

MEDICAL POLICY – 2.01.17


Sublingual Immunotherapy as a Technique of Allergen-Specific Therapy

BCBSA Ref Policy: 2.01.17

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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

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.

Policy Coverage Criteria

Sublingual Immunotherapy	Medical Necessity
<ul style="list-style-type: none"> • Oralair® • Grastek® • Ragwitek® • Odactra™ 	<p>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:</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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). <p>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:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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) <p>Sublingual immunotherapy as a technique of allergy immunotherapy is considered investigational for all other uses.</p>



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

Code	Description
CPT	
95199	Unlisted allergy/clinical immunologic service or procedure

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. H₁antihistamines (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.

Evidence Review



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. 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. 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. 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

In 2015, the American Academy of Otolaryngology–Head and Neck Surgery Foundation published clinical practice guidelines on allergic rhinitis that contained the following statement³³:

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.



American Academy of Allergy, Asthma and Immunology et al

In 2017, the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology jointly published updated practice parameters on sublingual immunotherapy (SLIT).³⁴ 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

Recommendation	SOR	LOE
FDA-approved SLIT should be used to treat allergic rhinitis/rhinoconjunctivitis, and not for any other condition.	Strong	A/B
SLIT may not be suitable for patients who have conditions that reduce their ability to survive a systemic reaction or the associated treatment	Strong	D
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	Weak	C
Dosing equivalence should not be assumed between SLIT tablets and extracts of the same allergen; each formulation should have its own safety profile established	Weak	C
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	Strong	D
Epinephrine should be prescribed to patients receiving SLIT tablets, and patients should be trained in its use	Strong	D
The SLIT dose should be reduced if a patient misses treatment for >1 week	Weak	D
Patients receiving SLIT should be scheduled for regular follow-up care with a specialist	Moderate	D

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

In 2013, AAAAI and the European Academy of Allergy and Clinical Immunology published a consensus report on allergy immunotherapy.³⁵ 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....”

In 2011, a joint task force of the AAAAI, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology issued updated practice parameters for allergen immunotherapy.³⁶ 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.

European Academy of Allergy and Clinical Immunology

In 2018, the European Academy of Allergy and Clinical Immunology published evidence-based guidelines on allergic rhinoconjunctivitis.³⁷ The EAACI guidelines suggest that both SLIT and subcutaneous immunotherapy are effective for allergic rhinitis (AR), however, there was insufficient data to determine which is more effective. **Table 2** summarizes the recommendations for treatment of adults using SLIT.

Table 2. Recommendations on Use of SLIT

Recommendation	GOE	LOE
For seasonal allergic rhinitis		
“Pre-/coseasonal SLIT is recommended for seasonal ARs for short-term benefit”	A	I
“Continuous SLIT can be recommended for seasonal AR for short-term benefit”	A	I
“SLIT with aqueous solutions can be recommended for seasonal AR for short-term benefit”	B	I
“SLIT with grass pollen tablets is recommended for AR for short-term benefit”	A	I
“Grass pollen SLIT tablets or solution with continuous therapy is recommended for AR for long-term benefit”	A	I
For perennial allergic rhinitis		
“SLIT with aqueous solutions may not be recommended for perennial AR for short-term benefit”	C	I
“SLIT with HDM tablets is recommended for AR for short-term benefit”	A	I
“HDM SLIT tablet with continuous therapy can be recommended for AR for long-term benefit”	B	I

FDA: Food and Drug Administration; GOE: grade of evidence; LOE: level of evidence; SLIT: sublingual immunotherapy.



In 2014, the European Academy of Allergy and Clinical Immunology published evidence-based guidelines on the diagnosis and management of food allergy.³⁸ Based on single-arm studies (level III evidence), the guideline authors concluded: "Food allergen-specific immunotherapy for primary food allergy is a promising immunomodulatory treatment approach, but it is associated with risk of adverse reactions, including anaphylaxis; it is therefore not currently recommended for routine clinical use." Based on expert opinion (level IV evidence), it was recommended: "For patients with respiratory or other allergy symptoms to inhalant allergens that may also cause cross-reactive food allergy, specific immunotherapy is only recommended for the treatment of the respiratory symptoms, not for cross-reactive food allergy."

