SELECTED MEDICAL POLICIES – 5.01.10
Immune Prophylaxis for Respiratory Syncytial Virus

BCBSA Ref. Policy: 5.01.10
Effective Date: Nov. 1, 2018
Last Revised: March 1, 2019
Replaces: 5.01.504
RELATED MEDICAL POLICIES: None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Respiratory syncytial virus (RSV) is the most common cause of infection in the small airways of the lungs (bronchiolitis) and pneumonia in children. Very young children who were born too early (prematurity) or have chronic lung disease (CLD) of prematurity, congenital heart disease, or immune problems are at highest risk to get pneumonia. Providing a regular infusion of antibodies against the RSV virus during RSV season may decrease lung infections and hospital stays. This policy outlines when the Plan covers these infusions, based on guidelines of the American Academy of Pediatrics.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synagis® (palivizumab)</td>
<td>Monthly administration of immune prophylaxis for respiratory</td>
</tr>
<tr>
<td>Drug</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>------</td>
<td>-------------------</td>
</tr>
<tr>
<td>syncytial virus (RSV) with Synagis® (palivizumab) during the RSV season may be considered medically necessary in the following infants and children in accordance with guidelines-based recommendations (American Academy of Pediatrics [2014]):</td>
<td></td>
</tr>
</tbody>
</table>

1. **In the first year of life**, ie, younger than 12 months at the start of the RSV season or born during the RSV season, for the following:
   a. Infants born before 29 weeks, 0 days of gestation
   b. Preterm infants with chronic lung disease (CLD) of prematurity, defined as birth at less than 32 weeks, 0 days of gestation and a requirement for more than 21% oxygen for at least the first 28 days after birth
   c. Certain infants with hemodynamically significant heart disease (eg, infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures; infants with moderate to severe pulmonary hypertension; infants with lesions adequately corrected by surgery who continue to require medication for heart failure)
      i. Decisions regarding Synagis® (palivizumab) prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist
   d. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways (eg, ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy)
   e. Children with cystic fibrosis who have at least one of the following conditions:
      i. Clinical evidence of CLD
         **AND / OR**
      ii. Nutritional compromise

2. **In the second year of life**, ie, younger than 24 months at the start of the RSV season:
<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a. Children who were born at less than 32 weeks, 0 days of gestation and required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) during the 6-month period before the start of the second RSV season</td>
</tr>
<tr>
<td></td>
<td>b. Children with cystic fibrosis who have either:</td>
</tr>
<tr>
<td></td>
<td>i. Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography (CT) that persists when stable)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>ii. Weight for length less than the 10th percentile</td>
</tr>
<tr>
<td></td>
<td>3. In the first or second year of life:</td>
</tr>
<tr>
<td></td>
<td>a. Children who will be profoundly immunocompromised (eg, will undergo solid organ or hematopoietic cell transplantation or receive chemotherapy) during the RSV season</td>
</tr>
<tr>
<td></td>
<td>4. After surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of Synagis® (palivizumab) may be considered medically necessary after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation (ECMO) for infants and children younger than 24 months.</td>
</tr>
</tbody>
</table>

**Immune prophylaxis for RSV with Synagis® (palivizumab) is considered not medically necessary in:**

1. Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)  
2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for heart failure  
3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition  
4. Children with congenital heart disease in the second year of life
Drug Investigational

Synagis® (palivizumab) Other indications for immune prophylaxis for RSV are considered investigational (unless criteria for medical necessity [outlined above] are satisfied), including but not limited to:

- Controlling outbreaks of health care-associated disease (nosocomial infection)
- Use in children with Cystic Fibrosis (CF)
- Use in children with Down syndrome without other risk factors
- Use in children over 2 years of age

Documentation Requirements

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Gestational age at birth (when the baby was born during the pregnancy, counted in weeks)

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 90378</td>
<td>Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information
Consideration of Age

Immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab (Synagis®) is considered medically necessary in infants and children during the RSV season in accordance with current (2014) guidelines from the American Academy of Pediatrics and medical literature. The evidence for the use of immune prophylaxis for RSV in infants with Down syndrome or children over the age of 2 is insufficient without other risk factors.

