MEDICAL POLICY

Excellus

SUBJECT: ALLERGEN IMMUNOTHERAPY	EFFECTIVE DATE: 01/20/00 REVISED DATE: 12/20/01, 10/16/02, 10/15/03, 02/19/04, 12/16/04, 11/17/05, 09/21/06, 09/20/07, 09/18/08, 09/17/09, 09/16/10, 09/15/11, 09/20/12, 09/19/13, 08/21/14, 09/17/15, 09/15/16, 09/21/17, 09/20/18
POLICY NUMBER: 2.01.11 CATEGORY: Technology Assessment	PAGE: 1 OF: 8

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer reviewed literature, allergen immunotherapy is considered **medically appropriate** in patients:
   A. with demonstrated hypersensitivity that cannot be adequately managed by medications or avoidance, and
   B. when there is a desire to avoid long-term pharmacotherapy, or
   C. in patients with coexisting allergic rhinitis and asthma where symptoms of asthma occur after natural exposure to aeroallergens and there is demonstrable evidence of clinically relevant specific IgE.

II. Based upon our criteria and assessment of the peer-reviewed literature, the following methods of immunotherapy are considered **investigational**:
   A. Acupuncture;
   B. DNA immunization/vaccination;
   C. Immunization with immunostimulatory sequences;
   D. Intranasal therapy;
   E. Mutated protein therapy;
   F. Peptide therapy;
   G. Provocative-neutralization therapy for food allergies;
   H. Repository emulsion therapy;
   I. Serial dilution endpoint titration therapy (Rinkel therapy);
   J. Sublingual-swallow, sublingual-spit, oral therapy (administration of antigen drops/tablets under the tongue) that has not been approved for marketing via these routes of administration by the U. S. Food and Drug Administration (FDA); and
   K. Urine autoinjections, autogenous urine immunization (intramuscular injections of sterilized urine).

III. Contraindications to sublingual immunotherapy (SLIT) with FDA approved formulations:
   A. severe, unstable or uncontrolled asthma;
   B. history of any severe local reaction or any severe systemic allergic reaction to SLIT; and
   C. history of eosinophilic esophagitis for Grastek® and Ragwitek®.

This policy does not address Xolair (omalizumab). Refer to the Health Plan Drug policy regarding medical necessity criteria for Xolair.

Refer to Corporate Medical Policy # 2.01.04 regarding Clinical Ecology/ Multiple Chemical Sensitivities/Idiopathic Environmental Intolerance.

Refer to Corporate Medical Policy # 2.01.10 regarding Allergy Testing.

Refer to Corporate Medical Policy # 8.01.20 regarding Acupuncture.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

I. The Center for Biologics Evaluation and Research (CBER) regulates allergenic products. Currently, there are two types of licensed allergen extracts administered for allergen immunotherapy:
   A. **Injectable allergen extracts:** Benefits for injections of allergens should be individualized for each patient and are considered under the *medical portion of the member's subscriber contract*, when medically appropriate.
   B. **Sublingual allergen extract tablets:** Sublingual immunotherapy (SLIT) formulations that have been approved for marketing by the FDA, is dispensed by a pharmacist and benefits are considered under the *pharmacy portion of the member's subscriber contract*, when medically appropriate. The first dose of sublingual immunotherapy is administered in a healthcare setting under the supervision of a physician for monitoring of adverse reactions.

II. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Allergen immunotherapy, desensitization or hypersensitization**,** may be appropriate in patients not adequately managed with medications and avoidance of the allergen(s), when there is a desire to avoid long-term pharmacotherapy, or in patients with coexisting allergic rhinitis and asthma where symptoms of asthma occur after natural exposure to aeroallergens and there is demonstrable evidence of clinically relevant specific IgE.

