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 | Medical Necessity
--- | ---
- Oralair®
- Grastek®
- Ragwitek®

Sublingual immunotherapy using Oralair®, Grastek®, or Ragwitek® may be considered medically necessary, when used according to U. S. Food and Drug Administration labeling, for the treatment of pollen-induced allergic rhinitis 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 as a technique of allergy immunotherapy is considered investigational for all other uses.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Unlisted allergy/clinical immunologic service or procedure</td>
</tr>
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</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).
Use of Oralair®, Grastek®, and Ragwitek®

Contraindications

Contraindications include severe, unstable or uncontrolled asthma; history of any severe reactions (local or systemic) to sublingual or other immunotherapy; or a 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 (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 patients 10 to 17 years of age. Titration can be completed over 3 days at home, 100 IR [index of reactivity] 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).

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)
   
   o 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

   o For mild or intermittent symptoms, oral or nasal antihistamine may be considered first-line treatment

   o Newer generation (selective) oral antihistamines generally 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 mellitus, 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®, and Oralair®, are considered medically necessary is based on the ages approved in the FDA labeling.

**Benefit Application**

Sublingual immunotherapy may be offered by specialized clinics.

**Evidence Review**

**Background**

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.

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 multiple years of maintenance injections at the highest dose. Allergen-specific immunotherapy has been used to treat a variety of 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 randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, medication use, and treatment-related morbidity. Three sublingual pollen extracts are U.S. Food and Drug Administration-approved 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. Most RCTs evaluating SLIT for patients with dust mite allergies have been placebo-controlled. Meta-analyses have found high levels of heterogeneity among studies. The most recent meta-analysis, published in 2015, had mixed findings; some outcomes but not others favored SLIT over placebo or pharmacologic treatment. Trials comparing SLIT and SCIT have tended not to find differences in efficacy, but conclusions are limited due to small sample sizes. The evidence is insufficient to determine the effects of the technology on 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 and 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 a clinical practice guideline 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 who have inadequate response to symptoms with pharmacologic therapy with or without environmental controls.

Recommendation based on RCTs and systematic reviews, with a preponderance of benefit over harm.

American Academy of Allergy, Asthma and Immunology et al

In 2013, the American Academy of Allergy, Asthma and Immunology and the European Academy of Allergy and Clinical Immunology 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 authors 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 American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology 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.
**European Academy of Allergy and Clinical Immunology**

In 2014, the European Academy of Allergy and Clinical Immunology published evidence-based guidelines on the diagnosis and management of food allergy.\(^{33}\) Based on single-arm studies (level III evidence), 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), guideline authors stated: “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.\(^{34}\) 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 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>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></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>1740</td>
<td>Apr 2018</td>
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<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>53</td>
<td>Dec 2018</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>Apr 2020</td>
</tr>
<tr>
<td>NCT01373242</td>
<td>Peanut Sublingual Immunotherapy and Induction of Clinical Tolerance in Peanut Allergic Children</td>
<td>50</td>
<td>Jun 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02277483</td>
<td>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 Text</td>
<td>45</td>
<td>Dec 2016 (unknown)</td>
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<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 Text</td>
<td>46</td>
<td>Mar 2017 (unknown)</td>
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</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
Regulatory Status

In April 2014, 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, the FDA approved Oralair® (Stallergenes S.A., Antony, France) 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, the FDA approved Grastek® (Merck, Darmstadt, Germany) Timothy grass pollen (Phleum pretense) allergen extract (Merck, Whitehouse Station, NJ) for patients 5 to 65 years of age. Grastek® is marketed in Europe as Grazax®.

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

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<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>
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<td>11/14/06</td>
<td>Replace Policy - Policy updated with literature review; policy statement unchanged. References added.</td>
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<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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<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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<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<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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<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>
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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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<td>03/03/17</td>
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**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
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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

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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:
Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
U.S. Department of Health and Human Services
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
U.S. Department of Health and Human Services
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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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).

-Amharic (Amharic):

- Arabic (Arabic):

- Chinese (Chinese):

- Creole (Ivory Coast): Avis a gen Enfòmasyon Enpòtan lapadan. Avi a gen Enfòmasyon Enpòtan ki enpòtan nan aplikasyon yon lan oswa ki enpòtan nan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan ari sa a. Ou ka gen pou nan en fòk ak ase ajen sa a sèt livil pou ka men ki enpòtan nan ari sa a. Ou ki enpòtan nan kouvèti asirans sa a lan os wa sosyodans sa a. Ou ki enpòtan nan kouvèti asirans sa a lan os wa sosyodans sa a. You can also file a civil rights complaint with the U.S. Department of Health and Human Services. Complaint forms are available at

- Creole (Cayenne):

- English:

- French (French):

- German (Deutsche):

- Hindi (Hindi):

- Indonesian (Bahasa Indonesia):

- Italian (Italian):

- Japanese (Japanese):

- Karen (Karen): Tsaaw ntauw tshaj no muaj cov ntsiab lus tseem ceeb. Tej zauram tsaw ntauw tshaj no muaj cov ntsiab lus tseem ceeb tsoj koi dain twav thov kev pab los yoy koi qhoj kev pab cuam los ntsaw Premera Blue Cross. Tej zauram tsaw ntauw hneb tseem ceeb usw pav tsoj koi dain twav no. Tej zauram tsaw ntauw tshaj no muaj cov ntsiab lus tseem ceeb los ntsaw Premera Blue Cross.

- Japanese (Japanese):

- Khmer (Khmer):

- Korean (Korean):

- Kreyòl ayisyen (Creole):

- Lao (Hmong):

- Malay (Malay):

- Marathi (Marathi):

- Mozambiquense (Português):

- Nepali (Nepali):

- Polish (Polski):

- Portuguese (Português):

- Punjabi (Punjabi):

- Quechua (Quechua):

- Romanian (Română):

- Russian (Русский):

- Spanish (Español):

- Tamil (Tamil):

- Turkish (Türkçe):

- Urdu (Urdi):

- Vietnamese (Vietnamese):

- Xhosa (Xhosa):

- Yoruba (Yoruba)
800-722-1471 (TTY: 800-842-5357)