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.

Synagis is typically reserved for use during the RSV Season (November through April); however, in March of 2021, the CDC began to note an increase in RSV infections out of the typical season and following a significant drop in RSV cases during the COVID-19 pandemic, beginning in April 2020. This atypical RSV season led the AAP to publish guidance in August of 2021 urging Synagis administration to eligible infants where RSV activity approaches the typical fall-winter season levels. MO HealthNet will continue to assess and review guidance for out-of-season Synagis administration and will evaluate the need for additional doses on a month-to-month basis, dependent on RSV virology.

<table>
<thead>
<tr>
<th>Drug/Drug Class:</th>
<th>Synagis Clinical Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Implementation Date:</td>
<td>October 1, 2003</td>
</tr>
<tr>
<td>Revised Date:</td>
<td>August 25, 2022</td>
</tr>
<tr>
<td>Prepared for:</td>
<td>MO HealthNet</td>
</tr>
<tr>
<td>Prepared by:</td>
<td>MO HealthNet/Conduent</td>
</tr>
<tr>
<td>Criteria Status:</td>
<td>☒ Revision of Existing Criteria</td>
</tr>
</tbody>
</table>

### Program-Specific Information

**Date Range FFS 7-01-2021 to 10-31-2021 (atypical RSV season)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
<th>Avg Spend per Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYNAGIS 50 MG/0.5 ML VIAL</td>
<td>345</td>
<td>$599,214.00</td>
<td>$1,736.85</td>
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<tr>
<td>SYNAGIS 100 MG/1 ML VIAL</td>
<td>624</td>
<td>$2,023,551.14</td>
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</tbody>
</table>

**Date Range FFS 11-01-2021 to 4-30-2022 (typical RSV Season)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
<th>Avg Spend per Claim</th>
</tr>
</thead>
<tbody>
<tr>
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<td>$1,815.76</td>
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<td>1,358</td>
<td>$4,354,398.61</td>
<td>$3,206.48</td>
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</tbody>
</table>

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

| Data Sources: | ☐ Only Administrative Databases | ☒ Databases + Prescriber-Supplied |
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 (The 2022 – 2023 season will begin on September 1, 2022, based on local RSV levels) 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

- Laboratory Results:
- Progress Notes:
- MedWatch Form:
- Other: X

Disposition of Edit

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

Max of 5 doses per RSV season

References