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Developed By: Medical Criteria Committee	

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Description:

Respiratory Syncytial Virus (RSV) is a viral infection that affects the respiratory tract. Premature infants and children with chronic lung disease (CLD) are at highest risk for contracting RSV. RSV prophylaxis is initiated at the onset of the RSV season and terminated at the end of RSV season. In North America, peak RSV activity typically occurs between November and March.

Synagis (palivizumab) is a biological agent used to prevent RSV in high-risk infants and children. Given by intra-muscular injection, Synagis is a humanized monoclonal antibody against RSV produced by recombinant DNA technology. A total of 3 to 5 monthly doses of Synagis are typically given to cover a patient during the RSV season.

RespiGam (RSV-IGIV) is another biological agent previously used to prevent RSV. As of March 15, 2004 the supply of RespiGam had been depleted and no product is available for sale from the manufacturers. It is not considered further in this policy.

Criteria:

- I. ODS will approve Synagis as medically necessary when the recipient meets one of the following criteria:
 - A. Infants and children less than 2 years of age at the onset of RSV season who have bronchopulmonary dysplasia or other chronic lung disease and have required medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for their condition within 6 months before the start of the RSV season. These infants and children should receive a maximum of 5 doses.
OR
 - B. Infants up to 12 months of age at the onset of RSV season with a history of preterm birth before 32 weeks gestation (≤ 31 weeks 6 days). These infants should receive a maximum of 5 doses.
OR
 - C. Infants born between 32 to less than 35 weeks gestation (defined as 32 weeks 0 days through 34 weeks 6 days) within 3 months before the start of RSV season or any time throughout RSV season who also have one of the following risk factors:
 - i. The infant attends daycare
 - ii. One or more siblings or other children younger than 5 years live permanently in the same household;Infants who meet criteria C should receive RSV prophylaxis only until they reach 3 months of age or a maximum of 3 doses, whichever comes first.
OR
 - D. Infants less than 12 months of age at the start of RSV season who have either significant congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory tract secretions should receive a maximum of 5 doses of Synagis during the first year of life.
OR
 - E. Infants and children with congenital heart disease who are 24 months of age or younger at the onset of the RSV season and exhibit one of the following:
 - i. Infants receiving medication to control congestive heart failure; or
 - ii. Infants with moderate to severe pulmonary artery hypertension; or

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- iii. Infants with cyanotic heart disease
Infants who meet criteria E should receive a maximum of 5 doses of Synagis.
- II. RSV prophylaxis is not covered for the following:
- A. Children older than 2 years of age at the start of the RSV season
 - B. Children with a history of a prior severe reaction to Synagis or other components of the product
 - C. Continued use of RSV prophylaxis beyond 5 months per year
 - D. When used as treatment for established RSV disease
 - E. High risk children with prior laboratory confirmed RSV infections (virus culture, RSV antigen, or high positive titers of RSV antibody)
 - F. Infants and children with hemodynamically insignificant heart disease (e.g. secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta and patent ductus arteriosus)

Information to be Submitted with Pre-Authorization Request:

1. Chart notes from the ordering physician documenting the above criteria

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