Market Applicability

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

*FHK - Florida Healthy Kids

**Synagis (palivizumab)**

**Override(s)**

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
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</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Up to 5 doses during the months of October to March or November to April.</td>
</tr>
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**Medications**

<table>
<thead>
<tr>
<th>Medications</th>
<th>Dose Limit</th>
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<tbody>
<tr>
<td>Synagis (palivizumab) 50mg/0.5mL Intramuscular injection</td>
<td>Dependent upon criteria below</td>
</tr>
<tr>
<td>Synagis (palivizumab) 100mg/mL Intramuscular injection</td>
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In 2014, the American Academy of Pediatrics (AAP) issued updated guidelines regarding the use of immune prophylaxis for respiratory syncytial virus (RSV). A summary of the AAP RSV guidance is as follows:

**Preterm Infants without Chronic Lung Disease (CLD) of Prematurity or Congenital Heart Disease (CHD)**

- Infants born before 29 weeks, 0 days gestation in the first year of life

**Preterm Infants with CLD**

- Infants born before 32 weeks, 0 days gestation and a requirement for >21% oxygen for at least 28 days after birth in the first year of life

**Preterm Infants with CHD**

- Prophylaxis may be administered in first year of life to certain infants with hemodynamically significant heart disease
- Consultation with a cardiologist if recommended for patients with cyanotic heart disease for prophylaxis decisions

**Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder**

- Prophylaxis may be considered in first year of life to children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways

**Immunocompromised Children**

- Prophylaxis may be considered in children under 24 months who will be profoundly immunocompromised during the RSV season

**Children with Down Syndrome**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0309-18
**Market Applicability**

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<tr>
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- Insufficient data available to routinely recommend prophylaxis

**Children with Cystic Fibrosis**

- Insufficient data available to routinely recommend prophylaxis

**Timing of Prophylaxis for Alaska Native and American Indian Infants**

- Greater flexibility in use of prophylaxis as a result of potentially higher disease burden
- Use of government RSV surveillance data may be helpful in decision-making

**Discontinuation of Prophylaxis Among Children who Experience Breakthrough RSV Hospitalization**

- Discontinue prophylaxis

**Prophylaxis in the Second Year of Life**

- Recommended in children who require ≥28 days of supplemental oxygen after birth and continue to require medical intervention (supplemental oxygen, chronic corticosteroid therapy, diuretics)

**Number of Monthly Doses in Season**

- Maximum of 5

**Other**

- Prophylaxis is not recommended for prevention of primary asthma or reduction of subsequent wheezing episodes
- Prophylaxis is not recommended for prevention of nosocomial disease
- Not recommended for use in RSV treatment

**APPROVAL CRITERIA**

Note: Because 5 monthly doses of palivizumab will provide more than 6 months of adequate serum concentrations for most infants, administration should be limited to peak RSV seasons in the continental US, of October to March or November to April. Qualifying infants born during RSV season will need fewer than 5 doses for protection until the season ends.

Specific information about national and regional RSV trends, especially pertaining to the peak variations in Florida and Alaska, is available from the National Respiratory and Enteric Virus Surveillance System NREVSS at: http://www.cdc.gov/surveillance/nrevss/rsv/index.html.

Synagis (palivizumab) may be approved if the following criteria are met (2014 AAP):

I. A maximum of 5 doses of Synagis (palivizumab)may be approved for **infants during the first RSV season within the first year of life** with any of the following:
   A. Born before 29 weeks, 0 days' gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season; **OR**

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B. Chronic lung disease* of prematurity defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth(not including asthma, reactive airway disease and cystic fibrosis without significant symptoms); OR

C. Hemodynamically significant congenital heart disease* (such as, infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension; OR

D. Anatomic pulmonary abnormalities (for example, tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough; OR

E. Cystic fibrosis with clinical evidence of chronic lung disease* or nutritional compromise (weight for length less than tenth percentile);

OR

II. A maximum of 5 doses of Synagis (palivizumab) may be approved for children during their second RSV season with any of the following:
   A. Preterm infant born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth AND continues to require medical intervention within 6 months of the start of the second RSV season (including supplemental oxygen, chronic corticosteroid therapy or diuretics); OR
   B. Cystic fibrosis with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile;

OR

III. A maximum of 5 doses of Synagis (palivizumab) may be approved for children younger than 24 months of age with any of the following:
   A. Profoundly immunocompromised, such as severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cells/mm³; OR
   B. Undergoing cardiac transplantation.

OR

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IV. One additional dose of Synagis (palivizumab) may be approved for children younger than 24 months of age who have approval for a course of treatment and who undergo cardiopulmonary bypass for surgical procedures.

* Clinical documentation supporting the presence of hemodynamically significant congenital heart disease or chronic lung disease must be submitted when required.

Synagis (palivizumab) approval is limited to RSV season.

Synagis (palivizumab) may not be approved for any of the following:

I. Continued RSV prophylaxis for children who experience breakthrough RSV hospitalization; OR
II. Treatment of known RSV disease; OR
III. Children who reach 24 months of age prior to the beginning of RSV season; OR
IV. Primary asthma prevention or to reduce subsequent episodes of wheezing; OR
V. Children with surgically corrected congenital heart disease or hemodynamically insignificant heart disease (including secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) who do not otherwise meet approval criteria; OR
VI. Children with Down syndrome who do not otherwise meet approval criteria.

State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
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<tbody>
<tr>
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Key References:

2. American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory

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