World Allergy Organization

In 2013, the World Allergy Organization updated its position paper on SLIT.³⁹ Evidence-based conclusions included:

- "Grass-pollen sublingual immunotherapy (SLIT) is effective in seasonal allergic rhinitis in children ≥ 5 years of age."
- "Grass-pollen SLIT is probably effective in children ≥ 4 to < 5 years of age."
- "Grass or house dust mite (HDM) SLIT may be used for allergic rhinitis in children with asthma... More large randomized trials are needed.... "
- "Use of SLIT for latex allergy, atopic dermatitis, food allergy, and Hymenoptera venom is under investigation; more evidence is needed to support the use of SLIT for these indications"
- "Patients eligible for SLIT should have a 'history of symptoms related to allergen exposure and a documented positive allergen-specific IgE [immunoglobulin E] test.'"
- "SLIT may be considered as initial treatment ... particularly [for] patients whose allergy is uncontrolled with optimal pharmacotherapy (that is, those who have severe chronic upper airway disease) ... patients in whom pharmacotherapy induces undesirable side effects ... patients who do not want to be on constant or long-term pharmacotherapy."
- "Failure of pharmacotherapy is not an essential prerequisite for ... SLIT."



Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in [Table 3](#).

Table 3. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01373242	Peanut Sublingual Immunotherapy and Induction of Clinical Tolerance in Peanut Allergic Children	49	Aug 2018 (ongoing)
NCT02304991	Peanut Sublingual Immunotherapy Induction of Clinical Tolerance of Newly Diagnosed Peanut Allergic 12 to 48 Month Old Children	50	May 2020
NCT02216175	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	66	Dec 2020
Unpublished			
NCT02443805^a	Efficacy and Safety of STG320 Sublingual Tablets of House Dust Mite (HDM) Allergen Extracts in Adults and Adolescents With HDM-associated Allergic Rhinitis	1607	Jun 2018 (completed)
NCT02005627	Randomized Placebo-controlled Study of Grass Pollen Allergen Immunotherapy Tablet (AIT) for Seasonal Rhinitis: Time Course of Nasal, Cutaneous and Immunological Outcomes	46	Mar 2017 (unknown)
NCT02277483	Efficacy and Safety of LAIS® Mites Sublingual Tablets in Patients Aged Over 60 Years Suffering From House Dust Mite-induced Allergic Rhino-conjunctivitis With/Without Asthma	45	Dec 2016 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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 pratense) 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) allergen 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*).

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History



Date	Comments
11/05/97	Add to Medicine Section - New Policy
11/03/98	Replace Policy - Scheduled review, no criteria changes.
08/12/03	Replace Policy - Policy regarding sublingual immunotherapy and SET-guided immunotherapy reviewed; policy statement unchanged.
08/09/05	Replace Policy - Policy revised with literature search; policy retitled, now focuses solely on sublingual immunotherapy; other forms of immunotherapy no longer addressed.
06/16/06	Update Scope and Disclaimer - No other changes.
11/14/06	Replace Policy - Policy updated with literature review; policy statement unchanged. References added.
05/13/08	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
05/12/09	Replace Policy - Policy updated with literature search; no change to the policy statement.
05/11/10	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
06/13/11	Replace Policy - Policy updated with literature review; no change in policy statement. References 8 and 11 added; other references renumbered/removed. ICD-10 codes added to policy.
05/22/12	Replace policy. Policy updated with literature review; no change in policy statement. References 2, 4, 5, 10-12 added; other references renumbered/removed.
07/25/12	Related Policies Update – Title to 2.01.01 has been changed to include: (i.e., Multiple Chemical Sensitivities)
08/24/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	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.
07/24/13	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.
07/14/14	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 updated with literature review through April, 2014. References 1-8, 14-16, 20-42, 47, 52, and 55 added, 10 and 54 updated; 22 deleted; others renumbered/removed. Policy statement changed as noted. Coding update: CPT codes 95144-95165 and ICD-9 and ICD-10 diagnosis and procedure codes removed from policy.
06/17/15	Annual Review. Policy updated with literature review through March 11, 2015;



Date	Comments
	references 12, 29-30, 42, 44-47, 51-54, 57-58, and 69-70 added; reference 41 updated. Policy statements unchanged.
08/28/15	Update Related Policies. Remove 2.01.01 as it was archived.
12/01/16	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.
03/03/17	Policy moved to new format. No change to policy statement.
12/01/17	Annual Review, approved November 9, 2017. Policy updated with literature review through August 24, 2017; references 15-17 and 25 added; note 11 updated. Policy statements unchanged.
01/01/19	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.
03/01/19	Minor update, added Documentation Requirements section.

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 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)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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).

አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታወቅ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。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者費用補貼。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)。

Oromoo (Cushite):

Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

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 devez 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 ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnu ntawm Premera Blue Cross. Tej zaum muaj cov hnu tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas pab kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag 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 esserci 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. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (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。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポート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 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາອ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កំណត់ថ្លៃជាតំបន់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអន្តរជាតិរបស់អ្នក ឬប្រាក់ដុល្លារចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

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).

Română (Romanian):

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

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).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 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):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).