

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302, 05402, 52280

Contractor Type

Carrier
Intermediary
MAC - A
MAC - B

LCD Database ID Number

LCD Version Number

LCD Title

Allergy Testing and Allergy Immunotherapy

Contractor's Determination Number

ALRG-001

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CMS National Coverage Policy

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act, section 1862(a)(6).

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Medicare Manual:

- 200 - Allergy Testing and Immunotherapy (Rev. 1, 10-01-03) B3-15050;
- A - Allergy Testing
- B - Allergy Immunotherapy

Formerly:

Medicare Carrier Manual 2050.1, 2005.2, 2050.2, 2049.4, 15050
Coverage Issues Manual: 45-28; 50-2; 50-53; 65-9

Primary Geographic Jurisdiction

Intermediary: Alaska, Alabama, Arizona, Arkansas, California - Entire State, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri - Entire State, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, American Samoa, Guam, Northern Mariana Islands, U.S. Virgin Islands

Legacy B: Wisconsin, Illinois, Michigan, Minnesota

MAC AB: Iowa, Missouri, Nebraska, Kansas

Oversight Region

Region I

Region V

Region VII

Original Determination Effective Date

Revision Effective Date

Indications and Limitations of Coverage and/or Medical Necessity

LCD Description

I. Allergy Testing

A. Allergy sensitivity tests:

The performance and evaluation of selective cutaneous and mucous membrane tests in correlation with history, physical examination, and other observations of the patient. These tests are performed to determine body sensitivity and reaction to the antigen for the purpose of diagnosing the presence of allergic reaction to antigenic stimuli. The number of tests performed should be judicious and dependent upon the history, physical finding and clinical judgment. All patients should not necessarily receive the same tests or the same number of sensitivity tests. Intradermal tests are injections of small amounts of antigen into the superficial layers of the skin.

B. Patch testing:

Patch testing is the gold standard method of identifying the cause of allergic contact dermatitis, a delayed cell-mediated type IV hypersensitivity reaction. It is a diagnostic test reserved for patients with skin eruptions for which a contact allergy source is likely.

The patch test procedure can induce an eczematous reaction in miniature by applying suspect allergens to normal skin, allowing the physician to determine a specific patient allergy. Patch tests are applied to the skin on the patient's back and left in place for 48 hours. The test is interpreted after 48 hours, and typically once again at 72 or 96 hours, and the reactions are systematically scored and recorded. The patient is then informed and educated regarding specific allergies and avoidance of exposure. Avoidance of the identified allergen(s) is critical to patient improvement and resolution of the dermatitis.

Examples of contact allergens (antigens) include nickel, rubber additives, and topical antibiotics. These allergens are part of a useful, but limited series of 24 allergens. While this series of 24 allergens represents some of the most common contact allergies, there are a significant number of patients who suffer intractable contact dermatitis for which the 24 allergens are inadequate to diagnose their problem. A supplemental series of allergens in this case can enhance accurate diagnosis, patient education, and treatment. This supplemental series is particularly critical in the diagnosis of occupationally induced dermatitis.

II. Allergy Immunotherapy

Allergen immunotherapy is defined as 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 natural exposure to these allergens. Immunotherapy includes all methods that attempt to overcome abnormal immune responses by inducing clonal deletion, anergy, immune tolerance, or immune deviation.

IT begins with the injection of low doses of antigenic or allergenic extract made specifically for an individual patient, to prevent untoward reactions, with gradually increasing doses injected once or twice a week. Immunotherapy (hyposensitization) may extend over a period of years, usually on an increasing dosage scale. This is followed by a build-up of tolerance to the antigen, as evidenced by the markedly higher doses that can be administered and a decline in the symptoms and medication requirements of the patient. After the maintenance dose is achieved and clinical improvements are seen, the interval between injections may range between one and six weeks.

Indications and Limitations of Coverage and/or Medical Necessity

I. Allergy sensitivity tests:

- A. 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. These are considered technical services. The Physician work of taking a history, performing the physical examination, deciding on the antigens to be used, interpretation of results, counseling & prescribing treatment should be reported using a visit or consultation code.
- B. To be covered by Medicare, antigens must meet all of the following criteria:
 - 1. Skin testing must be performed based on history and physical exam
 - 2. Have proven efficacy as demonstrated through scientifically valid medical studies published in a peer-review journal
 - 3. Exist in the patient's environment with a reasonable probability of exposure
- C. **Provocative tests:**

Procedures for which there is limited or no evidence of validity include the cytotoxic test, the provocation-neutralization procedure, electrodermal diagnosis, applied kinesiology, the "reaginic" pulse test, and chemical analysis of body tissues. Controlled studies for the cytotoxic and provocation-neutralization tests demonstrated that the results are not reproducible and do not correlate with clinical evidence of allergy. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. Similarly, the "reaginic" pulse test and chemical analysis of body tissues for various exogenous chemicals have not been substantiated as valid tests for allergy.

