

New and/or Updated Clinical Policies

7/7/2023

PA Health & Wellness (PHW) is adding and/or revising one or more Clinical Policies that are becoming more restrictive and will provide guidelines for use in determining coverage criteria for a well-defined set of specific and clinically appropriate services. The applicable treatment plan as identified in the policy document provides guidance on how claims for certain services are managed. These guidelines are to be used only when there is no other policy, criteria, or coverage statement, as it allows the Plan to control costs. PHW will not supersede the PA State Fee Schedule determination (i.e. - If an item is determined non-experimental and paid for on the State MA fee Schedule it is part of the benefit plan, and the item will be reimbursed at least at that rate.) The policies that dictate the coding and billing rules applied are based on industry standards and guidelines as published and defined in the Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), and public domain specialty society edits, unless specifically addressed in the fee-for-service provider manual published by the State of Pennsylvania or regulations.

To ensure accurate reimbursement, the updated policies will provide the clinically based rule content used to evaluate claims. This is in addition to all other reimbursement processes that PA Health & Wellness currently employs.

The effective date of the change(s) for each policy is 60-days from the date of this document. These policies apply to all PA Health & Wellness products, unless otherwise noted.

The new/updated policies documents can be found embedded on the chart below.

| Policy Number | Policy Name | Line of Business (LOB) |
|---------------|---|---------------------------|
| PA.CP.MP.100 | Allergy Testing and Therapy PA.CP.MP.100 Allergy Testing and Therapy_I | Medicaid |



Clinical Policy: Allergy Testing and Therapy

Reference Number: PA.CP.MP.100 Date of Last Revision: 12/8/2022

Effective Date: 10/19

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. 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.

Please note: unit limitations for allergy testing and treatment are based on the CMS Medicaid/Medicare NCCI MUE limitations:

| | lits - Practitioner S | CI VICES | | | | |
|--|--|--|--|---|------------------|--|
| Based on NCCI Medically Unlikely | y Edits (MUEs) | | | | | |
| lased on 2019 1Q NCCI MUE Edits | s - Practitioner Services | | | | | |
| ublishing to the public requires approval | | | | | | |
| ledically Unlikely Edits (MUEs) define for each H0 | CPCS / CPT code the maximum units of s | service (UOS) that a provider | would report under m | nost circumstances for a single beneficiary on a single d | late of service. | |
| ractitioner services also refers to ambulatory surg | gical centers. | | | | | |
| ME refers to provider claims for durable medical | equipment. | | | | | |
| | | | | | | |
| | ://www.medicaid.gov/me | | | | | |
| Quarter Begin Date | Category | HCPCS/CPT Code | MUE Value | MUE Rationale | | |
| Quarter Begin Date 1/1/2019 | Category Practitioner Services | HCPCS/CPT Code 86005 | MUE Value | MUE Rationale Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 | MUE Value 2 20 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 95004 | MUE Value 2 20 80 | MUE Rationale Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 95004 95017 | MUE Value 2 20 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 95004 | MUE Value 2 20 80 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 95004 95017 | MUE Value 2 20 80 27 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Society Comment | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services Practitioner Services Practitioner Services Practitioner Services | 86005 86005 86008 95004 95017 95018 | MUE Value 2 20 80 27 19 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Society Comment CMS NCCI Policy | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services Practitioner Services Practitioner Services Practitioner Services Practitioner Services Practitioner Services | HCPCS/CPT Code 86005 86008 95004 95017 95018 95024 | MUE Value 2 20 80 27 19 40 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Society Comment CMS NCCI Policy Clinical: Medicare Data | | |
| Quarter Begin Date 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services | HCPCS/CPT Code 86005 86008 95004 95017 95018 95024 95027 | MUE Value 2 20 80 27 19 40 90 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Society Comment CMS NCCI Policy Clinical: Medicare Data Clinical: Medicare Data | | |
| 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 1/1/2019 | Category Practitioner Services | HCPCS/CPT Code 86005 86008 95004 95017 95018 95024 95027 95028 | MUE Value 2 20 80 27 19 40 90 30 | MUE Rationale Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Society Comment CMS NCCI Policy Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data Clinical: Medicare Data | | |

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.



Allergy Testing and Immunotherapy

- 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 members/enrollees 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.
- 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 lifethreatening 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). ^{19*}

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)
- 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



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

Limitations

Allergy Testing

- Retesting with the same antigen(s) should rarely be necessary within a 3-year period. Exceptions include 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.



