

Benefit Coverage:

Synagis is a covered benefit when the medical necessity guidelines for Synagis are met. Annually, Neighborhood's Pharmacy and Therapeutics Committee reviews the American Academy of Pediatrics' Red Book Guidelines to establish medical necessity criteria for Neighborhood eligible members. Prior authorization is required. Ordering practitioners are required to complete Neighborhood's Synagis Prior Authorization form and forward it to the contracted vendor selected by Neighborhood to administer Synagis in the home environment. For the 2010-2011 RSV season, the selected vendor is Walgreen's Infusion Services.

Descriptions:

Palivizumab is a humanized monoclonal antibody for IM injection that inhibits respiratory syncytial virus (RSV) replication. It is supplied as lyophilized powder in single use vials of 50mg and 100mg.

Synagis is used for the prevention of severe lower respiratory tract diseases caused by RSV in pediatric patients at high risk of developing RSV disease. Safety and efficacy of palivizumab have been established in infants with chronic lung disease, formerly known as bronchopulmonary dysplasia (BPD), infants with a history of prematurity (≤ 35 weeks gestational age at birth), and children with hemodynamically significant congenital heart disease (CHD). Palivizumab is not indicated for treatment of reactive airway disease/asthma. Palivizumab is not approved for use in adults.

Coverage Determination:

Typically in the Northern Hemisphere RSV season lasts from November to April. Based on pharmacokinetic data available, the necessary trough concentration of 30mcg/mL will be maintained for a full month after repeated doses when given on this schedule. The American Academy of Pediatrics policy issued in 2003 recommends that in most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the start of RSV season and the last dose at the beginning of March to provide protection into April. Only one injection will be covered per each 28-30 day period for up to 5 injections during the RSV season.

Additional information required for processing requests includes:

- NICU history (NICU discharge summary is preferred)
- History of Synagis being administered while newborn in the NICU
- History of other medical reasons or diagnoses such as severe neuromuscular disease, congenital abnormalities of the airways, or severe immunodeficiency disease to explain why child should receive Synagis prophylaxis.

Criteria for Synagis:

One of the following three (3) criteria must be met to qualify for Synagis.

1) The child is less than 24 months (at the beginning of RSV season) and has had bronchopulmonary dysplasia/chronic lung disease requiring meds or oxygen within the past 6 months.

Note: Reactive airway disease is not a qualifying diagnosis.

2) The child is less than 24 months with hemodynamically significant congenital heart disease with any of the following:

- Congestive Heart Failure
- Cardiac Meds
- Anticipated Heart Surgery
- Oxygen Requirement
- Pulmonary Hypertension
- Cyanotic Defects

3). History of Prematurity (as described by one of these 3 scenarios)

a) Child born at less than 29 weeks gestation and will be less than 12 months old at the beginning of the RSV season, or

b) Child born 29 – 32 weeks of gestation and will be less than 6 months old at the beginning of the RSV season, or

c) Child born between 32 - 35 weeks gestation and will be less than 3 months old (90 days) at the beginning of the RSV season, and has 1 or more of the following risk factors

- Child Care Attendance
- Siblings less than 5 years old

Note: Infants born between 32 – 35 weeks gestation who meet this criteria, will receive monthly injections until age 3 months.

CMP Number: PTG 003.00

CMP Cross Reference:

References:



Clinical Medical Policy Synagis

American Academy of Pediatrics: Revised Indications for the Use of Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prevention of Respiratory Syncytial Virus Infections; PEDIATRICS Vol. 112 No. 6 December 2003, pp. 1442-1446

<http://aappolicy.aappublications.org/cgi/content/full/pediatrics;112/6/1442>

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