1. Organ challenge test materials may be applied to the mucosae of the conjunctivae, nares, GI tract, or bronchi. Considerable experience with these methods is required for proper interpretation and analysis.
2. All organ challenge tests should be preceded by a control test with diluent and, if possible, the procedure should be performed on a double blind or at least single-blind basis.
3. **Nasal challenge tests:**
Nasal challenge tests may be informative provided that the patient's nasal mucosa does not manifest nonspecific irritative responses and the results can be interpreted by objective measurements.
Ophthalmic mucous membrane tests (95060) and direct nasal mucous membrane tests (95065) are approved if levels of allergic mediators (such as histamine and tryptase) are measured and a placebo control is performed. This is usually performed in allergy research laboratories. It is also approved in the office setting if the physician is there to observe objective measurement of reactions which might include redness of the eyes, tearing and sneezing.
4. **Bronchial challenge tests:**
Bronchial challenge tests are often used to evaluate new allergens and may be used to substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples.
 - a. Bronchial challenge tests should be performed as dose-response assays wherein provocation concentration thresholds can be determined on the basis of allergen concentration required to cause a significant decrease in measured pulmonary function.
 - b. Bronchial challenge tests with occupational allergens need to be carefully controlled with respect to dose and duration of exposure. When industrial small molecular weight agents are assessed, tests should be performed under conditions of continuous monitoring of the specific chemical being assessed so as not to exceed the threshold limit level permitted in the workplace.
5. **Challenge Ingestion Food Testing** (95075) 110.12 formerly CIM50-22
(Effective for services performed on and after August 1, 1978.)

Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis if it is reasonable and necessary for the individual patient.

WPS Medicare will cover this test for the following indications:

Food allergy, dermatitis
Anaphylactic shock due to adverse food reaction
Allergy to medicinal agents
Allergy to foods

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders.

Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of section 1862(a)(1) of the Medicare law, and no program payment is made for this procedure when it is so used.

- D. When allergy testing is necessary, skin testing is the preferred method. 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.

The American College of Allergy Asthma and Immunology Practice Parameters indicate the following:

"The evaluation of inhalent allergy may require up to 70 prick-puncture tests followed by up to 40 intracutaneous tests, which are ordinarily performed when prick puncture tests are negative. Under special circumstances and in certain geographical areas, a greater number of prick/puncture tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required.

The number of prick puncture tests performed for suspected food hypersensitivity may vary from less than 20 to as many as 80 tests, depending on the clinical situation."

- E. **Specific IgE in Vitro Test (RAST, MAST, FAST) 86003**

These tests detect antigen-specific IgE antibodies in the patient's serum. They are useful when testing for inhalant allergens (pollens, molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs or latex, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism, or in children younger than four years of age.

In-vitro testing is not as sensitive as skin testing, but is covered when skin testing is not possible or would be unreliable as indicated below. When in-vitro testing is ordered or performed, the medical record must clearly document the indication. In-vitro testing is covered only as a substitute for skin testing. It is not covered when done in addition to a skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed. The number of tests done; choices of antigens, frequency of repetition and other coverage issues are the same as for skin testing. Control testing is essential for proper interpretation. It is rarely necessary to test for more than 50 allergies and, if food allergy is not suspected, fewer than 30 are usually sufficient. Testing must be based on a careful history/physical examination which suggests IgE-mediated disease. If testing is inconclusive, and contraindications for skin testing have been resolved, then skin testing may be done and is covered. The medical record must document this rationale. Twelve (12) allergens per panel are used but no more than 2 panels/beneficiary over a 12-month period are allowed. The medical necessity of more tests must be submitted with the claim.

1. In-vitro allergen specific IgE testing is limited to the following:
 - a. Direct skin testing (95024) is not possible due to extensive dermatitis, dermatographism, ichthyosis, generalized eczema or the necessary continued use of H-1 blockers (antihistamines), or in the rare patient with a persistent unexplained negative histamine control.

- b. Testing in patients who have been receiving long-acting antihistamines, tricyclic antidepressants, beta-blockers or medications that may put the patient at undue risk if they are discontinued.
- c. Testing of uncooperative patients with mental or physical impairments.
- d. The evaluation of cross-reactivity between insect venoms;
- e. As adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases; and
- f. When clinical history suggests an unusually greater risk of anaphylaxis from skin testing than usual (e.g., when an unusual allergen is not available as a licensed skin test extract).

