SYNAGIS® (palivizumab)

Policy Number: 2012D0009A  Effective Date: January 1, 2014

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:
This policy provides information about Synagis® (palivizumab) and its recommended use. Synagis® is a monoclonal antibody used for the prevention of respiratory syncytial virus (RSV), a common seasonal viral agent that poses a serious infectious threat to young children. Synagis® is appropriately used in carefully selected high-risk infants and young children to prevent complications from RSV, which can include respiratory failure, hospitalizations and deaths.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:
Respiratory Syncytial Virus (RSV) immune prophylaxis with Synagis®(palivizumab), during RSV season and described number of doses, may be considered MEDICALLY NECESSARY in the following selected high-risk infants and young children, based on guidelines from the American Academy of Pediatrics (AAP, 2012):

1. **Chronic Lung Disease:** Infants and children younger than 24 months of age with chronic lung disease (CLD) who have required medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) within six months before the anticipated RSV season, **to a maximum of five monthly doses.**

2. **Premature Birth:**
   a. Infants born before 32 weeks’ gestation (31 weeks, 6 days or less) according to the following schedule, **to a maximum of five monthly doses:**
      - Infants born at 28 weeks, 6 days gestation or earlier, who are younger than 12 months of age at the start of palivizumab therapy for the RSV season; OR
      - Infants born at 29 weeks, 0 days to 31 weeks, 6 days of gestation, who are younger than six months of age at the start of palivizumab therapy for the RSV season.
   b. Infants born between 32 weeks, 0 days and 34 weeks, 6 days gestation, and are younger than three months at the start of palivizumab therapy for the RSV season and have at least one of the following two risk factors, may receive monthly doses until age three months, **to a maximum of three monthly doses:**
      - Infant attends child care; OR
      - Infant has at least one sibling younger than five years of age.

   **Note:** If an infant born between 32 weeks, 0 days and 34 weeks 6 days, is receiving palivizumab immunoprophylaxis and experiences a breakthrough RSV infection, monthly prophylaxis may continue until a maximum of 3 doses have been administered.

3. **Neuromuscular Disease or Congenital Abnormalities of the Airway:** Infants less than or equal to 12 months of age, born with congenital abnormalities of the airway, interstitial lung disease, OR a neuromuscular condition that compromises handling of respiratory secretions, during the first year of life, **to a maximum of five monthly doses.**

4. **Immunodeficiencies:** Infants and children, who are 24 months of age or younger, with severe immunodeficiencies (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, or severe immunodeficiency resulting from chemotherapy).
5. **Congenital Heart Disease (CHD):** prophylaxis with palivizumab for children with CHD should be made on the basis of the degree of physiologic cardiovascular compromise.
   a. Infants and children, who are 24 months of age or younger with hemodynamically significant cyanotic or acyanotic complicated congenital heart disease, at the start of RSV season, to a maximum of five monthly doses.
   b. For children with CHD, meeting the above criteria for palivizumab, an additional postoperative dose of palivizumab may be considered medically necessary after a surgical procedure requiring cardiopulmonary bypass.

   **Note:** Prophylaxis with Synagis® (palivizumab) for children younger than 24 months of age with CHD should be made on the basis of the degree of physiologic cardiovascular compromise. The ones most likely to benefit from immunoprophylaxis include those:
   - Receiving medication to control congestive heart failure; OR
   - With moderate to severe pulmonary hypertension; OR
   - With cyanotic heart disease.

**Synagis® (palivizumab)** is considered to be NOT MEDICALLY NECESSARY when administered out of season, when administered in doses greater than needed to provide protection in season, when administered in excess of 5 doses per single RSV season, or when administered to persons other than those at defined high risk, as specified above.

