

Clinical Policy: Allergy Testing and Therapy

Reference Number: PA.CP.MP.100 Plan Effective Date: 04/2018 Date of Last Revision: 10/2024 Coding Implications Revision Log

Description

Allergy testing is performed to determine immunologic sensitivity or reaction to antigens for the purpose of identifying the cause of the allergic state. This policy addresses immediate (IgE-mediated) hypersensitivity and delayed (cell-mediated) hypersensitivity.¹ Allergen immunotherapy is the repeated administration of specific allergens to patients with IgE-mediated conditions, for the purpose of providing protection against the allergic symptoms and inflammatory reactions associated with exposure to these allergens.²

Please note: unit limitations for allergy testing and treatment are based on state specific guidelines (defined in the provider fee schedule). In the absence of state-specific rules, the CMS Medicaid/Medicare NCCI MUE limitations are applied.

Policy/Criteria

- I. It is the policy of PA Health & Wellness (PHW), that allergy testing is **medically necessary** for members/enrollees with clinically significant allergic symptoms and the following indications:
 - **A.** As part of a complete diagnostic evaluation by a licensed practitioner acting within their scope of practice to perform allergy and immunology services;
 - **B.** Antigens include only those that are reasonably possible for the member/enrollee to be exposed to;
 - C. Chosen test and units allowed per year are as follows:
 - 1. *Percutaneous* testing (scratch, puncture, prick) (CPT 95004, 95017, 95018) for offending allergens such as pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, or drugs.
 - 2. *Intracutaneous* (intradermal), *sequential and incremental testing* (CPT 95024, 95027, 95028) when percutaneous tests are negative;
 - 3. *Skin endpoint titration* (95027) for determining the starting dose for immunotherapy for member/enrollee highly allergic to an inhalant allergen or hymenoptera venom allergy (insect stings);
 - 4. In vitro testing (CPT 86003, 86005, 86008);
 - 5. Patch testing (CPT 95044);
 - 6. If photo patch test(s) (CPT 95052) are performed (same antigen/same session) with patch or application test(s) (CPT 95044), only the photo patch tests should be reported;
 - 7. If photo tests (CPT 95056) are performed with patch or application test(s) (CPT 95044), only the photo tests should be reported.
 - 8. Ingestion (oral) challenge testing (CPT 95076, 95079) for food, drugs, or other substances if skin testing is negative or allergy diagnosis is uncertain.



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- **II.** It is the policy of PHW that allergy immunotherapy administered in a medical facility is **medically necessary** when meeting all of the following indications:
 - **A.** Positive skin test or serologic evidence of an IgE-mediated antibody for allergens which cause any of the following:
 - 1. Allergic (extrinsic) asthma;
 - 2. Dust mite atopic dermatitis;
 - 3. Hymenoptera (bees, hornets, wasps, fire ants) allergic reactions;
 - 4. Mold-induced allergic rhinitis;
 - 5. Perennial allergic rhinitis;
 - 6. Seasonal allergic rhinitis or conjunctivitis;
 - **B.** Symptoms of allergic rhinitis or asthma after natural exposure to the allergen; or a life-threatening allergy to insect stings (bees, hornets, wasps, and fire ants);
 - **C.** Avoidance or pharmacologic therapy does not control allergic symptoms or member/enrollee has unacceptable side effects with pharmacologic therapy;
 - **D.** If rapid desensitization/rush immunotherapy is requested, it is only medically necessary for medication or hymenoptera (bees, hornets, wasps, fire ants) sensitivities;
 - **E.** Antigens are prepared by the clinical staff directly overseen by the physician who examined the patient and who has training and expertise in allergen immunotherapy (i.e., allergist, immunologist, or otolaryngologist. Other specialties must provide evidence of expertise and training consistent with the ACAAI Allergen Immunotherapy Extract Preparation Instructional Guide).^{3*}

Note: Please see background section for information on training requirements for immunotherapy preparation and administration.*

Note: For FDA approved sublingual immunotherapy, please refer to applicable pharmacy policy for coverage criteria.

