Clinical Policy: Allergy Testing and Therapy

Reference Number: TX.CP.MP.100
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Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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]

Policy/Criteria

I. Allergy Testing and Therapy Credentialing Requirements for Providers

Non-allergists, including Primary Care Providers (PCPs), may apply for credentialing to perform allergy skin testing and to prescribe immunotherapy.

A. Allergy Testing and Immunotherapy

Allergy skin testing and therapy may be provided to Superior members who are under the care of an allergist, immunologist, otolaryngologist, pulmonologist or credentialed allergy service physician. The allergist, immunologist, otolaryngologist or pulmonologist or other credentialed provider must maintain the responsibility for prescribing and determining the composition and dosing of the allergen serum.

Providers other than the four specialty provider types listed above must be credentialed to perform allergy skin testing and immunotherapy. The credentialing process requires submission of an attestation, as well as submission of evidence of formal training, clinical experience, and subject matter expertise in the field of allergy skin testing and immunotherapy. The attestation includes confirmation of the knowledge and understanding of allergy clinical practice guidelines and having the necessary equipment and staff to safely administer immunotherapy (allergy shots) to patients at the provider's practice location. These recommendations include:

- Allergen and venom extract storage (4°C refrigerator with alarm)
- 1 ml (for AIT) and 3 ml (for VIT) disposable (safety) syringes with 27-gauge 5/8 inch needles
- Epi-pen auto injectors -0.3 mg for adults and 0.15 mg for children
- Crash cart, basic life support (BLS) + level
- Glucagon

- Vital Signs monitor
- Oxygen administration equipment
- Clinical personnel with BLS + training
- Clinical personnel trained to give shots and to recognize and treat anaphylaxis

The required attestation form is included on page 23 of this policy, and also posted on the health plan's public website for use. After completion, all attestation requests should be mailed to credentialing@centene.com.

Providers will receive notice of verification, or of denial or requests for additional information within 30 days of submission. Providers must receive verification before administering allergy shots.

B. Allergy Immunotherapy Administration ONLY

Immunotherapy administration (allergy shots) may be provided to Superior members who are under the care of an allergist, immunologist, otolaryngologist, pulmonologist or credentialed allergy service physician. These physicians maintain the responsibility for prescribing and determining the composition and dosing of the allergen serum.

Additionally, Superior in-network providers who have been credentialed for immunotherapy administration are permitted to administer allergy shots in their offices and clinics.

Superior does not require a prior authorization for non-allergists who wish to only administer allergy shots prescribed by a credentialed allergy services provider if the non-allergist has completed and submitted the required attestation. The provider must attest to knowledge and understanding of allergy clinical practice guidelines and having the necessary equipment and staff to safely administer immunotherapy (allergy shots) to patients at the provider's practice location. These recommendations include:

- Allergen and venom extract storage (4°C refrigerator with alarm)
- 1 ml (for AIT) and 3 ml (for VIT) disposable (safety) syringes with 27-gauge 5/8 inch needles
- Epi-pen auto injectors -0.3 mg for adults and 0.15 mg for children
- Crash cart, basic life support (BLS) + level
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Providers will receive notice of verification, or of denial or requests for additional information within 30 days of submission. Providers must receive verification before administering allergy shots.

II. It is the policy of health plans affiliated with Centene Corporation® 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.

III. It is the policy of health plans affiliated with Centene 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, including allergist, immunologist, pulmonologist or otolaryngologist. Other specialties must provide evidence of expertise and training consistent with the ACAAI Allergen Immunotherapy Extract Preparation Instructional Guide).[3*]
F. Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (CPT 95165) do not exceed:
    - 84 units per day or 160 units per year for Medicaid and CHIP Members
    - 30 units per day or 120 units per year for Marketplace Members
    - 30 units per day for Medicare Members

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.

IV. It is the policy of health plans affiliated with Centene 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, electro-sensitivity, 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;
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;
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.

- For members receiving allergy immunotherapy, medical records must document administration (subcutaneous injections). The number of injections documented should be consistent with the units of allergy immunotherapy (95165).
  - Note: Injections are covered via CPT codes 95115 or 95117. All documentation must be maintained in the client's record to support medical necessity at the time of any post-payment utilization review.
  - If injections are administered at an outside location/provider, that should be documented in the medical record.

