



## Synagis® (palivizumab)

When requesting Synagis® (palivizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

### FDA-approved indications

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients with:

- A history of premature birth
- Bronchopulmonary dysplasia
- Hemodynamically significant congenital heart disease (CHD)

### Approved Off-label Compendial uses

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients with:

- Chronic lung disease of prematurity
- Congenital abnormality of the airway
- Neuromuscular disease
- Immunocompromised status
- Cystic fibrosis

### Coverage Guidelines

The individual is requesting Synagis for the prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV).

#### **For preterm infant:**

- The individual is born before 29 weeks, 0 days gestation **AND**
- The individual will be less than 12 months of age at the start of the RSV season

#### **For chronic lung disease of prematurity:**

- The individual is born before 32 weeks, 0 days gestation **AND**
- The individual required greater than 21% oxygen for at least the first 28 days after birth **AND**
- The individual will be less than 12 months of age at the start of the RSV season **OR**

- The individual will be less than 24 months of age at the start of the RSV season and continues to require medical support (e.g., chronic corticosteroids therapy, diuretic therapy, bronchodilator therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season

**For congenital heart disease (CHD):**

- The individual has hemodynamically significant CHD **AND**
- The individual will be less than 12 months of age at the start of the RSV season **OR**
- The individual will be less than 24 months of age at the start of the RSV season and will undergo cardiac transplantation surgery during the RSV season

**For congenital abnormality of the airway/neuromuscular disease**

- The individual's condition impairs the ability to clear respiratory secretion **AND**
- The individual will be less than 12 months of age at the start of the RSV season

**For immunocompromised child:**

- The individual is profoundly immunocompromised during the RSV season **AND**
- The individual will be less than 24 months of age at the start of the RSV season

**For cystic fibrosis:**

- The individual will be less than 12 months of age at the start of the RSV season and has clinical evidence of chronic lung disease or nutritional compromise **OR**
- The individual will be less than 24 months of age at the start of the RSV season and manifests severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography, abnormalities on chest computed tomography that persist when stable) **OR**
- The individual will be less than 24 months of age at the start of the RSV season and weight for length is less than the 10<sup>th</sup> percentile

**Duration of Approval: Approve up to maximum 5 monthly doses**

## References

1. Synagis [prescribing information]. Gaithersburg, MD; MedImmune, LLC. May 2017. Available at: <https://www.azpicentral.com/synagis/synagis.pdf#page=1>. Accessed on September 05, 2017.
2. Committee on Infectious Disease and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. 2014 Aug;134(2):415-420. Available at: <http://pediatrics.aappublications.org/content/pediatrics/134/2/415.full.pdf>. Accessed on September 05, 2017.