

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 less than 12 months of age 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:
 - o The individual will be less than 12 months of age at the start of the RSV season; OR
 - o The individual will be less than 24 months of age at the start of the RSV season and has required medical therapy (e.g., chronic corticosteroid 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 less than 12 months of age at the start of the RSV season; AND
- Synagis is prescribed by or in consultation with a cardiologist or intensivist; AND
- One of the following applies:
 - o The individual has hemodynamically significant cyanotic CHD;
 - o The individual has acyanotic heart disease, is receiving medication to control heart failure, and will require cardiac surgical procedures;
 - o The individual has lesions that have been adequately corrected by surgery and continues to require medication for congestive heart failure; OR
 - o The individual has moderate to severe pulmonary hypertension.

Abnormality of the airway/neuromuscular disorder

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

Immunocompromised child:

- The individual will be profoundly immunocompromised during the RSV season (e.g., chemotherapy, hematopoietic stem cell or solid organ 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

1. Synagis® [prescribing information]. Gaithersburg, MD: MedImmune, Inc.; November 2021.
2. Centers for Disease Control and Prevention. Respiratory syncytial virus activity – United States, 2014-2017. *MMWR*. 2018;67(2):71-76. Available at: <http://www.cdc.gov/surveillance/nrevss/rsv/reports.html>. Accessed on August 23, 2021.
3. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Technical report. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):e620-638.
4. Respiratory Syncytial Virus. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH (Eds). Red Book: 2021-2024 Report of the Committee of Infectious Diseases. 32nd Edition, Itasca, IL: American Academy of Pediatrics; 2021.
5. 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.
6. American Academy of Pediatrics. Interim guidance for use of palivizumab prophylaxis to prevent hospitalization from severe respiratory syncytial virus infection during the current atypical interseasonal RSV spread. Updated August 10, 2021. Available at: <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/>. Accessed on August 23, 2021.