Medical Coverage Policy | Respiratory Syncytial Virus Immunoglobulin

EFFECTIVE DATE: 11|06|2013
POLICY LAST UPDATED: 08|12|2015

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. BlueCHiP for Medicare: Coverage for this vaccine is not applicable as this is limited to children who are not eligible for Medicare.

MEDICAL CRITERIA

Commercial Products

Synagis® (palivzumab) 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;
- Less than 12 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;
- Less than 3 months of age at the start of the RSV season;
- Less than 90 days old at the time of dosing;

One or more of the following risk factors:

- Group child care attendance (i.e., in a group setting outside the infant's home);
- 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 of prematurity when:

Infant may receive a maximum of 5 monthly doses when all of the following criteria are met:

- The medication is prescribed by or in consultation with a specialist (i.e., neonatologist, pediatric intensivist, pulmonologist, or infections disease specialist);
- The child has chronic lung disease of prematurity;
- The child was born before 32 weeks, 0 days gestation;

- The child received greater than 21 percent oxygen supplementation for at least the first 28 days after birth,

And one of the following indications:

- Child is 12 months of age or younger at the start of the RSV season, **Or**;
- Child less than 12-24 months of age at the start of the RSV season with chronic lung disease (CLD), [formerly designated Bronchopulmonary Dysplasia] who required ongoing 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.

Cystic Fibrosis:

Infant may receive a maximum of 5 monthly doses when any of the following criteria is met:

- The infant is 12 months or younger and meets the criteria for CLD (see above);
- The infant is younger than 24 months and there is evidence of nutritional compromise (weight or length less than the 10th percentile);
- The infant is older than 12 months but less than 24 months and has manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable).

Hemodynamically significant Congenital Heart Disease (CHD):

Infant may receive a maximum of 5 monthly doses when all of the following criteria is met:

- The medication is being prescribed by or in consultation with a pediatric cardiologist;
- Children less than 12 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.
  - those requiring a cardiac surgical procedure
  - those who will or has undergone a cardiac transplantation during the RSV season

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.

Immunocompromised Children with all of the following:

- The patient is 24 months of age or younger;
- The patient has received a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season;
- The patient lymphocyte count is below the normal range for patient's age

PRIOR AUTHORIZATION

BlueCHiP for Medicare

Not applicable

Commercial Products

Prior authorization is recommended for all commercial products.

POLICY STATEMENT

Commercial Products

Respiratory syncytial virus immunoglobulin is considered medically necessary when the medical criteria above 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 breakthrough 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.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Benefit Booklet, 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.

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.

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.

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.

CODING

BlueCHiP for Medicare

The following codes are not covered for BlueCHiP for Medicare:

Commercial Products

The following codes are covered:

90378: Respiratory syncytial virus immune globulin (RSV-IgIM), for intramuscular use, 50mg, each

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, November 2015
Provider Update, November 2014
Provider Update, January 2014
Provider Update, October 2012
Provider Update, September 2011
Provider Update, December 2010
Provider Update, December 2009
Provider Update, October 2008
Policy Update, December 2007
Policy Update, October 2006
Policy Update, November 2005
Policy Update, November 2000
Policy Update, April 1998

REFERENCES

1. Respiratory syncytial virus--United States, July 2007-June 2011. MMWR Morb Mortal Wkly Rep 2011; 60(35):1203-6.
2. Wang D, Cummins C, Bayliss S et al. Immunoprophylaxis against respiratory syncytial virus (RSV) with palivizumab in children: a systematic review and economic evaluation. Health Technol Assess 2008; 12(36):iii, ix-x, 1-86.
3. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. The IMpact-RSV Study Group. Pediatrics 1998; 102(3 Pt 1):531-7.
4. Feltes TF, Cabalka AK, Meissner HC et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. J Pediatr 2003; 143(4):532-40.

5. Reduction of respiratory syncytial virus hospitalization among premature infants and infants with bronchopulmonary dysplasia using respiratory syncytial virus immune globulin prophylaxis. The PREVENT Study Group. Pediatrics 1997; 99(1):93-9.
6. Prevention of respiratory syncytial virus infections: indications for the use of palivizumab and update on the use of RSV-IGIV. American Academy of Pediatrics Committee on Infectious Diseases and Committee of Fetus and Newborn. Pediatrics 1998; 102(5):1211-6.
7. Meissner HC, Long SS. 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):1447-52.
8. *2009 Red Book. Report of the Committee on Infectious Disease. Respiratory Syncytial Virus.* Vol 2009. Elk Grove Village, IL: American Academy of Pediatrics.
9. From the American Academy of Pediatrics: Policy statements--Modified recommendations for use of palivizumab for prevention of respiratory syncytial virus infections. Pediatrics 2009; 124(6):1694-701.
10. Cohen SA, Zanni R, Cohen A et al. Palivizumab use in subjects with congenital heart disease: results from the 2000-2004 Palivizumab Outcomes Registry. Pediatr Cardiol 2008; 29(2):382-7.
11. http://www.mhswi.com/files/2008/11/2012-2013-Synagis-Authorization-Guidelines.pdf

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