**Synagis® (palivizumab)** is considered to be NOT MEDICALLY NECESSARY for infants and children with hemodynamically insignificant heart disease because, according to the AAP, they are not at increased risk of RSV. Examples of conditions, but not limited to, are:
- Secundum atrial septal defect
- Small ventricular septal defect
- Pulmonic stenosis
- Uncomplicated aortic stenosis
- Mild coarctation of the aorta
- Patent ductus arteriosus
- Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy

All other indications for Respiratory Syncytial Virus (RSV) immune prophylaxis with **Synagis® (palivizumab)**, (not otherwise addressed) are considered EXPERIMENTAL AND INVESTIGATIONAL, including but not limited to:
- Children > 24 months at the initial request for immunoprophylaxis
- Adults with any diagnosis
- Patients undergoing stem cell transplantation
- Infants and children with cystic fibrosis
- Hematopoietic stem cell transplant (BMT, peripheral blood, placental or cord blood)
- Advanced AIDS
- Sickle cell disease

1. **Clinical Considerations:** According to AAP 2012 guidelines:
   - Synagis® (palivizumab), a humanized monoclonal antibody, is administered by intramuscular injection in monthly doses of 15 mg/kg body weight during the respiratory syncytial virus (RSV) season.
   - Administer using aseptic technique, preferably in the anterolateral aspect of the thigh. Do not use the gluteal muscle routinely as an injection site because of the risk of damage to the sciatic nerve. The dose per month = (patient weight [kg] × 15 mg/kg ÷ 100 mg/mL of palivizumab). Give injection volumes larger than 1 mL as a divided dose.
   - A maximum of 5 monthly doses is recommended for infants in this category.
   - According to AAP, hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge. Thus, any palivizumab doses received prior to discharge from a hospital stay (e.g., NICU, nursery) count as one of the seasonal doses.
   - Adverse Reactions: Adverse events with palivizumab therapy are generally mild and similar to placebo. The adverse reactions most commonly observed in palivizumab-treated patients were upper respiratory tract infection, otitis media, fever, rhinitis, rash, diarrhea, cough, vomiting, gastroenteritis, and wheezing. The most serious adverse reactions occurring with palivizumab treatment are anaphylaxis and other acute hypersensitivity reactions. Palivizumab does not interfere with childhood vaccination schedules.

**BACKGROUND:**

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infection and rehospitalization in preterm infants with or without chronic lung disease (CLD), formerly known as bronchopulmonary dysplasia. RSV pneumonia is also the most frequent reason for admission to the pediatric intensive care unit (PICU) for respiratory failure.[1] Almost all children have been infected with RSV by age 24 months, and re-infection throughout life is common. Characteristics that increase the risk of severe or fatal RSV infections include preterm birth, cyanotic or complicated congenital heart disease; including conditions causing pulmonary hypertension and underlying pulmonary disease, especially chronic lung disease of prematurity.[13,14] Among children under the age of 5 in the United States, RSV infection accounts for an estimated 1 of 334 hospitalizations, 1 of 38 visits to an emergency department, and 1 of 13 visits to a primary care office each year.[4,13] Approximately 3%, or about 57,527, of children with RSV-related illness in this age group are hospitalized. However, this number of hospitalizations has also been estimated higher at 75,000-125,000 per year.[15]

Outbreaks of RSV illness are usually seasonal. In most areas of the United States, the usual time for the beginning of the RSV outbreaks is October to December, and termination is March to May, but regional differences occur. The onset of RSV infection occurs earlier in southern states than in northern states. According to the Centers for Disease Control and Prevention (CDC), onset of the RSV season occurs when the median percentage of specimens testing positive for RSV is 10% or higher, over a 2-week period.[10,13,14]

During the months of April through October, sporadic individual cases of RSV illness do occur. In addition, outbreaks of RSV illness have been reported during the summer months.[8,9] It is unknown at this time if the
severely affected. When a healthy infant or child is infected with the RSV virus, their immune system manufactures antibodies in order to fight the virus. Synagis® (palivizumab) is a humanized mouse monoclonal antibody (IgG1 K) produced by recombinant DNA technology which has neutralizing and fusion-inhibitory activity against RSV. It is approved for the prevention of RSV infection of the lower respiratory tract in certain infants and children.

