

PROTOCOL OVERVIEW

Immunoprophylaxis for respiratory syncytial virus (RSV) with intramuscular palivizumab (Synagis) is considered medically necessary for the prevention of serious lower respiratory tract disease in infants and young children who are at high risk and meet the following criteria:

INDICATIONS

- I. Palivizumab prophylaxis may be administered to infants born before 29 weeks gestation who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 doses will be needed. Up to five (5) doses of palivizumab (Synagis) within the RSV season (generally during the period from November 1 through March 31) when the following criteria are met:
 - a. Less than or equal to 24 months of age on Nov. 1st with history of treated chronic lung disease in the previous 6 months (with oxygen, steroids, bronchodilators, or diuretics). (Note: asthma, reactive airway disease and cystic fibrosis do not meet the definition of chronic lung disease in the AAP Guidelines).
 - b. Less than or equal to 24 months of age on Nov. 1st with hemodynamically significant congenital heart disease (e.g., cyanotic or acyanotic heart disease, moderate to severe pulmonary hypertension, those receiving medication to control congestive heart failure). (Note: the following groups of infants are not at increased risk of RSV and generally do not need Immunoprophylaxis:
 - i. 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
 - ii. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
 - iii. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
 - c. Children less than 12 months of age on Nov. 1st and born at 28, or less, weeks of gestation
 - d. Children less than 6 months of age on Nov. 1st and born 29-32 weeks of gestation
 - e. Infants less than 3 months of age on Nov. 1st and born 32-35 weeks of gestation with one of the following risk factors:
 - i. Attends childcare with at least one other young child
 - ii. Another child living in the household is less than 5 years of age (Note: infants in this category should receive a maximum of 3 monthly doses).
- II. If a child experiences a breakthrough RSV infection, monthly prophylaxis should continue until a maximum of 3 doses have been administered to patients in the 32 to 35 weeks gestation group or until a maximum of 5 doses for children in the other defined risk groups.
- III. Continued RSV Immunoprophylaxis with monthly doses of palivizumab (Synagis) when the National Respiratory and Enteric Surveillance System (NREVSS) epidemiologic data have confirmed that the present-year RSV season has ended is considered not medically necessary.
- IV. Immunoprophylaxis for RSV is considered investigational and not medically necessary for children ages 24 months and older prior to the commencement of the RSV season.

CITATIONS

American Academy of Pediatrics, Pediatrics, “Updated guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection” August 2014

American Academy of Pediatrics (AAP), 2009 Red Book Online, Section 3: Summaries of Infect. Diseases. Chapter on Respiratory Syncytial Virus (RSV). Report of the Committee on Infectious Diseases. Elk Grove Village, IL: AAP; 2009

Anthem Blue Cross Medical Policy, “Prevention of Respiratory Syncytial Virus Infections”, policy #DRUG.00015, 8/19/2010

California Department of Health Care Services letter to All County California Children Services (CCS) Program Administrators, Medical Consultants, and Staff Children’s Medical Services (CMS) Branch Staff, Subject: Palivizumab (Synagis), Aug. 31, 2009

Inland Empire Health Plan, Letter to IPA Medical Directors, “2010-2011 Synagis (palivizumab) Criteria”, Oct. 14, 2010