Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

SYNAGIS® (palivizumab)

GPI CODING:

195020600020**

DESCRIPTION:

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.

APPROVAL DURATION:

Up to 5 doses from October 21, 2013 through March 31, 2014

Quantity Limits
Maximum of one dose (15 mg/kg) will be dispensed per 28 days
Strength dispensed is limited to 50 mg vials quantity dependent on weight:

Weight Range (kg)	Weight Range (lb)	Synagis Dose	Quantity Limit (# 50 mg vials)
0 - 4.3 kg	0 – 9.5 lb	0 – 65 mg	1
4.4 - 8.7 kg	9.6 – 19.1lb	66 mg – 130 mg	2
8.73 kg – 13 kg	19.2 – 28.6 lb	131 mg – 195 mg	3
13.1 kg – 17.3 kg	28.7 - 38.1 lb	196 mg – 260 mg	4
17.4 kg – 21.7 kg	38.2 – 47.7 lb	261 mg - 325 mg	5
21.72 kg – 26 kg	47.78 – 57.2 lb	326 mg – 390 mg	6

CRITERIA FOR SYNAGIS

Immunoprophylaxis for respiratory syncytial virus (RSV)

I. Five doses of Synagis within the RSV season during the first year of life may be approved if infant is:
   A. Born at 28, or less, weeks of gestation (up to and including 28 weeks, 6 days) and less than 12 months of age at the start of the RSV season; **OR**
   B. Born at 29 to 32 weeks gestation (beginning 29 weeks, 0 day through 31 weeks, 6 days) and less than 6 months of age at the start of the RSV season; **OR**
   C. Chronic lung disease (CLD) [formerly designated bronchopulmonary dysplasia (BPD)] who have required medical treatment within six months before the start of the RSV season with oxygen, steroids, bronchodilators or diuretics; (Note: Asthma, reactive airway disease and cystic fibrosis do not meet the definition of chronic lung disease in the AAP Guidelines); **OR**
   D. Hemodynamically significant (for example, but not limited to, receiving medication for congestive heart failure or moderate to severe pulmonary hypertension) cyanotic or acyanotic congenital heart disease (CHD); **OR**
   E. Congenital abnormalities of the airway or neuromuscular disease, born before 35 weeks of gestation, with congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretion

II. Three doses of Synagis during one RSV season in the first year of life may be approved if:
   A. Infant born between 32 and 35 weeks gestation (beginning 32 weeks, 0 day through 34 weeks, 6 days); **AND**
   B. Less than 3 months of age at the start of the RSV season; **AND**
   C. Less than 90 days old at the time of dosing; **AND**
   D. One or more of the following risk factors are present:
      i. Attends group child care (defined as a home or facility where care is provided along with at least one other infant or young child), **OR**
      ii. If there are siblings or other children living in the household who are less than 5 years of age

III. An additional dose of Synagis may be approved for children in an approved course of treatment who undergo cardiopulmonary bypass for surgical procedures due to documented reduction in serum levels post-bypass

IV. Completion of dosing schedule of Synagis may be approved for an infant or child who is receiving RSV immunoprophylaxis and experiences break-through RSV infection

V. Five doses of Synagis within the RSV season during the second year of life may be approved if child has:
   A. Chronic lung disease (CLD) [formerly designated Bronchopulmonary Dysplasia (BPD)] who have required medical treatment within six months before the start of the RSV season with oxygen, steroids, bronchodilators or diuretics. (Note: Asthma, reactive airway disease and cystic fibrosis do not meet the definition of chronic lung disease in the AAP guidelines); **OR**
   B. Hemodynamically significant (for example, but not limited to, receiving medication for congestive heart failure or moderate to severe pulmonary hypertension) cyanotic or acyanotic congenital heart disease (CHD)

VI. Synagis may NOT be approved for the following:
   A. Administration of more than 5 doses of Synagis in one RSV season
   B. Administration of more than 3 doses of Synagis or any dose after 90 days of age for infants born between 32 and 35 weeks gestational age unless they have a condition listed in criteria II
   C. Immunoprophylaxis for respiratory syncytial virus for children less than 24 months of age when the above criteria are not met
   D. Continued RSV immunoprophylaxis regimen with monthly doses of Synagis when the National Respiratory and Enteric Virus Surveillance System (NREVSS) epidemiologic data has confirmed that the present-year RSV season has ended
   E. Immunoprophylaxis for respiratory syncytial virus is considered investigational and not for children ages 24 months or older prior to the commencement of the RSV season
   F. Synagis is considered investigational for treatment in children or infants with known RSV disease except as indicated above
   G. Immunoprophylaxis for respiratory syncytial virus is considered investigational for infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
   H. Immunoprophylaxis for respiratory syncytial virus is considered investigational for infants and children with surgically corrected congenital heart disease unless they continue to require medication for congestive heart failure

I. Immunoprophylaxis for respiratory syncytial virus is considered investigational and not medically necessary for all other indications such as use in recipients of hematopoietic stem cell transplants and cystic fibrosis patients who do not otherwise meet criteria above