SPECIALTY GUIDELINE MANAGEMENT

SYNAGIS (palivizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk* of RSV disease.

The following points should be considered when prescribing Synagis:

- 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.

* In the absence of a specific definition of “high risk” in the Synagis package labeling, the American Academy of Pediatrics has endeavored to provide guidance for the use of Synagis. Refer to Appendix A for summary of recommendations.

B. Compendial Uses

RSV prophylaxis in infants with congenital abnormalities of the airway or neuromuscular disease that compromise handling of respiratory secretions

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of up to 5 doses may be granted for the prevention of serious lower respiratory tract disease caused by RSV when a member has any of the following diagnoses and meets the criteria pertaining to the diagnosis:

1. Prematurity
2. CHD (See Appendix B)
3. Chronic Lung Disease (CLD) of Prematurity
4. Congenital Airway Abnormality
5. Neuromuscular Condition

A. Prematurity

All of the following criteria are met:

1. Member’s gestational age is < 28 weeks, 6 days.
2. Member’s chronological age at the start of RSV season is <12 months.
B. CHD
   All of the following criteria are met:
   1. CHD is hemodynamically significant.
   2. Member meets either of the following criteria:
      a. Member’s chronological age at the start of RSV season is < 12 months.
      b. Member’s chronological age at the start of RSV season is between 12 to 24 months and the member will be undergoing cardiac transplantation during the RSV season.

C. CLD of prematurity
   ALL of the following criteria must be met:
   1. Member’s gestational age is < 31 weeks, 6 days.
   2. Member requires > 21% oxygen for at least the first 28 days after birth.
   3. Member meets either of the following criteria:
      a. Member’s chronological age at the start of their first RSV season is < 12 months.
      b. Member’s chronological age at the start of the subsequent RSV season is < 24 months and the member continues to require medical support (e.g., chronic corticosteroids, diuretic therapy, supplemental oxygen) during the 6-month period prior to the start of the RSV season.

D. Congenital airway abnormality
   ALL of the following criteria must be met:
   1. The condition compromises handling of respiratory secretions.
   2. Member’s chronological age at the start of RSV season is < 12 months.

E. Neuromuscular condition
   ALL of the following criteria must be met:
   1. The condition compromises handling of respiratory secretions.
   2. Member’s chronological age at the start of RSV season is < 12 months.

III. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following limits apply:
A. RSV season requests: maximum of 5 doses per RSV season
B. Off-season requests: 1 dose per request up to a maximum of 5 doses per RSV season

CVS Caremark PBM Synagis Season for 2016-2017 will be November 1, 2016 to March 31, 2017. Other health plans may differ.

IV. OTHER

For all off-season Synagis requests, the RSV activity for the requested region must be ≥ 10% within 2 weeks of the intended dose according to the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS). The local health department or the CDC NREVSS will be consulted to assess the RSV activity for that region (http://www.cdc.gov/surveillance/nrevss/rsv/index.html). Other Specialty Guideline Management criteria apply.

V. APPENDIX (if necessary)

Appendix A: Recommended Use of Synagis for Prevention of RSV Infection
Recommendations from the American Academy of Pediatrics for the prevention of RSV infection with Synagis are summarized in Table below. Synagis should be administered intramuscularly at a dose of 15 mg/kg once per month beginning prior to the onset of the RSV season, which typically occurs in November. Because 5 monthly doses of Synagis will provide more than 6 months of serum Synagis concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States.
# Table. Recommended Use of Synagis for Prevention of RSV Infection

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Prematurity</strong></td>
<td>- Preterm infants born at 28 weeks, 6 days of gestation or earlier who are younger than 12 months at the start of the RSV season</td>
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| **Congenital Heart Disease**                   | - Infants and children < 12 months of age with hemodynamically significant CHD  
  - Those most likely to benefit from prophylaxis include:  
    - 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 and children < 24 months of age who undergo cardiac transplantation during the RSV season  
| **Chronic Lung Disease of Prematurity**         | - For the first RSV season during the first year of life:  
  Preterm infants who develop CLD of prematurity defined as:  
   - Gestational age ≤ 31 weeks, 6 days AND  
   - Requirement for > 21% oxygen for at least the first 28 days after birth  
  - For the second RSV season during the second year of life:  
  Preterm infants who:  
   - Satisfy the above definition of CLD of prematurity AND  
   - Continue to require medical support* for CLD during the 6-month period prior to the start of the second RSV season  
| **Congenital Abnormality of the Airway/Neuromuscular Condition** | - Infants who have either a significant congenital abnormality of the airway or a neuromuscular condition that compromises handling of respiratory secretions for the first year of life  

*Medical support includes supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy.

**Abbreviations:** CHD = congenital heart disease; CLD = chronic lung disease (formerly bronchopulmonary dysplasia); RSV = respiratory syncytial virus.

*Must be hemodynamically significant. See Table above for examples of infants and children who are most likely to benefit from Synagis.

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**Appendix B: Examples of Congenital Heart Anomalies**

- Atrial or ventricular septal defect
- Coarctation of aorta
- Tetralogy of Fallot
- Pulmonary or aortic valve stenosis
- Tricuspid atresia
- Ebstein’s anomaly
- Pulmonary atresia
- Transposition of great arteries
- Truncus arteriosus
- Hypoplastic left/right ventricle
- Single ventricle
- Double-outlet right ventricle
  - Total anomalous pulmonary venous return

*Must be hemodynamically significant. See Table above for examples of infants and children who are most likely to benefit from Synagis.
VI. REFERENCES