- **III.** It is the policy of PHW that the following are considered **not medically necessary** because safety or effectiveness have not been established:
 - **A.** Testing for the following antigens:
 - 1. Newsprint;
 - 2. Tobacco smoke;
 - 3. Dandelion;
 - 4. Orris root;
 - 5. Phenol;
 - 6. Alcohol;
 - 7. Sugar;
 - 8. Yeast;
 - 9. Grain mill dust;
 - 10. Soybean dust (except when the patient has a known exposure to soybean dust such as a food processing plant);
 - 11. Wool (unless patient has history of continuous exposure to sheep or unprocessed wool);
 - 12. Marigold;



- 13. Honeysuckle;
- 14. Fiberglass;
- 15. Green tea:
- 16. Chalk;
- 17. Cornstarch;
- 18. Cotton;
- 19. Formaldehyde;
- 20. Smog.
- **B.** The following tests for the evaluation allergic reactions:
 - 1. Antigen leukocyte cellular antibody (ALCAT) automated food allergy testing;
 - 2. Applied kinesiology or Nambudripad's allergy elimination test (NAET (i.e., muscle strength testing or measurement after allergen ingestion);
 - 3. Anti-Fc epsilon receptor antibodies testing;
 - 4. Anti-IgE receptor antibody testing;
 - 5. Blood, urine, or stool micro-nutrient assessments;
 - 6. Candidiasis test;
 - 7. Chemical analysis of body tissues (e.g., hair);
 - 8. Chlorinated pesticides (serum);
 - 9. Chronic urticarial index testing;
 - 10. Clifford materials reactivity testing;
 - 11. Complement (total or components);
 - 12. Complement antigen testing;
 - 13. C-reactive protein;
 - 14. Cytokine and cytokine receptor assay;
 - 15. Cytotoxic testing for food, environmental or clinical ecological allergy testing (Bryans Test, ACT);
 - 16. Electrodermal testing or electro-acupuncture;
 - 17. Electromagnetic sensitivity syndrome/disorder (allergy to electricity, electrosensitivity, electrohypersensitivity, and hypersensitivity to electricity);
 - 18. Environmental cultures and chemicals;
 - 19. Eosinophil cationic protein (ECP) test;
 - 20. ELISA/Act qualitative antibody testing;
 - 21. Food immune complex assay (FICA);
 - 22. General immune system assessments;
 - 23. Immune complex assay;
 - 24. Ingestion challenge food testing for diagnosing rheumatoid arthritis, depression, or respiratory disorders not associated with anaphylaxis or similar systemic reactions;
 - 25. In vitro metal allergy testing;
 - 26. Iridology;
 - 27. Leukocyte histamine release test (LHRT)/basophil histamine release test;
 - 28. Live Cell Analysis;
 - 29. Lymphocyte function assay;
 - 30. Lymphocytes (B or T subsets);



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- 31. Lymphocyte Response Assay (LRA) by ELISA/ACT and Lymphocyte Mitogen Response Assays (LMRA) by ELISA/Act;
- 32. Mediator release test (MRT);
- 33. Metabolic assessments;
- 34. Ophthalmic mucus membrane tests/conjunctival challenge test;
- 35. Prausnitz-Kustner (P-K testing) passive cutaneous transfer test;
- 36. Provocative and neutralization testing and neutralization therapy (sublingual, intracutaneous and subcutaneous) also referred to as the Rinkel Test, for food allergies, inhalants, and environmental chemicals because available evidence does not show these tests and therapies are effective;
- 37. Provocative nasal test;
- 38. Pulse test (pulse response test, reaginic pulse test);
- 39. Qualification of nutritional assessments;
- 40. Rebuck skin window test;
- 41. Secretory IgA (salvia);
- 42. Sage Complement Antigen Test;
- 43. Testing for multiple chemical sensitivity syndrome (a.k.a., idiopathic environmental intolerance [IEI], clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease);
- 44. Testing of specific immunoglobulin G (IgG) (e.g., by Radioallergosorbent [RAST] or Enzyme-linked immunosorbent assay [ELISA]);
- 45. Testing of total serum IgG, immunoglobulin A (IgA) and immunoglobulin M (IgM);
- 46. Testing for venom blocking antibodies;
- 47. VeriMAP Peanut Diagnostic[™] (bead-based epitope assay).
- C. The following services in relation to allergy testing and immunotherapy:
 - 1. Desensitization with commercially available extracts of poison ivy, poison oak, or poison sumac;
 - 2. Desensitization for hymenoptera sensitivity using whole body extracts, with the exception of venom extracts and fire ant extracts;
 - 3. Desensitization with bacterial vaccine (BAC: bacterial, antigen complex, streptococcus vaccine, staphylo/strepto vaccine, serobacterin, staphylococcus phage lysate);
 - 4. Food allergenic extract immunotherapy;
 - 5. Intracutaneous desensitization (Rinkel Injection Therapy, RIT);
 - 6. Neutralization therapy (intradermal and subcutaneous);
 - 7. Repository emulsion therapy;
 - 8. Non-FDA approved sublingual immunotherapy;
 - 9. Urine auto-injection (autogenous urine immunotherapy);
 - 10. Allergen immunotherapy for the management of skin and mucous membrane disease such as urticaria, and Candida vulvovaginitis;
 - 11. Home administration of allergy immunotherapy;
 - 12. Ingestion challenge food testing performed by the patient in the home;
 - 13. Intradermal testing for food allergies;



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- 14. Food allergen testing for patients who present with gastrointestinal symptoms suggestive of food intolerance;
- 15. Rush immunotherapy for inhalant allergens.

