

Neighborhood Health Plan of Rhode Island Treatment Guideline for Synagis® (Palivizumab)

- Location:** Through Pawtuxet Valley Infusion Company.
- Authorization:** The 2003 American Academy of Pediatrics (AAP) criteria below are used for the approval process.
- Description:** Palivizumab is a humanized monoclonal antibody for IM injection that inhibits respiratory syncytial virus (RSV) replication. It is supplied as lyophilized powder in single use vials of 50mg and 100mg.
- Indications:** Prevention of severe lower respiratory tract diseases caused by RSV in pediatric patients at high risk of developing RSV disease. Safety and efficacy of palivizumab have been established in infants with chronic lung disease, formerly known as bronchopulmonary dysplasia (BPD), infants with a history of prematurity (≤ 35 weeks gestational age at birth), and children with hemodynamically significant congenital heart disease (CHD). Palivizumab is not indicated for treatment of reactive airway disease/asthma. Palivizumab is not approved for use in adults.
- Reasons for Monitoring:** Cost Potential for fraud or misuse Toxicity
- Criteria for Use:**
1. Infants and children less than two years of age with a diagnosis of chronic lung disease (CLD) who have required medical therapy within the 6 months prior to the anticipated RSV season. Medical therapy for CLD is considered to be supplemental oxygen, bronchodilator, diuretic, or corticosteroid therapy. **OR**
 2. Premature infants born at 32 weeks of gestation or less without a diagnosis of CLD or who do not meet the criteria above but fall into one of these two categories:
 - a.) Born at 29-32 weeks of gestation and chronological age of ≤ 6 months at the onset of RSV season; **OR**
 - b.) Born at 28 weeks of gestation or less and chronological age ≤ 12 months at onset of RSV season; **OR**
 3. Premature infants born between $\Rightarrow 32$ and $\Rightarrow 35$ weeks of gestation who are ≤ 6 months of age at onset of RSV season (i.e. November 1st) **and** who have two or more additional risk factors present (mentioned below) that may predispose infants to respiratory complications:
Risk factors: child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease.
 4. Children ≤ 24 months of age with hemodynamically significant congenital heart disease (CHD) at the onset of RSV season evidenced by:
CHF, cyanotic defects, pulmonary hypertension, oxygen use, use of cardiac medications, anticipated cardiac surgery, uncorrected or partially corrected lesions
- Frequency of Administration:** Palivizumab should be administered as an IM injection monthly on a regular schedule, every 28 to 30 days during RSV season. Typically in the Northern Hemisphere RSV season lasts from November to April. Based on pharmacokinetic data available, the necessary trough concentration of 30mcg/mL will be maintained for a full month after repeated doses when given on this schedule. The American Academy of Pediatrics policy issued in 2003 recommends that in most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the start of November and the last dose at the beginning of March to provide protection into April. Only one injection will be covered per each 28-30 day period for a total of 5 injections during the RSV season.
- Submitting Claim:** Use ICD.9 Code of V05.8 (Need for other prophylactic vaccination and inoculation against single disease; other specified diseases) and either 765 or 765.0 through 765.9 (Disorders relating to short gestation) or the most appropriate chronic respiratory disease (770.7) or congenital heart disease-related ICD.9 Codes. Submit a claim for drug and administration. **Include drug NDC number, J1565 HCPCS code, and ICD.9 Codes.** If an infusion provider provides the service at home, the Infusion Company will bill for the

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vaccine.

- Contraindications**
1. Patient does not meet criteria
 2. Patient has history of hypersensitivity to any components of the product.

- References:**
1. Meissner HC, Anderson LJ, Pickerin LK. Annual variation in respiratory syncytial virus season and decisions regarding immunoprophylaxis with palivizumab. *Pediatrics* 2004; 114:1082-1084.
 2. American Academy of Pediatrics. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. *Pediatrics* 2003;112:1442-1446.
 3. Robinson RF, Nahata MC. Respiratory syncytial virus (RSV) immune globulin and palivizumab for prevention of RSV infection. *Am J Health-Syst Pharm.* 2000; 57:259-267.
 4. Synagis Package Insert and Correspondence. MedImmune, Inc. Gaithersburg, MD 20878. September 23, 2003.
 5. Palivizumab: preferred agent for prevention of RSV infection in high-risk infants. *Drugs & Therapy Perspectives.* July 2000; 16 (2): 1-5.
 6. Abstract presented at the AAP October 2002 National Conference and Exhibition. Medical communications from Medimmune: Palivizumab (PV) reduces hospitalizations due to respiratory syncytial virus (rsv) in young children with serious congenital heart disease (CHD). Sent October 28, 2002. *Pediatric Cardiology.* 2002;23(6):664
 7. Krilov LR. Respiratory Syncytial Virus: Update on Infection, Treatment, and Prevention. *Curr Infect Dis Rep* 2001 June;3(3):242-246.