

2015-2016 Season
Synagis® (palivizumab)

Solution for Injection: 100mg/mL and 50mg/0.5mL

INDICATION:

“Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.”¹

RSV SEASON:

The RSV season for all geographical regions in Alaska as recognized by Alaska Medicaid is November 30th* through May 15th*. Please note, only doses of palivizumab delivered on November 30th* through May 15th* will be considered for coverage (see below).

**Floating RSV Season: The Department will monitor RSV circulation beginning 10/1/2015. If the percentage and number of positive RSV tests indicates an earlier season onset or offset or a delayed season offset other than the covered dates of service defined above, the Department may adjust the covered dates of services to reflect the need for prophylaxis. Changes to the covered dates of service will be communicated to the prescriber and pharmacy via fax to the numbers provided on the prior authorization request form.*

The Department may recognize an earlier season onset if ≥ 2 tests and $> 10\%$ of tests are positive from two or more geographic locations for a single week between 10/1/2015 and 11/30/2015. Any change to the season onset date would be accompanied by a revision to the criteria for approval below to reflect the revised onset date. The RSV season offset will also be monitored and adjustments to the season end date will be based on the number and percent of positive tests.

The maximum number of doses of Synagis® covered during the RSV season is 5 monthly doses and will not be increased due to changes in the RSV season dates.

CRITERIA FOR APPROVAL:

- ❖ Infants born at 32 weeks to less than 35 weeks (34 weeks, 6 days) gestation without chronic lung disease (CLD) or significant congenital heart disease (CHD):²
 1. The infant is born less than 3 months before the onset or during the RSV season (born September 3rd or after); **AND**
 2. At least one of the risk factors listed below is present; **THEN**
 3. The infant may be approved for no more than 3 monthly doses of palivizumab or a monthly dose until the infant reaches 90 days of age, whichever occurs first.
 4. **IF** the infant experiences a breakthrough RSV infection and has not received 3 monthly doses before reaching 90 days of age, **THEN** prophylaxis with palivizumab may continue monthly for up to 3 doses total for the RSV season.

RISK FACTORS:

- Child care or day care attendance
- Sibling present younger than 5 years of age
- Crowded living environment (≥ 3 children per bedroom or ≥ 7 people per household)
- Lack of running water in the home

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- ❖ Infants born at 29 weeks to less than 32 weeks gestation (31 weeks, 6 days or less) without chronic lung disease (CLD) or significant congenital heart disease (CHD):²
 1. The infant is born at 29 weeks to 31 weeks, 6 days gestation; **AND**
 2. The infant is younger than 6 months of age at the start of the RSV season (born after May 30th); **THEN**
 3. The infant may be approved for no more than 5 monthly doses of palivizumab.

- ❖ Infants born at less than 29 weeks gestation:²
 1. The infants is born at 28 weeks, 6 days gestation or earlier; **AND**
 2. The infant is less than 12 months old at the start of the RSV season (born after November 30th the previous year); **THEN**
 3. The infant may be approved for no more than 5 monthly doses of palivizumab during the current RSV season.

- ❖ Infants with congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions:²
 1. The infant has a congenital abnormality of the airway or a neuromuscular condition that compromises handling of respiratory secretions; **AND**
 2. The infant is less than 12 months of age at the onset of the RSV season (born after November 30th the previous year); **THEN**
 3. The infant may be approved for no more than 5 monthly doses of palivizumab during the current RSV season (*see below).

- ❖ Infants and children born with congenital heart disease (CHD):²
 1. The child/infant is 24 months of age or younger at the onset of the RSV season (born on or after November 30th two years prior); **AND**
 2. The child/infant has hemodynamically significant cyanotic or acyanotic congenital heart disease²; **THEN**
 3. The child/infant may be approved for no more than 5 monthly doses of palivizumab during the current RSV season.
 4. **IF** the child/infant undergoes a surgery utilizing cardiopulmonary bypass during the RSV season an extra post-operative dose of palivizumab may be authorized.

- ❖ Infants and children with chronic lung disease of prematurity (CLD):²
 1. The child/infant is less than 24 months of age at the onset of the RSV season (born after November 30th two years prior); **AND**
 2. The child/infant has received medical therapy for CLD within the 6 months prior to the onset of the RSV season (after May 30th of the current year); **THEN**
 3. The child/infant may be approved no more than 5 monthly doses of palivizumab during the current RSV season (*see below).

***Note:** The American Academy of Pediatrics has issued revised guidance regarding palivizumab prophylaxis for infants and children.³ While the coverage criteria for the 2015-2016 RSV season reflect the 2009 recommendations, clinicians are encouraged to review the revised guidance prior to requesting or initiating palivizumab prophylaxis.

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REFERENCES / FOOTNOTES:

1. Synagis[®] [package insert]. Gaithersburg, MD; MedImmune, LLC, March 2014.
2. Committee on Infectious Diseases, Policy Statement-Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections. *Pediatrics* 2009 0: peds.2009-2345.
3. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. *Pediatrics*; originally published online July 28, 2014; DOI: 10.1542/peds.2014-1665.