Limitations

Allergy Testing^{4,5,6}

- Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include children and adolescents with documented food allergy requiring follow up and young children with negative skin tests or older children and adults with negative skin tests in the face of persistent symptoms;
- Routine repetition of skin tests is not indicated (e.g., annually);
- Measurements of total IgE levels (CPT code 82785-Gammaglobulin [immunoglobulin]; IgE) are not appropriate for most general allergies for the purpose of identifying the cause of the allergic state. Total serum IgE levels should not be billed unless evidence exists for allergic bronchopulmonary Aspergillosis (ABPA), select immunodeficiencies, such as the syndrome of hyper-IgE, eczematous dermatitis, atopic dermatitis in children and recurrent pyogenic infections, or in the evaluation for omalizumab therapy;
- Serial, repeat testing of total IgE will be subject to medical review.

Documentation Requirements

Medical record documentation (e.g., history & physical, office/progress notes, procedure report, test results) must include the following information:

- A complete medical and immunologic history and appropriate physical exam obtained by face-to-face contact with the patient;
- The medical necessity for performing the test;
- The test methodology used;
- The measurement (in mm) of reaction sizes of both wheal and erythema response (in vivo testing);
- The quantitative result (in kIU/L) for specific IgE testing (in vitro testing);
- The interpretation of the test results and how the results of the test will be used in the patient's plan of care;
- Periodic clinical evaluation of treatment benefits and, if no benefit within 12-24 months, other treatment options which should be considered;
- Clinical re-evaluation at three to five years to determine need for continuing immunotherapy.

Background

Allergy Testing

Allergy is a form of exaggerated sensitivity or hypersensitivity to a substance that is either inhaled, ingested, injected, or comes in contact with the skin or eye. The term allergy is used to describe situations where hypersensitivity results from heightened or altered reactivity of the immune system in response to external substances. Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any part of the body. The reactions may be acute, subacute, or chronic; immediate or delayed, and may be



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caused by a variety of offending agents (e.g., pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, drugs).⁷ Allergy testing is performed to determine a patient's immunologic sensitivity or reaction to particular allergens for the purpose of identifying the cause of the allergic state.⁸

Allergy testing must be a part of a complete diagnostic evaluation by a physician with specialized training in allergy and immunotherapy. A complete medical and immunologic history and appropriate physical examination must be done prior to performing diagnostic testing. The testing must be performed based on this history and a physical exam, which documents that the antigens being used for testing exist with a reasonable probability of exposure in the patient's environment. The number of tests performed must be judicious and related to the history, physical findings, and clinical judgment specific to each individual.¹

In vivo immunologic tests have been shown to be reliable and valid diagnostic tools and include skin tests with standardized allergenic extracts by prick/puncture (percutaneous) and intradermal (intracutaneous) techniques, photo and patch testing, inhalation bronchial challenge testing, and ingestion challenge testing. Percutaneous testing remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected. Percutaneous tests require medical supervision, since there is a small but significant risk of anaphylaxis. Overall, skin testing is quick, safe, and cost-effective.¹

Intradermal tests are usually performed when increased sensitivity is needed when percutaneous tests (CPT codes 95004, 95017, 95018) are negative and there is still a strong suspicion of allergen sensitivity. For intradermal testing, the clinician should narrow the area of investigation so that the minimal number of skin tests necessary for diagnosis is performed. Intradermal testing is appropriate when IgE-mediated reactions occur to inhalants, hymenoptera (insect stings), and specific drugs, such as penicillins and macromolecular agents.⁵ The usual testing program may include two concentrations of an extract: a weaker concentration and a stronger concentration. It would not be expected that three or more concentrations of one extract would be necessary. Skin end-point dilution testing is a variant of intradermal testing that analyzes the highest dilution of a substance that produces a reaction and may be used to determine the starting dose(s) of allergen immunotherapy.¹

