



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Synagis (palivizumab)

Class: Biologic

Formulary medication: N/A

Effective Date: August 2009

Policy/Criteria:

- **2009-2010 Season- November 1, 2009 thru March 31, 2010**
- **Infants with CLD**
 - Younger than 24 months
 - Who also received medical therapy (O₂, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the season (NOV 09)
 - Maximum of 5 doses should be provided
 - Patients with the most severe CLD who continue to receive medical therapy may benefit from the second season
- **Infants born before 32 weeks GA (31 weeks, 6 days or less)**
 - Born at 28 weeks of GA or earlier- if younger than 12 months of age
 - Born at 29-32 weeks of GA or earlier- if younger than 6 months of age
 - Maximum of 5 doses should be provided
- **Infants born at 32 to less than 35 weeks GA (32 weeks, 0 days through 34 weeks, 6 days)**
 - Prophylaxis is offered to infants at greatest risk of hospitalization
 - Infants younger than 3 months of age at the start of the RSV season

- On the basis of the age of patients at the time of discharge from the hospital, fewer doses may be required, because these infants will receive 1 dose every 30 days until the infant is 90 days of age
- Infants who are born during the RSV season
- Who are likely to have an increased risk of exposure to RSV- when one of the following two risk factors is present:
 - Infant attends child care, defined as a home of facility where care is provided for any number of infants or young toddlers in the child care facility
 - Infant has a sibling younger than 5 years of age
 - Infants in this category should receive prophylaxis only until they reach 3 months of age, and should receive a maximum of 3 monthly doses. Administration of palivizumab is not recommended after 3 months of age
- **Infants with congenital abnormalities of the airway or neuromuscular disease**
 - May be considered for infants born before 35 weeks of GA
 - Maximum of 5 doses during the first year of life
- **Infants and children with congenital heart disease**
 - Children who are 24 months of age or younger
 - With hemodynamically significant cyanotic or acyanotic congenital heart disease-
 - Infants who are receiving medication to control congestive heart failure
 - Infants with moderate to severe pulmonary hypertension
 - Infants with cyanotic heart disease
 - The following groups of infants are not at increased risk of RSV and generally should not receive immunoprophylaxis:
 - 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)
 - 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
 - Maximum of 5 doses should be provided
- **Immunocompromised children**
 - No specific recommendation was made
- **Children with severe immunodeficiencies** (eg, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) may benefit from prophylaxis.

- **Patients with cystic fibrosis**

- Recommendation for routine prophylaxis in patients with cystic fibrosis cannot be made

- **Other consideration**

- Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge.
- If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should continue until a maximum of 3 doses have been administered to infants in the 32 to less than 35 weeks' gestation group (defined as 32 weeks, 0 days through 34 weeks, 6 days) or until a maximum of 5 doses for infants with congenital heart disease, CLD, or preterm birth before 32 weeks' gestation. This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often cocirculates in a community.
- RSV is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. Among hospitalized infants, the major means to reduce RSV transmission is strict observance of infection control practices, including prompt initiation of precautions for RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric or neonatal intensive care unit or stem cell transplantation unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose.
- Palivizumab does not interfere with response to vaccines.

Clinical Justification:

1. This policy is adopted from the American Academy of Pediatrics recommendations and guidelines for RSV prophylaxis.

Reference:

1. American Academy of Pediatrics. Respiratory Syncytial Virus. In: Pickering LK, ed. *Red Book: 2009 Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:560-569. Available at: <http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110>. Accessed July 10, 2009):