Respiratory Syncytial Virus (RSV) Season and Synagis® Criteria

August 2012

Dear Sunshine State Health Plan Clinician,

Enclosed please find the Sunshine State Health Plan Synagis® Authorization Guidelines for the 2012-2013 RSV season. These guidelines were developed based on recommendations of the American Academy of Pediatrics and local Florida physicians.

The statistics from previous years indicate RSV appears earlier in some counties and remains active later in other counties. As a result, Sunshine State Health Plan will be staggering the start dates for the Synagis® series of injections. The table below provides a list of all counties, their associated regions, and season dates.

<table>
<thead>
<tr>
<th>Region</th>
<th>Counties</th>
<th>Season</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>Marion, Citrus, Hernando, Pasco, Pinellas, Hillsborough, Sumter, Seminole, Lake, Orange, Osceola, Brevard, Volusia, Flagler</td>
<td>August 1st thru March 31st</td>
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<tr>
<td>Northwest</td>
<td>Escambia, Santa Rosa, Okaloosa, Walton, Holmes, Jackson Bay, Calhoun, Gulf, Franklin, Liberty, Gadsden, Leon, Wakulla, Washington, Jefferson</td>
<td>October 1st thru April 30th</td>
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<tr>
<td>Southeast</td>
<td>Indian River, St Lucie, Martin, Palm Beach, Broward, Dade, Monroe</td>
<td>October 1st thru April 30th &amp; May 1st thru September 30th</td>
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<tr>
<td>Southwest</td>
<td>Collier, Wendry, Lee, Glades, Charlotte Highlands, DeSoto, Okeechobee, Hardee, Polk, Manatee, Sarasota</td>
<td>September 1st thru April 30th</td>
</tr>
</tbody>
</table>

Sunshine State Health Plan will again use CVS/Caremark as its preferred provider of Synagis® for the 2012-2013 RSV season. Beginning immediately, all requests for Synagis® should be forwarded to Sunshine State Health Plan for initial screening to determine if the request meets criteria for coverage. A copy of the CVS/Caremark enrollment form is enclosed. When submitting the request, please include the NICU discharge summary to expedite the review process.

CVS/Caremark will be responsible for the delivery of the injectable product and the overall coordination of the drug distribution process. All injectable products will be billed directly to Sunshine State Health Plan by CVS/Caremark and shipped to your office. Administration charges for the injection should be billed directly to Sunshine State Health Plan on a (HCFA) CMS 1500 claim form using CPT code 96372. You can also bill for an appropriate office visit for each administration of the drug.
CVS/Caremark specializes in specialty injectables and can provide the support and follow-up with members to ensure compliance and positive clinical outcomes. CVS/Caremark offers:

- 24-hour availability. Pharmacists are available 24 hours a day for patient support and counseling.
- Convenient, prompt, and discreet delivery. Medication will be delivered to the provider office or other requested location when medically necessary.
- Patient education and compliance monitoring.
- Easy refills by completing all milligram calculations for your office before each shipment.
- Patient education and compliance monitoring program.
- Coordination of care with Sunshine State Health Plan to ensure medication compliance.

To submit your request, fax the completed CVS/Caremark enrollment form to (866) 351-7388. For questions, contact the Sunshine State Health Plan Pharmacy Department at (866) 796-0530.

Thank you for your cooperation,

Sherman Podolsky, MD
Medical Director, Sunshine State Health Plan

Enclosures: 2012-2013 Authorization Guidelines
2012-2013 Enrollment Form
### Synagis® 2012-2013 Authorization Guideline