Research from clinical trials indicate that palivizumab trough serum concentrations greater than 30 days after the 5th dose will be well above the protective concentration for most infants. If the first dose is administered in November, 5 monthly doses of palivizumab will provide substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and end.

Treatment options for established RSV disease are limited with only one drug, ribavirin, approved for treatment. Ribavirin has in-vitro, antiviral activity against RSV. However, a consistent decrease in need for mechanical ventilation, decrease in length of stay in the pediatric intensive care unit, or reduction in days of hospitalization among ribavirin recipients has not been demonstrated. Ribavirin is not recommended for routine use but may be considered for use in select patients with documented, potentially life-threatening RSV infection. A vaccine is a theoretical prevention strategy; however, no vaccine is yet available. Through efforts to develop a vaccine, it was learned that the titers of maternally derived RSV-neutralizing antibody prevent serious RSV illness. Respiratory Syncytial Virus Immune Globulin Intravenous (RSV-IgIV), a hyperimmune, polyclonal globulin prepared from donors selected for high serum titers of RSV neutralizing antibody was FDA approved in 1996, but is no longer available.

**Others at Risk for Severe Illness Due to RSV Infection:** Increasingly, RSV infection is recognized as an important cause of respiratory illness in high-risk adults and the elderly. High-risk adults include those with chronic heart disease, chronic lung disease, or compromised immune systems; the elderly include those 65 or older, particularly if they reside in a long-term care facility or participate in other senior day-care programs.

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**REGULATORY STATUS:**

**1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

**FDA Approved Indication:** Synagis® (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The safety and efficacy of palivizumab has not been established for treatment of RSV disease.

**FDA Recommended Dosing:** The recommended dose of palivizumab is 15 mg per kg of body weight given monthly by intramuscular injection. Up to five doses will be allowed per recipient over the course of the RSV season. Some patients will be eligible for fewer doses, depending on their gestational and chronological age. The first dose of palivizumab should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV
season. Synagis® serum levels are decreased after cardio-pulmonary bypass. Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis® as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled. The efficacy of Synagis® at doses less than 15 mg per kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

**Drug Availability:** Synagis® is supplied in single-dose vials at the concentration of 100 mg/mL for 1M injection in 1) 50 mg vial containing 50 mg palivizumab in 0.5 mL, and 2) 100 mg vial containing 100 mg palivizumab in 1 mL.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

For Medicare Advantage members, drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.

This medical policy only addresses instances when Sinagis is covered under a member's medical benefit (Part B). It does not address coverage under a member’s Pharmacy Benefit (Part D).

Medicare does not have a National Coverage Determination (NCD) or Local Coverage Determinations (LCDs) for Synagis® (palivizumab).

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**


While the RSV season is not expected to begin until November 15th, MHCP will allow Synagis dispensing to begin November 7th to facilitate delivery and scheduling of the November dose.

**Dosing Allowance Policy:**

The calculated dose of Synagis is 15 mg/kg. Because this drug is available only in 50 mg and 100 mg vials, and costs approximately $1,000 per 50 mg, there is the potential for significant waste. The following table should be followed and shows a 10% difference in allowed dose from the calculated dose.

Table 1. MN DHS Dosing Allowance 10% difference from calculated dose

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Calculated dose (max wt) (15mg/kg)</th>
<th>Allowed dose (50 mg, 100 mg)</th>
<th>Dispense</th>
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<tbody>
<tr>
<td>0 to 3.6</td>
<td>54 mg</td>
<td>50 mg</td>
<td>one 50 mg vial</td>
</tr>
<tr>
<td>3.7 to 7.3</td>
<td>110 mg</td>
<td>100 mg</td>
<td>one 100 mg vial</td>
</tr>
<tr>
<td>7.4 to 11.1</td>
<td>166.5 mg</td>
<td>150 mg</td>
<td>one 100 mg one 50 mg vial</td>
</tr>
<tr>
<td>Weight Range</td>
<td>Dosage 1</td>
<td>Dosage 2</td>
<td>vials</td>
</tr>
<tr>
<td>--------------</td>
<td>---------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>11.1 to 14.6 kg</td>
<td>220 mg</td>
<td>200 mg</td>
<td>two 100 mg vials</td>
</tr>
<tr>
<td>14.7 to 18.1 kg</td>
<td>271.5 mg</td>
<td>250 mg</td>
<td>two 100 mg one 50 mg vial</td>
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</table>

