Immune Prophylaxis for Respiratory Syncytial Virus

Policy # 00177
Original Effective Date: 08/24/2005
Current Effective Date: 12/11/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab (Synagis®) during respiratory syncytial virus (RSV) season in infants and children who meet guidelines from the American Academy of Pediatrics (AAP) to be eligible for coverage.**

Patient Selection Criteria
Administration of immune prophylaxis for respiratory syncytial virus (RSV) will be considered when the criteria are met for the respective category of “high risk” patient:

1. Infants born prematurely [without chronic lung disease (CLD) OR WITHOUT hemodynamically significant cyanotic or acyanotic heart disease OR WITHOUT other listed “high risk” factors]:
   a. The infant is ≤ 1 year of age at the start of the respiratory syncytial virus (RSV) season and was born before 29 weeks, 0 days’ gestation (≤ 28 weeks, 6 days’ gestation).

2. Children WITH chronic lung disease (CLD) (one of the below sets of criteria must be met):
   a. Infants ≤ 1 year of age at the start of the respiratory syncytial virus (RSV) season:
      i. The infant was born at < 32 weeks, 0 days’ gestation; AND
      ii. The infant required > 21% oxygen for at least 28 days after birth.
   OR
   b. Children ≤ 2 years of age at the start of the respiratory syncytial virus (RSV) season (second season dosing):

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i. The child was born at < 32 weeks, 0 days’ gestation; AND
ii. The child required > 21% oxygen for at least 28 days after birth; AND
iii. The child has required medical therapy (i.e., supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy) during the 6 months before the start of the second respiratory syncytial virus (RSV) season.

3. **Infants with congenital heart disease (CHD):**
   a. The infant is ≤ 1 year of age at the start of the respiratory syncytial virus (RSV) season; AND
   b. The infant meets one of the following conditions:
      i. The infant has hemodynamically significant cyanotic congenital heart disease (CHD); OR
      ii. The infant has acyanotic heart disease AND is receiving medication to control congestive heart failure AND will require a cardiac surgical procedure; OR
      iii. The infant has moderate to severe pulmonary hypertension; OR
      iv. The infant has lesions that have been adequately corrected by surgery, but continues to require medication for congestive heart failure.

4. **Children with cardiac transplant:**
   a. The child is < 2 years of age at the start of the respiratory syncytial virus (RSV) season; AND
   b. The child has undergone or will undergo cardiac transplantation during the current respiratory syncytial virus (RSV) season.

5. **Infants with a congenital anatomic pulmonary abnormality or neuromuscular disease:**
   a. The infant is ≤ 1 year of age at the start of the respiratory syncytial virus (RSV) season; AND
   b. The infant’s congenital anatomic pulmonary abnormality or neuromuscular disease impairs the ability to clear secretions from the upper airways.

6. **Immunocompromised children:**
   a. The child is younger than 24 months of age at the start of the respiratory syncytial virus (RSV) season; AND
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b. The child is/will be profoundly immunocompromised during the respiratory syncytial virus (RSV) season (e.g., chemotherapy or transplant).

Note: Children receiving approval for Synagis will be eligible for monthly dosing from the time of authorization until the end of the Blue Cross Blue Shield of Louisiana (BCBSLA) respiratory syncytial virus (RSV) season.

Note: Monthly prophylaxis should be discontinued in any child who experiences a breakthrough respiratory syncytial virus (RSV) hospitalization

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers immune prophylaxis for respiratory syncytial virus (RSV) in children that do NOT meet the requirements of the most current American Academy of Pediatrics (AAP) respiratory syncytial virus (RSV) Prophylaxis Guidelines to be not medically necessary.**

Based on review of available data, the Company considers immune prophylaxis for respiratory syncytial virus (RSV) for any of the following (UNLESS OTHER “HIGH RISK” FACTORS ARE PRESENT and subsequent criteria in the patient selection criteria listed above are met) to be not medically necessary**:

- Prevention of respiratory syncytial virus (RSV) in infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Prevention of respiratory syncytial virus (RSV) in infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Prevention of respiratory syncytial virus (RSV) in patients with Cystic Fibrosis
- Prevention of respiratory syncytial virus (RSV) in patients with Down Syndrome.
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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Synagis for non-U.S. Food and Drug Administration (FDA) approved indications such as use in adults or treatment of respiratory syncytial virus (RSV) to be investigational.*

Policy Guidelines
Dosing and Administration
Palivizumab is administered by intramuscular injection at a dose of 15 mg/kg of body weight per month. The anterolateral aspect of the thigh is the preferred injection site. Routine use of the gluteal muscle for the injection site can cause sciatic nerve damage.

Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the respiratory syncytial virus (RSV) season to infants who qualify for prophylaxis. Qualifying infants born during the RSV season will require fewer doses. For example, infants born in January would receive their last dose in March (see Initiation and Termination of Immunoprophylaxis subsection below) (American Academy of Pediatrics [2014]).

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.

Breakthrough RSV
Guidelines make the following recommendation on breakthrough RSV: "If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood (<0.5%) of a second RSV hospitalization in the same season" (AAP [2014]).

Prevention of Health Care-Associated RSV Disease
RSV is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. Among hospitalized infants, the most effective ways of reducing RSV transmission is to strictly observe common infection control practices; this includes the restriction of visitors to the hospital room.
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neonatal intensive care unit during peak respiratory virus season, and to promptly initiate all standard precautions when coming into contact with RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric or neonatal intensive care unit or stem cell transplantation unit), the primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use for controlling outbreaks of healthcare-associated disease, and the use of palivizumab is not recommended for this purpose.

Interactions
Palivizumab does not interfere with response to other scheduled childhood vaccines.

However, palivizumab may interfere with RSV diagnostic tests that are immunologically based (eg, some antigen detection-based assays).

Risk Minimization Techniques
For all infants, particularly those who are preterm, the environment should be optimized to prevent RSV and other viral respiratory infections by doing the following: offering breast milk feeds, immunizing household contacts with influenza vaccine, practicing hand and cough hygiene, by avoiding tobacco or other smoke exposure, and by not attending large group child care during the first winter season, whenever possible (Technical report: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. Aug 2014;134(2):e620-e638. PMID 25070304).

Initiation and Termination of Immunoprophylaxis
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.

In the temperate climates of North America, peak RSV activity typically occurs between November and March, whereas in equatorial countries, RSV seasonality patterns vary and may occur throughout the year. The annual occurrence of the RSV season is predictable, but the severity, time of onset, peak activity, and end of the season cannot be predicted precisely. Substantial variation in timing of community outbreaks of RSV disease from year to year exists in the same community 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
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or February, and ending by late March or sometime in April. Communities in the southern United States, particularly in Florida, tend to experience the earliest onset of RSV activity. In recent years, the national duration of the RSV season has been 21 weeks (MMWR [2013]).

Clinical trial results have indicated that palivizumab trough serum concentrations more than 30 days after the fifth dose will be well above the protective concentration for most infants. Five monthly doses of palivizumab will provide more than 20 weeks of protective serum antibody concentration. In the continental United States, a total of 5 monthly doses for infants and young children with congenital heart disease, chronic lung disease of prematurity, or preterm birth before 32 weeks of gestation (31 weeks, 6 days) will provide an optimal balance of benefit and cost, even with variation in season onset and end.

Data from the Centers for Disease Control and Prevention have identified variations in the onset and offset of the RSV season in Florida that affect the timing of palivizumab administration. Northwest Florida has an onset in mid-November, which is consistent with other areas of the United States. In North Central and Southwest Florida, the onset of RSV season typically is late September to early October. The RSV season in Southeast Florida (Miami-Dade County) typically has its onset in July. Despite varied onsets, the RSV season is of equal duration in the different regions of Florida. Children who receive palivizumab prophylaxis for the entire RSV season should receive palivizumab only during the 5 months after the onset of RSV season specific to their region (maximum of 5 doses).

