



**FLORIDA MEDICAID**  
**PHARMACY SERVICES PROTOCOL**

**Synagis® (palivizumab)**

**Clinical Criteria for Synagis®(palivizumab):**

Synagis® may be approved for patients under the age of 2 years meeting the following criteria:

- If the patient has a diagnosis of Down Syndrome or Cystic Fibrosis.
- For patients less than 6 months of age as of July 1, request may be approved for **ONE** of the following:
  - If the patient was born at 32 weeks (32 weeks, 0 days) gestation or earlier
  - If the patient was born between 32-35 weeks gestation (between 32 weeks, 1 day and 35 weeks, 0 days), the patient must have one or more of the following risk factors for severe RSV disease:
    - Child care out of the home
    - Siblings attending school or day-care
    - Congenital abnormalities of the airways (with ICD-9 codes)
    - Severe neuromuscular disease (with ICD-9 codes)
  - If the patient has a Chronic Lung Disease [bronchopulmonary dysplasia (BPD)] that has required daily respiratory medications or treatments within the previous 6 months.
  - If the patient has a diagnosis of hemodynamically significant congenital heart disease\* (which often includes those receiving medication to control CHF, those with moderate to severe pulmonary hypertension, or those with cyanotic heart disease)
- For patients 6 months to less than 12 months of age as of July 1, request may be approved for **ONE** of the following:
  - If the patient was born at 28 weeks gestation or earlier
  - If the patient has a Chronic Lung Disease [bronchopulmonary dysplasia (BPD)] that has required daily respiratory medications or treatments within the previous 6 months.
  - If the patient has a diagnosis of hemodynamically significant congenital heart disease\* (which often includes those receiving medication to control CHF, those with moderate to severe pulmonary hypertension, or those with cyanotic heart disease)
- For patients 12 months to less than 24 months of age as of July 1, request may be approved for **ONE** of the following: **(Approval length up to the last day of their birth month or April 30<sup>th</sup>, whichever occurs first)**
  - If the patient has a Chronic Lung Disease [bronchopulmonary dysplasia (BPD)] that has required daily respiratory medications or treatments within the previous 6 months.
  - If the patient has a diagnosis of hemodynamically significant congenital heart disease\* (which often includes those receiving medication to control CHF, those with moderate to severe pulmonary hypertension, or those with cyanotic heart disease)

**\*NOTE:** Synagis will not be approved for those infants and children with hemodynamically insignificant heart disease.

**NOTE:** Pharmacies should not submit separate claims for different dosage strength vials to be administered on the same date. Only one compound claim submission will be necessary. For example, if the Synagis dosage is 150 mg the pharmacy should submit a compound claim that lists the two different strength vials (100mg and 50mg).

**Weight Criteria for Synagis®(palivizumab): (Refer to Weight Change Form)**

- All weights must be verified for dosing accuracy.