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).[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 Immunotherapy[9]
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 I*mmunotherapy*[10]
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 Schedules[9]
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 Therapy[9]
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 Administration[3]
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 Codes	Description
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, e.g., 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 Codes	Description
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 Codes	Description
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

ICD-10-CM Code	Description
H10.011 through H10.45	Conjunctivitis
J30.0	Vasomotor rhinitis
J30.1 through J30.9	Allergic rhinitis
J31.0	Chronic rhinitis
J45.20 through J45.998	Asthma
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 T50.995S	Poisoning by, adverse effects of and underdosing of drugs, medicaments and biological substances
T63.001A through T63.94XS	Toxic effects of venoms
T78.00XA through T78.1XXS	Anaphylactic reaction due to food
T78.49XA through T78.49XS	Other allergy
T80.52XA through T80.52XS	Anaphylactic reaction due to vaccination
T88.6XXA through T88.6XXS	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered
Z91.010 through Z91.018	Food allergy status

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

ICD-10-CM Code	Description
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified
L23.0 through L23.9	Allergic contact dermatitis
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 T50.995S	Poisoning by, adverse effects of and underdosing of drugs, medicaments and biological substances
T78.00XA through T78.1XXS	Anaphylactic reaction due to food
Z88.0 through Z88.9	Allergy status to drugs, medicaments and biological substances
Z91.010 through Z91.018	Food allergy status

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 H10.45	Conjunctivitis
J30.1 through J30.9	Allergic rhinitis
J31.0	Chronic rhinitis
J45.20 through J45.998	Asthma
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified

ICD-10-CM Code	Description
L23.0 through L23.9	Allergic contact dermatitis
L25.1 through L25.9	Unspecified contact dermatitis
L27.0 through L27.9	Dermatitis due to substances taken internally
L50.0	Allergic urticaria
L50.6	Contact urticaria
T36.0X5A through T50.995S	Poisoning by, adverse effects of and underdosing of drugs, medicaments and biological substances
T63.001A through T63.94XS	Toxic effects of venoms
T78.49XA through T78.49XS	Other allergy
T80.52XA through T80.52XS	Anaphylactic reaction due to vaccination
T88.6XXA through T88.6XXS	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered
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 Code	Description
T36.0X5A through T50.995S	Poisoning by, adverse effects of and underdosing of 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 Code	Description
B44.81	Allergic bronchopulmonary aspergillosis
H10.011 through H10.45	Conjunctivitis
J30.1 through J30.9	Allergic rhinitis
J30.0	Vasomotor rhinitis
J31.0	Chronic rhinitis
J45.20 through J45.998	Asthma
L20.84	Intrinsic (allergic) eczema

ICD-10-CM Code	Description
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified
L23.0 through L23.9	Allergic contact dermatitis
L25.1 through L25.9	Unspecified contact dermatitis
L27.0 through L27.9	Dermatitis due to substances taken internally
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 through T50.995S	Poisoning by, adverse effects of and underdosing of drugs, medicaments and biological substances
T63.001A through T63.94XS	Toxic effects of venoms
T78.00XA through T78.1XXS	Anaphylactic reaction due to food
T78.49XA through T78.49XS	Other allergy
T80.52XA through T80.52XS	Anaphylactic reaction due to vaccination
T88.6XXA through T88.6XXS	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered
Z88.0 through Z88.9	Allergy status to drugs, medicaments and biological substances
Z91.010 through Z91.018	Food allergy status

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created; specialist reviewed	01/16	02/16
Added anaphylactic reaction due to vaccinations to ICD-10-CM code list that support medical necessity for CPT Codes 86003, 86005, 95004, 95017, 95018, 95024, 95027, 95028; removed food allergy testing for patients who present with respiratory symptoms from III.C	12/16	01/17
Clarified that rapid desensitization is appropriate only for medication	02/17	02/17