**CRITERIA**

**Pulmonary**

1. Any infant or child under the age of 24 months with a diagnosis of Chronic Lung Disease (CLD) of prematurity (defined as gestational age less than 35 weeks) AND having one or more of the following clinical needs during the previous 6 months:
   a. Supplemental oxygen
   b. Regular use of inhaled or oral bronchodilators
   c. Recent use of corticosteroid therapy
   d. Regular or intermittent use of diuretics to treat pulmonary disease
   
   Up to five (5) monthly doses will be approved.

2. Any infant or child less than or equal to 12 months of age, as of November 7th, 2012, with a diagnosis of one or more of the following that impacts pulmonary function:
   a. Interstitial Lung Disease
   b. Neuromuscular disease
   c. Congenital airway abnormality
   
   Up to five (5) monthly doses will be approved.

**Congenital heart disease (CHD)** (see also Addendum A)

3. Any infant or child under the age of 24 months who has a diagnosis of hemodynamically significant congenital heart disease (CHD) and meets any of the following criteria:
   a. Receiving medication to control congestive heart failure (diuretics, antihypertensives)
   b. Moderate to severe pulmonary hypertension
   c. Cyanotic Heart Disease
   
   Up to five (5) monthly doses will be approved.

**Infants with a history of premature birth**

4. Any infant up to 12 months of age, born at 28 weeks or less gestation
   
   Up to five (5) monthly doses will be approved.

5. Any infant up to 6 months of age, born 29 to less than 32 weeks gestation
   
   Up to five (5) monthly doses will be approved.

6. Any infant younger than 3 months of age at the start of the RSV season, born at 32 to less than 35 weeks gestation and meets one of the following risk factors:
   a. Currently attends day care
   b. Has a sibling younger than 5 years of age
   
   Up to three (3) monthly doses will be approved or until the child reaches 3 months of age.
Addendum A
Patients with CHD who are NOT candidates for Synagis include:

- Hemodynamically insignificant heart disease
- Secundum ASD
- Small VSD
- Pulmonic stenosis
- Uncomplicated aortic stenosis
- Mild coarctation of the aorta
- Patent ductus arteriosus (PDA)
- Infants with corrected surgical lesions unless they continue to require medication for CHF
- Infants with mild cardiomyopathy who are not receiving medical therapy

Addendum B
There are no guideline/consensus recommendations to support Synagis prophylaxis in patients who have one of the following disorders:

- Hematopoietic stem cell transplant (BMT, peripheral blood, placental or cord blood)
- Severe combined immunodeficiency syndrome
- Advanced AIDS
- Cystic fibrosis
- RSV episode during the current season
- Repeated pneumonia
- Sickle cell disease
- Being one member of a multiple birth, another member of which is approved for Synagis
- Apnea or respiratory failure of newborn

CLINICAL EVIDENCE:
Several randomized clinical trials have demonstrated the success of Respiratory Syncytial Virus (RSV) immune prophylaxis with Synagis® (palivizumab), when appropriately used in carefully selected high-risk infants and young children.

