Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Synagis (palivizumab)

DRUG.00015

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

Medications	Dose Limit
Synagis (palivizumab) 50mg/0.5mL Intramuscular injection Synagis (palivizumab) 100mg/mL Intramuscular injection	Dependent upon criteria below

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.

Immunoprophylaxis for respiratory syncytial virus (RSV) with intramuscular palivizumab (Synagis) may be approved for the prevention of serious lower respiratory tract disease in infants and young children who are at high risk, when the criteria below are met:

I. A maximum of 5 doses of palivizumab within the RSV season which begins during the first year of life **may be approved** for infants with *any of the following* clinical presentations:
   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)(**Note:** Asthma, reactive airway disease and cystic fibrosis without significant symptoms do not meet the definition of chronic lung disease as per AAP Guidelines.); **OR**
   C. Hemodynamically significant congenital heart disease* : for example, but not limited to, 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**

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Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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D. Infants with 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.

II. A maximum of 5 doses of palivizumab **may be approved** for children younger than 24 months of age with any of the following clinical presentations during the RSV season:
   A. Profoundly immunocompromised, such as 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.

III. An additional dose of palivizumab **may be approved** for children in an approved course of treatment who undergo cardiopulmonary bypass for surgical procedures if cardiac or pulmonary hemodynamic support remains unchanged after surgery or if any other medically necessary criteria are present (for example, prematurity).

IV. A second season of palivizumab prophylaxis **may be approved** for preterm infants born at less than 32 weeks, 0 days gestation who require at least 28 days of oxygen after birth and who continue to require medical intervention within 6 months of the start of the second RSV season (for example, supplemental oxygen, chronic systemic corticosteroid therapy, or diuretics).

V. An infant with cystic fibrosis in the first year of life with clinical evidence of chronic lung disease* and/or nutritional compromise, defined as weight for length less than tenth percentile. A second season may be considered for children with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile.

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

May <u>NOT</u> be approved for the following:

- Administration of more than 5 doses of palivizumab in one RSV season, including in Florida
- Immunoprophylaxis for RSV with palivizumab for children less than 24 months of age when the above criteria are not met.
- Continued RSV immunoprophylaxis with palivizumab for children who experience breakthrough RSV hospitalization
- RSV immunoprophylaxis with palivizumab for primary asthma prevention or to reduce subsequent episodes of wheezing

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Investigational and may <u>NOT</u> be approved for the following:

- Immunoprophylaxis for RSV with palivizumab is considered **investigational and *<u>may not</u>* be approved** for children who reach ages 24 months prior to the commencement of the RSV season.
- Palivizumab is considered **investigational and *<u>may not</u>* be approved** for treatment in children or infants with known RSV disease.
- Immunoprophylaxis for RSV with palivizumab is considered **investigational and *<u>may not</u>* be approved** for infants and children with hemodynamically insignificant heart disease (for example, 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 criteria above.
- Immunoprophylaxis for RSV with palivizumab is considered **investigational and *<u>may not</u>* be approved** for infants and children with surgically corrected congenital heart disease who do not otherwise meet criteria above.
- Immunoprophylaxis for RSV with palivizumab is considered **investigational and *<u>may not</u>* be approved** for all other indications not otherwise addressed as medically necessary, including, but not limited to, individuals with cystic fibrosis or Down syndrome who do not otherwise meet criteria above.

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

<u>Key References</u>:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.