

Palivizumab (Synagis™)	
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Background

Palivizumab (Synagis™, a trademark of MedImmune, LLC) is a humanized monoclonal antibody to the respiratory syncytial virus (RSV). It is indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia, premature birth (≤ 35 weeks gestational age), and children with hemodynamically significant congenital heart disease.

Palivizumab is administered intramuscularly at a dose of 15 mg/kg once every 30 days. RSV prophylaxis should begin at the beginning of the RSV season and stop at the end of the season (November through April in Washington). In the continental United States, a total of 5 monthly doses for infants and young children with congenital heart disease, congenital abnormalities of the airway, neuromuscular disease, severe immunodeficiency, chronic lung disease of prematurity, or preterm birth before 32 weeks' gestation (31 weeks, 6 days) will provide an optimal balance of benefit and cost.

Prophylaxis may be considered for infants from 32 through less than 35 weeks' gestation (defined as 32 weeks, 0 days through 34 weeks, 6 days) who are born less than 3 months before the onset or during the RSV season and for whom at least 1 risk factor is present. Infants in this gestational age category should receive prophylaxis only 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. Once an infant has passed 3 months of age (90 days of age), the risk of hospitalization attributable to RSV lower respiratory tract disease is reduced.

Indications/Criteria

Palivizumab is considered medically necessary for the following indications:

Premature Birth

- Born ≤ 28 weeks gestation AND < 12 months of age at the start of RSV season
5 Doses

- Born 29 weeks, 0 days through 31 weeks, 6 days gestation AND < 6 months of age at the start of RSV season
5 doses
- Born 32 weeks, 0 days through 34 weeks, 6 days gestation AND < 3 months of age at the start of RSV season with ≥ 1 risk factor (i.e., infant attends childcare or has a sibling < 5 years old)
Max 3 doses

Chronic Lung Disease (Bronchopulmonary Dysplasia)

- < 24 months of age AND received medical therapy (i.e., supplemental oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months before the start of the RSV season

Congenital Abnormalities of the Airway

- < 12 months of age at the start of the RSV season AND born < 35 weeks gestation

Neuromuscular Disease that Compromises Handling of Respiratory Secretions

- < 12 months of age at the start of the RSV season AND born < 35 weeks gestation

Congenital Heart Disease

- ≤ 24 months of age AND receiving medication to control congestive heart failure, or diagnosed with moderate to severe pulmonary hypertension, or diagnosed with cyanotic heart disease

Severe Immunodeficiency

- Diagnosed with AIDS or severe combined immunodeficiency

Palivizumab is generally NOT indicated for the following groups:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with 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

- Patients with cystic fibrosis

Limitations/Exclusions

Healthy Options:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

Required Review and Approvals

Palivizumab injections require prior authorization by the CHP Medical Director or his/her designee. The number of authorized injections is based on the above criteria and valid through the remainder of the current RSV season.

References

American Academy of Pediatrics Redbook, available at:
<http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110>