Applicable To:
☑ Medicaid - Kentucky

Claims and Payment Policy: Allergy Testing and Immunotherapy (Kentucky)

Policy Number: CPP-112

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BACKGROUND

Allergy is the fifth leading chronic disease in the United States, and allergy and asthma affects one in five Americans. Allergy is a type I hypersensitivity response mediated by Immunoglobulin E (IgE). Following exposure to an allergen which binds to IgE on mast cells and basophils, these cells release mediators such as histamine that elicit an immediate response. Manifestations of this response include cutaneous, respiratory, cardiovascular, and gastrointestinal symptoms in addition to anaphylaxis, a potentially lethal reaction. IgE-mediated clinical conditions include hypersensitivity reactions to foods, insects, drugs, and latex; allergic rhinitis; asthma; urticaria; angioedema; atopic dermatitis; and allergic bronchopulmonary aspergillosis. Allergy tests are a crucial step in the management of these conditions.

The two most clinically utilized tests for allergy are office-based skins tests (in vivo testing) and laboratory tests that measure specific IgE antibodies (in vitro testing). Skin tests involve the introduction of an allergen extract into the skin by a prick or puncture technique or by an intradermal technique. In vitro tests are used a gamma counter to quantify radioactively labeled IgE antibody bound to a solid-phase antigen on a paper disc. The sensitivity of these assays compared to skin tests averages 70-75%, but it is notable that there is no gold standard for allergen-specific IgE testing by which to assess skin tests or in vitro tests. The three enzymatic assays may not yield the same results, and IgE levels from differing assays may not be interchangeable. For this reason, it is desirable to use the same assay over time for a patient.

Allergen immunotherapy (known in lay parlance as allergy shots) is based on the findings of skin or serum allergy testing in combination with the clinical history. This therapy exposes patients in a controlled fashion to specific allergens with the aim of achieving symptom remission. Studies have shown that allergy immunotherapy may prevent asthma in patients with allergic rhinitis.6 Patients receiving immunotherapy for allergy usually experience an initial increase in specific IgE antibody levels with a subsequent decrease in these levels over time. Patients note improvement of symptoms before the levels decrease, and a decrease in specific IgE levels is not necessary for immunotherapy to be efficacious.

POSITION STATEMENT

In accordance with CMS Local Coverage Determinations (LCDs), WellCare may deny or pend claims that do not align with CMS allergy immunotherapy and testing billing and coding guidelines. Providers may submit medical record documentation in support of payment. If the medical records support payment, the claim will be paid.

It is the policy of WellCare Health Plans that allergy testing is **medically necessary** for members 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 to be exposed to

C. Chosen test and units allowed per year are as follows:

- Percutaneous testing (also called "scratch testing;" CPT 95004, 95017, 95018) for offending allergens such as pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, or drugs, up to 100 units per year.
- 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;
- If photo tests (CPT 95056) are performed with patch or application test(s) (CPT 95044), only the photo tests should be reported.

It is the policy of WellCare Health Plans 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:

- Allergic (extrinsic) asthma,
- Dust mite atopic dermatitis,
- Hymenoptera (bees, hornets, wasps, fire ants) allergic reactions,
- Mold-induced allergic rhinitis,
- Perennial allergic rhinitis,
- 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 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 an allergist, immunologist, or otolaryngologist who has examined the patient

F. Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (CPT 95165) 120 units per year.

It is the policy of WellCare 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)

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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

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. Candidiasis test
4. Chemical analysis of body tissues (e.g., hair)
5. Chlorinated pesticides (serum)
6. Complement (total or components)
7. C-reactive protein
8. Cytokine and cytokine receptor assay
9. Cytotoxic testing for food, environmental or clinical ecological allergy testing (Bryans Test, ACT)
10. Electrodermal testing or electro-acupuncture
11. ELISA/Act qualitative antibody testing
12. Food immune complex assay (FICA)
13. Immune complex assay
14. Ingestion challenge food testing for diagnosing rheumatoid arthritis, depression, or respiratory disorders not associated with anaphylaxis or similar systemic reactions
15. In vitro metal allergy testing
16. Iridology
17. Leukocyte histamine release test (LHRT)/basophil histamine release test
18. Lymphocyte function assay
19. Lymphocytes (B or T subsets)
20. Lymphocyte Response Assay (LRA) by ELISA/ACT and Lymphocyte Mitogen
21. Response Assays (LMRA) by ELISA/Act
22. Mediator release test (MRT)
23. Ophthalmic mucus membrane tests/conjunctival challenge test
24. Prausnitz-Kustner (P-K testing) passive cutaneous transfer test
25. 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.
26. Provocative nasal test
27. Pulse test (pulse response test, reaginic pulse test)
28. Rebuck skin window test
29. Sage Complement Antigen Test
30. 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)
31. Testing of specific immunoglobulin G (IgG) (e.g., by Radioallergosorbent [RAST] or
32. Enzyme-linked immunosorbent assay [ELISA])
33. Testing of total serum IgG, immunoglobulin A (IgA) and immunoglobulin M (IgM)

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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. Sublingual provocative therapy
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.

Per CMS Billing and Coding Guidelines for Allergy Testing (LCD L36402), Evaluation and Management codes reported with allergy testing is appropriate only if a significant, separately identifiable E/M service is performed. When appropriate, use modifier - 25 with the E/M code to indicate it as a separately identifiable service. If E/ M services are reported, medical documentation of the separately identifiable service must be in the medical record..

Allergy testing is not performed on the same day as allergy immunotherapy in standard medical practice. These codes should, therefore, not be reported together. Additionally, the testing becomes an integral part to rapid desensitization kits (CPT code 95180) and would therefore not be reported separately.

