ILLINOIS DEPARTMENT OF Healthcare and Family Services

Synagis (palivizumab)
Prior Authorization Criteria

Program Rationale

Synagis (palivizumab) is a humanized monoclonal antibody that is FDA-approved for the prophylaxis of serious lower respiratory tract infections due to respiratory syncytial virus (RSV) in children at high risk of severe RSV infection.[1] Synagis is administered as an intramuscular injection at a dose of 15 mg/kg every 30 days during RSV season.

On July 28, 2014, updated guidelines for Synagis prophylaxis of hospitalization due to RSV infection were released by The American Academy of Pediatrics (AAP) and subsequently were recognized by the Centers for Disease Control and Prevention (CDC).[2-4] The AAP Committee on Infectious Diseases and Bronchiolitis Guideline Committee have determined that, "Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing."[2]

These prior authorization criteria are consistent with the published AAP guidelines available at http://pediatrics.aappublications.org/content/134/2/415.full.[2] According to the AAP, in the continental United States, peak RSV activity typically occurs between November and March.[2,3] Children who meet the below criteria may qualify for a maximum of 5 doses during the RSV season. Children who qualify for a 5-dose regimen should receive the first dose of Synagis in November, and the last dose in March, which will provide protection into April. Children born after November 2017 who meet these criteria will be approved for fewer doses of Synagis.

Approval Criteria

Synagis will be approved in the following scenarios:[2]

1. Children <12 months of age on November 1st of the current year and born <29 weeks gestational age.

2. Children <12 months of age on November 1st of the current year, with chronic lung disease (CLD) of prematurity, defined as <32 weeks gestational age and requiring >21% oxygen for at least 28 days after birth.

   Children <24 months of age on November 1st of the current year, with a history of CLD, meeting the above definition, and who continued to receive medical treatment such as oxygen, chronic corticosteroids, or diuretic medications during the previous 6 months.

3. Children <12 months of age on November 1st of the current year, with hemodynamically significant cyanotic or acyanotic congenital heart disease. Children in this group most likely to benefit from prophylaxis include:

   a. Children receiving medication to control congestive heart failure and who will require cardiac surgery

b. Children with moderate to severe pulmonary hypertension
c. Children with cyanotic heart disease

The following groups of infants are NOT at increased risk for RSV and generally should NOT receive Synagis:

a. Children with hemodynamically insignificant heart disease, including:
   i. Secundum atrial septal defect
   ii. Small ventricular septal defect
   iii. Pulmonic stenosis
   iv. Uncomplicated aortic stenosis
   v. Mild coarctation of the aorta
   vi. Patent ductus arteriosis

b. Children with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure

c. Children with mild cardiomyopathy who are not receiving medical therapy for the condition

d. Children in the second year of life.

4. Children <12 months of age on November 1st of the current year, with pulmonary abnormalities or neuromuscular disease that affects the ability to clear secretions.

5. Children <24 months of age on November 1st of the current year, who are severely immunocompromised (e.g. receiving chemotherapy) during RSV season.

Other conditions may be reviewed on a case-by-case basis.

Quantity Limits:

1. The approval timeframe for Synagis requests will begin November 1, 2017 and will end March 31, 2018. **Acceptance of 2017-2018 Prior Authorization Request Forms will begin October 16, 2017.**
2. Children meeting the criteria may receive a maximum of 5 doses of Synagis. No circumstances will allow for approval of a 6th dose.
3. Each dose must be billed as a 30-day supply.
4. Approval will be given for the current dosage and vial size(s). Throughout the RSV season, weight changes should be submitted on the Synagis request form when a different vial size(s) is/are required.

References

1. Synagis [package insert]. Gaithersburg, MD: MedImmune, Inc; May 2017.

2. American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Policy statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415-420.

3. American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Technical report: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):e620-638.

4. Center for Disease Control and Prevention. Respiratory Syncytial Virus (RSV): Prophylaxis and high-risk groups. http://www.cdc.gov/rsv/clinical/index.html. Updated March 7, 2017. Accessed September 6, 2017.