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

- Oralair
- Grastek
- Ragwitek
- Odactra

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sublingual immunotherapy using Oralair, Grastek, or Ragwitek may be considered medically necessary, when used according to U.S. Food and Drug Administration labeling (FDA), for the treatment of pollen-induced allergic rhinitis or rhinoconjunctivitis when the following conditions are met:</strong></td>
</tr>
<tr>
<td>- Individual has a history of rhinitis or rhinoconjunctivitis symptoms related to grass or short ragweed pollen exposure</td>
</tr>
<tr>
<td>- Individual has a documented positive pollen-specific skin test or pollen-specific immunoglobulin E test</td>
</tr>
<tr>
<td>- 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</td>
</tr>
<tr>
<td>- Individual’s symptoms are not adequately controlled by appropriate pharmacotherapy (see Related Information)</td>
</tr>
<tr>
<td><strong>Sublingual immunotherapy using Odactra may be considered medically necessary, when used according to FDA labeling, for the treatment of house dust mite-induced allergic rhinitis or rhinoconjunctivitis when the following conditions are met:</strong></td>
</tr>
<tr>
<td>- Individual has a history of rhinitis or rhinoconjunctivitis symptoms related to dust mite exposure</td>
</tr>
<tr>
<td>- Individual has a documented positive house dust mite-specific skin test or house dust mite-specific immunoglobulin E test</td>
</tr>
<tr>
<td>- 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</td>
</tr>
<tr>
<td>- Individual’s symptoms are not adequately controlled by appropriate pharmacotherapy (see Related Information)</td>
</tr>
</tbody>
</table>

**Sublingual immunotherapy as a technique of allergy immunotherapy is considered investigational for all other uses.**
**Documentation Requirements**

The individual’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>

**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. Individuals must be prescribed an epinephrine auto-injector and be trained on how to use it.
- Oralair is approved by the U.S. Food and Drug Administration (FDA) for individuals 10 to 65 years of age. Grastek and Ragwitek have been FDA-approved for individuals 5 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 (precoseasonal 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 individuals 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 individuals 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. Individuals must be prescribed an epinephrine autoinjector and be trained on how to use it.

- Odactra is approved by the FDA for individuals 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 and age, preference (e.g., route of administration, tolerance for adverse effects), and previous treatment history.
- Measures to increase treatment adherence (e.g., shared decision making, consideration of the individual’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, e.g., avoidance) approach to treatment is recommended.
- Allergen avoidance is the first step of treatment but may be unrealistic for some individuals.

Medication classes commonly 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, e.g., 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, an oral or nasal antihistamine may be considered first-line treatment.
- Newer generation (selective) oral antihistamines are recommended over older (nonselective) antihistamines. Individuals 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 (e.g., 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 individuals with certain comorbidities (e.g., diabetes, unstable hypertension).

• Oral leukotriene receptor antagonists may reduce asthma exacerbations in individuals 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. SCIT is the
standard of care. Due to the inconvenience of multiple injections, particularly in children,
alternative delivery routes have been investigated; of these, SLIT is the most prominent. SLIT
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 randomized controlled trials (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 the U.S. Food and Drug
Administration (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 an 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 FDA for treatment of house dust mite-induced allergic rhinitis with or without
conjunctivitis. Most RCTs evaluating SLIT for individuals 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. However, 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 an improvement in the net health outcome.

For individuals who have food allergy who receive SLIT, the evidence includes RCTs, systematic
reviews, and an unpublished interventional study. 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 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 in patients with non-peanut allergies; in patients with peanut allergy, while available studies indicate efficacy of SLIT relative to placebo or pre-treatment baseline, SLIT has not been found to be as effective as oral immunotherapy. No RCTs were identified that compared SLIT with SCIT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished trials that might influence this review are listed in Table 1.

