Synagis® (Palivizumab)
2020-2021 Authorization Guideline

Respiratory Syncytial Virus (RSV) Prophylaxis: Conditions Covered *(Follows American Academy of Pediatrics Recommendations)* *Maximum Monthly Synagis Doses per RSV Season = 5 at 15 mg/kg per dose*	**Age in Months at RSV Season Onset†**	
	0 to <12	**12 to <24**
Preterm Birth		
1. Infants born before 29 weeks, 0 days' gestation.	✓	
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 or if continues to need medication for congestive heart failure despite surgery; • Acyanotic heart disease with moderate to severe pulmonary hypertension; • Cyanotic heart defect if RSV prophylaxis is recommended by a pediatric cardiologist.	✓	
5. Infants undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season, and • 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.	✓	✓
6. Infants who undergo cardiac transplantation during the RSV season.	✓	✓
Anatomic Pulmonary Abnormalities and Neuromuscular Disorders		
7. Infants with an anatomic pulmonary anomaly or neuromuscular disorder that impairs the ability to clear secretions from the upper airway due to ineffective cough.	✓	
Profoundly Immunocompromised during the RSV Season		
8. Infants who will be profoundly immunocompromised during the RSV season (e.g., 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 of the following in addition to CLD of prematurity‡ or nutritional compromise: • 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 relating to Alaska Native and other American Indian infants that fall outside the criteria outlined above: • Alaska Native infants: Eligibility for prophylaxis may differ from the remainder of the U.S. on the basis of epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease 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.

‡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 the first 28 days after birth.

Additional Notes

Synagis is not Recommended for the Following Uses per the American Academy of Pediatrics:

- Treatment of RSV disease;
- Continued RSV prophylaxis after hospitalization for RSV disease during the current 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, and 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/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

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

Bibliography

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; May 2017. Available at https://www.azpicentral.com/synagis/synagis.pdf#page=1. Accessed February 8, 2019.
2. Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics.* August 2014; 134(2): e415-20. doi: 10.1542/peds.2014-1665.
3. Technical Report: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics.* August 2014; 134(2): e620-38. doi: 10.1542/peds.2014-1666.
4. Errata: RSV Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics. *Pediatrics.* December 2014; 134(6): 1221.
5. Respiratory syncytial virus infection (RSV): Trends and surveillance. Centers for Disease Control and Prevention website. Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases. Available at http://www.cdc.gov/rsv/research/us-surveillance.html. Page last reviewed: June 26, 2018. Accessed February 8, 2019.