Delayed hypersensitivity skin testing measures the presence of activated T cells that recognize a certain substance. It has been commonly used in three ways: anergy testing, testing for infection with intracellular pathogens, and testing for sensitivity to contact allergens. Accurate testing for contact allergy requires careful attention to technique, and limitation of testing to the specific allergens known to be associated with a contact reaction.¹

Other skin tests include photo testing and patch testing. Photo testing is skin irradiation with a specific range of ultraviolet light. Photo tests are performed for the evaluation of photosensitivity disorders. Patch testing is indicated to evaluate a nonspecific dermatitis, allergic contact dermatitis, pruritus, and other dermatitis to determine the causative antigen. Photo Patch testing uses two patches, with one of them being irradiated with ultraviolet light half way through the occlusive period. It is indicated to evaluate unique allergies resulting from light exposure.¹



Inhalation bronchial challenge testing involves the inhalation of agents that can trigger respiratory responses. The agents include drugs that cause airway constriction, antigens, and chemical sensitizers, usually related to occupational breathing problems. Generally, three measures of each determination (e.g., spirometry, prolonged post exposure evaluation of bronchospasm) are performed. The best of the three is accepted and represents one unit of service. A unit is defined as each set of three measurements.¹

Ingestion challenge test involves the administration of sequentially or incrementally larger doses of the test item. The test items may include food or antibiotics. The service is allowed once per patient encounter, regardless of the number of items tested, and includes evaluation of the patient's response to the test items.¹

Quantitative or semi-quantitative in vitro allergen specific IgE testing includes radioallergosorbent test (RAST), multiple radioallergosorbent tests (MAST), fluorescent allergosorbent test (FAST), enzyme-linked immunosorbent assay (ELISA) and ImmunoCAP. These tests detect specific IgE antibodies in the patient's blood serum. Examples of indications for in vitro testing (CPT codes 86003, 86005 and 86008) include:

- Severe dermatographism, ichthyosis or generalized eczema;
- Increased risk for anaphylactic response to skin testing based on clinical history (e.g., when an unusual allergen is not available as a licensed skin test extract);
- Inability to discontinue long-acting antihistamines, tricyclic antidepressants, or medications that may put the patient at undue risk if they are discontinued long enough to perform skin tests;
- Those with mental or physical impairments who are uncooperative;
- History is highly suggestive of an allergy and skin testing is negative or equivocal; or
- Evaluation of cross-reactivity between insect venoms.

Total serum IgE concentration testing is not indicated in all allergic patients but should be reserved for those patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease (e.g., Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma or pemphigoid, or for consideration of Xolair (omalizumab) administration in patients with moderate to severe asthma.

Allergen Immunotherapy⁹

Allergen immunotherapy is effective for pollen, mold, animal allergens, cockroach, and dust mite. Immunotherapy is indicated for patients who show evidence of specific IgE antibodies to clinically relevant allergens and whose allergic symptoms warrant the time and risk of allergen immunotherapy. This includes those with allergic asthma, allergic conjunctivitis, allergic rhinitis, or stinging insect hypersensitivity depending on the results of allergy testing (immediate hypersensitivity skin tests or in vitro tests for specific IgE). Initiating allergen immunotherapy may depend on the degree to which symptoms can be reduced by medication, the amount and type of medication required to control symptoms, and whether appropriate avoidance is possible.



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There is limited data showing effectiveness in atopic dermatitis when this condition is associated with aeroallergen sensitivity. Immunotherapy should not be given to patients with negative results for specific IgE antibodies or those with positive test results for specific IgE antibodies that do not correlate with suspected triggers, clinical symptoms, or exposure.

Venom immunotherapy is indicated for patients who have anaphylaxis after an insect sting and a positive skin test or other documented IgE sensitivity to specific insect venom. Patients with delayed systemic reactions with symptoms of anaphylaxis or serum sickness and with a positive skin test or presence of venom specific IgE by in vitro testing are also recommended for treatment.

Rapid desensitization is indicated in cases of allergy to insulin, penicillin, and horse serum, as well as sulfonamides, cephalosporins and other commonly used drugs. In patients with a positive history of reaction and with documented skin test reactivity, every effort should be made to avoid the use of these substances. When circumstances require the use of one of these substances, the patient will have to be desensitized. Full-dose therapy should be initiated immediately after reactions (treated and controlled), requiring strict physician monitoring in a setting with continuous monitoring of vital signs and cardio-respiratory status. In most cases, this can be performed in a physician's office if a physician trained to treat anaphylaxis is physically present for the entire duration. In cases where the initial reaction was severe, desensitization should be performed in the ambulatory care department of a hospital.

