



## Guidelines for Medication Coverage:

### Palivizumab (Synagis)

#### Background:

Respiratory Syncytial Virus (RSV) is the leading cause of lower respiratory infections in infants and young children. Each year, RSV is responsible for more than 90,000 hospitalizations and a 2% mortality rate among hospitalized children. Palivizumab is a humanized monoclonal antibody approved for prevention of serious respiratory tract infections due to RSV in young children with established chronic lung disease (bronchopulmonary dysplasia) or a history of prematurity.

#### Administration:

Palivizumab is administered as an intramuscular injection of 15mg/kg body weight given monthly throughout the RSV season. The first dose should be administered prior to the start of the RSV season, which typically lasts from November through March or April. A course of prophylaxis of five monthly doses is sufficient to provide protection during a normal RSV season.

#### Criteria for approval:

##### 1. Chronic Lung Disease / Bronchopulmonary Dysplasia:

Children less than two years of age with chronic lung disease requiring medical therapy (medications or supplemental oxygen) within six months prior to the anticipated RSV season should be immunized for the current RSV season.

Children with more severe chronic lung disease, especially those requiring continuous medical therapy for such, may require prophylaxis for two RSV seasons, or until the age of two.

##### 2. Prematurity:

- Infants born at 28 weeks or less gestational age should receive prophylaxis if the child was born within 12 months of the beginning of the RSV season.
- Infants born at 29 weeks 0 days to 32 weeks 0 days gestational age should receive prophylaxis if the child was born after 5/1/07.
- Infants born at 32 weeks 1 day to 35 weeks 0 days gestational age should receive prophylaxis only if the child was born after 5/1/07 and **two** or more of the following additional risk factors exist:
  - Exposure to environmental air pollutants, including tobacco smoke in the home
  - Child care center attendance
  - Congenital abnormalities of the airway
  - School age siblings in the household
  - Severe neuromuscular disease

**3. Hemodynamically significant cyanotic and acyanotic congenital heart disease:**

- Infants 24 months of age or younger who are currently receiving medication to control congestive heart failure.
- Infants 24 months of age or younger with moderate to severe pulmonary hypertension.
- Infants 24 months of age or younger with cyanotic heart disease.
- Note: Infants and children with hemodynamically insignificant heart disease (eg. Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) are not considered to be at increased risk from RSV and RSV prophylaxis is not generally warranted. In addition, prophylaxis is not warranted in infants with cardiac defects adequately corrected by surgery unless medication for congestive heart failure is necessary and in infants with mild cardiomyopathies not requiring medical therapy.

**Special Instructions:**

- 1) For patients with severe immunodeficiencies requiring IVIG therapy, physicians should consider substituting RSV-IVIG (Respigam) therapy for standard IVIG during the RSV season. RSV-IVIG provides RSV prophylaxis similar to palivizumab.
- 2) Palivizumab does not interfere with the response to other vaccines.

**Authorization Guidelines:**

- 1) All courses of palivizumab require prior authorization.
- 2) Authorization should be for up to 5 monthly injections.

**Original Approval:** November 2, 1998

**Revised:** September 9, 1999

**Reviewed and Approved:** September 3, 2003; February 5, 2004; November 4, 2004; September 1, 2005; September 7, 2006; September 6, 2007

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Medical Director

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Pharmacy Director

**References:**

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