Table 1. 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>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>Mar 2022</td>
</tr>
<tr>
<td>NCT05113394</td>
<td>Preventing Childhood Asthma Using Prophylactic House Dust Mite Allergen Immunotherapy</td>
<td>270</td>
<td>Aug 2029</td>
</tr>
<tr>
<td>NCT04881461</td>
<td>A Randomised, Parallel-group, Double-blind, Placebo-controlled Phase III Trial Assessing the Efficacy and Safety of 5-grass Mix SLIT-drops in Adults With Grass Pollen-induced Rhinoconjunctivitis</td>
<td>445</td>
<td>Sept 2023</td>
</tr>
<tr>
<td>NCT05476484</td>
<td>Comparative Real World Effectiveness of SQ Sublingual Immunotherapy (SLIT)-Tablets vs. Controls in Allergic Rhinitis and Asthma - Outcomes From a Multinational Register Study</td>
<td>49,844</td>
<td>Jun 2024</td>
</tr>
<tr>
<td>NCT05521711</td>
<td>TRADE Trial - Tree Nut Immunotherapy Route Development and Evaluation</td>
<td>60</td>
<td>Jan 2027</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT Number</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>------------</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>Dec 2020 (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>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 statement:\(^3\):

“Clinicians should offer, or refer to a clinician who can offer, immunotherapy (sublingual or subcutaneous) for individuals 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.”
In 2020, the American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) recommended allergen immunotherapy (either subcutaneous immunotherapy [SCIT] or sublingual immunotherapy [SLIT]) be offered to individuals with moderate or severe allergic rhinitis who are not controlled with allergen avoidance or pharmacotherapy; prefer immunotherapy; or those who may benefit due to comorbid conditions such as asthma.36

In 2017, the AAAAI and the ACAAI jointly published updated practice parameters on SLIT.37 These recommendations apply to the use of SLIT agents approved by the FDA at time of publication: 5-grass (Oralair), Timothy grass (Grastek), and ragweed (Ragwitek). Table 2 summarizes statements made.

### Table 2. 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.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In April 2014, the first sublingual allergen extract tablets were approved by the FDA through the biologics license application process for treatment of pollen-induced allergic rhinitis with or without conjunctivitis:

- On April 1, the FDA approved Oralair (Stallergenes) allergen extract for individuals 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, the FDA approved Grastek (Merck) Timothy grass pollen (Phleum pretense) allergen extract for individuals 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 individuals 18 to 65 years of age. On April 16, 2021, Ragwitek received FDA approval for use in individuals 5 to 17 years of age.

In March 2017, the FDA approved Odactra (Merck) allergen extract for individuals 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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>06/13/11</td>
<td>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.</td>
</tr>
<tr>
<td>05/22/12</td>
<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>
</tr>
<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>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<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 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.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>08/28/15</td>
<td>Update Related Policies. Remove 2.01.01 as it was archived.</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>04/01/21</td>
<td>Update Related Policies. Policy 2.04.76 archived and removed.</td>
</tr>
<tr>
<td>01/01/22</td>
<td>Annual Review, approved December 2, 2021. Policy updated with literature review through August 24, 2021; references added. Updated Ragwitek prescribing information to note April 2021 FDA approval for use in children aged 5-17 years.</td>
</tr>
<tr>
<td>12/01/22</td>
<td>Annual Review, approved November 21, 2022. Policy updated with literature review through August 22, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from &quot;patient&quot; to &quot;individual&quot; throughout the policy for standardization.</td>
</tr>
<tr>
<td>01/01/24</td>
<td>Annual Review, approved December 11, 2023. Policy updated with literature review through August 17, 2023; references added. Policy statements unchanged.</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). ©2024 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 (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and 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, sex, gender identity, or sexual orientation, 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: 711, 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 Ave 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.


Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURARK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).


注意: 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。


주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711)번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).


注意事項: 日本語を話される場合、無料の語音支援をご利用いただけます。800-722-1471 (TTY: 711)まで、お電話にてご連絡ください。


УБАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

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محمد: إذا كنت تتحدث اللغة، فإن خدمات المساعدة اللغوية تتوفر لك بالمجان. اتصل رقم 800-722-1471 (TTY: 711).

 rápida: se está hablando español, hay servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).