<table>
<thead>
<tr>
<th>Condition</th>
<th>Max Number of Doses</th>
<th>Age (in months) at Onset of RSV Season</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>0 &lt; 3</td>
</tr>
<tr>
<td>Hemodynamically significant Congenital Heart Disease (CHD) ² ³</td>
<td>5</td>
<td>Yes</td>
</tr>
<tr>
<td>• Infants/children requiring medication to control congestive heart failure (CHF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Infants/children with moderate to severe pulmonary hypertension</td>
<td></td>
<td></td>
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<tr>
<td>• Infants/children with cyanotic heart disease</td>
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<td></td>
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<tr>
<td>Chronic Lung Disease (CLD) formerly called bronchopulmonary dysplasia defined as: ⁴</td>
<td></td>
<td></td>
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<tr>
<td>• For infants &lt;32 weeks: Oxygen requirement at 36 weeks gestational age or at discharge</td>
<td></td>
<td></td>
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<tr>
<td>• For infants ≥ 32 weeks: Oxygen requirement at age 28 days or greater at discharge</td>
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<tr>
<td>Infants/Children who have received treatment for CLD within 6 months of the anticipated onset of the season with one of the following:</td>
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<tr>
<td>• Supplemental Oxygen; or</td>
<td></td>
<td></td>
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<tr>
<td>• Bronchodilator; or</td>
<td></td>
<td></td>
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<tr>
<td>• Diuretic; or</td>
<td></td>
<td></td>
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<tr>
<td>• Chronic corticosteroid therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premature infants &lt; 28 weeks, 6 days gestational age ²</td>
<td>5</td>
<td>Yes</td>
</tr>
<tr>
<td>OR Infants with a significant congenital abnormality of the airway or neuromuscular condition that compromises handling of respiratory secretions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premature infants ≥ 29 weeks, 0 days; ≤ 31 weeks, 6 days, gestational age ³</td>
<td>5</td>
<td>Yes</td>
</tr>
<tr>
<td>Premature infants ≥ 32 weeks, 0 days; ≤ 34 weeks, 6 days with one of the following two risk factors: ⁵</td>
<td>3</td>
<td>Yes</td>
</tr>
<tr>
<td>• Child care attendance ⁷</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sibling &lt; 5 years of age ⁸</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants of 35 weeks, 0 days and older gestational age (without CLD or Hemodynamically Significant CHD) ⁹ ¹⁰ ¹¹</td>
<td>0</td>
<td>No</td>
</tr>
</tbody>
</table>
Additional Notes:

1. If an infant receiving Synagis® has a breakthrough RSV infection during the season, Synagis® should continue to be given for a maximum of 3 doses for the 32 to <35 week infant category (until they reach 90 days of life) and for a maximum of 5 doses for the other high risk categories.

2. High-risk CHD patients receiving Synagis® who undergo heart surgery with the use of cardiopulmonary bypass should receive a dose of Synagis® post-op as soon as medically stable.

3. Patients with CHD who are NOT candidates for Synagis® include:
   - Hemodynamically insignificant heart disease
     - Secundum ASD
     - Small VSD
     - Pulmonic stenosis
   - Uncomplicated aortic stenosis
   - Mild coarctation of the aorta
   - Patent ductus arteriosus (PDA)
   - Infants with corrected surgical lesions unless they continue to require medication for CHF
   - Infants with mild cardiomyopathy who are not receiving medical therapy

4. Chronic Lung Disease can develop in preterm neonates treated with oxygen and positive pressure ventilation. Many cases are seen in infants who previously had respiratory distress syndrome (RDS). Chronic Lung Disease is not asthma, croup, recurrent upper respiratory infections, chronic bronchitis, bronchiolitis, or a history of a previous RSV infection.

5. Once an infant qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and should not stop when the infant reaches either 6 months or 12 months of age. A maximum of 5 doses is recommended in this category.

6. Premature infants 32 – 35 weeks should only receive prophylaxis until they turn 3 months old (maximum of 3 doses – many will require only 1 or 2 doses). Prophylaxis is not recommended after 3 months of age.

7. Participation in child care should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene.
   - Child care is defined as a home or facility where care is provided for two or more unrelated infants/young toddlers for more than 4 hours/week.

8. One or more siblings younger than 5 years of age, or other children younger than 5 years of age, that live permanently in the same household. Multiple births younger than 1 year of age (twins, triplets) do not qualify as fulfilling this risk factor.

9. All high risk infants and their contacts should be immunized against influenza beginning at 6 months of age.

10. Limited studies have suggested that some patients with cystic fibrosis may be at risk of RSV but it is not known whether RSV exacerbates the chronic lung disease in CF patients and there is insufficient data to determine the effectiveness of Synagis® in this population. Therefore there is no recommendation for routine prophylaxis for cystic fibrosis.

11. Synagis® has not been evaluated in randomized trials in immunocompromised children. However, children with severe immunodeficiencies (such as severe combined immunodeficiency syndrome or advanced AIDS) may benefit from prophylaxis.

