



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: palivizumab

Brand Name: Synagis®

Medication Class: immunoprophylaxis for RSV

FDA Approved Uses: immunoprophylaxis for RSV in infants and children, born prematurely, who are at high risk for RSV

Usual Doses: 15mg/kg/dose IM once monthly during the RSV season.

Duration of Therapy: For a maximum of 5 doses during the RSV season (beginning of November through March). Unless the infant is between 32-35 weeks gestation and is less than 3 months old at the start of the RSV season and has 1 risk factor such as day care attendance or a sibling younger than 5 years of age in which case the infant would receive prophylaxis until they reach 3 months of age but no more than a total of 3 monthly doses, whichever comes first.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Infants < 28 weeks gestation: <1 year old at the start of the RSV season (November)

**a maximum of 5 monthly doses is recommended for patients in this category.

Or

- Infant 29-32 weeks gestation (defined as 31 weeks, 6 days or less): < 6 months old at the start of the RSV season (November)

**a maximum of 5 monthly doses is recommended for patients in this category.

Or

- Infants 32-35 weeks gestation (defined as 32 weeks, 0 days through 34 weeks, 6 days): < 3 months old at the start of the RSV season (November) or who are born during the RSV season and has at least 1 of the following risk factors:
 - day care attendance
 - sibling younger than 5 years of age.

**For these infants prophylaxis should be received until they reach 3 months of age and should receive a maximum of 3 monthly doses (many will receive only 1 or 2 doses until they reach 3 months of age).

Or

- Infants < 35 weeks gestation who have either one of the following:
 - severe neuromuscular disease
 - congenital abnormalities of the airways

**a maximum of 5 monthly doses is recommended for patients in this category during the first year of life.

Or

- Infants and children < 24 months old at the start of the RSV season (November), with chronic lung disease, CLD, (formerly called BPD) and receive medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season (June through October).

**a maximum of 5 monthly doses is recommended for patients in this category.



Or

- Infants and children < 24 months of age hemodynamically significant cyanotic or acyanotic congenital heart disease.

**a maximum of 5 monthly doses is recommended for patients in this category.

Or

- Infants and children < 24 months of age with congenital heart disease and at least one of the following:
 - receiving medication to control CHF.
 - have moderate to severe pulmonary hypertension.
 - have cyanotic heart disease.

**a maximum of 5 monthly doses is recommended for patients in this category.

P&T Approval: _____ Date: _____