Synagis® (palivizumab)

SYNAGIS ACQUISITION FOR THE 2016-17 RSV SEASON

Wellmark Blue Cross and Blue Shield continues to partner with Hy-Vee Pharmacy Solutions (HPS) as our preferred specialty pharmacy vendor for Synagis® for the 2016-2017 respiratory syncytial virus (RSV) season. All network providers will be required to obtain Synagis through one of our two specialty pharmacy vendors (HPS or CVS Caremark, with HPS being preferred) for the 2016-2017 RSV season.

Synagis will still require prior authorization (PA); Wellmark’s PA criteria will continue to follow the recommendations of the American Academy of Pediatrics (AAP), which were last published in the July 2014 issue of Pediatrics. Wellmark’s pharmacy benefit manager, CVS/caremark will continue to review all PA requests to ensure that the criteria are met.

The following is a general outline of how Synagis can be requested and obtained for the 2016-2017 RSV season, with HPS as the preferred specialty pharmacy vendor:

- Provider identifies a Wellmark member who may benefit from Synagis immunoprophylaxis this season.
- Provider calls HPS at (866) 823-9868 to initiate enrollment
- Provider completes the Synagis enrollment form provided by HPS and faxes to HPS at (866) 823-9966 with any additional supporting clinical documents (e.g., care notes, NICU discharge summary, etc.).
- HPS staff works directly with CVS/caremark in determining whether the member qualifies for Synagis treatment per Wellmark’s PA criteria.
- If the member qualifies for Synagis therapy (as outlined in the Policy section below), HPS will make contact with the provider and member to coordinate delivery and monthly shipments.

Many benefits can be realized by utilizing HPS for Synagis acquisition this RSV season.

Providers receive the added benefit of:

- Integrated coordination and communication of the Synagis prior authorization (PA) process through HPS
- Decreased administrative and financial burden of acquiring, storing, and billing Synagis
- Convenient Synagis delivery to the office or patient's home, as requested.
- Coordination of home health nurse visits when a patient requires Synagis injections in the home
- Automatic coordination of monthly injections to maximize patient adherence
- Case management services to monitor dosage and patient adherence
- A direct HPS support line for questions relating to the procurement of Synagis: (866) 823-9868

Eligible members will:

- Potentially incur less out-of-pocket expense for Synagis as a result of the contracted rate with HPS (depending on the member’s benefit design)
- Have access to convenient Synagis delivery to their home or provider’s office. Home health nurse visits can be arranged to provide Synagis within the member’s home.
• Receive automatic coordination of refills to ensure monthly injections are received in a timely manner
• Receive assistance from HPS in determining insurance benefits, enabling them to better anticipate the out-of-pocket costs associated with Synagis therapy. Additionally, HPS will help identify patient assistance programs for those who may be eligible.
• Have access to a 24/7 telephone line to an RSV clinical specialist for Synagis-related questions/concerns
• Receive a customized RSV/Synagis® Wellness Kit

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Synagis® (palivizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. Synagis is a recombinant humanized monoclonal antibody which exhibits neutralizing and fusion-inhibitory activity against respiratory syncytial virus (RSV). Synagis is approved by the Food and Drug Administration (FDA) for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients considered to be high risk for developing complications from RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia ([BPD], now more commonly referred to as chronic lung disease of prematurity [CLD]), infants with a history of premature birth, and children with hemodynamically significant congenital heart disease (CHD). The primary benefit of immunoprophylaxis with Synagis is a reduction in RSV related hospitalizations; no prospective, randomized controlled trials have demonstrated a significant reduction in mortality or long-term respiratory outcomes. The safety and efficacy of Synagis have not been established for the treatment of RSV disease. Synagis is administered by intramuscular injection at a dose of 15 mg/kg once every 30 days during RSV season.

