PRIOR AUTHORIZATION CRITERIA
SYNAGIS®(palivizumab): 50mg vial, 100mg vial

PA CRITERIA FOR APPROVAL FOR FDA APPROVED INDICATIONS:

- The request for Synagis has all the following information submitted with the request: documentation of chronological age, gestational age, current weight, dose of medication and pertinent medical risk factors.
- If the child's current chronological age is less than 2 years of age at the beginning of Respiratory Syncytial Virus (RSV) season (November 1st), and the child has significant medical risk factors (chronic lung disease of prematurity (CLD) a.k.a. bronchopulmonary dysplasia (BPD)) requiring medical treatment either (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) within 6 months of the start of or during the current RSV season, severe immunodeficiencies/immunosuppression (**see Table 3**), or significant cardiac disease (i.e. those that require medication to control CHF, moderate to severe pulmonary hypertension or cyanotic heart disease) (**see Table 1 & 2**) that could be complicated by pulmonary disease.
- If the child was born prematurely with a gestational age of 28 weeks or less, and the child's current chronological age is less than or equal to 1 year at the beginning of RSV season (November 1st).
- If he child was born prematurely with a gestational age between 29 and 31 weeks & 6 days and the child's current chronological age is less than or equal to 6 months at the beginning of RSV season (November 1st).
- If the child was born prematurely with a gestational age of less than 35 weeks (i.e. 34 weeks & 6 days) and the child's current chronological age is less than or equal to 1 year at the beginning of RSV season (November 1st) and the child was born with a congenital abnormality of the airway or neuromuscular disease.
- If the child has a gestational age of 32 till less than 35 weeks (i.e. 34 weeks & 6 days) and the child's current chronological age is less than 3 months at the beginning of RSV season (November 1st) and the child has at least **1** of the following risk factors: sibling(s) younger than 5 years old or attends child care (defines as a home or facility where care is provided for any number of infants or young toddlers in the child care facility).****IMPORTANT NOTE**** These patients are only eligible to be approved a quantity of Synagis needed to treat the patient until he/she is 3 months (90 days) old OR until the end of March (**a maximum of 3 doses**), whichever is first.
- The request is for Synagis to be administered any time, but no more than once per 30 days, from November 1st through the end of March.
- The prescribed dose of Synagis is in accordance with the FDA dosing recommendations.

If the above conditions are met, the request will be approved with a quantity sufficient dependent on the patient's chronological age, gestational age, and/or clinical situation. For patients with a gestational age between 32 till less than 35 weeks (without any significant medical conditions) they will only be approved a **maximum quantity of 3 doses**. All other patients will be approved with a quantity sufficient to provide coverage from November 1st through March 31st (**a maximum of 5 doses**). If all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

PA CRITERIA FOR AUTHORIZATION OF AN ADDITIONAL DOSE OF SYNAGIS:

- To start treatment of Synagis **prior to November 1st** will be approved only if local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS): RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within ≤ 14 days prior to the patient's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality **AND** the patient meets the above stated criteria for their chronological and/or gestational age.
- An additional dose **after March 31st** of Synagis will be approved only if **THE PATIENT HAS NOT ALREADY RECEIVED THE MAXMIUM APPROVABLE DOSES** according to that patients chronological age, gestational age, and/or clinical situation (please see the **MAXIMUM APPROVABLE DOSES** section below) and local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS): RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within ≤ 14 days prior to the patient's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality.

If the above conditions are met then, for all requests after March 31st the patient will receive authorization for a 1 month duration. For all requests prior to November 1st: for patients born between 32 till less than 35 weeks of gestation (without any significant medical conditions) they will only be approved a **maximum quantity of up to 3 doses**. All other patients will be approved with **a quantity of 5 doses** If all of the above criteria are not met then the request is referred to a Medical Director for medical necessity review.

FDA INDICATIONS:
Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

DOSAGE AND ADMINISTRATION:
The recommended dose of Synagis is 15 mg/kg of body weight administered intramuscularly. Patients, including those who develop a RSV infection, should receive monthly doses throughout the RSV season. The first dose should be administered prior to commencement of the RSV season.

****MAXIMUM APPROVABLE DOSES****

1. Patients born between 32 till less than 35 weeks of gestation, and without any significant medical conditions, will only receive Synagis treatment until they are 3 months (90 days) old (**a maximum of 3 doses)**. Treatment with Synagis is not necessary for these patients past the age of 3 months old and, therefore, will not be approved.

2. For all other patients, they will only receive Synagis treatment for a **maximum of 5 doses**. There are no valid clinical/medical reasons for a 6th dose of Synagis and, therefore, all requests for a 6th dose will be denied.

Table 1.

EXAMPLES OF SIGNIFICANT AND APPROVABLE CARDIAC CONDITIONS
Examples of significant hemodynamic cyanotic congenital heart disease:
Tetralogy of Fallot, Transportation of the great vessels, Ebstein's anomally, Tricuspid atresia, Total anomalous pulmonary venous return, Truncus arteriosus, Hypoplastic left heart syndrome

Table 2.

NON-APPROVABLE CARDIAC CONDITIONS	
Insignificant hemodynamic heart disease (and therefore are NOT approvable indications):	**Indications in which patients are NOT at an increased risk for RSV (and therefore are NOT approvable indications)**
Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus	• Lesions adequately corrected by surgery (unless the patient continues to require medications for CHF) • Mild cardiomyopathy who are NOT receiving medical therapy

Table 3.

EXAMPLES OF SEVERE IMMUNODEFICIENCIES/IMMUNOSUPPRESSION:
Advanced Acquired Immunodeficieny Syndrome (AIDS), Transplant, Chemotherapy, Severe Combined Immunodeficiency (SCID)

REFERENCES:

1. American Academy of Pediatrics: Committee on Infectious Diseases and Committee on Fetus and Newborn, Prevention of respiratory syncytial virus infections: Indications for the use of Palivizumab and update on the use of RSV-IGIV. PEDIATRICS November 1998; Vol.102 No. 5:1211-1215.
2. Synagis® Package Insert, MedImmune, Inc/Ross, Gaithersburg, MD. April 2011.
3. American Academy of Pediatrics. [chapter title]. In: Pickering LK, Baker CJ, Long SS, Kimberlin DW, eds. *Red Book: 2009 Report of the Committee on Infectious Diseases.* 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009: 560-568.
4. Facts and Comparisons, St. Louis, 2005 eFacts CliniSphere Version ISBN 1-57439-036-8.
5. NREVSS: RSV Surveillance: Trends in the U.S. April 14, 2008. Available at : http://www.cdc.gov/surveillance/nrevss/index.htm. Accessed April 2008.
6. Update: Respiratory Syncytial Virus Activity—United States, 1995-96 Season. December 8, 1995: 44(48); 900-902. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00039753.htm. Accessed April 2008.
7. RSV Surveillance 2005-2006: A Nationwide Hospital and Office-Based RSV Epidemiology Pilot Study. Pan American Society for clinical Virology. March 2007: 34; 1-9.

Revision/Review Date: 9/2011
Associated Policy: Prior Authorization of Medications 236.200

NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary