Introduction

Treating allergies often involves giving the person small doses of what they are allergic to. This tends to increase a person’s immunity, or tolerance, to the substance. These substances are often given by injections (shots). But a newer method is to put the substance in drops and give them under the tongue. This is called sublingual (which means under the tongue) immunotherapy. This treatment is also sometimes called allergy drops. This policy explains when sublingual immunotherapy is medically necessary.

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.
Sublingual immunotherapy using Oralair®, Grastek®, or Ragwitek® may be considered medically necessary, when used according to Food and Drug Administration labeling, for the treatment of pollen-induced allergic rhinitis or rhinoconjunctivitis when the following conditions are met:

- Patient has a history of rhinitis or rhinoconjunctivitis symptoms related to grass or short ragweed pollen exposure
- Patient has a documented positive pollen-specific skin test or pollen-specific immunoglobulin E test.
  - Allergy must be confirmed by positive skin test or in vitro testing for pollen-specific immunoglobulin E antibodies to the species contained in the product or, for Grastek®, Timothy grass pollen extract, to cross-reactive species
- Patient’s symptoms are not adequately controlled by appropriate pharmacotherapy (see Related Information).

Sublingual immunotherapy using Odactra™ may be considered medically necessary, when used according to Food and Drug Administration labeling, for the treatment of house dust mite-induced allergic rhinitis or rhinoconjunctivitis when the following conditions are met:

- Patient has a history of rhinitis or rhinoconjunctivitis symptoms related to dust mite exposure.
- Patient has a documented positive house dust mite-specific skin test or house dust mite-specific immunoglobulin E test.
  - Allergy must be confirmed by positive skin test, using licensed house dust mite allergen extracts or in vitro testing for house dust mite-specific immunoglobulin E antibodies to the Dermatophagoides farinae or Dermatophagoides pteronyssinus species.
- Patient’s symptoms are not adequately controlled by appropriate pharmacotherapy (see Related Information)

Sublingual immunotherapy as a technique of allergy immunotherapy is considered investigational for all other uses.
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
- Name of sublingual immunotherapy that will be used
- Positive pollen or dust mite specific skin test or IgE test
- Pharmacotherapy attempted

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Unlisted allergy/clinical immunologic service or procedure</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

Use of Oralair®, Grastek®, and Ragwitek®

Contraindications

Contraindications include severe, unstable or uncontrolled asthma; history of any severe local reaction or any severe systemic allergic reaction to sublingual immunotherapy or any severe local reaction to sublingual allergen immunotherapy; and history of eosinophilic esophagitis.

Administration and Dose

- Prescribing information includes a black box warning for severe allergic reactions including anaphylaxis and severe laryngopharyngeal edema. Patients must be prescribed an epinephrine auto-injector and be trained on how to use it.
• Oralair is approved by the Food and Drug Administration (FDA) for patients 10 to 65 years of age. Grastek has been FDA-approved for patients 5 to 65 years of age. Ragwitek has been FDA-approved for patients 18 to 65 years of age.

• Treatment should begin 12 weeks (16 weeks for Oralair) before the expected onset of the allergy-inducing pollen season. Each product is dosed once daily and continued throughout the pollen season (preseasonal dosing).

• The first dose is administered under the supervision of a physician experienced in diagnosing and treating severe allergic reactions. Subsequent doses may be taken at home.

• For Oralair, dose titration is required in patients 10 to 17 years of age. Titration can be completed over 3 days at home, 100 index of reactivity (IR) on day 1, 2 times 100 IR on day 2, and 3 times 100 IR on day 3. In patients between 18 and 65 years, no dose titration is needed; treatment is initiated at the maintenance dose of 300 IR.

• Grastek and Ragwitek both are initiated at the maintenance dose (2800 bioequivalent allergy unit and 12 Amb a 1 unit, respectively).

Use of Odactra™

Contraindications

Contraindications are as listed above for Oralair, Grastek, and Ragwitek.

Administration and Dose

• Prescribing information includes a black box warning for severe allergic reactions including anaphylaxis and severe laryngopharyngeal edema. Patients must be prescribed an epinephrine autoinjector and be trained on how to use it.

• Odactra is approved by FDA for patients 18 to 65 years of age.

• Odactra is dosed at one 12 SQ-HDM tablet daily. Per FDA, “SQ-HDM is the dose unit for ODACTRA. SQ is a method of standardization of biological potency, major allergen content and complexity of the allergen extract. HDM is an abbreviation for house dust mite.”

• The first dose is administered under the supervision of a physician experienced in diagnosing and treating severe allergic reactions. Subsequent doses may be taken at home.
Pharmacotherapy of Pollen-Induced Allergic Rhinitis

There is general agreement from clinical practice guidelines on the pharmacologic treatment of pollen-induced allergic rhinitis or rhinoconjunctivitis:

- Treatment should be individualized based on symptom severity and duration, comorbidities, patient age, preference (eg, route of administration, tolerance for adverse effects), and previous treatment history
- Measures to increase treatment adherence (eg, shared decision making, consideration of the patient’s school or work schedule, use of a medication calendar or check-off list) are encouraged
- Goals of treatment are symptom reduction and improvements in functional capacity and quality of life
- A “step-up” (if treatment is inadequate) or “step-down” (if symptom relief is achieved with other interventions, eg, avoidance) approach to treatment is recommended
- Allergen avoidance is the first step of treatment but may be unrealistic for some patients

Six medication classes are used to treat allergic rhinitis:

1. H1 antihistamines (oral and intranasal)
2. Corticosteroids (oral [short-course for severe disease] and intranasal)
3. Leukotriene receptor antagonists (oral)
4. Sympathomimetic decongestants (oral and intranasal)
5. Chromones (intranasal)
6. Anticholinergic, ipratropium bromide (intranasal)

   - Treatment should be symptom-specific, eg, oral antihistamines may be less effective for prominent congestion than other treatments; prominent rhinorrhea may respond to intranasal ipratropium; rhinitis-only symptoms may be treated with local (intranasal) rather than systemic (oral) therapy
For mild or intermittent symptoms, oral or nasal antihistamine may be considered first-line treatment

Newer generation (selective) oral antihistamines are recommended over older (nonselective) antihistamines. Patients with insomnia and pregnant women may prefer older antihistamines because of their sedating effects and longer safety history, respectively

Intranasal corticosteroids may be effective for more severe or persistent symptoms

Combination treatment (eg, oral antihistamine plus intranasal corticosteroid, intranasal antihistamine and corticosteroid, antihistamine [oral or intranasal] plus sympathomimetic [oral or short-course (≤ 5 days to avoid rebound congestion) intranasal]) may be effective for symptoms nonresponsive to single medications

Oral sympathomimetics may cause insomnia; their use is limited in patients with certain comorbidities (eg, diabetes, unstable hypertension)

Oral leukotriene receptor antagonists may reduce asthma exacerbations in patients with comorbid asthma

**Consideration of Age**

The ages stated in this policy for which Grastek®, Ragwitek®, Oralair®, and Odactra™ are considered medically necessary are based on the ages approved in the FDA labeling.

**Benefit Application**

Sublingual immunotherapy may be offered by specialized clinics.
Description

Sublingual immunotherapy (SLIT) is a potential alternative to subcutaneous immunotherapy (SCIT) for providing allergen-specific therapy. SLIT is proposed as a more convenient alternative delivery route for treating a variety of allergic disorders.

Background

Allergen-specific immunotherapy involves administering well-characterized allergen extracts, the potencies of which are measured and compared with a reference standard. An initial induction or build-up phase progressively increases the allergen dose; this is followed by years of maintenance injections at the highest dose. Allergen-specific immunotherapy has been used to treat various conditions, including insect allergy, allergic rhinitis, and asthma. Subcutaneous immunotherapy is the standard of care. Due to the inconvenience of multiple injections, particularly in children, alternative delivery routes have been investigated; of these, sublingual immunotherapy is the most prominent. Sublingual immunotherapy targets absorption to the sublingual and buccal mucosa. Allergen preparations used for sublingual immunotherapy are held under the tongue for one to several minutes and then swallowed or spit out.

Summary of Evidence

For individuals who have pollen-induced allergic rhinitis or rhinoconjunctivitis who receive SLIT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, quality of life, hospitalizations, medication use, and treatment-related morbidity. Three sublingual pollen extracts are approved by FDA for treatment of pollen-induced allergic rhinitis with or without conjunctivitis. Large, well-designed RCTs supporting the marketing applications for these products have provided consistent evidence of efficacy and safety. Although trials were placebo-controlled, rather than SCIT-controlled, minimum clinically important criteria for demonstrating efficacy were prespecified and were met in most studies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have house dust mite-specific allergy who receive SLIT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, quality of life, hospitalizations, medication use, and treatment-related morbidity. One sublingual extract is approved by the Food and Drug Administration for treatment of house dust mite-induced
allergic rhinitis with or without conjunctivitis. Most RCTs evaluating SLIT for patients with dust mite allergies have been placebo-controlled. Meta-analyses have found high levels of heterogeneity among studies. A more recent meta-analysis, published in 2015, had mixed findings; some outcomes but not others favored SLIT over placebo or pharmacologic treatment. Trials comparing SLIT with SCIT have tended not to find differences in efficacy, but conclusions are limited due to small sample sizes. More recent large, well-designed RCTs supporting the marketing applications for these products have provided consistent evidence of efficacy and safety. Although trials were also placebo-controlled, rather than SCIT-controlled, minimum clinically important criteria for demonstrating efficacy were prespecified and met in the largest studies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcomes.

For individuals who have food allergy who receive SLIT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, quality of life, hospitalizations, medication use, and treatment-related morbidity. A few RCTs have evaluated SLIT for treatment of food allergies, and these studies have had small sample sizes and have tended to be rated as low quality by systematic reviewers. The available RCTs have not consistently found that SLIT is more effective than placebo or oral immunotherapy. No RCTs were identified that compared SLIT with SCIT. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

*American Academy of Otolaryngology–Head and Neck Surgery Foundation*

The American Academy of Otolaryngology–Head and Neck Surgery Foundation (2015) published clinical practice guidelines on allergic rhinitis that contained the following statement:

Clinicians should offer, or refer to a clinician who can offer, immunotherapy (sublingual or subcutaneous) for patients with AR [allergic rhinitis] who have inadequate response to symptoms with pharmacologic therapy with or without environmental controls.

Recommendation based on RCTs [randomized controlled trials] and systematic reviews, with a preponderance of benefit over harm.
The AAAAI and the American College of Allergy, Asthma, and Immunology (2017) jointly published updated practice parameters on sublingual immunotherapy (SLIT). These recommendations apply to use of SLIT agents approved by the Food and Drug Administration at time of publication: 5-grass (Oralair), Timothy grass (Grastek), and ragweed (Ragwitek). Table 1 summarizes statements made.

