

Medical Coverage Policy | Respiratory Syncytial Virus Prophylaxis, Preauth



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OVERVIEW

This policy documents the criteria for coverage of the Respiratory Syncytial Virus Immunoglobulin Vaccine, (RSV) the most common cause of lower respiratory infections in children. At highest risk are those younger than 2 years of age with prematurity, chronic lung disease (CLD, [formerly known as bronchopulmonary dysplasia]), congenital heart disease, or multiple congenital anomalies. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants.

Blue CHiP for Medicare: Coverage for this vaccine is not applicable as this is limited to children which are not eligible for Medicare.

PRIOR AUTHORIZATION

Commercial

Prior Authorization is recommended for all commercial products.

POLICY STATEMENT

Respiratory syncytial virus immunoglobulin is considered **medically necessary** when the medical criteria below is met. Benefits may vary between groups/contracts.

Other indications that are not medically necessary;

- Immunoprophylaxis for respiratory syncytial virus is **not medically necessary** 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).
- Immunoprophylaxis for respiratory syncytial virus is considered **not medically necessary** for infants and children with surgically corrected congenital heart disease unless they continue to require medication for congestive heart failure.

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

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

Additional information:

RSV seasons may vary by state and in most cases, more than five doses are **not medically necessary** as Synagis® is usually administered for five doses starting in early November through March. If the public health department extends the influenza season, it may be **medically necessary** to administer a sixth dose. Documentation **must** be submitted with the request for additional doses.

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. If the public health department extends the influenza season, it may be **medically**

necessary to administer a sixth dose. Documentation **must** be submitted with the request for additional doses.

MEDICAL CRITERIA

Synagis® (palivizumab) is covered when one (1) of the following criteria is met:

Prematurity

Infant may receive a maximum of 5 monthly doses:

Less than 12 months of age at start of RSV season **AND** born 28 weeks (up to and including 28 weeks, 6 days) gestation or less; **OR**

Less than 6 months of age at the start of RSV season **AND** born at 29 to 32 weeks (beginning 29 weeks 0 day through 31 weeks, 6 days) gestation.

Infant may receive a maximum of 3 monthly doses during RSV season in the first year of life when **ALL** of the following apply::

Born between 32 and 35 weeks (beginning 32 weeks, 0 day through 34 weeks, 6 days) gestation; **AND**

Less than 3 months of age at the start of the RSV season; **AND**

Less than 90 days old at the time of dosing; **AND**

One or more of the following risk factors:

Group child care attendance (i.e., in a group setting outside the infant's home); **OR**

Siblings living in the household are less than 5 years of age.

Note: This criteria for infants born between 32 and 35 weeks gestational age do not apply to infants with conditions listed elsewhere in this policy.

Chronic Lung Disease

Infant may receive a maximum of 5 monthly doses:

Child less than 24 months of age at the start of the RSV season with chronic lung disease (CLD) [formerly designated Bronchopulmonary Dysplasia] who required on-going medical treatment within the last 6 months, with oxygen, steroids, bronchodilators, or diuretics.

Note: Asthma or reactive airway disease does not meet the definition of chronic lung disease.

Congenital Heart Disease (CHD):

Infant may receive a maximum of 5 monthly doses:

Children less than 24 months of age at the start of the RSV season with hemodynamically significant CHD, including, but not limited to the following conditions:

those receiving medication for congestive heart failure

those with moderate to severe pulmonary artery hypertension

those with cyanotic heart disease.

Congenital Abnormalities of the Airway or Neuromuscular disease:

Infant may receive a maximum of 5 monthly doses:

With congenital malformations of the airway, or a neuromuscular condition that compromises handling of respiratory secretions.

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

BACKGROUND

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory infections in children. At highest risk are those younger than 2 years of age with prematurity, chronic lung disease (CLD), [formerly

known as bronchopulmonary dysplasia]), congenital heart disease, or multiple congenital anomalies. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants.

Respiratory syncytial virus (RSV) infections typically occur in the winter months, starting from October to December and ending from March to May. Considerable variation in the timing of community outbreaks is observed year to year.

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory infections in children. At highest risk are those younger than 2 years of age with prematurity, chronic lung disease (CLD, [formerly known as bronchopulmonary dysplasia]), congenital heart disease, or multiple congenital anomalies. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants

Based on the weight of the clinical evidence from randomized clinical trials, systematic reviews and strong clinical consensus, immune prophylaxis for RSV has demonstrated reductions in RSV-related hospitalizations in select populations of susceptible infants and children. Therefore, immune prophylaxis for RSV may be considered medically necessary for the patients listed in the policy statement above. For all other uses of immune prophylaxis, the clinical evidence is not convincing that RSV hospitalizations will decrease. Therefore, the policy statements above note indications which are considered investigational or not medically necessary. The policy statements are in agreement with the 2009 AAP Guidelines.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable physician administered benefit and services not medically necessary coverage.

Specialty Drug Coverage:

For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

CODING

The following codes are covered:
90378:

The following service is not separately reimbursed:

S9562: Home injectable therapy, Palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

RELATED POLICIES

None

PUBLISHED

Provider Update January 2014
Provider Update Oct 2012

Provider Update, Sept 2011

Provider Update, Dec 2010

Provider Update, Dec 2009

Provider Update, Oct 2008

Policy Update, Dec 2007

Policy Update, Oct 2006

Policy Update, Nov 2005

Policy Update, Nov 2000

Policy Update, Apr 1998

REFERENCES

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11. <http://www.mhswi.com/files/2008/11/2012-2013-Synagis-Authorization-Guidelines.pdf>

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