**Background/Overview**

**Respiratory Syncytial Virus Infections**

RSV infections typically occur in the winter months, starting from late October to mid-January and ending anywhere from March to May. Considerable variation in the timing of community outbreaks is observed from year to year. According to U.S. Centers for Disease Control and Prevention, the onset of the RSV season occurs when the median percentage of specimens testing positive for RSV is 10% higher over a 2-week period. Annually in the U. S., RSV infection has been associated with an estimated 57527 hospitalizations and 2.1 million outpatient visits among children less than 5 years of age. While RSV is a near-ubiquitous infection, infants with underlying medical issues, especially a history of prematurity with associated lung problems, are at risk of developing serious complications from bronchiolitis secondary to RSV.
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Palivizumab (Synagis) is a humanized monoclonal antibody, made using recombinant DNA technology, directed against a site on the antigenic site of the F protein of RSV.

Other RSV preventive agents, including vaccines, have been under development. A recombinant RSV fusion protein nanoparticle vaccine has been shown to induce an immune response in a phase 2 trial.

This evidence review does not address therapies to treat RSV infection.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 1998, the biologic drug palivizumab (Synagis®; MedImmune) was approved for marketing by the Food and Drug Administration through a biologics license application (103770) for use in the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at a high-risk of RSV disease. In 2004, the Food and Drug Administration approved a liquid formulation of Synagis®, supplied as a sterile solution ready for injection, thus providing improved convenience for administration. This formulation is used in the physician office or home setting. There are no therapeutic equivalents to this drug.

Rationale/Source

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections in children. Several factors that put certain children at a higher risk for contracting RSV have been identified: they are age (<2 years old), prematurity, chronic lung disease of prematurity (formerly known as bronchopulmonary dysplasia), congenital heart disease, immunodeficiencies, and multiple congenital anomalies. Immune prophylaxis against RSV is a preventive strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants. For individuals with high-risk indications for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes several randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are overall survival (OS), symptoms, morbid events, and hospitalizations. Evidence from systematic reviews of RCTs has demonstrated that RSV prophylaxis with palivizumab is associated with reductions in RSV-related hospitalizations and length of intensive care unit stays. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
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For individuals with cystic fibrosis without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes an RCT, several prospective and retrospective cohort studies, and multiple systematic reviews. The relevant outcomes are OS, symptoms, morbid events, and hospitalizations. Although some studies have demonstrated reductions in hospitalizations in palivizumab-treated patients, studies that used contemporaneous controls did not. In the available RCT, rates of adverse events were high in both the palivizumab and the placebo groups, making it difficult to draw conclusions about the net benefit of palivizumab. A more recent nonrandomized study using non-contemporaneous controls found fewer RSV infections in palivizumab-treated patients with cystic fibrosis. Additional studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with immunodeficiencies without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes case series. The relevant outcomes are OS, symptoms, morbid events, and hospitalizations. Descriptive findings from a consensus panel and case reports of two infants with primary immunodeficiencies and two infants with acquired immunodeficiencies in whom palivizumab was used with good compliance and efficacy have been reported in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Down syndrome without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes a prospective cohort study. The relevant outcomes are OS, symptoms, morbid events, and hospitalizations. The available cohort study reported reduced rates of RSV-related hospitalization in treated patients but had methodologic limitations, including the use of a non-contemporaneous comparative cohort from a different country; such limitations introduce uncertainty into any conclusions that can be made. The evidence is insufficient to determine the effects of the technology on health outcomes.

Decisions about the use of palivizumab prophylaxis involve selecting patients likely to derive the most benefit from reductions in RSV hospitalizations. Input obtained in 2009 supported the use of immune prophylaxis for RSV for the indications listed in the policy statements, which include patients with immunocompromised states and cystic fibrosis, and are consistent with the existing guidelines-based recommendations.
Supplemental Information
Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 3 physician specialty societies (7 responders) while this policy was under review in 2009. Most providing input agreed with the policy statements; these statements concurred with the American Academy of Pediatrics (2009) guidelines.

Practice Guidelines and Position Statements

American Academy of Pediatrics
The AAP (2014) updated its guidelines on the use of palivizumab in high-risk infants. In 2017, the guidelines were reviewed by the AAP, the American Academy of Family Physicians, American College of Chest Physicians, American College of Emergency Physicians, and the Committee on Infectious Diseases. Following that review, the AAP concluded that its recommendations should remain unchanged (see Table 1).

