



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

**Effective Date:** December 1, 1996

**Department(s):** Utilization Management

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**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. Administration of more than 5 monthly doses is not recommended within the continental United States, as this will provide more than 6 months (>24 weeks) of serum palizivumab concentrations above the desired level for most children. A dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April. If initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses.

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

**a. Chronological age as indicated below:**

**i. Infants during the first year of life** with any of the following:

- chronic lung disease/bronchopulmonary dysplasia (CLD/BPD) of prematurity, defined as gestational age <32 weeks, 0 days and a requirement for >21% Oxygen for at least the first 28 days after birth;
- a congenital abnormality of the airway or a neuromuscular disease that compromises the handling of respiratory secretions( such as cerebral palsy, muscular dystrophy, spinal muscular atrophy);
- the infant is Alaskan Native or American Indian( Navajo and White Mountain Apache);
- with hemodynamically significant acyanotic congenital heart disease (including but not limited to those who are receiving medication to control congestive heart failure and will require cardiac surgical procedures; and those with moderate to severe pulmonary hypertension); and when recommended by a pediatric cardiologist for cyanotic congenital heart disease; NOTE- children with hemodynamically significant congenital heart disease are not at

increased risk of RSV infection during the second year of life.

- With cystic fibrosis AND either CLD/BPD as defined above , OR nutritional compromise as evidenced by weight for length less than the 10<sup>th</sup> percentile on a pediatric growth chart
- **Premature infants during the first year of life born before 29 weeks, 0 days gestation. Note-palivizumab prophylaxis is not recommended in the second year of life on the basis of prematurity alone.**

**Children during the second year of life with any of the following:**

- **chronic lung disease**/bronchopulmonary dysplasia as defined above, who have required medical therapy (e.g., supplemental oxygen, diuretic or corticosteroid therapy) within six months before the start of the RSV season. NOTE- prophylaxis is NOT recommended for infants with CLD/BPD who do not continue to require medical support during the second year of life.
- **Cystic fibrosis and** either symptoms of severe lung disease( history of hospitalization for pulmonary exacerbation in the first year of life or abnormal chest x-ray or chest CT that persists when clinically stable) or weight for length less than the 10<sup>th</sup> percentile on a pediatric growth chart.

**ii. Infant or child less than 24 months of age with any of the following:**

- **Immunocompromise** ( e.g., severe combined immunodeficiency or advanced acquired immunodeficiency syndrome )
- **Cardiac Transplantation**

**b. Cardiopulmonary bypass**

For any infant or child who is receiving Synagis and undergoes cardiopulmonary bypass, a postoperative dose or end of extracorporeal membrane oxygenation 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;

- e. When RSV occurs as a breakthrough infection during Synagis prophylactic therapy, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season.
- f. Those with cystic fibrosis or Down Syndrome without one of the indications for Synagis in this policy. (Cystic fibrosis and Down Syndrome alone are not indications for RSV prophylaxis.)
- g. Prevention of health care-associated RSV disease (ie in the inpatient setting).

## References

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