Allergy Testing and Immunotherapy

- 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 3 to 5 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 caused by a variety of offending agents (e.g., pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, drugs). 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. 17

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.¹⁴

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.¹⁴

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 macroglobular agents.¹⁵ 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.¹⁴



Allergy Testing and Immunotherapy

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.¹⁴

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. 14

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.¹⁴

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.¹⁴

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.



CLINICAL POLICY Allergy Testing and Immunotherapy

Allergen Immunotherapy¹⁸

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.

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 Immunotherapy⁸

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 Schedules¹⁸



Allergy Testing and Immunotherapy

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 1 to 3 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 Therapy¹⁸

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 2 year period when there is no apparent clinical benefit.

Immunotherapy Preparation and Administration¹⁹

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.



CLINICAL POLICY Allergy Testing and Immunotherapy

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 2020, 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. Consistent with CMS allowed units.

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) |



| CPT®* | Description |
|---------|---|
| Codes | Description |
| 95052 | Photo notch tost(s) (specify number of tosts) |
| | Photo patch test(s) (specify number of tests) Photo tests |
| 95056 | |
| 95070 | Inhalation bronchial challenge testing (not including necessary pulmonary |
| 05076 | function tests), with histamine, methacholine, or similar compounds |
| 95076 | Ingestion challenge test (sequential and incremental ingestion of test items, eg, |
| 05070 | 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 |
| 0.54.44 | Professional services for the supervision of preparation and provision of |
| 95144 | antigens for allergen immunotherapy, single dose vial(s) (specify number of |
| | vials) |
| | Professional services for the supervision of preparation and provision of |
| 95145 | antigens for allergen immunotherapy (specify number of doses); single |
| | stinging insect venom |
| | Professional services for the supervision of preparation and provision of |
| 95146 | antigens for allergen immunotherapy (specify number of doses); 2 single |
| | stinging insect venoms |
| | Professional services for the supervision of preparation and provision of |
| 95147 | antigens for allergen immunotherapy (specify number of doses); 3 single |
| | stinging insect venoms |
| | Professional services for the supervision of preparation and provision of |
| 95148 | antigens for allergen immunotherapy (specify number of doses); 4 single |
| | stinging insect venoms |
| | Professional services for the supervision of preparation and provision of |
| 95149 | antigens for allergen immunotherapy (specify number of doses); 5 single |
| | stinging insect venoms |
| | Professional services for the supervision of preparation and provision of |
| 95165 | antigens for allergen immunotherapy; single or multiple antigens (specify |
| | number of doses) |
| | Professional services for the supervision of preparation and provision of |
| 95170 | 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 |
| 93100 | serum) |
| 95199 | Unlisted allergy/clinical immunologic service or procedure |

CPT Code Table 2: Procedure codes considered not medically necessary



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| 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 codes with an * indicate additional digits are needed.
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 |
| H10.01* 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 | |
| L20.0 through | Atopic dermatitis |
| L20.9 | |
| L23.0 through | Allergic contact dermatitis |
| L23.9* | |
| L24.9 | Irritant contact dermatitis, unspecified cause |
| L25.1 through | Unspecified contact dermatitis |
| L25.9 | |
| L27.0 through | Dermatitis due to substances taken internally |
| L27.9 | |
| L30.2 | Cutaneous autosensitization |
| 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 | Description |
|------------------|--|
| R06.2 | Wheezing |
| T36.0X5A through | Adverse effect of drugs |
| T50.995S | |
| T63.001* through | Toxic effects of venoms |
| T63.94* | |
| T78.00X* 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 | Anaphylactic reaction due to adverse effect of correct drug or |
| through | medicament properly administered |
| T88.6XXS | |
| 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 Code | Description |
|----------------|--------------------------------|
| 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 |

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 Code | Description |
|------------------|---------------------------------|
| L27.2 | Dermatitis due to ingested food |
| T36.0X5A through | Adverse effect of drugs |
| T50.995S | _ |



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| ICD-10-CM Code | Description |
|------------------|--|
| 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 | Description |
|------------------|---|
| Code | |
| H10.01* 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 |
| T36.0X5A | Adverse effects of drugs |
| through T50.995S | |
| T63.001* through | Toxic effects of venoms |
| T63.94* | |
| 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 | |