Allergen injection immunotherapy involves regular injection(s) of offending allergen(s), in the form of antigen extract(s), over a period of time; with the goal of reducing symptoms. Immunotherapy begins on a weekly or biweekly basis, with low extract dose(s), to prevent untoward reactions, and gradually increases the dose(s) injected as immunity to the antigen(s) develop. After a maintenance antigen dose is achieved, the interval between injection(s) may range from two to six weeks. Immunotherapy may be administered continuously for several years.

Rush, or rapid, immunotherapy is an accelerated immunotherapy build-up schedule that entails administering incremental doses of allergen at intervals varying between 15 and 60 minutes over 1 to 3 days until the target therapeutic dose is achieved. Rush immunotherapy schedules for inhalant allergens can be associated with a greater risk of systemic reactions, particularly in high-risk patients (e.g., those with markedly positive prick/ puncture test responses), and premedication with antihistamines and corticosteroids appears to reduce the risk associated with rush immunotherapy. However, rush protocols for administration of Hymenoptera (stinging insect) venom immunotherapy have not been associated with a similar high incidence of systemic reactions.

Cluster immunotherapy is an accelerated build-up schedule that entails administering several injections at increasing doses (generally 2-3 per visit) sequentially in a single day of treatment on nonconsecutive days. The maintenance dose is generally achieved more rapidly than with a conventional (single injection per visit) build-up schedule (generally within 4 to 8 weeks).

Sublingual allergen immunotherapy involves the administration of an allergenic extract tablet that is placed under the tongue and rapidly dissolves. To date, four formulations of sublingual immunotherapy (SLIT) have been approved for marketing in the U. S. by the FDA:

I. On April 1, 2014, the FDA approved **Oralair®** for treatment of certain grass pollen-induced allergic rhinitis, with or without conjunctivitis, in patients age 10-65, who have grass pollen allergy to Kentucky Blue grass, Orchard grass, Perennial Rye grass, Sweet Vernal grass, and/or Timothy grass. Treatment with Oralair is started four months before the start of the grass pollen season and continued throughout the season.
II. On April 14, 2014, the FDA approved **Grastek®** for the treatment of Timothy grass pollen-induced allergic rhinitis, with or without conjunctivitis, in patients age 5-65. Treatment with Grastek is started twelve weeks before the start of the grass pollen season and continued throughout the season.

III. On April 17, 2014, the FDA approved **Ragwitek®** for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, in patients age 18-65 years. Treatment with Ragwitek is started twelve weeks before the start of the ragweed pollen season and continued throughout the season.
IV. On March 1, 2017 the FDA approved **Odactra**, the first allergen extract to be administered under the tongue (sublingually) to treat house dust mite (HDM)-induced nasal inflammation (allergic rhinitis), with or without eye inflammation (conjunctivitis), in people 18 through 65 years of age.

RATIONALE:

Allergen immunotherapy used to treat IgE mediated disease by injection with specific allergenic extracts is a widely accepted medical practice. The efficacy of immunotherapy has been demonstrated in multiple double blind, placebo-controlled studies. Continuing efforts have been made to improve the efficacy of immunotherapy, reduce the risk of reactions and the number of injections necessary through the use of adjuvants, various administration routes, by chemical alteration and modification and polymerization of allergens. However, the results of clinical trials have not proven the safety and efficacy of these methods and remain investigational.

In January 2011, the American Academy of Allergy, Asthma and Immunology (AAAAI), the American College of Allergy, Asthma and Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology (JCAAI) published an update to their practice parameter addressing allergy immunotherapy. Oral immunotherapy and SLIT for food hypersensitivity are also considered investigational." (Cox, et al, 2011). According to the AAAAI website a new practice parameter on SLIT is currently under development. Food allergy desensitization through multiple oral immunotherapy (OIT) protocols is currently under research and some initial long-term follow-up data is being reviewed. However, more research is required to develop accepted protocols and understand how the patients fare after treatment. How long does desensitization last? Do patients eventually achieve complete tolerance of the allergen? Do patients adhere to their regular dosing of the allergen? What happens if they stop eating the allergen? (AAAI 2016). Research presented at the 2017 AAAAI Annual Meeting includes advances regarding the use of peanut, tree nut and wheat immunotherapy.

