SYNAGIS (palivizumab)

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) during the RSV season with palivizumab meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes in infants and children in accordance with current (2014) guidelines from the American Academy of Pediatrics ("Updated guidance", 2014):

1. In the first year of life, i.e., younger than 12 months at the start of the RSV season or born during the RSV season in:
    a. Infants born before 29 weeks, 0 days' gestation;
    b. Preterm infants with chronic lung disease (CLD) of prematurity, defined as birth at less than 32 weeks, 0 days' gestation and a requirement for more than 21% oxygen for at least the first 28 days after birth;
    c. Certain infants with hemodynamically significant heart disease (e.g., infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures; infants with moderate to severe pulmonary hypertension; infants with lesions adequately corrected by surgery who continue to require medication for heart failure);
        i. Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist.
    d. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways (e.g., ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy);
    e. Children with cystic fibrosis who have at least one of the following conditions:
        i. Clinical evidence of CLD; **AND/OR**
        ii. Nutritional compromise.

2. In the second year of life, i.e., younger than 24 months at the start of the RSV season in:
    a. Children who were born at less than 32 weeks, 0 days' gestation and required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) during the 6-month period before the start of the second RSV season.
    b. Children with cystic fibrosis who have either:
        i. Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable); **OR**
        ii. Weight for length less than the 10th percentile.

3. In the first or second year of life in:
    a. Children who will be profoundly immunocompromised (e.g., will undergo solid organ or hematopoietic stem cell transplantation or receive chemotherapy) during the RSV season.

4. After surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of palivizumab meets member benefit certificate primary coverage criteria as soon as the individual is medically stable after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

5. Will not be used for the following:
    a. 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); **OR**
    b. Infants with lesions adequately corrected by surgery, unless they continue to require medication for heart failure; **OR**
    c. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition; **OR**
    d. Children with congenital heart disease in the second year of life; **OR**
    e. Infants and children receiving monthly palivizumab prophylaxis who experience a breakthrough RSV hospitalization. (Monthly prophylaxis should be discontinued at the time of breakthrough because of the extremely low likelihood of a second RSV hospitalization in the same season); **AND**

6. Must be dosed in accordance with the FDA label.

Dosage and Administration

Dosing per FDA Guidelines

The recommended dose of palivizumab is 15 mg per kg of body weight, administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season.

Children undergoing cardio-pulmonary bypass should receive an additional dose of palivizumab as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.

Palivizumab is available as 50 mg per 0.5 mL and 100 mg per 1 mL in single-dose liquid solution vials.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Immunoprophylaxis for respiratory syncytial virus, for any indication or circumstance not described above, does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes or is considered **not medically necessary** for members with contracts without primary coverage criteria administration of immune prophylaxis for respiratory syncytial virus (RSV) during the RSV season with palivizumab.

Other indications for immune prophylaxis for respiratory syncytial virus does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes including, but not limited to, controlling outbreaks of health care-associated disease; or use in
immunocompromised children or children with cystic fibrosis or Down syndrome without other risk factors; or in children over 2 years of age, unless criteria for medical necessity (outlined above) are satisfied.

For members with contracts without primary coverage criteria, other indications for immune prophylaxis for respiratory syncytial virus are considered **investigational** including, but not limited to, controlling outbreaks of health care-associated disease; or use in immunocompromised children or children with cystic fibrosis or Down syndrome without other risk factors; or in children over 2 years of age, unless criteria for medical necessity (outlined above) are satisfied. Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Additional Policy Guidelines

Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis. Qualifying infants born during the RSV season will require fewer doses. For example, infants born in January would receive their last dose in March.

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.

Initiation of immunoprophylaxis in November and continuation for a total of 5 monthly doses will provide protection into April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February.

In the temperate climates of North America, peak RSV activity typically occurs between November and March, whereas in equatorial countries, RSV seasonality patterns vary and may occur throughout the year. The inevitability of the RSV season is predictable, but the severity of the season, the time of onset, the peak of activity, and the end of the season cannot be predicted precisely. Substantial variation in timing of community outbreaks of RSV disease from year to year exists in the same community and between communities in the same year, even in the same region. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV activity.

In the continental United States, a total of 5 monthly doses for infants and young children with congenital heart disease, chronic lung disease (CLD) of prematurity, or preterm birth before 32 weeks' gestation (31 weeks, 6 days) will provide an optimal balance of benefit and cost, even with variation in season onset and end.

Children who receive palivizumab prophylaxis for the entire RSV season should receive palivizumab only during the 5 months after the onset of RSV season in their region (maximum of 5 doses), which should provide coverage during the peak of the season, when prophylaxis is most effective.