**SYNAGIS® CRITERIA**

**Pharmacology:**
A humanized monoclonal antibody (IgG1K) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of respiratory syncytial virus (RSV). Palivizumab exhibits neutralizing and fusion-inhibitory activity against RSV. These activities inhibit RSV replication in laboratory experiments.

**Indication:**
For the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

**Medications:**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosage Strengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synagis®</td>
<td>palivizumab</td>
<td>50 mg and 100 mg (lyophilized powder or liquid solution)</td>
</tr>
</tbody>
</table>

**Criteria for Approval:**
A. Patients in their second year of life with:
   o Chronic lung disease (CLD) who continue to require medical therapy (i.e., supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy)
   o Profoundly immunocompromised which includes:
     ▪ Congenital heart disease
     ▪ Congestive heart failure (CHF)
     ▪ Moderate to severe pulmonary hypertension
     ▪ Cyanotic heart disease; OR
B. Patients born ≤ 29 weeks of gestation and are currently ≤ 1 year of age, OR
C. Patients in their first year of life with:
   o CLD due to prematurity (< 32 weeks gestation and required > 21% oxygen for at least 28 days after birth), OR
   o Hemodynamically significant heart disease including congenital heart disease, OR
   o Pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways

**Criteria for Denial:**
A. Failure to meet criteria for authorization, OR
B. Infants and children with hemodynamically insignificant heart disease including:
   1. Secundum atrial septal defect
   2. Small ventricular septal defect
   3. Pulmonic stenosis
   4. Uncomplicated aortic stenosis
   5. Mild coarctation of the aorta
   6. Patent ductus arteriosus, OR
C. Infants with lesions adequately corrected by surgery unless they continue to require medication for CHF, OR
D. Infants with mild cardiomyopathy who are not receiving medical therapy
E. Children with cystic fibrosis as the primary diagnosis and without other diagnosis listed above
F. Children with Downs syndrome without other diagnosis listed above

**Length of Authorization:** Between Oct through April only (Five doses only, not to exceed the RSV season of Oct-April)
References:

4. Clinical Practice Guidelines. Diagnosis and Management of Bronchiolitis, Subcommittee on Diagnosis and Management of Bronchiolitis PEDIATRICS Vol. 118 No. 4 October 2006, pp. 1774-1793.

<table>
<thead>
<tr>
<th>Review:</th>
<th>Reason for Review:</th>
<th>Date Approved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy &amp; Therapeutic Committee</td>
<td>New</td>
<td>11/2/06</td>
</tr>
<tr>
<td>Commissioner</td>
<td>New</td>
<td>11/16/06</td>
</tr>
<tr>
<td>Pharmacy &amp; Therapeutic Committee</td>
<td>Update</td>
<td>4/16/09</td>
</tr>
<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>5/12/09</td>
</tr>
<tr>
<td>DUR Board</td>
<td>Revision</td>
<td>3/22/10</td>
</tr>
<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>4/30/10</td>
</tr>
<tr>
<td>DUR Board</td>
<td>Revision</td>
<td>5/31/16</td>
</tr>
<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>6/18/16</td>
</tr>
<tr>
<td>DUR Board</td>
<td>Revision</td>
<td>10/11/16</td>
</tr>
<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>11/22/2016</td>
</tr>
</tbody>
</table>