

# Synagis® 2011-2012 Authorization Guideline<sup>1</sup>

Condition	Max Number of Doses	Age (in months) at Onset of RSV Season				
		0 to < 3	3 to < 6	6 to < 12	12 to < 24	≥ 24
Hemodynamically significant Congenital Heart Disease (CHD) <sup>2,3</sup> <ul style="list-style-type: none"> <li>• Infants/children requiring medication to control congestive heart failure (CHF)</li> <li>• Infants/children with moderate to severe pulmonary hypertension</li> <li>• Infants/children with cyanotic heart disease</li> </ul>	5	Yes	Yes	Yes	Yes	No
*Chronic Lung Disease (CLD) formerly called bronchopulmonary dysplasia defined as: <ul style="list-style-type: none"> <li>• For infants &lt;32 weeks: Oxygen requirement at 36 weeks gestational age or at discharge</li> <li>• For infants ≥ 32 weeks: Oxygen requirement at age 28 days or greater at discharge</li> </ul> Infants/Children who have received treatment for CLD within 6 months of the anticipated onset of the season with one of the following: <ul style="list-style-type: none"> <li>• Supplemental Oxygen; <b>or</b></li> <li>• Bronchodilator; <b>or</b></li> <li>• Diuretic; <b>or</b></li> <li>• Chronic corticosteroid therapy</li> </ul>	5	Yes	Yes	Yes	Yes	No
Premature infants ≤ 28 weeks, 6 days gestational age <b>OR</b> Infants with a significant congenital abnormality of the airway or neuromuscular condition that compromises handling of respiratory secretions	5	Yes	Yes	Yes	No	No
Premature infants ≥ 29 weeks, 0 days; ≤ 31 weeks, 6 days, gestational age	5	Yes	Yes	No	No	No
Premature infants ≥ 32 weeks, 0 days; ≤ 34 weeks, 6 days with one of the following two risk factors: <sup>4</sup> <ul style="list-style-type: none"> <li>• Child care attendance<sup>5</sup></li> <li>• Sibling &lt; 5 years of age</li> </ul>	3	Yes	No	No	No	No
Infants of 35 weeks, 0 days and older gestational age (without CLD or Hemodynamically Significant CHD) <sup>6,7,8</sup>	0	No	No	No	No	No

## Additional Notes:

1. If an infant receiving Synagis® has a breakthrough RSV infection during the season, Synagis® should continue to be given for a maximum of 3 doses for the 32 to <35 week infant category (until they reach 90 days of life) and for a maximum of 5 doses for the other high risk categories.
2. High-risk CHD patients receiving Synagis® who undergo heart surgery with the use of cardio-pulmonary bypass should receive a dose of Synagis® post-op as soon as medically stable.
3. Patients with CHD who are NOT candidates for Synagis® include:
  - Hemodynamically insignificant heart disease
    - Secundum ASD
    - Small VSD
    - Pulmonic stenosis
    - Uncomplicated aortic stenosis
    - Mild coarctation of the aorta
    - Patent ductus arteriosus (PDA)
  - Infants with corrected surgical lesions unless they continue to require medication for CHF
  - Infants with mild cardiomyopathy who are not receiving medical therapy
4. Premature infants 32 – 35 weeks should only receive prophylaxis until they turn 3 months old (maximum of 3 doses – many will require only 1 or 2 doses). Prophylaxis is not recommended after 3 months of age.
5. Participation in child care (two or more unrelated infants/children for more than 4 hours per week) should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene.
- 6. All high risk infants and their contacts should be immunized against influenza beginning at 6 months of age.**
7. Limited studies have suggested that some patients with cystic fibrosis may be at risk of RSV but it is not known whether RSV exacerbates the chronic lung disease in CF patients and there is insufficient data to determine the effectiveness of Synagis® in this population. Therefore there is no recommendation for routine prophylaxis for cystic fibrosis.
8. Synagis® has not been evaluated in randomized trials in immunocompromised children. However, children with severe immunodeficiencies (such as severe combined immunodeficiency syndrome or advanced AIDS) may benefit from prophylaxis.

## Reference:

1. American Academy of Pediatrics. Policy Statement – Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections. *Pediatrics* Vol. 124 December 2009, pp 1694-1701. Accessed July 1, 2011.
2. \*American Academy of Pediatrics Subcommittee on Diagnosis and Management of Bronchiolitis. Diagnosis and management of bronchiolitis. *Pediatrics* 2006; 118: 1774-93.
3. \*Bancalari E, Abdenour GE, Feller R, Gannon J. Bronchopulmonary dysplasia: clinical presentation. *J Pediatr*. Nov 1979;95(5 Pt 2):819-23
4. \*Shennan AT, Dunn MS, Ohlsson A, et al. Abnormal pulmonary outcomes in premature infants: prediction from oxygen requirement in the neonatal period. *Pediatrics*. Oct 1988;82(4):527-32.
5. \*Walsh MC, Yao Q, Gettner P, et al. Impact of a physiologic definition on bronchopulmonary dysplasia rates. *Pediatrics*. Nov 2004;114:1305-11
6. \*American Academy of Pediatrics and The American College of Obstetricians and Gynecologists. Bronchopulmonary Dysplasia. Guidelines for Perinatal Care: 6<sup>th</sup> Edition. 2008; 273-276.