Desensitization may need to be repeated if future circumstances require an additional course of the offending allergen. Rapid desensitization in the form of rush immunotherapy may also be appropriate for hymenoptera venom (bees, hornets, wasps, fire ants), according to a recent American Academy of Allery, Asthma & Immunology practice parameter.

Sublingual Immunotherapy¹⁰

The American Academy of Allergy, Asthma & Immunology recommends only FDA-approved sublingual immunotherapy (SLIT) products for the treatment of allergic rhinitis/rhinoconjunctivitis and not for any other related or unrelated condition. Off label use of aqueous SLIT extracts or any other non- FDA approved SLIT formulation is not endorsed.

Treatment Schedules⁹

The starting dose of an allergenic extract and the progression of the dose must be individualized for each patient. The immunotherapy build-up schedule entails administration of gradually increasing doses during a period of approximately 14 to 28 weeks. In conventional schedules a single dose increase is given on each visit, and the visit frequency can vary from one to three times a week. Accelerated schedules such as rush or cluster immunotherapy entail administration of several injections at increasing doses on a single visit. Accelerated schedules offer the advantage of achieving the therapeutic dose earlier but might be associated with increased risk of systemic reaction in some patients.

Length of Therapy⁹



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The duration of all forms of immunotherapy must be individualized. A presumption of failure can be made when, after 12 to 24 months of therapy, a person does not experience a noticeable decrease of symptoms, an increase in tolerance to the offending allergen and a reduction in medication usage. Treatment will not be reimbursed after a two-year period when there is no apparent clinical benefit.

Immunotherapy Preparation and Administration³

The training of personnel involved in preparation of allergen immunotherapy extracts is a critical requirement for safety and efficacy. It is a technical skill that requires specific training and a high level of attention to detail.

The suggested qualifications of extract preparation personnel based on the AAAAI Practice Parameter on Allergen Immunotherapy and The United States Pharmacopeial Convention (USP) Chapter 797 Pharmaceutical Compounding- Sterile Preparations standards include the following:

- Demonstrate understanding of appropriate hand hygiene, garbing, surface disinfection, aseptic technique, achieving and/or maintaining sterility, calculating/measuring/mixing, use of equipment and documentation.
- Pass a written test on aseptic technique and extract preparation.
- Annually pass a media-fill or equivalent test verifying use of aseptic technique.
- Annually pass a gloved fingertip-thumb sampling test verifying hand sterility after passing three initial tests.

• Be reinstructed and reevaluated if failing the written test, media-fill test, or gloved fingertip-thumb sampling test.

• Allergist offices must keep records of training, assessment results, evaluations, and qualifications for all compounding personnel, including any corrective actions following assessments and evaluations.

The major risk of allergen immunotherapy is anaphylaxis. Allergen immunotherapy should, therefore, be administered under the supervision of an appropriately trained physician who can recognize early symptoms and signs of anaphylaxis and administer emergency medications where necessary. In addition, immunotherapy should be administered only in facilities equipped to treat anaphylaxis.

Evaluation and management codes are separately reimbursable on the same day as allergen immunotherapy only when a significant, separately identifiable service is performed.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.



CPT Code Table 1: Procedure codes considered medically necessary when diagnosis code
requirements are met per the ICD-10 tables.

CPT ^{®*}	Description		
Codes			
86003	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each		
86005	Allergen specific IgE; qualitative, multiallergen screen (eg., disk, sponge, card)		
86008	Allergen specific IgE; quantitative or semiquantitative, recombinant		
	or purified component, each		
86160	Complement; antigen, each component		
86161	Complement; functional activity, each component		
86162	Complement; total hemolytic (CH50)		
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests		
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests		
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests		
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests		
95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests		
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests		
95044	Patch or application test(s) (specify number of tests)		
95052	Photo patch test(s) (specify number of tests)		
95056	Photo tests		
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing		
95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); each additional 60 minutes of testing (list separately in addition to code for primary procedure)		
95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection		
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections		
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials)		
95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom		



CPT ^{®*}	Description
Codes	
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)
95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, equine serum)
95199	Unlisted allergy/clinical immunologic service or procedure

CPT Code Table 2: Procedure codes considered not medically necessary

CPT ^{®*}	Description		
Codes			
86001	Allergen specific IgG quantitative or semiquantitative, each allergen		
86332	Immune complex assay		
86343	Leukocyte histamine release test (LHR)		
86485	Skin test; candida		
86628	Antibody; Candida		
95060	Ophthalmic mucous membrane tests		
95065	Direct nasal mucous membrane test		
0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme- linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy		
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme- linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction		

