RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections in children. At highest risk are those younger than 2 years of age with prematurity, chronic lung disease (CLD) of prematurity (formerly known as bronchopulmonary dysplasia), congenital heart disease or multiple congenital anomalies. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants. Based on the weight of the clinical evidence from randomized clinical trials, systematic reviews and strong clinical consensus, immune prophylaxis for RSV has demonstrated reductions in RSV-related hospitalizations in select populations of susceptible infants and children.
RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Criteria:

See Resources section for FDA-approved dosage.

- Monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) during the RSV season with FDA approved dosage of palivizumab is considered **medically necessary** with documentation of no previous significant hypersensitivity reaction to palivizumab and **ANY** of the following:

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, and documentation of **ANY** of the following:
   
   - Infants born before 29 weeks, 0 days’ gestation
   - 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
   - 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)
   - 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)
   - Children with cystic fibrosis who have **ANY** of the following:
     
     - Clinical evidence of CLD
     - Nutritional compromise

2. In the second year of life, i.e., younger than 24 months at the start of the RSV season, and **ANY** of the following:

   - 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
   - Children with cystic fibrosis and **ANY** of the following:
     
     - 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)
     - Weight for length less than the 10th percentile
RESPIRATORY Syncytial Virus (RSV) Prophylactic Treatment (cont.)

Criteria: (cont.)

- Monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) during the RSV season with FDA approved dosage of palivizumab is considered medically necessary with documentation of no previous significant hypersensitivity reaction to palivizumab and ANY of the following: (cont.)
  3. In the first or second year of life, 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. Postoperative dose of palivizumab after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months who still require prophylaxis

- Immunoprophylaxis for respiratory syncytial virus is considered not medically necessary with documentation of ANY of the following:
  1. 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)
  2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for heart failure
  3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
  4. Children with congenital heart disease in the second year of life

- Immune prophylaxis for respiratory syncytial virus for all other indications not previously listed or if above criteria not met are considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting

These indications include, but are not limited to:

- Children greater than 24 months of age
- Controlling outbreaks of health care-associated disease
- Use in immunocompromised children (unless criteria for medical necessity outline above are satisfied)
- Children with cystic fibrosis (unless criteria for medical necessity outline above are satisfied)
- Children with Down syndrome (unless criteria for medical necessity outline above are satisfied)
RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Resources:

Literature reviewed 09/13/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 09/18/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


FDA Product Approval Information for Synagis®:

- FDA-approved indication and dosage:

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<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<td>Prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The safety and efficacy of Synagis have not been established for treatment of RSV disease.</td>
<td>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 Synagis 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.</td>
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