Synagis (palivizumab)

Override(s)	Approval Duration
Prior Authorization	RSV season as determined by CDC surveillance data (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) or local health department* Up to 5 doses during November through March

Medications	Dosing Limit
Synagis (palivizumab) 50mg/0.5mL vial Intramuscular injection Synagis (palivizumab) 100mg/mL vial Intramuscular injection	15 mg/kg once per month

In 2014, the American Academy of Pediatrics (AAP) issued updated guidelines regarding the use of immune prophylaxis for respiratory syncytial virus (RSV). AAP reaffirmed this guidance in 2019. A summary of the AAP RSV guidance is as follows:

Preterm Infants without Chronic Lung Disease (CLD) of Prematurity or Congenital Heart Disease (CHD)
• Infants born before 29 weeks, 0 days gestation in the first year of life
Preterm Infants with CLD
• Infants born before 32 weeks, 0 days gestation and a requirement for >21% oxygen for at least 28 days after birth in the first year of life
Infants with CHD
• Prophylaxis may be administered in first year of life to certain infants with hemodynamically significant heart disease • Consultation with a cardiologist if recommended for patients with cyanotic heart disease for prophylaxis decisions
Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder
• Prophylaxis may be considered in first year of life to children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways
Immunocompromised Children
• Prophylaxis may be considered in children under 24 months who will be profoundly immunocompromised during the RSV season
Children with Down Syndrome
• Insufficient data available to routinely recommend prophylaxis
Children with Cystic Fibrosis
• Insufficient data available to routinely recommend prophylaxis

Timing of Prophylaxis for Alaska Native and American Indian Infants
• Greater flexibility in use of prophylaxis as a result of potentially higher disease burden • Use of government RSV surveillance data may be helpful in decision-making
Discontinuation of Prophylaxis Among Children who Experience Breakthrough RSV Hospitalization
• Discontinue prophylaxis
Prophylaxis in the Second Year of Life
• Recommended in children who require ≥28 days of supplemental oxygen after birth and continue to require medical intervention (supplemental oxygen, chronic systemic corticosteroid therapy, diuretics)
Number of Monthly Doses in Season
• Maximum of 5
Other
• Prophylaxis is not recommended for prevention of primary asthma or reduction of subsequent wheezing episodes • Prophylaxis is not recommended for prevention of nosocomial disease • Not recommended for use in RSV treatment

APPROVAL CRITERIA

Note: Because 5 monthly doses of palivizumab will provide more than 6 months of adequate serum concentrations for most infants, administration should be limited to peak RSV seasons in the continental United States, November through March. Qualifying infants born during RSV season will need fewer than 5 doses for protection until the season ends.

*Specific information about national and regional RSV trends, especially pertaining to the peak variations in Florida and Alaska as well as atypical interseason RSV, is available from the National Respiratory and Enteric Virus Surveillance System NREVSS at: http://www.cdc.gov/surveillance/nrevss/rsv/index.html. The start of RSV season is signaled by surveillance data showing antigen positive test rates ≥10% OR PCR positive test rates ≥3%.

Requests for Synagis (palivizumab) may be approved if the following criteria are met (2014 AAP, 2024 AAP):

I. Individual has not received Beyfortus (nirsevimab) for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease for this RSV season; **AND**

II. Individual does not have access to Beyfortus (nirsevimab) for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease; **AND**

III. A maximum of 5 doses of Synagis (palivizumab) may be approved for **infants during the first RSV season within the first year of life** with any of the following:

A. Born before 29 weeks, 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the **start** of the RSV season; **OR**

B. Documentation is provided indicating chronic lung disease of prematurity defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth (not including asthma, reactive airway disease and cystic fibrosis without significant symptoms); **OR**

C. Documentation is provided indicating hemodynamically significant congenital heart disease (including infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension); **OR**

D. Documentation is provided indicating anatomic pulmonary abnormalities (for example, tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough; **OR**

E. Documentation is provided indicating cystic fibrosis with clinical evidence of chronic lung disease or nutritional compromise (weight for length less than tenth percentile);

OR

IV. A maximum of 5 doses of Synagis (palivizumab) may be approved for **children during their second RSV season** (the second RSV season may fall in the first or second year of life) with any of the following:

A. Documentation is provided indicating the individual is a preterm infant born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth AND continues to require medical intervention within 6 months of the start of the second RSV season (including supplemental oxygen, chronic systemic corticosteroid therapy or diuretics); **OR**

B. Documentation is provided indicating cystic fibrosis with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile;

OR

V. A maximum of 5 doses of Synagis (palivizumab) may be approved for **children younger than 24 months of age** with any of the following:

A. Documentation is provided indicating profound immunocompromised status (including severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, undergoing organ or

hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cells/mm^3); **OR**

B. Documentation is provided indicating the individual is undergoing cardiac transplantation.

OR

VI. One additional dose of Synagis (palivizumab) may be approved for children younger than 24 months of age who have approval for a course of treatment and who undergo cardiopulmonary bypass for surgical procedures.

Synagis (palivizumab) approval is limited to RSV season as determined by CDC surveillance data (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) or local health department.
Up to 5 doses may be approved during the months of November through March.
Initiating therapy or providing additional doses for continued therapy in regions with high levels of interseasonal RSV activity may be approved on a case by case basis.

Synagis (palivizumab) may not be approved for any of the following:

I. Continued RSV prophylaxis for children who experience breakthrough RSV hospitalization; **OR**
II. Treatment of known RSV disease; **OR**
III. Children who reach 24 months of age prior to the beginning of RSV season; **OR**
IV. More than two seasons of RSV prophylaxis (unless individual is profoundly immunocompromised or undergoing cardiac transplantation); **OR**
V. Primary asthma prevention or to reduce subsequent episodes of wheezing; **OR**
VI. Children with surgically corrected congenital heart disease or hemodynamically insignificant heart disease (including secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) who do not otherwise meet approval criteria; **OR**
VII. Children with Down syndrome who do not otherwise meet approval criteria; **OR**
VIII. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. AAP Recommendations for the Prevention of RSV Disease in Infants and Children. Red Book Online. February 21, 2024. Available at https://publications.aap.org/redbook/resources/25379. Accessed: July 11, 2024.
2. American Academy of Pediatrics. Updated guidance: Use of palivizumab prophylaxis to prevent hospitalization from severe respiratory syncytial virus infection during the 2022-2023 RSV season. Last updated: November 17, 2022. 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: July 11, 2024.
3. American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection: Policy Statement. *Pediatrics*. 2014; 134(2):415-420. Erratum in: Pediatrics. 2014; 134(6):1221. Available at: http://pediatrics.aappublications.org/content/134/2/415.full. Accessed: July 11, 2024.
4. American Academy of Pediatrics Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection: Technical Report. *Pediatrics*. 2014; 134(2):e620-e638. Available at: http://pediatrics.aappublications.org/content/134/2/e620.full.pdf+html. Accessed: July 11, 2024.
5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2024.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.