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| ICD-10-CM Code | Description |
|----------------------------|---|
| Z88.0 through Z88.9 | Allergy status to drugs, medicaments, and biological substances |
| Z91.030 through Z91.038 | Insect allergy status |

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

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

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 |
| H10.01* 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 |
| 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) |



| Allergy Testing and | |
|---------------------|---|
| ICD-10-CM | Description |
| Code | |
| 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 | 02/19 | |
| 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. | | |
| Added reference to CMS allowed units | 07/19 | |
| Under III. C., revised "sublingual provocative therapy" to state "non | 10/2020 | 12/2020 |
| 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. | | |
| Added "(scratch, puncture, prick)" to description in I.C.1. Updated | 12/2020 | 2/9/2021 |
| 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. | | |



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| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|------------------|---------------|
| 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 | | |
| Added J30.0 to ICD-10-CM Code Table 1. Minor revision to | 12/22/2021 | |
| 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. | | |
| Annual review complete. Removed codes 86160, 86161 and 86162 from the | 12/8/2022 | |
| 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. | | |

References

- 1. Adkinson N, Yunginger J, Busse W, Bochner B, Holgate S, Middleton E, eds. *Middleton's Allergy: Principles and Practice*. 6th ed. St Louis, MO: Mosby; 2003.
- 2. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol*. 2011;127(1 Suppl):S1 to S55. doi:10.1016/j.jaci.2010.09.034
- 3. Allergen Immunotherapy for Medicare Beneficiaries. Department of Health and Human Services. Office of Inspector General Report OEI-09-00-00531. https://oig.hhs.gov/oei/reports/oei-09-00-00531.pdf. Published February 2006. Accessed August 11, 2022.
- 4. Lawlor GJ, Fischer TJ, Adelman DC. *Manual of Allergy and Immunology*, 3rd ed. Boston, MA: Little Brown and Company; 1995.



- 5. Kowal K, DuBuske L. Overview of skin testing for allergic disease. UpToDate. www.uptodate.com. Updated April 3, 2020. Accessed August 11, 2022.
- 6. 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
- 7. Kowal K, DuBuske L. Overview of in vitro allergy testing. UpToDate. www.uptodate.com. Updated May 3, 2021. Accessed August 11, 2022.
- 8. 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
- 9. Creticos PS. Subcutaneous immunotherapy (SCIT) for allergic disease: Indications and efficacy. UpToDate. www.uptodate.com. Updated August 26, 2019. Accessed August 11, 2022.
- 10. Sampson HA, Aceves S, Bock A, 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
- 11. Keet C, Wood RA. Food allergy in children: Prevalence, natural history, and monitoring for resolution. UpToDate. www.uptodate.com. Updated July 16, 2021. Accessed August 11, 2022.
- 12. Wang J. Peanut, tree nut, and seed allergy: Management. UpToDate. www.uptodate.com. Updated December 18, 2020. Accessed August 11, 2022.
- 13. Choosing Wisely. American Academy of Allergy, Asthma and Immunology. Ten things physicians and patients should question. Accessed at: https://www.choosingwisely.org/societies/american-academy-of-allergy-asthma-immunology/. Published April 4, 2012 (updated March 3, 2014). Accessed August 12, 2022.
- 14. Local coverage determination: allergy testing (L34313). Centers for Medicare and Medicaid Services Website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised October 19, 2019). Accessed August 16, 2022.
- 15. Local coverage determination: allergy skin testing (L33417). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised April 15, 2021). Accessed August 17, 2022.
- 16. Local coverage determination: allergy testing (L33261). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised July 11, 2021). Accessed August 17, 2022.
- 17. Local coverage determination: allergy testing (L36402). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published March 18, 2016 (revised November 26, 2020). Accessed August 17, 2022.
- 18. Local coverage determination: immunotherapy (L32553). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised October 21, 2021). Accessed August 17, 2022.
- 19. American College of Allergy, Asthma, and Immunology. Allergen Immunotherapy Extract Preparation: Instructional Guide. https://college.acaai.org/sites/default/files/acaai-mixinginstructionguide.pdf. Published October 2019. Accessed August 25, 2022.
- 20. 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



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21. The United States Pharmacopeial Convention (USP) Chapter 797 Pharmaceutical Compounding- Sterile Preparations. https://www.uspnf.com/. Accessed September 8, 2022.