

Specialty Pharmacy Program

Synagis® (palivizumab)

DESCRIPTION

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

APPROVAL DURATION

Approval duration:

- Up to 5 times during the months of November through March.

APPROVAL CRITERIA

Note: The U.S. Food and Drug Administration (FDA) label for immune prophylaxis for RSV with Synagis indicates that administration should occur on a monthly basis during the RSV season, which varies according to region. The American Academy of Pediatrics (AAP) guidelines were updated in 2009 with changes to their recommendation which differ from the FDA label, in terms of the number of doses to provide, as well as the individuals likely to benefit from such treatment. The updated AAP guidelines emphasize the role of the National Respiratory and Enteric Virus Surveillance System (NREVSS) in documenting the variation in RSV disease outbreaks from year to year and across geographic regions. However, this variation occurs within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by March.

Immunoprophylaxis for respiratory syncytial virus (RSV) with intramuscular palivizumab (Synagis) may be approved for the prevention of serious lower respiratory tract disease in infants and young children who are at high risk, when the criteria below are met:

- I. Five (5) doses of Synagis within the RSV season during the first year of life are may be approved for infants with any of the following clinical presentations:
 - A. Born at 28, or less, weeks of gestation (up to and including 28 weeks, 6 days) and less than 12 months of age at the start of the RSV season; OR
 - B. Born at 29 to 32 weeks gestation (beginning 29 weeks, 0 day through 31 weeks, 6 days) and less than 6 months of age at the start of the RSV season; OR
 - C. Chronic lung disease (CLD) [formerly designated Bronchopulmonary Dysplasia (BPD)] who have required medical treatment within six months before the start of the RSV season 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); OR
 - D. Hemodynamically significant (for example, but not limited to, receiving medication for congestive heart failure or moderate to severe pulmonary hypertension) cyanotic or acyanotic congenital heart disease (CHD); OR
 - E. Congenital abnormalities of the airway or neuromuscular disease, born before 35 weeks of gestation, with congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions.
- II. Up to three (3) doses of Synagis during one RSV season in the first year of life may be approved when ALL of the following:
 - A. Infant born between 32 and 35 weeks gestation* (beginning 32 weeks, 0 day through 34 weeks, 6 days); AND
 - B. Less than 3 months of age at the start of the RSV season; AND
 - C. Less than 90 days old at the time of dosing; AND
 - D. One or more of the following risk factors are present:

1. Attends group child care (defined as a home or facility where care is provided along with at least one other infant or young child), OR
 2. If there are siblings or other children living in the household who are less than 5 years of age.
- * Please Note: The criteria for infants born between 32 and 35 weeks gestational age do not apply to infants with conditions listed in criteria I. above.
- III. An additional dose of Synagis may be approved for children in an approved course of treatment who undergo cardiopulmonary bypass for surgical procedures due to documented reduction in serum levels post-bypass.
 - IV. Completion of dosing schedule of Synagis may be approved for an infant or child who is receiving RSV immunoprophylaxis and experiences break-through RSV infection.
 - V. Five (5) doses of Synagis within the RSV season during the second year of life may be approved for children with any of the following clinical presentations:
 - A. Chronic lung disease (CLD) [formerly designated Bronchopulmonary Dysplasia (BPD)] who have required medical treatment within six months before the start of the RSV season 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); OR
 - B. Hemodynamically significant (for example, but not limited to, receiving medication for congestive heart failure or moderate to severe pulmonary hypertension) cyanotic or acyanotic congenital heart disease (CHD).
 - VI. Synagis may NOT be approved for the following:
 - A. Administration of more than 5 doses of Synagis in one RSV season.
 - B. Administration of more than 3 doses of Synagis or any dose after 90 days of age for infants born between 32 and 35 weeks gestational age unless they have a condition listed in criteria A. above.
 - C. Immunoprophylaxis for respiratory syncytial virus for children less than 24 months of age when the above criteria are not met.
 - D. Continued RSV immunoprophylaxis regimen with monthly doses of Synagis when the National Respiratory and Enteric Virus Surveillance System (NREVSS) epidemiologic data has confirmed that the present-year RSV season has ended.
 - VII. Synagis is considered investigational and may NOT be approved for the following:
 - A. Immunoprophylaxis for respiratory syncytial virus is considered investigational and not for children ages 24 months or older prior to the commencement of the RSV season.
 - B. Synagis is considered investigational for treatment in children or infants with known RSV disease except as indicated above.
 - C. Immunoprophylaxis for respiratory syncytial virus is considered investigational for infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
 - D. Immunoprophylaxis for respiratory syncytial virus is considered investigational for infants and children with surgically corrected congenital heart disease unless they continue to require medication for congestive heart failure.
 - E. Immunoprophylaxis for respiratory syncytial virus is considered investigational and not medically necessary for all other indications not otherwise addressed as medically necessary, including, but not limited to, its use in recipients of hematopoietic stem cell transplants and cystic fibrosis patients who do not otherwise meet criteria above.