Subject: Respiratory Syncytial Virus (RSV) Prophylaxis with Synagis*

Effective Date: December 1, 1996

Department(s): Utilization Management

Policy: Palivizumab (Synagis) is reimbursable under Plans administered by QualCare, Inc., for the prevention of disease due to RSV in high risk infants and children, as defined below.

Objective: To assure proper and consistent reimbursement for medically appropriate and necessary use of a specific prophylactic immune globulin preparation.

Procedure:

1. The RSV “season” is defined as the period from November through April. This is the interval during which Synagis is reimbursable.

2. Synagis is reimbursable under any of the following circumstances:

   a. Chronological age

      (1) 24 months of age or younger with chronic lung disease/bronchopulmonary dysplasia (CLD/BPD) who have required medical therapy (e.g., supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy) within six months before the start of the RSV season.

      (2) 24 months of age or younger with hemodynamically significant cyanotic or acyanotic congenital heart disease (including but not limited to those who are receiving medication
to control congestive heart failure and those with moderate to severe pulmonary hypertension).

(3) **24 months of age or younger with severe immunocompromise** (e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome)

b. **Gestational age at birth**

(1) Infants born at **32 weeks of gestation or earlier**, whether or not they have CLD/BPD, based on the following chronological and gestational age criteria (at the start of the RSV season):

(a) Infants born at **28 weeks of gestation or earlier**, during their first RSV season, whenever that occurs during the first 12 months of life.

(b) Infants born between **29 and 32 weeks of gestation** who are within the first 6 months of life at the start of the RSV season.

Once a child qualifies for initiation of Synagis at the start of the RSV season, the preparation being administered is reimbursable throughout the season, irrespective of the time at which the child reaches either 6 or 12 months of age.

(2) Infants born **between 32 and 35 weeks of gestation** and who are within the first 3 months of life at the start of the RSV season: Synagis is reimbursable if **one** of the following risk factors are present:

- Attendance at group day care outside the child’s home
- Presence of another child in the child’s home less than five years of age

Infants in this category [2.b.(2)] should receive Synagis only until they reach 3 months of age and
should not receive more than 3 monthly doses; many will receive only 1 or 2 doses by the time they reach 3 months of age.

(3) Infants born before 35 weeks of gestation with either of the following:

- Congenital airway abnormalities
- Severe neuromuscular disease (which must be identified by name by the requesting physician)

c. Cardiopulmonary bypass

For any infant or child who is receiving Synagis and undergoes cardiopulmonary bypass, a postoperative dose of Synagis is reimbursable.

3. Synagis is not reimbursable for the following groups of infants and children:

a. Those 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)

In questionable cases the pediatrician should be asked whether heart disease is hemodynamically significant.

b. Those with cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure

c. Those with mild cardiomyopathy who are not receiving medical therapy for it

d. Those with active RSV disease, except when this occurs as a breakthrough infection during Synagis prophylactic therapy. When such a breakthrough RSV infection occurs, Synagis shall continue to be reimbursable through the end of the current RSV season.

e. Those with cystic fibrosis without one of the indications for Synagis in this policy. (Cystic fibrosis alone is not an indication for RSV prophylaxis.)
References


Robinson KA, Odelola OA, Saldanha IJ, McKoy NA. Palivizumab for prophylaxis against respiratory syncytial virus infection in children with cystic fibrosis. Cochrane Database Syst Rev.2012;2:CD007742( Feb)


Barr FE, Graham BS. Treatment and prevention of respiratory syncytial virus infection. UpToDate version 16.1. available at www.uptodate.com/online/content/topic.do?topicKey=pedi_id/22362&view=print accessed 05/21/08


American Academy of Pediatrics Committee on Infectious Diseases and Committee on Fetus and Newborn. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. *Pediatrics* 2003; 112(6 Pt 1): 1442-1446 (Dec)


Original Effective Date: 12/01/1996
Revised Date: 10/27/98
Approved By/Date: QM Committee/10/27/98
1998 Revision Effective Date: 11/01/1998
Revised By/Date: B. Fisher, MD/10/23/2005
Approved By/Date: QM Committee 12/12/05
Revised By/Date: B. Fisher, MD 05/21/08
Approved By/Date: QM Committee 07/22/08
Revised By/Date: B. Fisher, MD 05/22/10
Approved By/Date: QM Committee 06/08/10
Reviewed without Revision By/Date: MMcNeil, MD 04/20/12
Approved By/Date: QM Committee 05/08/12
Reviewed w/o Revision By/Date: MMcNeil, MD 05/20/14
Approved by/Date: QM Committee 6/10/14

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.