Executive Summary

**Purpose:** Ensure appropriate utilization and control of Synagis® (palivizumab) injection

**Why Issue Selected:** Synagis® (palivizumab) injection was FDA approved in June 1998 for the prevention of infection in high-risk pediatric patients due to respiratory syncytial virus (RSV), the most common cause of pneumonia and bronchiolitis in infancy and early childhood. Synagis is the first monoclonal antibody approved to provide passive immunity for an infectious disease. Severe RSV disease is the most common reason infants under 1 year of age are hospitalized in the United States. The American Academy of Pediatrics (AAP) recommends limiting the usage of Synagis to certain preterm infants and infants with certain chronic illnesses. During the 2019-2020 RSV Season (November through April) there were 680 MO HealthNet participants approved for Synagis.

**Program-Specific Information:**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Vial Size</th>
<th>Vial Count</th>
<th>Cost</th>
<th>MAC Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYNAGIS 50 MG/0.5 ML VIAL</td>
<td>977</td>
<td>$1,560,228.36</td>
<td>$1,551.19</td>
<td></td>
</tr>
<tr>
<td>SYNAGIS 100 MG/1 ML VIAL</td>
<td>2,139</td>
<td>$6,521,211.66</td>
<td>$2,929.09</td>
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</tr>
</tbody>
</table>

**Type of Criteria:**
- ☒ Appropriate Indications
- ☐ Increased risk of ADE
- ☐ Preferred Drug List
- ☒ Clinical Edit

**Data Sources:**
- ☑ Databases + Prescriber-Supplied
- ☐ Only Administrative Databases

**Setting & Population**

- Drug class for review: Synagis® (palivizumab) injection
- Age range: All appropriate MO HealthNet participants ≤ 24 months of age

**Approval Criteria**

- Claim is during RSV Season (November through April) AND
- For prematurity:
  - Participant aged ≤ 12 months and born ≤ 28 weeks gestation OR
• Participant aged ≤ 6 months and born between 29 and 32 weeks gestation OR
  • Participant aged ≤ 3 months and born between 32 and 35 weeks gestation AND
    ▪ Enrolled in childcare OR
    ▪ Has siblings that are < 5 years of age OR
• For chronic lung disease:
  • Participant aged < 12 months and born < 32 weeks gestation with chronic lung disease AND
    ▪ required more than 21% oxygen for 28 days following birth AND
    ▪ currently requiring medical therapy (oxygen on a continuous basis, bronchodilator, diuretic, corticosteroid or ventilator dependent) OR
  • Participant aged < 24 months and born < 32 weeks gestation with chronic lung disease AND
    ▪ required more than 21% oxygen for 28 days following birth AND
    ▪ required continued medical therapy throughout the past 6 months (oxygen on a continuous basis, bronchodilator, diuretic, corticosteroid or ventilator dependent) OR
• For congenital heart disease:
  • Participant aged ≤ 24 months with hemodynamically significant cyanotic and acyanotic congenital heart disease AND
    ▪ Receiving medication to control CHF (digoxin, beta blockers, calcium channel blockers, ACE inhibitors, nitroglycerin, anti-coagulants, diuretics, or supplemental oxygen) OR
    ▪ Moderate to severe pulmonary hypertension OR
    ▪ Cyanotic heart disease OR
• For congenital abnormality of the airway or neuromuscular disease that impairs ability to clear secretions: Participant aged < 12 months OR
• For severe immunodeficiencies that may benefit from prophylaxis as determined by clinical consultant review: Participant aged ≤ 24 months

### Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Therapy exceeds 5 doses per RSV season

### Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

### Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

### Default Approval Period

Max of 5 doses per RSV season

### References