Table 1. Guidelines on Use of Palivizumab Prophylaxis for Infants

<table>
<thead>
<tr>
<th>Recommendations for Using Palivizumab Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prophylaxis recommended</strong></td>
</tr>
<tr>
<td>• Infants born before 29 weeks, 0 days of gestation, during first year of life</td>
</tr>
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</table>
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- Infants born before 32 weeks, 0 days of gestation with chronic lung disease of prematurity, during first year of life

- Children in the second year of life who require 28 or more days of supplemental oxygen and continue to require medical intervention during respiratory syncytial virus season

Prophylaxis may be considered

- Infants with hemodynamically significant heart failure, during first year of life

- Infants with a pulmonary abnormality or neuromuscular disease that impairs ability to clear secretions from lower airways, during first year of life

- Children younger than 24 months who are profoundly immunocompromised during respiratory syncytial virus season
Prophylaxis not recommended

- Healthy infants born at or after 29 weeks, 0 days of gestation

- There is insufficient evidence for children with cystic fibrosis or Down syndrome without other risk factors

AAP (2014) also published guidelines on the diagnosis, management, and prevention of bronchiolitis (updating 2006 guidelines), and made the following recommendations about the use of palivizumab for respiratory syncytial virus prevention (see Table 2).

Table 2. Guidelines on the Diagnosis, Management, and Prevention of Bronchiolitis

<table>
<thead>
<tr>
<th>Recommendation</th>
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<tbody>
<tr>
<td>&quot;Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater.&quot;</td>
<td>B</td>
<td>Strong</td>
</tr>
<tr>
<td>&quot;Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants &lt;32 weeks 0 days' gestation who require &gt;21% oxygen for at least the first 28 days of life.&quot;</td>
<td>B</td>
<td>Moderate</td>
</tr>
<tr>
<td>&quot;Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the respiratory syncytial virus&quot;</td>
<td>B</td>
<td>Moderate</td>
</tr>
</tbody>
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season to infants who qualify for palivizumab in the first year of life."

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Policy History
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Current Effective Date: 12/11/2019
08/03/2005 Medical Director review
08/16/2005 Medical Policy Committee review
08/24/2005 Managed Care Advisory Council approval
12/20/2005 Medical Policy Committee review. Clarification of post-operative dose following procedures requiring cardiopulmonary bypass to reflect the intent of policy to provide eligibility for children that would otherwise qualify for administration of immune prophylaxis for RSV.
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/05/2007 Medical Director review

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09/19/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
09/03/2009 Medical Policy Committee approval.
09/09/2010 Medical Policy Committee review
09/01/2011 Medical Policy Committee review
09/14/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012 Medical Policy Committee review
04/25/2012 Medical Policy Implementation Committee approval. Deleted the maximum of five doses from all of the criteria statements for immune prophylaxis for respiratory syncytial virus. Changed the criteria bullet to liberalize coverage regarding infants born at 28 weeks of gestation or earlier. These infants used to be eligible for coverage during their first respiratory syncytial virus season, but are now candidates for prophylaxis during the respiratory syncytial virus season, whenever that occurs during the first 12 months of life.
04/04/2013 Medical Policy Committee review
04/23/2013 Medical Policy Implementation Committee approval. Added a few statements to clarify the administration of the policy. Clarified that multiple births do fulfill the requirement of another sibling in the household. Also added verbiage clarifying the dates of the BCBSLA RSV season and continuation of the season. Also clarified that patients receive the entire season for dosing unless specified in the patient selection criteria.
08/07/2014 Medical Policy Committee review
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08/03/2015  Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015  Medical Policy Committee review
12/16/2015  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2016  Coding update
12/01/2016  Medical Policy Committee review
01/01/2017  Coding update: Removing ICD-9 Diagnosis Codes
10/01/2017  Coding update
12/07/2017  Medical Policy Committee review
12/20/2017  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018  Medical Policy Committee review
12/19/2018  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019  Medical Policy Committee review

Next Scheduled Review Date:  12/2020

**Coding**
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
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<th>Code Type</th>
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<td>CPT</td>
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</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into
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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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