Dosing and Administration

Synagis® (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 best way to reduce RSV transmission is to strictly observe common infection control practices; this includes the restriction of visitors to the 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), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose.

Interactions

Synagis® (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, 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 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 Synagis® (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 in their region (maximum of 5 doses).

Evidence Review

Description

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.
Background

Respiratory Syncytial Virus Infections

Respiratory syncytial virus (RSV) infections typically occur in the winter months, starting from late October to mid-January and ending anywhere from March to May.\(^1\) Considerable variation in the timing of community outbreaks is observed 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 United States, RSV infection has been associated with an estimated 57,527 hospitalizations and 2.1 million outpatient visits among children less than 5 years of age.\(^2\) 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.

Chronic Lung Disease

Chronic lung disease (CLD) of prematurity (formerly known as bronchopulmonary dysplasia) is a general term for long-term respiratory problems in premature infants. CLD results from lung injury to newborns who consequently must use a mechanical ventilator and supplemental oxygen for breathing. With injury, lung tissues become inflamed and scarring can result. Causes of lung injury include the following: prematurity, low amounts of surfactant, oxygen use, and mechanical ventilation. Risk factors for developing CLD include birth at less than 34 weeks of gestation; birth weight less than 2000 grams (4 pounds, 6.5 ounces); hyaline membrane disease; pulmonary interstitial emphysema; patent ductus arteriosus; Caucasian race; male sex; maternal womb infection (chorioamnionitis); and family history of asthma.

Treatment

Synagis® (palivizumab) is a humanized monoclonal antibody, made using recombinant DNA technology, directed against a site on the antigenic site of the F protein of RSV.\(^3\)

Other RSV preventive agents, including vaccines, have been under development.\(^4\) A recombinant RSV fusion protein nanoparticle vaccine has been shown to induce an immune response in a phase 2 trial.\(^5\)

This policy does not address therapies to treat RSV infection.
Summary of Evidence

For individuals with high-risk indications for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes several RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. Evidence from systematic reviews of RCTs has demonstrated that RSV prophylaxis with Synagis® (palivizumab) is associated with reductions in RSV-related hospitalizations and intensive care unit stays. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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. Relevant outcomes are overall survival, 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 noncontemporaneous controls found fewer RSV infections in palivizumab-treated patients with CF. 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. Relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. Descriptive findings from a consensus panel and case reports of 2 infants with primary immunodeficiencies and 2 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. Relevant outcomes are overall survival, 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 noncontemporaneous 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.
Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

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 2009 American Academy of Pediatrics guidelines.

Practice Guidelines and Position Statements

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2014) updated its guidelines on the use of Synagis® (palivizumab) in high-risk infants. In 2017, the guidelines were reviewed by 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, 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>
<th>Prophylaxis recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Infants born before 29 weeks, 0 days of gestation, during first year of life</td>
<td></td>
</tr>
<tr>
<td>• Infants born before 32 weeks, 0 days of gestation with chronic lung disease of prematurity, during first year of life</td>
<td></td>
</tr>
<tr>
<td>• Children in the second year of life who require 28 or more days of supplemental oxygen and continue to require</td>
<td></td>
</tr>
</tbody>
</table>
Recommendations for Using Palivizumab Prophylaxis

**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 RSV prevention (see Table 2)\(^2^8\).

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

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
<th>SOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater.”</td>
<td>B</td>
<td>Strong</td>
</tr>
<tr>
<td>“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.”</td>
<td>B</td>
<td>Moderate</td>
</tr>
<tr>
<td>“Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the respiratory syncytial virus season to infants who qualify for palivizumab in the first year of life.”</td>
<td>B</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