Sublingual immunotherapy (SLIT) is a potential alternative to subcutaneous immunotherapy (SCIT) for providing allergen-specific therapy. Despite multiple placebo-controlled studies evaluating SLIT, questions remain about the optimal dosing, duration of treatment, and the use of multiple allergens. Four sublingual pollen extracts - Oralair®, Grastek®, and Ragwitek® and Odactra -have been approved by the FDA 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 pre-specified and were met in most studies. Patients in these trials had received previous treatment for their pollen-induced rhinitis or rhinoconjunctivitis symptoms.

SLIT is being investigated for other allergies (e.g., other seasonal, food allergies, however, current evidence is insufficient to form conclusions about the use of SLIT for these indications, and no allergy extracts for these uses have been FDA approved.

Several studies-including well-powered double-blind, randomized controlled trials versus placebo have shown that based on overall efficacy and side effects the evidence for SCIT versus SLIT is equipoised. (Durham 2016) There were no significant differences in any outcome measures between the two groups (for TNSS: $P>0.05$; for TMS: $P>0.05$; for IL-4 levels: $P>0.05$). It was concluded that the clinical efficacy of single-allergen SLIT is comparable with that of multi-allergen SCIT in 6-13-year-old children with HDM-induced AR. (Wang 2017). In a cost-minimization analysis comparing patients with persistent moderate-to-severe house dust mite (HDM) allergic rhinitis using SCIT as the standard care versus SLIT the authors concluded it is clearly cost-savings to treat patients with SLIT compared to SCIT. (Ronborg 2016).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	95115	Professional services for allergen immunotherapy, not including provision of allergenic extracts; single injection
	95117	two or more injections
	95120	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single injection
	95125	two or more injections
	95130	single stinging insect venom
	95131	two stinging insect venoms
	95132	three stinging insect venoms
	95133	four stinging insect venoms
	95134	five stinging insect venoms
	95144	Professional services for the supervision and provision of antigens for allergen immunotherapy, single or multiple antigens, single dose vials (specify number of vials)
	95145	Professional services for the supervision and provision of antigens for allergen immunotherapy (specify the number of doses); single stinging insect venom
	95146	two single stinging insect venoms
	95147	three single stinging insect venoms
	95148	four single stinging insect venoms
	95149	five single stinging insect venoms
	95165	Professional services for the supervision and provision of antigens for allergen immunotherapy; not stinging insect, single or multiple antigens (specify number of doses), **Note: Not appropriate for sublingual immunotherapy.**
	95170	whole body extract of biting insect or other arthropod (specify number of doses)
	95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, horse serum)
	95199	Unlisted allergy/clinical immunologic service or procedure **Note: Used for FDA approved formulations of sublingual immunotherapy.**

HCPCS:	No code(s)	
ICD10:	H10.411-H10.419	Chronic giant papillary conjunctivitis (code range)
	H10.45	Other chronic allergic conjunctivitis
	J30.0-J30.9	Vasomotor and allergic rhinitis (code range)
	J45.20-J45.998	Asthma (code range)
	L50.0	Allergic urticaria
	L50.3	Dermatographic urticaria
	Z51.6	Encounter for desensitization to allergens
	Z91.010-Z91.09	Allergy status, other than to drugs and biological substances (code range)

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KEY WORDS:

Allergy shots, Allergen/Allergy Immunotherapy, Grastek®, Oralair®, Ragwitek®, Sublingual immunotherapy (SLIT).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination addressing Food Allergy Testing and Treatment. Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=266&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=allergy&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&.

There is currently a National Coverage Determination addressing Antigens Prepared for Sublingual Administration. Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=155&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=allergy&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&.