ICD-10-CM Code Table 1: Diagnoses that support medical necessity for CPT codes 86003, 86005, 86008, 95004, 95017, 95018, 95024, 95027, 95028

ICD-10-CM Code	Description
B44.81	Allergic bronchopulmonary aspergillosis
H10.011 through	Conjunctivitis
H10.45	
J30.1 through J30.9	Allergic rhinitis
J30.0	Vasomotor rhinitis
J31.0	Chronic rhinitis



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ICD-10-CM Code	Description		
J45.20 through	Asthma		
J45.998			
L20.0 through L20.9	Atopic dermatitis		
L23.0 through L23.9	Allergic contact dermatitis		
L24.9	Irritant contact dermatitis, unspecified cause		
L25.1 through L25.9	Unspecified contact dermatitis		
L27.0 through L27.9	Dermatitis due to substances taken internally		
L30.2	Cutaneous autosensitization		
L50.0	Allergic urticaria		
L50.1	Idiopathic urticaria		
L50.6	Contact urticaria		
L50.8	Other urticaria		
L50.9	Urticaria, unspecified		
R06.2	Wheezing		
T36.0X5A through	Poisoning by, adverse effects of and underdosing of drugs, medicaments		
T50.995S	and biological substances		
T63.001A through	Toxic effects of venoms		
T63.94XS			
T78.00XA through	Anaphylactic reaction due to food		
T78.1XXS			
T78.49XA through	Other allergy		
T78.49XS			
T80.52XA through	Anaphylactic reaction due to vaccination		
T80.52XS			
T88.6XXA through	Anaphylactic reaction due to adverse effect of correct drug or medicament		
T88.6XXS	properly administered		
Z91.010 through	Food allergy status		
Z91.018			

ICD-10-CM Code Table 2: Diagnoses that support medical necessity for CPT code 95044

ICD-10-CM	Description		
Code			
L20.84	Intrinsic (allergic) eczema		
L20.89	Other atopic dermatitis		
L20.9	Atopic dermatitis, unspecified		
L23.0 through	Allergic contact dermatitis		
L23.9			
L50.0	Allergic urticaria		
L50.1	Idiopathic urticaria		
L50.6	Contact urticaria		
L50.8	Other urticaria		
L50.9	Urticaria, unspecified		



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ICD-10-CM Code Table 3: Diagnoses that support medical necessity for CPT codes 95052, 95056

ICD-10-CM Code	Description
L56.1	Drug photoallergic response
L56.2	Photocontact dermatitis (berloque dermatitis)
L56.3	Solar urticaria

ICD-10-CM Code Table 4: Diagnoses that support medical necessity for CPT codes 95076, 95079

ICD-10-CM	Description	
Code		
L27.2	Dermatitis due to ingested food	
T36.0X5A	Adverse effect of drugs	
through T50.995S		
T78.00X* through	Anaphylactic reaction due to food	
T78.1XXS		
Z88.0 through	Allergy status to drugs, medicaments and biological substances	
Z88.9		
Z91.010 through	Food allergy status	
Z91.018		

ICD-10-CM Code Table 5: Diagnoses that support medical necessity for CPT codes 95115, 95117, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, and 95199

ICD-10-CM Code	Description	
H10.011 through	Conjunctivitis	
H10.45		
J30.1 through	Allergic rhinitis	
J30.9		
J31.0	Chronic rhinitis	
J45.20 through	Asthma	
J45.998		
L20.84	Intrinsic (allergic) eczema	
L20.89	Other atopic dermatitis	
L20.9	Atopic dermatitis, unspecified	
L23.0 through	Allergic contact dermatitis	
L23.9*		
L25.1 through	Unspecified contact dermatitis	
L25.9		
L27.0 through	Dermatitis due to substances taken internally	
L27.9		
L50.0	Allergic urticaria	
L50.6	Contact urticaria	



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ICD-10-CM	Description
Code	
T36.0X5A	Adverse effects of drugs
through T50.995S	
T63.001* through	Toxic effects of venoms
T63.94* XS	
T78.49XA	Other allergy
through	
T78.49XS	
T80.52XA	Anaphylactic reaction due to vaccination
through	
T80.52XS	
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament
through	properly administered
T88.6XXS	
Z88.0 through	Allergy status to drugs, medicaments, and biological substances
Z88.9	
Z91.030 through	Insect allergy status
Z91.038	