POLICY

I. Synagis® (palivizumab) may be considered **medically necessary** for use as immunoprophylaxis for RSV in infants who were born at less than 29 weeks’ gestation (28 weeks, 6 days and earlier) **AND** who are younger than 12 months of age at the onset of RSV season

   Approval will be for a **maximum of 5 doses**

II. Synagis® (palivizumab) may be considered **medically necessary** for use as immunoprophylaxis for RSV in preterm infants and children born before 32 weeks gestation (31 weeks, 6 days and earlier) with chronic lung disease of prematurity (CLD) defined as a greater than 21% oxygen requirement for at least 28 days after birth when the following criteria are met:

   • The patient is younger than 12 months of age at the onset of RSV season **OR**
   • The patient is younger than 24 months of age at the start of RSV season **AND** has required medical therapy (e.g. supplemental oxygen, bronchodilators, diuretics, corticosteroid therapy) in the 6 months prior to the start of the second RSV season
Approval will be for a maximum of 5 doses.

III. Synagis® (palivizumab) may be considered medically necessary for use as immunoprophylaxis for RSV in infants and children with congenital heart disease (CHD) who are less than 12 months of age at the onset of RSV season when the following criteria are met:
- The patient has a diagnosis of hemodynamically significant congenital heart disease (CHD) including ONE of the following:
  o Acyanotic heart disease for which the patient is receiving medication to treat congestive heart failure AND will require cardiac surgical procedures
  o moderate to severe pulmonary hypertension
  o cyanotic heart disease in consultation with a pediatric cardiologist

Approval will be for a maximum of 5 doses.*

*For children with heart disease meeting the above criteria, an additional postoperative dose of palivizumab may be considered medically necessary following cardiopulmonary bypass or the conclusion of extracorporeal membrane oxygenation.

IV. Synagis® (palivizumab) may be considered medically necessary for use as immunoprophylaxis for RSV in infants and children younger than 24 months of age at the onset of RSV season that have undergone cardiac transplantation during RSV season.

Approval will be for a maximum of 5 doses.

V. Synagis® (palivizumab) may be considered medically necessary for use as immunoprophylaxis for RSV in infants with congenital abnormalities of the airways or neuromuscular disease that compromises the handling of secretions when the patient is younger than 12 months of age at the onset of RSV season.

Approval will be for a maximum of 5 doses.

VI. Synagis® (palivizumab) may be considered medically necessary for use as immunoprophylaxis for RSV in infants and children younger than 24 months of age who are profoundly immunocompromised (e.g. including those who have undergone solid organ transplant, undergoing hematopoietic stem cell transplant, receiving chemotherapy) during the RSV season.

Approval will be for a maximum of 5 doses†

VII. Synagis® (palivizumab) may be considered medically necessary for use as immunoprophylaxis for RSV in infants and children with a diagnosis of cystic fibrosis and meet the following criteria:
- The patient is less than 12 months of age at the onset of RSV season and have ONE of the following:
  o Clinical evidence of CLD
  o Nutritional compromise
  OR
- The patient is less than 24 months of age at the onset of RSV season and have ONE of the following:
  o Manifestations of severe lung disease defined as a previous hospitalization for pulmonary exacerbation in the first year of life or an abnormal chest radiography or chest computed tomography that persist when stable
VIII. Synagis is considered **not medically necessary** for patients who do not meet the criteria set forth above.

Prior approval is required. Call Hy-Vee Pharmacy Solutions at (866) 823-9868 to enroll.

**PROCEDURES AND BILLING CODES**

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- 90378  Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

**REFERENCES**

- Synagis® (palivizumab) [package insert]. Gaithersburg, MA: MedImmune, Inc; March 2014.
- Available at: [http://aapredbook.aappublications.org/content/1/SEC131/SEC249.body?sid=1ecd49df-e50b-43c1-b104-cf8b694d8f1b](http://aapredbook.aappublications.org/content/1/SEC131/SEC249.body?sid=1ecd49df-e50b-43c1-b104-cf8b694d8f1b). Accessed on August 10, 2012.

**POLICY HISTORY**

Policy #: 05.01.08
Policy Creation: September 1998
Reviewed: July 2016
Revised: July 2015
Effective: August 5, 2015