QOE: Quality of Evidence  
SOR: Strength of Recommendation
Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

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 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.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/99</td>
<td>Add to Prescription Drug Section - New Policy</td>
</tr>
<tr>
<td>11/02/99</td>
<td>Replace policy - Policy reviewed and updated.</td>
</tr>
<tr>
<td>09/21/00</td>
<td>Replace policy - Policy reviewed and updated.</td>
</tr>
<tr>
<td>07/01/02</td>
<td>Replace policy - Policy language revised pertaining to dates of RSV season, making it generic. No criteria changes for prophylactic administration.</td>
</tr>
<tr>
<td>06/17/03</td>
<td>Replace policy - Policy reviewed; no changes required.</td>
</tr>
<tr>
<td>11/16/03</td>
<td>Replace policy - Policy updated with revised recommendations for the use of palivizumab (Synagis) in infants of 32 –35 weeks gestational age</td>
</tr>
<tr>
<td>01/13/04</td>
<td>Replace policy - Policy changed from PR to BC. Policy updated; added indication for infants with hemodynamically significant heart disease and for those born between 32-35 weeks gestation with additional high-risk factors. Policy based on AAP guidelines. Policy held for notification, effective 4/15/04.</td>
</tr>
<tr>
<td>03/08/05</td>
<td>Replace policy - Policy reviewed; references added; RSV immune prophylaxis in stem cell transplantation added to the investigational policy statement.</td>
</tr>
<tr>
<td>01/10/06</td>
<td>Replace policy - Policy reviewed with literature search; no change to policy statement. Information added regarding new liquid formulation of Synagis to policy guidelines.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace policy - Policy reviewed with literature search; no change to policy statement.</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Minor Update - Policy statement clarified regarding definition of weeks of gestation.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace policy - Policy updated with literature search. The policy statement has been modified to reflect the 2009 AAP. References added.</td>
</tr>
<tr>
<td>11/10/09</td>
<td>Minor Update - Minor update was made to number 4 in the policy statement: “infants born before 35 wks of gestation” was deleted and “Infants less than one year of age” was added.</td>
</tr>
<tr>
<td>12/14/10</td>
<td>Replace policy - Policy updated with literature search. References 15 and 16 added. Policy statements unchanged. Reviewed by a practicing pediatrician.</td>
</tr>
<tr>
<td>12/29/10</td>
<td>Codes Updated - Code 90378 added; no other changes.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12/16/11</td>
<td>Replace policy – Policy updated with literature search. Policy statement number 4 modified with removal of “born before 35 weeks of gestation” to be consistent with the AAP guidelines. Other policy statements are unchanged. Codes updated: CPT codes 96365, 96366 and 963372; ICD-10 codes added.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Policy updated with literature search through June 18, 2013. References 3 and 6 added; references 1, 10 and 15 updated. Policy statements unchanged. CPT code 90772, 96365, 96366 and 96372, along with ICD-9 Procedure Code 99.29, removed from policy; these are not reviewed due to the dollar amount charged.</td>
</tr>
<tr>
<td>09/08/14</td>
<td>Annual Review. Policy updated with literature review through July, 2014. References 1-2, 16-17, 20-22, 25, 27-28, 30, 32 added; reference 31 updated; others renumbered/removed. Policy statements revised to reflect the 2014 updated guidance from AAP. Coding update: ICD-9 and ICD-10 codes removed; these do not facilitate administration of the policy.</td>
</tr>
</tbody>
</table>
**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
- Civil Rights Coordinator - Complaints and Appeals
  PO Box 91102, Seattle, WA 98111
  Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
  Email AppealsDepartmentInquiries@Premera.com

