Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Synagis (palivizumab)

Override(s)	Approval Duration
Prior Authorization	Up to 5 doses during the months of October to March or November to April.

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). 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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

• 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 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 US, of October to March or November to April. 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, is available from the National Respiratory and Enteric Virus Surveillance System NREVSS at: http://www.cdc.gov/surveillance/nrevss/rsv/index.html.

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

I. 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. 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**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

C. 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. 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. Cystic fibrosis with clinical evidence of chronic lung disease* or nutritional compromise (weight for length less than tenth percentile);

OR

II. A maximum of 5 doses of Synagis (palivizumab) may be approved for **children during their second RSV season** with any of the following:
   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 corticosteroid therapy or diuretics); **OR**
   B. 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

III. 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. Profoundly immunocompromised (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. Undergoing cardiac transplantation.

OR

IV. 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.

***** Clinical documentation supporting the presence of hemodynamically significant congenital heart disease or chronic lung disease must be submitted when required.

Synagis (palivizumab) approval is limited to RSV season.

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

I. All other indications not included above; **OR**
II. Continued RSV prophylaxis for children who experience breakthrough RSV hospitalization; **OR**
III. Treatment of known RSV disease; **OR**
IV. Children who reach 24 months of age prior to the beginning of RSV season; **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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. 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: September 6, 2019.
2. 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: September 6, 2019.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 6, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.