1. EVIDENCE FROM AVAILABLE PUBLISHED STUDIES:

   PREMATURITY:
   A moderate number of controlled studies have evaluated the effects of palivizumab (PLV) (Synagis®) prophylaxis for respiratory syncytial virus (RSV) infection in preterm infants, ≤ 35 weeks gestational age (GA). All studies showed a beneficial effect of PLV, with the most consistent being a marked reduction in hospitalization rates in groups of infants treated with PLV (e.g., 55% reduction). However, only one of the studies reviewed was placebo-controlled and randomized due to ethical concerns associated with administering a placebo in more recent studies, and none of the studies examined the effects of PLV prophylaxis beyond 2 years after treatment. Overall, PLV was safe, and no serious complications or injuries were reported. Importantly, none of the studies compared PLV with other prophylaxis for RSV infection, and the evidence was insufficient to establish definitive patient selection criteria for RSV
infection in preterm infants.

**CONGENITAL HEART DISEASE:**
Palivizumab is not approved by the Food and Drug Administration (FDA) for patients with congenital heart disease (CHD). The use of palivizumab in infants with hemodynamically significant heart disease represents an off label indication. The AAP introduced this recommendation in 2003, based on the results of a 4-year, multi-center, prospective, placebo-controlled randomized clinical trial of 1,287 children, less than 2 years of age with hemodynamically significant congenital heart disease. The trial demonstrated that palivizumab significantly reduced the rate of hospitalizations, hospital days, and days of increased oxygen usage in children with serious CHD. The study was conducted at 76 centers in North America and Europe, and the children who were randomized received 5 monthly intramuscular injections (15 mg/kg) of either palivizumab or placebo during the RSV season. Compared to placebo, the palivizumab group had 45% fewer hospitalizations due to RSV (p = 0.003). The data showed significantly fewer RSV-related hospital days (p = 0.003) and fewer days of increased oxygen usage (p = 0.014) in the treated group than in the placebo group. The proportions of subjects in the placebo and palivizumab groups who experienced any adverse events were similar.

According to the AAP Committee on Infectious Diseases, decisions regarding the use of palivizumab prophylaxis in children with congenital heart disease should be made on the basis of the degree of physiological cardiovascular impairment. Infants most likely to benefit from immunoprophylaxis include those receiving medication to control congestive heart failure, those with moderate to severe pulmonary artery hypertension, and infants with cyanotic heart diseases. A decrease in the serum concentration of palivizumab by a mean of 58% has been reported after surgical procedures that use cardiopulmonary bypass. Thus, after surgical procedures that use cardiopulmonary bypass, the AAP recommends a post-operative dose of palivizumab (15 mg/kg) be considered for children 2 years of age or less who still require prophylaxis as soon as the patient is medically stable.

**CYSTIC FIBROSIS:**
The AAP guidelines (2012) noted that limited studies suggest that some patients with cystic fibrosis (CF) may be at increased risk of RSV infection. However, there are insufficient data to determine the effectiveness of palivizumab use in this patient population. Therefore, a recommendation for routine prophylaxis in patients with CF cannot be made. Furthermore, the European Cystic Fibrosis Society Vaccination Group (Malfroot et al, 2005) stated that there are no recommendations for palivizumab in CF as an alternative but expensive prophylaxis.

**IMMUNODEFICIENCIES:**
The use of RSV-IGIV or palivizumab in patients with documented immunodeficiencies has also been suggested, however, palivizumab prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, the literature indicates that children with severe immunodeficiencies (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome) may benefit from prophylaxis.

A Cochrane systematic evidence review found no studies demonstrating statistically significant benefits of treatment with immune globulins added to supportive care compared with supportive care alone (Fuller and Del Mar, 2006).
2. EXTERNAL SOURCES/ GROUPS POLICY:

American Academy of Pediatrics (AAP):
There have been no changes to the AAP recommendations for RSV prophylaxis in the 2012-2013 season – the guidelines include the following:

- Children less than two years of age with chronic lung disease.
- Premature infants who were born at less than 28 weeks and who are less than twelve months old at the start of RSV season (October to May).
- Premature infants who were born between 29-32 weeks and who are less than six months old at the start of RSV season.
- Premature infants who were born between 32-35 weeks and who are less than three months old at the start of RSV season and who have at least one risk factors - either they are attending daycare or they have a sibling less than five years old at home.
- Certain children who are younger than 2 years with congenital heart disease, including congestive heart failure, pulmonary hypertension, and cyanotic heart disease.
- Certain infants with congenital abnormalities of the airway or neuromuscular disease.