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room 509F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice Has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):
لا يوجد عددًا حديثًا منوفقين في قاعدة بيانات برمج الكورسات المتوفرة في Premera Blue Cross. هذا يعني أن هذه المعلومات كانت متوفرة عبر الإنترنت من خلال موقعنا الرسمي. يمكن أن تكون هذه الملاحظات غير دقيقة أو غير دقيقة. قد يكون هناك خطأ في التعليمات المذكورة في هذه المعلومات. قد تحتاج رسائل إعلامية عبر البريد الإلكتروني لمتابعة المعلومات الصحيحة أو الخاطئة. قد تكون هذه المعلومات غير دقيقة أو غير دقيقة. قد تكون هذه المعلومات غير دقيقة أو غير دقيقة. قد تكون هذه المعلومات غير دقيقة أو غير دقيقة.
Call 800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的讯息。本通知可能有关於您透过 Premera Blue Cross 提交的申请或保险的重要讯息。本通知内可能有关於重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):
Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devrez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût.
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan idann. Avi sila a kapab genyen enfòmasyon enpòtan konsanap yow ou sou konven kou vevi asirans lan atrave Premera Blue Cross. Kapab genyen dat ki enpòtan nan avy sila a. Ou ka gen pou pan krik aksyon avan sèten dat limit pou ka tenbe kou vevi asirans sante w la ou sou pou yo ka ede w ak avèk depans yo. Se dwa w pou reserwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):
Tsaab ntawv tshiay no muaj cov ntsihb lus tseem ceeb. Tej zaum tsab ntawv tshiay no muaj cov ntsihb lus tseem ceeb borg kooj daim ntwaw thov kev gab los ngoy koyk kev gab cuam los ntawm Premera Blue Cross. Tej zaum muaj cov hnub tseem ceeb cuam los rau hauv daim ntwaw no. Tej zaum koyj juv uaa tau u ee yam uab keb koyj uas tis pub dhaaw cov cajy nyoyng uas teev tseeg rau hauv daim ntwaw no mas koyj thay juv uab taus kev gab cuam kho mo los ngoy kev gab pob teem tej ngi kho mo ntwaw. Koyj muaj cai kom laww muab cov ntsihb lus no uas tau muab sau uaa koyj hom lub pub daww rau koyj. Hau rau 800-722-1471 (TTY: 800-842-5357).

Ilokano (Ilocano):
Daytoy a Pakdaara ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaara mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonenyo wonno coverage babelen Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaara. Mabalin nga adda rumbeng nga aramideno nga adda sakyb dagiti partikular a naipting ngadda aldaw tapno mapagatinalay tido coverage iti salun-atyo wonno coverage tagaditi gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasabo nga awan iti bayadanyo. Tumawагit iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamà 800-722-1471 (TTY: 800-842-5357).
Japanese (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知には記載されている情報が正確であることをご確認ください。健康保険や補償を維持するには、定期の日までに行動を取らなければならずがあります。ご使用の言語による情報をサポーティが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관련하여 그리고 Premera Blue Cross를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 성명을 귀하의 만족도 비용 부담없이 될 수 있는 권리가 있습니다。800-722-1471 (TTY: 800-842-5357)로 전화하십시오。

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay nagaurang naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang pahina dito sa paunawa. Maaaring magingalangian ka na magsagawa ng habang sa ilang mga tukang panahon unaan mapanatili ang iyong pagsakop sa kalusugan o tulungan sa walang gastos. Mas karapatan ka na makakuha ng ganitong impormasyon at tulungan sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลที่สำคัญ อ้างอิงจากข้อมูลที่มีอยู่ในคู่มือของ Premera Blue Cross และนโยบายในการใช้ที่คุณจะต้องซื้อในกรณีที่คุณจะต้องสามารถทำสิ่งที่ต้องการที่ระบุในคู่มือของ Premera Blue Cross ล้วน หรือเกี่ยวกับการติดตามการเดินทางที่ระบุในคู่มือของ Premera Blue Cross ที่มีให้ข้อมูล คุณจะได้รับการคืนเงินและค่าใช้จ่ายในการเดินทางที่ระบุในคู่มือของ Premera Blue Cross ที่มีให้ข้อมูล.

Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):