### Table 1. Recommendations on Use of SLIT

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-approved SLIT should be used to treat allergic rhinitis/rhinoconjunctivitis, and not for any other condition.</td>
<td>Strong</td>
<td>A/B</td>
</tr>
<tr>
<td>SLIT may not be suitable for patients who have conditions that reduce their ability to survive a systemic reaction or the associated treatment</td>
<td>Strong</td>
<td>D</td>
</tr>
<tr>
<td>Given insufficient information on the safety of initiating or continuing SLIT during pregnancy or breastfeeding, it should be used very cautiously in pregnant or breastfeeding patients</td>
<td>Weak</td>
<td>C</td>
</tr>
<tr>
<td>Dosing equivalence should not be assumed between SLIT tablets and extracts of the same allergen; each formulation should have its own safety profile established</td>
<td>Weak</td>
<td>C</td>
</tr>
<tr>
<td>First doses of SLIT should be administered in a medical facility under the supervision of a physician or other health care professional with experience in the diagnosis and treatment of anaphylaxis. The patient should be observed in the medical facility for 30 minutes after the administration of SLIT</td>
<td>Strong</td>
<td>D</td>
</tr>
<tr>
<td>Epinephrine should be prescribed to patients receiving SLIT tablets, and patients should be trained in its use</td>
<td>Strong</td>
<td>D</td>
</tr>
<tr>
<td>The SLIT dose should be reduced if a patient misses treatment for &gt;1 week</td>
<td>Weak</td>
<td>D</td>
</tr>
<tr>
<td>Patients receiving SLIT should be scheduled for regular follow-up care with a specialist</td>
<td>Moderate</td>
<td>D</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; LOE: level of evidence; SLIT: sublingual immunotherapy; SOR: strength of recommendation.

The AAAAI and the European Academy of Allergy and Clinical Immunology (2013) published a consensus report on allergy immunotherapy. The report summarized the literature and current practices in the United States and Europe; it did not include clinical recommendations. The report concluded: “Allergy immunotherapy (AIT) is effective in reducing symptoms of allergic asthma and rhinitis, as well as venom-induced anaphylaxis. In addition, AIT modifies the underlying course of disease. However, AIT remains a niche treatment secondary to
symptomatic drugs because of its cost, long duration of treatment and concerns regarding safety and effectiveness."

A joint task force of the AAAAI, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology (2011) issued updated practice parameters for allergen immunotherapy. The document stated that randomized controlled trials of sublingual immunotherapy (SLIT) in patients with allergic rhinitis and asthma have demonstrated significant improvement in symptoms. The authors noted that there were no Food and Drug Administration-approved extract formulations for a noninjection route of immunotherapy.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

### Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT Number</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02304991</td>
<td>Peanut Sublingual Immunotherapy Induction of Clinical Tolerance of Newly Diagnosed Peanut Allergic 12 to 48 Month Old Children</td>
<td>50</td>
<td>June 2020</td>
</tr>
<tr>
<td>NCT02216175</td>
<td>Phase 2/3 Clinical Trial to Assess the Effect of a Sublingual Treatment Phase Prior to Oral Immunotherapy in Children With Cow’s Milk Allergy</td>
<td>66</td>
<td>Dec 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01373242</td>
<td>Peanut Sublingual Immunotherapy and Induction of Clinical Tolerance in Peanut Allergic Children</td>
<td>49</td>
<td>Aug 2018 (completed)</td>
</tr>
<tr>
<td>NCT02443805*</td>
<td>Efficacy and Safety of STG320 Sublingual Tablets of House Dust Mite (HDM) Allergen Extracts in Adults and Adolescents With HDM-associated Allergic Rhinitis</td>
<td>1607</td>
<td>Jun 2018 (completed)</td>
</tr>
<tr>
<td>NCT02005627</td>
<td>Randomized Placebo-controlled Study of Grass Pollen Allergen Immunotherapy Tablet (AIT) for Seasonal Rhinitis: Time Course of Nasal, Cutaneous and Immunological Outcomes</td>
<td>46</td>
<td>Mar 2017 (unknown)</td>
</tr>
<tr>
<td>NCT02277483</td>
<td>Efficacy and Safety of LAIS® Mites Sublingual Tablets in Patients Aged Over 60 Years Suffering From House Dust</td>
<td>45</td>
<td>Dec 2016</td>
</tr>
</tbody>
</table>
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In April 2014, the first sublingual allergen extract tablets were approved by the U.S. Food and Drug Administration (FDA) through the biologics license application process for treatment of pollen-induced allergic rhinitis with or without conjunctivitis:

- On April 1, FDA approved Oralair® (Stallergenes) allergen extract for patients 10 to 65 years of age. Oralair® contains freeze-dried pollen allergen extracts of 5 grasses: Kentucky Blue Grass, Orchard, Perennial Rye, Sweet Vernal, and Timothy.

