Synagis® (Palivizumab)
2021-2022 Authorization Guideline

Respiratory Syncytial Virus (RSV) Prophylaxis *Covered Conditions per the American Academy of Pediatrics, reaffirmed February, 2019* *Synagis doses per RSV Season: 5 at 15 mg/kg per dose (6 doses if cardio-pulmonary bypass)*	**Age in Months at RSV Season Onset†≠**	
	0 to <12	12 to <24
Preterm Infant		
1. Infants with gestational age <29 weeks	✓	
Chronic Lung Disease (CLD) of Prematurity		
2. Infants with CLD of prematurity‡	✓	
3. Infants with both of the following: • CLD of prematurity‡ • Continued requirement for supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy within 6 months of RSV season onset		✓
Congenital Heart Disease (CHD)		
4. Infants with hemodynamically significant CHD - any of the following: • Acyanotic heart disease if receiving medication to control congestive heart failure and will require a cardiac surgical procedure • Acyanotic heart disease with moderate to severe pulmonary hypertension • Cyanotic heart defect if RSV prophylaxis is recommended by a pediatric cardiologist	✓	
5. Infants undergoing cardio-pulmonary bypass during the current RSV season* ** Infants who continue to require RSV prophylaxis after cardio-pulmonary bypass should receive an additional Synagis dose as soon as possible after the procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled (for a total of 6 doses).*	✓	✓
6. Infants who undergo cardiac transplantation during the RSV season	✓	✓
Anatomic Pulmonary Abnormalities and Neuromuscular Disorders		
7. Infants with an anatomic pulmonary abnormality or neuromuscular disorder that impairs the ability to clear secretions from the upper airway (e.g., due to ineffective cough)	✓	
Profoundly Immunocompromised during the RSV Season		
8. Infants who will be profoundly immunocompromised during the RSV season (e.g., due to solid organ or hematopoietic stem cell transplantation, chemotherapy, severe combined immunodeficiency, chronic granulomatous disease)	✓	✓
Cystic Fibrosis		
9. Infants with cystic fibrosis and clinical evidence of either of the following: • Chronic lung disease (CLD) of prematurity‡ • Nutritional compromise	✓	
10. Infants with cystic fibrosis who have either CLD of prematurity‡ or nutritional compromise, and either of the following: • Manifestations of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography/computed tomography that persist when stable) • Weight for length less than the 10th percentile	✓	✓
Alaska Native and Other American Indian Infants		
11. Medical director consultation is required for requests falling outside the above criteria and relating to Alaska native or other American Indian infants. • Alaska Native infants: Prophylaxis eligibility may differ from the remainder of the U.S. based on RSV epidemiology in Alaska, particularly in remote regions where RSV disease burden is significantly greater than in the general U.S. population. • Other American Indian infants: Limited information is available concerning the burden of RSV disease among American Indian populations; however, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.		

†RSV Season Onset: The RSV season may commence as early as September and continue through May. In Florida, the RSV season may begin at any time throughout the year. No matter the season duration, only 5 doses are recommended; < 5 if middle of season.
≠ Elevated interseasonal activity has been observed since March 2021, the CDC has indicated that at this time it is not possible to anticipate the likely spread, peak, or duration of activity with any certainty; requests for RSV prophylaxis outside of the typical season by region may be considered. Traditionally RSV season onset was defined by consecutive weeks when RSV antigen-based tests exceeded 10% positivity. Due to the increased use of PCR testing, alternative statistical methods are used to determine seasonality in real time. Local and State health departments should be consulted to determine the real-time RSV season. Additional information on RSV trends by state can be found by visiting: https://www.cdc.gov/surveillance/nrevss/rsv/state.html.
‡CLD of prematurity (also known as bronchopulmonary dysplasia or BPD) is defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.

The American Academy of Pediatrics does not recommend Synagis for the following uses:

- Treatment of RSV disease
- RSV prophylaxis post hospitalization for RSV disease during the current RSV season
- Routine RSV prophylaxis for
  - Infants with hemodynamically insignificant congenital heart disease (CHD) (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, or patent ductus arteriosus)
  - Infants with Down syndrome unless criteria in the above table are met
  - Prevention of health care-associated RSV disease
  - Primary asthma prevention or to reduce subsequent episodes of wheezing

Synagis Contraindications:
Hypersensitivity to Synagis (e.g., anaphylaxis, anaphylactic shock, urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, unresponsiveness).

Synagis Description and Mechanism of Action:
Synagis (palivizumab), a recombinant humanized mouse immunoglobulin (IgG1) monoclonal antibody, provides passive immunity against RSV by binding the RSV envelope fusion protein (RSV F) on the surface of the virus and blocking a critical step in the membrane fusion process. Palivizumab also prevents cell-to-cell fusion of RSV-infected cells.

Synagis Formulations:
Sterile, preservative-free liquid solution (100 mg/mL) for intramuscular injection*

- 1 mL single-dose vial containing 100 mg palivizumab
- 0.5 mL single-dose vial containing 50 mg palivizumab

**Thimerosal, or other mercury-containing salts, is not used in the production of Synagis. Synagis cannot be stored once opened.*

Bibliography

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10. Rose EB, Wheatley A, Langley G, et al. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. Morbidity and Mortality Weekly Report (MMWR). January 19, 2018. 67(2): 71-76. Available at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a4.htm.