References:


PATIENT INFORMATION

Patient Name: ____________________________
Address: _______________________________
City, St., Zip: __________________________ 
County: _________________________________
Home Phone: ____________________________
Alternate Ph.: __________________________ 
Last Four of SS #: ______________________ 
Date of Birth: ____________________________
Parent/Guardian Name: ____________________

INFORMATION

ATTACH NICU DISCHARGE SUMMARY

< 24 weeks of gestation (765.21) 24-26 weeks of gestation (765.22)
25-26 weeks of gestation (765.23) 27-28 weeks of gestation (765.24)
30-31 weeks of gestation (765.25) 32 weeks: Oxygen requirement at age 28 days or greater or at discharge.
33-34 weeks of gestation (765.26) 35-36 weeks of gestation (765.27)
37 weeks+ of gestation (765.28) Other:

Patient Evaluation:

• Patient’s gestational age (Required): _______ weeks _______ days  • Birth Weight: _______ g/kg/lbs  • Current Weight: _______ g/kg/lbs  • Date Recorded: _______

• Chronic Lung Pulmonary Disease** (CLD/BPD) and less than 24 months at start of RSV Season?  Yes  No  ICD-9: _______

** Chronic Lung Disease is generally defined:
• For infants <32 weeks: Oxygen requirement at 36 weeks gestation age or at discharge.
• For infants ≥ 32 weeks: Oxygen requirement at age 28 days or greater at discharge.
• CLD is NOT defined as: asthma, group, recurrent upper respiratory infections, chronic bronchitis, bronchiolitis, or a history of a previous RSV infection.

• Treatment for CLD within 6 months of onset of RSV season with:

Oxygen Date:
Corticosteroids Date:
Diuretics Date:
Bronchodilator Date:

• Diagnosis of hemodynamically significant congenital heart disease and less than 24 months of age?  Yes  No  ICD-9: _______

• Patient has the following conditions: (Check One)

Diagnosis of Moderate-Severe Pulmonary Hypertension  Cyanotic Heart Disease  ICD-9: _______ Date: _______

Acyanotic Heart Disease

• Medications to control CHF (list):

• Prematurity:  Yes  No  Gestational age of ≤ 28 weeks, 6 days AND less than 12 months at the start of the RSV season

Gestational age of 29 weeks, 6 days – 31 weeks, 6 days AND less than 6 months at the start of RSV season

Gestational age of 32 weeks, 6 days – 34 weeks, 6 days with the following risk factor(s) AND less than 3 months

Siblings Name(s): __________________________ Date of Birth(s): __________________________

Child care attendance (defined as 2 or more unrelated children > 4 hours per week) Date started: _______ OR will start: _______ Daycare name: _______

• Compromised handling of respiratory secretions AND less than 12 months at the start of RSV season.  Yes  No

• Congenital abnormality of the airway ICD-9: _______  Neuromuscular condition ICD-9: _______

• Multiple births?  Yes  No  Multiple births younger than 1 year of age (twins, triplets) do not qualify as fulfilling this risk factor.

• Names of sibling RSV candidates (please submit separate enrollment form) __________________________

• NICU History:  Yes  No  If yes, NICU name:

Was this season’s first Synagis dose given in the NICU?  Yes  No  If yes, date(s): __________________________ (Please include NICU summary)

Previous injections?  Yes  No  If yes, dates: __________________________  Expected date of first/next injection: __________________________

List Allergies: __________________________

Other medical history: __________________________

Home Health Coordination:  *Please note, separate authorization is required for injection training/home health visit. Call (800) 835-5916 for prior authorization.

• Specialty Pharmacy to coordinate injection training/home health nurse visit as necessary.  Yes  No  *Agency of choice: _______

MEDICATION  STRENGTH  DIRECTIONS  QUANTITY  REFILLS

Synagis® (palivizumab)  50 and/or 100mg vials  Inject 15mg/kg IM one time per month  QS to achieve 15mg/kg dose

Epinephrine (when required for home administration)  1:1000 amp  Inject 0.01mg/kg subcutaneously as directed for anaphylaxis

Ancillary Supplies and Kits Provided As Needed for Administration

Prescriber has counseled parent/guardian on Synagis therapy and CVS Caremark may contact parent/guardian

PRODUCT SUBSTITUTION PERMITTED  (Date)  DISPENSE AS WRITTEN  (Date)

Note: The phone number on your fax-back referral confirmation letter will show the CVS Caremark pharmacy contact information for this patient. Please make note of it.


** IMPORTANT NOTICE: This facsimile transmission is intended to be delivered only to the named addressee and may contain material that is confidential, privileged, proprietary or exempt from disclosure under applicable law. If it is received by anyone other than the named addressee, the recipient should immediately notify the sender at the address and telephone number set forth herein and obtain instructions as to disposal of the transmitted material. In no event should such material be read or retained by anyone other the named addressee, except by express authority of the sender to the named addressee. RSV Synagis 072712.