Indications: Respiratory syncytial virus (RSV): For the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤ 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD).

Authorization Guidelines:
A. 3 months of age, or younger, at the start of RSV season:
   - GA 32 weeks 0 days to 34 weeks 6 days AND
   - One of the following risk factors:
     - the infant attends child care, defined as a home or facility in which care is provided for any number of infants or toddlers; OR
     - 1 or more siblings, or other children, younger than 5 years live permanently in the same household

B. 6 months of age, or younger, at the start of RSV season:
   - GA 29 weeks to 31 weeks 6 days

C. 12 months of age, or younger, at the start of RSV season:
   - Gestational Age (GA) ≤ 28 weeks, OR
   - Infants with significant congenital abnormalities of the airway, or a neuromuscular condition that compromises handling of respiratory tract secretions.

D. 2 years of age, or younger, at the start of RSV season with all of the following:
   - A diagnosis of chronic lung disease of prematurity (CLD), [formerly known as bronchopulmonary dysplasia or BPD])
   - Has required medical therapy with supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy for their CLD within 6 months prior to RSV season

E. 2 years of age, or younger, at the start of RSV season with all of the following:
   - A diagnosis of hemodynamically significant* cyanotic or acyanotic congenital heart disease (CHD)
   - Is receiving medication to control congestive heart failure, has moderate-severe pulmonary hypertension, or cyanotic heart disease
Initial Approval:
1 dose per month for a maximum of 5 doses:
- Infants <2 years of age with CLD requiring medical therapy
- Infants <2 years of age with CHD requiring medical therapy
- Premature infants born at GA ≤31 weeks 6 days
- Certain infants with neuromuscular disease or congenital abnormalities of the airways

1 dose per month until infant reaches 3 months of age (maximum of 3 doses):
- Infants with GA of 32 weeks 0 days to 34 weeks 6 days with at least 1 risk factor and born less than 3 months before the onset, or during, RSV season.

Additional Information:
The following groups of infants with CHD are not at increased risk of RSV and generally should not receive Synagis:
- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus);
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure; and
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.
- Immunocompromised children: Synagis® prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised children cannot be made, infants and young children with severe immunodeficiency (eg, severe combined immunodeficiency or advanced AIDS) may benefit from prophylaxis.)
- Patients with cystic fibrosis: Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. Whether RSV infection exacerbates the chronic lung disease of cystic fibrosis is not known. In addition, insufficient data exist to determine the effectiveness of Synagis® use in this patient population. Therefore, a recommendation for routine prophylaxis in patients with cystic fibrosis cannot be made

References:
2. Respiratory Syncytial Virus --- United States, July 2007--June 2011 Weekly September 9, 2011 / 60(35);1203-1206 Accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6035a4.htm?s_cid=mm6035a4_w on 07/30/2012
3. CDC website: http://www.cdc.gov/Features/dsRSV/