Medical Policy

Sublingual Immunotherapy as a Technique of Allergen-Specific Therapy

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Policy Number: 588
BCBSA Reference Number: 2.01.17

Related Policies
- Serial Endpoint Testing for the Diagnosis and Treatment of Allergic Disorders, #270
- Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Clinical Ecology), #264

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Sublingual immunotherapy using Oralair®, Grastek®, or Ragwitek® is MEDICALLY NECESSARY, when used according to FDA-labelling, 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 (IgE) test.
- Patient’s symptoms are not adequately controlled by appropriate pharmacotherapy.

Sublingual immunotherapy as a technique of allergy immunotherapy is INVESTIGATIONAL for all other uses.

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<td>Commercial PPO and Indemnity</td>
<td>No</td>
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<td>Medicare HMO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

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 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 injection of allergen-specific immunotherapy (SCIT) is the standard approach. Due to the inconvenience of multiple injections, particularly in children, alternative delivery routes have been investigated; of these, sublingual immunotherapy (SLIT) is the most prominent. SLIT targets absorption to the sublingual and buccal mucosa. Allergen preparations used for SLIT are held under the tongue for one to several minutes and then swallowed or spit out.

Summary
Sublingual immunotherapy (SLIT) is a potential alternative to subcutaneous immunotherapy (SCIT) for providing allergen-specific therapy. Three new sublingual pollen extracts (1 multiple-allergen product [Oralair®], 2 single-allergen products [Grastek® and Ragwitek®]) were FDA-approved for treatment of pollen-induced allergic rhinitis with or without conjunctivitis. Large, well-designed, randomized controlled trials supporting the marketing applications for these products provide 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. Patients in these trials had received previous treatment for their pollen-induced rhinitis or rhinoconjunctivitis symptoms. Therefore, SLIT using Oralair®, Grastek®, or Ragwitek® may be considered medically necessary in patients with pollen-induced allergic rhinitis or rhinoconjunctivitis who have symptoms uncontrolled by pharmacologic treatment.

SLIT is being investigated for other allergies, eg, other seasonal allergies, food allergies, and in patients sensitized to house dust mites. Current evidence is insufficient to form any conclusion about the use of SLIT for these indications, and FDA-approved allergy extracts for these uses are lacking. Therefore, SLIT is investigational for all other uses.

Some evidence from clinical trials has been published on the comparative effectiveness of SLIT versus SCIT, but the quantity and quality of evidence is less than that for efficacy versus placebo. Several 2013 systematic reviews tended to find better outcomes with SCIT than with SLIT, but findings were inconclusive due to small numbers of trials and variability in study design. There also are insufficient data to draw firm conclusions about the relative safety of SLIT versus SCIT. A 2012 meta-analysis of placebo-
controlled trials suggested that there may be more mild-to-moderate adverse events with SLIT than with
SCIT, but there are data only on a few serious adverse events.

Policy History

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<td>12/2011</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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<td>6/2010</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