According to the AAP regarding the initiation and termination of immunoprophylaxis, peak RSV activity normally occurs between November and March in the temperate climates of North America. In the same community, significant variation has been reported in timing of community outbreaks of RSV disease from year to year and between communities in the same year, even in the same region. These variations occur within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April.

Infants and children who qualify for palivizumab prophylaxis for the entire RSV season (infants and children with chronic lung disease of prematurity or congenital heart disease or preterm infants born before 32 weeks’ gestation) should receive palivizumab only during the five months following the onset of RSV season in their region (maximum of 5 doses), which should provide coverage during the peak of the season, when prophylaxis is most effective. In general, the initiation of immunoprophylaxis in November and continuation for a total of 5 monthly doses will provide protection into April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February. Preterm infants with gestational age of 32 weeks, 0 days to 34 weeks, 6 days with at least 1 risk factor and born 3 months before or during RSV season should only receive a maximum of 3 doses for the season.

According to the AAP, decisions regarding the use of palivizumab prophylaxis in children with congenital heart disease should be made on the basis of the degree of physiological cardiovascular impairment. Infants most likely to benefit from immunoprophylaxis include those receiving medication to control congestive heart failure, those with moderate to severe pulmonary artery hypertension, and infants with cyanotic heart diseases. A decrease in the serum concentration of palivizumab by a mean of 58% has been reported after surgical procedures that use cardiopulmonary bypass. Thus, after surgical procedures that use cardiopulmonary bypass, the AAP recommends a post-operative dose of palivizumab (15 mg/kg) be considered for children 2 years of age or less who still require prophylaxis as soon as the patient is medically stable.

The AAP concluded that the following groups of infants are not at increased risk of RSV and generally should not receive immunoprophylaxis: infants with hemodynamically insignificant heart disease (e.g.
secundum atrial septal defect), small ventricular septal defect (VSD), pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus. In addition, prophylaxis is not necessary in infants with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure, and infants with mild cardiomyopathy who are not receiving medical therapy for their condition.

The Center for Disease Control and Prevention (CDC):
National Respiratory and Enteric Virus Surveillance System (NREVSS) is a laboratory-based system that monitors temporal and geographic patterns associated with the detection of RSV and other viruses. Annual summaries and alerts based on NREVSS data have been published periodically in CDC's Morbidity and Mortality Weekly Report at http://www.cdc.gov/mmwr/. CDC surveillance summaries of weekly RSV laboratory test result data for each region of the United States are posted at: http://www.cdc.gov/surveillance/nrevss/rsv/state.html.

APPLICABLE CODES:
The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>S9562</td>
<td>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</td>
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<td>Respiratory syncytial virus (RSV)</td>
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<td>279.06</td>
<td>Common variable immunodeficiency</td>
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<td>279.2</td>
<td>Combined immunity deficiency</td>
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<td>279.3</td>
<td>Unspecified immunity deficiency</td>
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<td>745.0</td>
<td>Bulbus cordis anomalies and anomalies of cardiac septal closure, common truncus</td>
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<td>Complete transposition of great vessels</td>
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### REFERENCES:


7. Personal communication from the American Academy of Pediatrics Committee on Infectious Disease. October 6, 2008.


**POLICY HISTORY:**

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<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<td>01-30-2013</td>
<td>Approved by the Interim Medical Policy Committee (IMPC).</td>
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<tr>
<td>02-11-2013</td>
<td>Reviewed and approved by the Pharmacy and Therapeutic Committee (P&amp;T).</td>
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<td>11-15-2013</td>
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</tbody>
</table>

**QUESTIONS AND ANSWERS:**

Q1:  
A1:  

**ATTACHMENTS:**