Twelve (12) allergens per panel are used but no more than 2 panels/beneficiary over a 12-month period are allowed. The medical necessity of more tests must be submitted with the claim.

- 2. Total Serum IgE (82785, 83518) is covered for follow-up of bronchopulmonary aspergillosis and it may be necessary to diagnose atopy in small children. It is also covered in association with the drug Omalizumab, Xolair (The patient's pretreatment serum IgE level and body weight are used to determine doses and dosing frequency). It is not appropriate in most general allergy testing. Instead, individual IgE tests are performed against a specific antigen.
- 3. Quantitative multi-allergen screen (86005) is a non-specific screen that does not identify a specific antigen. It is a screening tool and therefore not covered by Medicare.

F. **Intracutaneous testing, delayed reaction** - more than 6 tests, Procedure code 95028 may be covered but requires additional justification and case-by-case review for the number of tests performed and the medical necessity except when the skin test is used for:
*A collagen sensitivity. (CPT code 95028 and HCPCS *Q3031) must be administered prior to collagen implant therapy (Injectable Bulking Agent Implantation for Urinary Incontinence, and it must be evaluated over a four-week period. Coverage Issues Section 65-9*

G. **Intradermal Dilutional Testing (IDT)** (also known as Skin Endpoint Titration [SET]) Intradermal dilutional testing is intradermal testing of sequential and incremental dilutions of a single antigen. The endpoint is determined by intradermal testing with the use of approximately 0.1-ml of generally serial five-fold dilution extract. It is the weakest dilution that produces a positive skin reaction and initiates progressive increase in the diameter of the wheals with each stronger dilution. In a guideline, revised in 2003, the American Academy of Otolaryngic Allergy (AAOA) recommends screening prick tests with relevant antigens to determine which to use in subsequent intradermal dilutional testing. If screening is positive and immunotherapy is contemplated, the AAOA recommends no more than 40 antigen be tested unless indicated by unusual clinical circumstances.

H. **Patch Testing:**
 Allergy patch testing is a covered procedure only when used to diagnose allergic contact dermatitis after the following exposures:

Dermatitis due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other chemical products, food in contact with skin, plants (except food), cosmetics, metals, other and unspecified.

- a. A maximum of 50 patch tests per beneficiary per year is allowed without the submission of documentation with the claim to support medical necessity.
- b. Greater than 50 patch tests per patient per year requires the submission of documentation with the claim to support medical necessity.

I. The following tests are considered not medically necessary:

- Provocative Testing - 95078
- Blood, Urine or Stool Micro-nutrient Assessments
- Qualification of Nutritional Assessments
- IgG (ELISA) Tests -86001
- Environmental Cultures and Chemicals
- Live Cell Analysis
- Passive Transfer
- Rebutck Skin Window
- Leukocyte Histamine Release - 86343
- Metabolic Assessments
- General Immune System Assessments
- Secretory IgA (Saliva)
- Qualitative multi-allergen screen - 86005
- Food Allergenic Extract Immunotherapy
- Cytotoxic Food Testing

II. Allergy Immunotherapy

Indications for immunotherapy are determined by diagnostic testing appropriate to the individual needs of each patient and his/her clinical history of allergic diseases. Allergen immunotherapy should be differentiated from the process of desensitization, which usually applies to the rapid progressive administration of an allergenic substance to render effector cells less reactive.

The technique of allergen immunotherapy should also be differentiated from unproven techniques such as sublingual treatment and neutralization-provocation therapy.

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.

Indications for immunotherapy are determined by appropriate diagnostic procedures coordinated with clinical judgment and knowledge of the natural history of allergic diseases. Controlled studies have shown that allergen immunotherapy is effective for patients with allergic rhinitis or conjunctivitis, allergic asthma, and stinging insect hypersensitivity.

- A. The necessity of allergen immunotherapy may also depend on the degree to which symptoms can be reduced by medications; the ability of the patient to tolerate possible side effects of the medication; the amount, type and cost of the medications required to control symptoms; and whether proper avoidance is possible.