Reviews, Revisions, and Approvals	Revision Date	Approval Date
and hymenoptera sensitivities and added ICD-10 codes for insect allergy status to CPT 95180 for rapid desensitization. Combined code ranges in all ICD-10 coding tables including J30.1 – J30.9; J45.2* - J45.998; L25.1 – L25.9; L27.0 – L27.9; T78.00X* - T78.1XXS. Added initial encounters to ICD-10 codes that previously only included subsequent and sequela encounter. Added H10.01* - H10.45; T63.001* - T63.94* to ICD-10-CM code table 1 Added expanded code range for conjunctivitis H10.01* - H10.45; L23.0 – L23.9*; L25.1 – L25.9; L27.0 – L27.9; L50.0, L50.6, T36.0X5A – T50.995S; T78.49XA – T78.49XS; T80.52XA – T80.52XS; Z88.0 – Z88.9 to ICD-10-CM code table 5. Added expanded code range T36.0X5A – T50.995S to ICD-10 code table 6		
Under Documentation requirements, removed statement about medical necessity for in vitro vs in vivo testing	04/17	04/17
Frequency limitations for allergy testing and treatment have been removed from this policy as they 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.	6/17	6/17
Added L50.1, L50.8, and L50.9 to ICD-10-CM Code Table 1 and Table 2	07/17	07/17
References reviewed and updated. Codes reviewed.	01/18	01/18
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.	01/19	01/19
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.	11/19	12/19
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 through Z88.9 in ICD-10 Tables 4 & 5. References reviewed and updated. Replaced member with member/enrollee in all instances.	10/20	10/20
Added ICD-10 code range Z91.010 through Z91.018 to Tables 1 & 4.	10/20	10/20
Added J30.0 to ICD-10-CM Code Table 1. Minor revision to description of CPT 95070. CPT 95071 deleted in 2021.	03/21	03/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.	09/21	09/21
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.	03/22	03/22
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.	05/22	05/22
Annual review. 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.	09/22	09/22
Annual review. 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.	09/24	09/24
Incorporated allergy credentialing information, included allergy attestation forms, and added additional medical record documentation.	11/24	

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Important reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

Provider Attestation Statement
Allergy Skin Testing and Immunotherapy for Non-Allergists

Please submit via email to Credentialing@SuperiorHealthPlan.com or fax to 866-702-4831.

Physician's Name:	
Provider Type:	
NPI Number:	
Tax ID Number:	
Physical Address:	
Contact Number:	

Please check one or both of the following attestation statements which apply to you:

☐ I attest that I, as a non-allergist, am clinically trained to provide allergy skin testing and immunotherapy.
(Please provide evidence of formal training, clinical experience, and subject matter expertise in the field of allergy skin testing and immunotherapy.)

☐ I attest that I understand allergy clinical practice guidelines recommend that I have the following equipment and staff to safely provide immunotherapy (allergy shots) to patients at my location of practice:

- ☐ Aeroallergen and venom extract storage (4 degrees C refrigerator with alarm)
- ☐ 1 ml (for AIT) and 3 ml (for VIT) disposable (safety) syringes with 27 gauge 5/8 inch needles
- ☐ Epi-pen auto injectors – 0.3 mg for adults and 0.15 mg for children
- ☐ Crash cart – BLS+ level
- ☐ Glucagon
- ☐ Vital Signs monitor
- ☐ Oxygen administration equipment
- ☐ Personnel with BLS+ training
- ☐ Personnel trained to give shots, recognize and treat anaphylaxis

Physician Signature:		Date:	
Printed Name:			

By signing this document, I certify that the information provided herein is true, accurate and complete to the best of my knowledge. I understand that under my Provider Participation Agreement, Superior HealthPlan, and applicable Regulators including the Centers for Medicare and Medicaid Services, and the Texas Health and Human Services (HHS) or their Representatives, may inspect and evaluate my records related to Members and the provision of and payment for services to audit compliance with this review requirement, and other contractual requirements and Federal and State Laws or Regulations.

Provider Attestation Statement
Allergy Immunotherapy (Allergy Shot Administration ONLY) for Non-Allergists

Physician's Name:	
Provider Type:	
NPI Number:	
Tax ID Number:	
Physical Address:	
Contact Number:	

Please check the following attestation statement, and the specific equipment and trainings which apply to your place of service:

- ☐ I attest that I understand allergy clinical practice guidelines recommend that I have the following equipment and staff to safely provide immunotherapy (allergy shots) to patients at my location of practice:
  - ☐ Aeroallergen and venom extract storage (4 degrees C refrigerator with alarm)
  - ☐ 1 ml (for AIT) and 3 ml (for VIT) disposable (safety) syringes with 27 gauge 5/8 inch needles
  - ☐ Epi-pen auto injectors – 0.3 mg for adults and 0.15 mg for children
  - ☐ Crash cart – BLS+ level
  - ☐ Glucagon
  - ☐ Vital Signs monitor
  - ☐ Oxygen administration equipment
  - ☐ Personnel with BLS+ training
  - ☐ Personnel trained to give shots and to recognize and treat anaphylaxis

Physician Signature:		Date:	
Printed Name:			

By signing this document, I certify that the information provided herein is true, accurate and complete to the best of my knowledge. I understand that under my Provider Participation Agreement, Superior HealthPlan, and applicable Regulators including the Centers for Medicare and Medicaid Services, and the Texas Health and Human Services (HHS) or their Representatives, may inspect and evaluate my records related to Members and the provision of and payment for services to audit compliance with this review requirement, and other contractual requirements and Federal and State Laws or Regulations.