of age at the start of RSV season who undergo cardiac transplantation during RSV season.

Immune prophylaxis for RSV **is considered not medically necessary** for

- Infants and children with hemodynamically insignificant heart disease including but not limited to:
  - secundum atrial septal defect,
  - small ventricular septal defect,
  - pulmonic stenosis,
  - uncomplicated aortic stenosis,
  - mild coarctation of the aorta, and
  - patent ductus arteriosus.
- 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.

**4. Neuromuscular Disorder, Congenital Airway Anomaly or Pulmonary Abnormalities**

Infants less than 12 months of age at the start of RSV season with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway because of ineffective cough.

**5. Immunocompromised**

Infants and children less than 24 months of age at the start of RSV season who are profoundly immunocompromised during RSV season due to chemotherapy or other conditions.

**6. Cystic Fibrosis (CF)\***

- a. Infants with CF less than 12 months of age at the start of RSV season with clinical evidence of CLD and/or nutritional compromise.
- b. Children with CF less than 24 months of age at the start of RSV season with at least one of the following manifestations of severe lung disease:
  - Previous hospitalization for pulmonary exacerbation in the first year of life
  - Abnormalities on chest radiography or chest computed tomography that persist when stable
- c. Children with CF less than 24 months of age at the start of RSV season with a weight for length less than the 10<sup>th</sup> percentile.

**Dosage and Administration**

The recommended dose of Synagis® is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of Synagis® at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses.

**Discontinuation of Synagis®**

If any infant or young child receiving monthly Synagis® prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

**\*Miscellaneous Information**

The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis® for these patients will be done on a case by case basis by the clinical reviewer.

**REFERENCES:**

1. American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guideline 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;134(2):415-420