Approvable Criteria:

Intramuscular palivizumab (Synagis) is medically necessary to prevent respiratory syncytial virus (RSV) for infants and young children at high-risk as outlined below:

Approve for a maximum of 5 months during the RSV season in children who meet ONE of the following conditions:

1. **Preterm infants with Chronic Lung Disease (CLD)**
   - Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as < 32 weeks’ gestation AND required > 21% oxygen for at least 28 days after birth.
   - In the second year of life, prophylaxis is recommended only for infants who satisfy the above definition of CLD AND who continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

2. **Preterm infants born before 29 weeks’ gestation who are < 12 months of age at the start of the RSV season** (For infants born during the RSV season, fewer than 5 monthly doses will be needed.)

3. **Infants with anatomic pulmonary abnormalities or a neuromuscular disease during the first year of life**
   - Impaired ability to clear secretions from the upper airway because of ineffective cough.

4. **Infants ≤ 12 months of age with hemodynamically significant Congenital Heart Disease (CHD)**
   - Infants with acyanotic heart disease that are receiving medication to control heart failure and will require cardiac surgical procedures.
   - Infants with moderate to severe pulmonary hypertension.
   - Infants who have had lesions adequately corrected by surgery and continue to require medication for their congestive heart failure.
   - Prescribed by or in consultation with a pediatric cardiologist.
   - Following cardiopulmonary bypass or at the conclusion of extracorporeal membrane oxygenation, in children who are receiving Synagis prophylaxis, a postoperative dose (15mg/kg) should be considered for infants and children < 24 months of age due to documented reduction in serum levels during surgery.

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5. **Children < 24 months of age who are profoundly immunocompromised during the RSV season** (e.g., receiving chemotherapy, transplantation)
   - Prescribed by or in consultation with an immunologist or infectious disease specialist.

Infants or young children who experience break-through RSV infection should complete the scheduled injections of Synagis.

Any variance from the above criteria is considered **not medically necessary**.

**Administration and Dosage:** 15 mg/kg IM once monthly beginning the month prior to RSV prevalence in the community and continuing throughout the RSV season. *(Typically November through April. If patient meets criteria in November, approve for 5 months; if patients meet criteria in December, approve for 4 months, etc.)*

**SPECIALTY PHARMACY PRODUCT**

* References:
  - Synagis (palivizumab) prescribing information. Gaithersburg, MD: MedImmune; 2014 Mar.