ICD-10-CM Code Table 6: Diagnoses that support medical necessity for CPT code 95180

ICD-10-CM Code	Description
T36.0X5A through T50.995S	Adverse effect of other drugs, medicaments and biological substances
Z91.030 through Z91.038	Insect allergy status

ICD-10-CM Code Table 7: Diagnoses that do *not* support medical necessity for CPT codes 86160, 86161 and 86162

ICD-10-CM	Description
Code	
B44.81	Allergic bronchopulmonary aspergillosis
H10.011 through	Conjunctivitis
H10.45	
J30.1 through	Allergic rhinitis
J30.9	
J30.0	Vasomotor rhinitis
J31.0	Chronic rhinitis
J45.2* through	Asthma
J45.998	
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified



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ICD-10-CM	Description
Code	
L23.0 through	Allergic contact dermatitis
L23.9*	
L25.1 through	Unspecified contact dermatitis
L25.9	
L27.0 through	Dermatitis due to substances taken internally
L27.9	
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria
L50.9	Urticaria, unspecified
L56.1	Drug photoallergic response
L56.2	Photocontact dermatitis (berloque dermatitis)
L56.3	Solar urticaria
R06.2	Wheezing
T36.0X5A	Adverse effect of drugs
through T50.995S	
T63.001* -	Toxic effects of venoms
T63.94*	
T78.00X* through	Anaphylactic reaction due to food
T78.1XXS	
T78.49XA	Other allergy
through T78.49XS	
T80.52XA	Anaphylactic reaction due to vaccination
through T80.52XS	
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament
through	properly administered
T88.6XXS	
Z88.0 through	Allergy status to drugs, medicaments and biological substances
Z88.9	
Z91.010 through	Food allergy status
Z91.018	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created	04/18	06/18
Added to III.A, testing of the following antigens as not medically necessary: cornstarch, cotton, formaldehyde and smog. References reviewed and updated. Added 86008 to in vitro testing, and CPT code table 1 and relevant to ICD-10 code table 1. Added B44.81 to ICD-10 code table 1. Added T88.6XXA – T88.6XXS to ICD-10 code table 5.	02/19	



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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added reference to CMS allowed units	07/19	
Under III. C., revised "sublingual provocative therapy" to state "non FDA approved sublingual immunotherapy" and added reference to refer to pharmacy benefit for coverage criteria. Removed background statement "In vitro testing is appropriate under conditions where skin testing is not possible or is not reliable." Specialist reviewed. Added R06.2 to ICD-10-CM code table 1.	10/2020	12/2020
Added "(scratch, puncture, prick)" to description in I.C.1. Updated IIIB. adding several not medically necessary tests. Updated background, adding section on sublingual immunotherapy. CPT codes added to not medically necessary CPT Table 2: 86160, 86161, 86162, 86332, 86343, 86485, 86628, 0165U, 0178U. Revised description of ICD-10 codes Z88.0-Z88.9 in ICD-10 Tables 4 & 5. and updated. Replaced member with member/enrollee in all instances. Added ICD-10 code range Z91.010-Z91.018 to Tables 1 & 4. Specialist reviewed. References reviewed	12/2020	2/9/2021
Added J30.0 to ICD-10-CM Code Table 1. Minor revision to description of CPT-95070. CPT-95071 deleted in 2021. Annual review. References reviewed and updated. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Criteria and coding reviewed by specialist.	12/22/2021	
Annual review complete. Removed codes 86160, 86161 and 86162 from the not medically necessary table. Added ICD-10 Table 7 with codes that do not support medical necessity for 86160 through 86162. Added the following ICD-10 codes as medically necessary in ICD-10 code table 1: L20.0, L20.81-L20.83 (within code range L20 through L20.9), L24.9, L30.2. Updated criteria in II. E. to "Antigens are prepared by the clinical staff directly overseen by the physician who examined the patient and who has training and expertise in allergen immunotherapy (i.e., allergist, immunologist or otolaryngologist. Other specialties must provide evidence of expertise and training consistent with the AAAI Allergen Immunotherapy Extract Preparation Instructional Guide)." Added note to reference new information in background for information on training requirements for immunotherapy preparation and administration. Separated criteria from III. B. 42. into 43. In "Limitations" section for retesting added "Exceptions include children and adolescents with documented food allergy requiring follow up". Updated background with information on training requirements for immunotherapy preparation and administration. Added CPT codes 86160, 86161, and 86162 to the medically necessary CPT code list and added "when diagnosis code requirements are met per the ICD-10 tables" to the medically necessary CPT code table description. Added 86001 to the not medically necessary CPT code table. Reviewed, updated, and added references and included citations.	12/8/2022	