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Allergy testing is covered when clinically significant symptoms exist and conservative therapy has failed. Allergy testing includes the performance, evaluation, and reading of cutaneous and mucous membrane testing along with the physician taking a history including immunologic history, performing the physical examination, deciding on the antigens to be used, and interpreting results.

Standard skin testing is the preferred method when allergy testing is necessary. Each test should be billed as one unit of service per procedure code, not to exceed two strengths per each unique antigen. Histamine and saline controls are appropriate and can be billed as two antigens. The number of antigens should be individualized for each patient based on history and environmental exposure.

Allergy Testing and Immunotherapy

Per the CMS Pub National Correct Coding Initiative (NCCI) Policy Manual, Chapter 11- CPT codes 90000-99999, K. Allergy Testing and Immunotherapy, if percutaneous or intracutaneous (intradermal) single test (CPT codes 95004 or 95024) and “sequential and incremental" tests (CPT codes, 95017, 95018, or 95027) are performed on the same date of service, both the "sequential and incremental" test and single test codes may be reported if the tests are for different allergens or different dilutions of the same allergen. The unit of service to report is the number of separate tests.

A single test and a “sequential and incremental” test for the same dilution of an allergen should not be reported separately on the same date of service. For example, if the single test for an antigen is positive and the physician proceeds to “sequential and incremental” tests with three additional different dilutions of the same antigen, the physician may report one unit of service for the single test code and three units of service for the “sequential and incremental” test code.

Evaluation and management (E/M) codes reported with allergy testing or allergy immunotherapy are appropriate only if a significant, separately identifiable service is performed. If E/M services are reported, modifier 25 should be utilized.

In general allergy testing is not performed on the same day as allergy immunotherapy in standard medical practice. Allergy testing is performed prior to immunotherapy to determine the offending allergens. CPT codes for allergy testing and immunotherapy are generally not reported on the same date of service unless the physician provides allergy immunotherapy and testing for additional allergens on the same day.

Physicians should not report allergy testing CPT codes for allergen potency (safety) testing prior to administration of immunotherapy. Confirmation of the appropriate potency of an allergen vial for immunotherapy is an inherent component of immunotherapy. Additionally, allergy testing is an integral component of rapid desensitization kits (CPT code 95180) and is not separately reportable.

Non-covered Allergy Testing

Per Billing and Coding Guidelines for Allergy and Immunotherapy LCD (L34597), non-covered allergy testing includes the following:

Sublingual Intracutaneous and subcutaneous Provocative and Neutralization Testing: Effective October 31, I988, sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded from coverage because available
evidence does not show that these tests and therapies are effective.

Cytotoxic Food Tests: Effective August 5, I985, cytotoxic leukocyte tests for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective.

Non-covered Immunotherapy

Sublingual immunotherapy (SLIT) involves the use of FDA approved allergenic extracts administered orally. In early 2014, the FDA approved oral administration of 3 allergenic extracts, two for grasses and one for ragweed. These extracts are not approved by the FDA for anyone over the age of 65 years. Effective October 31, 1988, sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded from coverage because available evidence does not show that these tests and therapies are effective.

Place of Service (POS)

Per LCD (L34597) guidelines, the following POS is covered for Allergy Testing and Immunology:

- CPT procedure codes 95115, 95117 and 95144 are payable only in an office setting (11).
- CPT procedure codes 95145-95170 are payable in the office (11) and in a hospital outpatient department (22). These codes are also payable in a skilled nursing facility (31), but only if the physician is present.
- CPT procedure codes 95060, 95065, 95180 are payable in office (11) and hospital settings (21, 22, 23).

CODING & BILLING

CPT Code Table 1: Procedure codes considered medically necessary

Code	Description
86003	Allergy specific IgE; quantitative or semiquantitative, crude allergen extract, each
86005	Allergen specific IgE; qualitative, multiallergen screen (dipstick, paddle, or disk)
86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
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
95060	Ophthalmic mucous membrane tests

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IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims or claim line processing and/or reimbursement related to the administration of health plan benefits. They are not recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for diagnosing, treating, and making clinical recommendations to the member. CPPs are subject to, but not limited to, the following:

- State and federal laws and regulations;
- Policies and procedures promulgated by the Centers for Medicare and Medicaid Services, including National Coverage Determinations and Local Coverage Determinations;
- The health plan's contract with Medicare and/or a state's Medicaid agency, as applicable;
- Other CPPs and clinical policies as applicable including, but not limited to, *Pre-Payment and Post-Payment Review*.
- The provisions of the contract between the provider and the health plan; and
- The terms of a member's particular benefit plan, including those terms outlined in the member's Evidence of Coverage, Certificate of Coverage, and other policy documents.

In the event of a conflict between a CPP and a member's policy documents, the terms of a member's benefit plan will always supersede the CPP.

The use of this policy is neither a guarantee of payment, nor a prediction of how a specific claim will be adjudicated. Any coding information is for informational purposes only. No inference should be made regarding coverage or provider reimbursement as a result of the inclusion, or omission, in a CPP of a CPT, HCPCS, or ICD-10 code. Always consult the member's benefits that are in place at time of service to determine coverage or non-coverage. Claims processing is subject to a number of factors, including the member's eligibility and benefit coverage on the date of service, coordination of benefits, referral/authorization requirements, utilization management protocols, and the health plan's policies. Services must be medically necessary in order to be covered.

References to other sources and links provided are for general informational purposes only, and were accurate at the time of publication. CPPs are reviewed annually but may change at any time and without notice, including the lines of business for which they apply. CPPs are available at www.wellcare.com. Select the "Provider" tab, then "Tools" and then "Payment Guidelines".

RULES, PRICING & PAYMENT COMMITTEE HISTORY AND REVISIONS

Date	Action
10/30/2019	• Approved by RGC