- On April 11, FDA approved Grastek® (Merck) Timothy grass pollen (Phleum pretense) allergen extract for patients 5 to 65 years of age. (Grastek® is marketed in Europe as Grazax®.)

- On April 17, the FDA approved Ragwitek® (Merck) short ragweed pollen allergen extract for patients 18 to 65 years of age.

In March 2017, FDA approved Odactra (Merck) allergan extract for patients 18 to 65 years of age who have house dust mite-induced allergic rhinitis with or without conjunctivitis. Odactra contains freeze-dried extracts of dust mites (Dermatophagoides farinae and Dermatophagoides pteronyssinus).

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/05/97</td>
<td>Add to Medicine Section - New Policy</td>
</tr>
<tr>
<td>11/03/98</td>
<td>Replace Policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy regarding sublingual immunotherapy and SET-guided immunotherapy reviewed; policy statement unchanged.</td>
</tr>
<tr>
<td>08/09/05</td>
<td>Replace Policy - Policy revised with literature search; policy retitled, now focuses solely on sublingual immunotherapy; other forms of immunotherapy no longer addressed.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<td>11/14/06</td>
<td>Replace Policy - Policy updated with literature review; policy statement unchanged. References added.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>05/12/09</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement.</td>
</tr>
<tr>
<td>05/11/10</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
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<td>Replace policy. Policy updated with literature review; no change in policy statement. References 2, 4, 5, 10-12 added; other references renumbered/removed.</td>
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<tr>
<td>07/25/12</td>
<td>Related Policies Update – Title to 2.01.01 has been changed to include: (i.e., Multiple Chemical Sensitivities)</td>
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<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<tr>
<td>05/28/13</td>
<td>Replace policy. Policy updated with literature review through January 22, 2013; no change in policy statement. References 4, 8 and 14 added; other references renumbered/removed.</td>
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<tr>
<td>07/24/13</td>
<td>Replace policy. Policy updated with literature review through April 20, 2013. No change in policy statement. References 2, 3, 14, 17 and 18 added; other references renumbered/removed.</td>
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<td>07/14/14</td>
<td>Annual Review. Policy statement changed to medically necessary for Oralair®, Grastek®, and Ragwitek® to treat grass or short ragweed pollen allergies when criteria are met. These medications are investigational for all other uses. Policy</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------------------------</td>
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<tr>
<td>08/28/15</td>
<td>Update Related Policies. Remove 2.01.01 as it was archived.</td>
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<tr>
<td>12/01/16</td>
<td>Annual Review, approved November 8, 2016. Policy updated with literature review through August 11, 2016; references 2, 9, 13, 15, and 24-26 added. Policy statements unchanged. Language added to the Rationale section to indicate that the age application of the policy is based on FDA-labeling.</td>
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<tr>
<td>03/03/17</td>
<td>Policy moved to new format. No change to policy statement.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Annual Review, approved December 13, 2018. Policy updated with literature review through August 2018; references 22-24, 34, and 37 added; references 7 and 14 updated. Policy statement added that sublingual immunotherapy using Odactra may be considered medically necessary, when used according to Food and Drug Administration labeling, for the treatment of house dust mite-induced allergic rhinitis or rhinoconjunctivitis when the specified conditions are met.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
<tr>
<td>01/01/20</td>
<td>Annual Review, approved December 10, 2019. Policy updated with literature review through August 2019; references added, Policy statements unchanged.</td>
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</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 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.

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Email AppealsDepartmentInquiries@Premera.com

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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)

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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 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 clave 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):