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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. Updated description and background with no clinical significance. References reviewed and updated. Coding reviewed. Reviewed by external specialist.	05/2024	06/2024
Annual review. Aligned with Corporate review schedule; Added Criteria I.C.8. to include ingestion (oral) challenge testing. Grammatical updates added to Criteria II.A.1., II.A.2., II.A.3., II.A.4., and II.A.5. Grammatical updates added under Limitations and under Documentation Requirements with no impact on criteria. Reviewed, reformatted and updated coding tables and descriptions. Removed CPT code 95070 from policy. References reviewed and updated.	10/2024	

References

- 1. Local coverage determination: allergy testing (L34313). Centers for Medicare and Medicaid Services Website. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published October 01, 2015 (revised October 01, 2019). Accessed August 12, 2024.
- Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update [published correction appears in J Allergy Clin Immunol. 2011 Mar;127(3):840]. J Allergy Clin Immunol. 2011;127(1 Suppl):S1 to S55. doi:10.1016/j.jaci.2010.09.034
- 3. American College of Allergy, Asthma, and Immunology. Allergen Immunotherapy Extract Preparation: Instructional Guide. <u>https://college.acaai.org/sites/default/files/acaai-</u> <u>mixinginstructionguide.pdf</u>. Published October 2019. Accessed August 28, 2024.
- 4. Kowal K, DuBuske L. Overview of in vitro allergy tests. UpToDate. <u>www.uptodate.com</u>. Updated April 19, 2024. Accessed August 12, 2024.
- Local coverage determination: allergy skin testing (L33417). Centers for Medicare and Medicaid Services website. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published October 01, 2015 (revised April 15, 2021). Accessed August 12, 2024.
- Burks AW, Jones SM, Boyce JA, et al. NIAID-sponsored 2010 guidelines for managing food allergy: applications in the pediatric population. *Pediatrics*. 2011;128(5):955 to 965. doi:10.1542/peds.2011-0539
- Local coverage determination: allergy testing (L33261). Centers for Medicare and Medicaid Services website. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published October 01, 2015 (revised July 11, 2021). Accessed August 12, 2024.
- Local coverage determination: allergy testing (L36402). Centers for Medicare and Medicaid Services website. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published March 18, 2016 (revised October 01, 2022). Accessed August 28, 2024.
- Local coverage determination: allergy immunotherapy (L32553). Centers for Medicare and Medicaid Services website. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published October 01, 2015 (revised November 02, 2023). Accessed August 28, 2024.
- Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. *Ann Allergy Asthma Immunol*. 2017;118(3):276 to 282.e2. doi:10.1016/j.anai.2016.12.009
- 11. Department of Health and Human Services. Allergen Immunotherapy for Medicare Beneficiaries. Department of Health and Human Services Office of Inspector General Report



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OEI-09-00-00531. <u>https://oig.hhs.gov/oei/reports/oei-09-00-00531.pdf</u>. Published February 2006. Accessed August 27, 2024.

- 12. Kowal K, DuBuske L. Overview of skin testing for IgE-mediated allergic disease. UpToDate. <u>www.uptodate.com</u>. Updated November 30, 2022. Accessed August 27, 2024.
- Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol*. 2008;100(3 Suppl 3):S1 to S148. doi:10.1016/s1081-1206(10)60305-5
- 14. Creticos PS. Subcutaneous immunotherapy (SCIT) for allergic rhinoconjunctivitis and asthma: Indications and efficacy. UpToDate. <u>www.uptodate.com</u>. Updated December 02, 2022. Accessed August 28, 2024.
- 15. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update—2014. *J Allergy Clin Immunol.* 2014;134(5):1016 to 25.e43. doi:10.1016/j.jaci.2014.05.013
- Keet C, Wood RA. Food allergy in children: Prevalence, natural history, and monitoring for resolution. UpToDate. <u>www.uptodate.com</u>. Updated August 11, 2023. Accessed August 28, 2024.
- 17. Wang J. Peanut, tree nut, and seed allergy: Management. UpToDate. <u>www.uptodate.com</u>. Updated January 10, 2023. Accessed August 28, 2024.
- The United States Pharmacopeial Convention (USP) Chapter 797 Pharmaceutical Compounding- Sterile Preparations. <u>https://www.uspnf.com/</u>. Accessed August 28, 2024.