

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 (e.g., chronic lung disease),
- 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:

- Congenital abnormality of the airway,
- A neuromuscular disorder,
- Immunocompromised status,
- A previous or upcoming cardiac transplantation.

Coverage Guidelines

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

Preterm infant:

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

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
- One of the following applies:
 - The individual will be less than or equal to 12 months of age at the start of the RSV season; OR
 - The individual will be less than or equal to 24 months of age at the start of the RSV season and has required medical therapy (e.g., chronic corticosteroids therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

Congenital heart disease (CHD):

- The individual will be 12 months of age or less at the start of the RSV season; AND
- One of the following applies:
 - The individual has hemodynamically significant cyanotic CHD;
 - The individual has acyanotic heart disease and is receiving medication to control heart failure and will require cardiac surgical procedures;
 - The individual has lesions that have been adequately corrected by surgery and continues to require medication for congestive heart failure; OR
 - The individual has moderate to severe pulmonary hypertension; AND
- Synagis is prescribed by or in consultation with a cardiologist or intensivist.

Congenital abnormality of the airway/neuromuscular disorder

- The individual's condition impairs the ability to clear respiratory secretions; AND
- The individual will be 12 months of age or less at the start of the RSV season.

Immunocompromised child:

- The individual will be profoundly immunocompromised during the RSV season (e.g., chemotherapy, transplant);
- The individual will be less than 24 months of age at the start of the RSV season; AND
- Synagis is prescribed by or in consultation with an immunologist or an infectious disease specialist.

Cardiac transplant

- The individual has undergone or will undergo cardiac transplantation during the current RSV season;
- The individual will be less than 24 months of age at the start of the RSV season; AND
- Synagis is prescribed by or in consultation with a cardiologist, intensivist, or transplant physician.

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

Dosing Recommendation

The recommended dose is 15 mg/kg, administered intramuscularly, once monthly during the RSV season.

References

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3. The Impact RSV Study Group. palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high risk infants. *Pediatrics*. 1998;102:531-537.

4. Feltes TF, Cabalka AK, Meissner HC, et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr*. 2003;143:532-540.
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6. Respiratory Syncytial Virus. In: Kimberlin DW, Brady MT, Jackson MA, Long SS (Eds). Red Book: 2018 Report of the Committee of Infectious Diseases. 31st Edition, Itasca, IL: American Academy of Pediatrics; 2018.
7. Robinson KA, Odelola OA, Saldanha IJ. Palivizumab for prophylaxis against respiratory syncytial virus infection in children with cystic fibrosis. *Cochrane Database Syst Rev*. 2016;7:CD007743. doi: 10.1002/14651858.CD007743.pub6.
8. Boeckh M, Berrey MM, Bowden RA, et al. Phase 1 evaluation of the respiratory syncytial virus-specific monoclonal antibody palivizumab in recipients of hematopoietic stem cell transplants. *J Infect Dis*. 2001;184:350-354.
9. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantations recipients: A global perspective. *Biol Blood Marrow Transplant*. 2009;15:1143-1238.