- B. Aeroallergen immunotherapy is indicated for patients with allergic rhinitis due to seasonal pollinosis caused by trees, grasses and weeds, and in the treatment of mold-induced rhinitis. It is also indicated for perennials such as cat and dog dander, dust mite and cockroach.
- C. Venom immunotherapy is indicated for patients who have a severe systemic anaphylactic reaction 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.
- D. Rapid desensitization is indicated in cases of allergy to insulin, penicillin and horse serum, as well as sulfonamides, cephalosporins and other commonly used drugs (e.g. aspirin). 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 requires strict physician monitoring in a hospital intensive care setting with continuous monitoring of vital signs and cardio-respiratory status. Desensitization may need to be repeated if future circumstances require an additional course of the offending allergen.
- E. Standardized dust mite extracts appear effective for immunotherapy. Other environmental allergens (e.g., kapok, jute, feathers, and unstandardized house dust extracts) are of questionable value in immunotherapy, however, and generally should not be used.
- F. Allergen-induced asthma is an indication for immunotherapy along the guidelines for allergic rhinitis when there is a poor response to environmental control or pharmacologic treatment.
Allergen immunotherapy is divided into codes that describe the injection only and codes that describe the preparation of the antigen to be delivered for injection by a different physician.
- G. Clinical studies to date do not support the use of allergen immunotherapy for food hypersensitivity, chronic urticaria, or angioedema. Therefore, allergen immunotherapy for patients with these conditions is not recommended.
- H. The following services are considered investigational and are considered not medically necessary services.
- a. Desensitization with commercially available extracts of poison ivy, poison oak, or poison sumac
 - b. Desensitization for hymenoptera sensitivity using whole body extracts, with the exception of fire ant extracts.
 - c. Desensitization with bacterial vaccine (BAC: bacterial, antigen complex, streptococcus vaccine, staphylo-strepto vaccine, serobacterin, staphylococcus phage lysate)
 - d. Food allergenic extract immunotherapy
 - e. Intracutaneous desensitization (Rinkel Injection Therapy, RIT)
 - f. Intracutaneous titration
 - g. Neutralization therapy (intradermal and subcutaneous)
 - h. Repository emulsion therapy

- i. Sublingual desensitization
 - j. Sublingual provocative therapy
 - k. Urine autoinjection (autogenous urine immunotherapy)
 - l. Allergen immunotherapy for the management of skin and mucous membrane disease such as atopic dermatitis, urticaria, and Candida vulvovaginitis
 - m. Intranasal immunotherapy
 - n. Postmortem examination for IgE antibodies to identify allergens responsible for lethal anaphylaxis (post mortem work is not-covered by Medicare);
- I. **Treatment Schedules**
The starting dose of an allergenic extract and the progression of the dose must be individualized for each patient. The standard schedule uses a weekly injection that begins with one to two treatments per week, with gradual tapering of the frequency of injections when maintenance levels are achieved. Administration of high doses of allergen (e.g., 1:100 to 1:30 wt/vol or the highest dose tolerated) is the ultimate goal for this type of schedule. However, the weekly schedule often requires several months of increasing concentrations before maximum or maintenance dosage is attained.
- J. **Length of Therapy**
The duration of all forms of immunotherapy must be individualized. A presumption of failure can be made when, after 12-24 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.
For many patients, the recommended duration of allergen immunotherapy is 3 to 5 years. However, the duration of immunotherapy should be individualized on the basis of clinical response, disease severity, immunotherapy reaction history, and patient preference. Treatment will not be reimbursed after a 2-year period when there is no apparent clinical benefit.
- K. Patients who are mentally or physically unable to communicate clearly with the allergist and those with a history of noncompliance are not good candidates for allergy immunotherapy.
- L. *Immunotherapy with whole-body extracts of biting insects or other arthropod (95170) is covered only for fire ant extracts.*
- M. Evaluation and management codes are separately reimbursable on the same day as allergen immunotherapy only when a significant, separately identifiable service is performed.

Coverage Topic

Doctor Office Visits
Hospital Care (Inpatient)
Outpatient Hospital Services
Pathology and Laboratory

Coding Guidelines

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that

Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

11x	Hospital-inpatient (including Part A)
12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
21x	SNF-inpatient, Part A
22x	SNF-inpatient or home health visits (Part B only)
23x	SNF-outpatient (HHA-A also)
71x	Clinic-rural health
73x	Clinic-independent provider based FQHC (eff 10/91)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the article services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the fiscal intermediary. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH may elect to bill their carrier or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI using revenue codes 096X, 097X or 098X.

0510	Clinic-general classification
0517	Clinic-family practice clinic (eff 10/96)
0519	Clinic-other
0520	Free-standing clinic-general classification
0521	Free-standing clinic-rural health clinic
0522	Free-standing clinic-rural health home
0523	Free-standing clinic-family practice
0524	Visit by RHC/FQHC practitioner to a member in a covered Part A stay at the SNF
0525	Visit by RHC/FQHC practitioner to a member in a SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility

0528	Visit by RHC/FQHC practitioner to other non RHC/FQHC site (e.g., scene of accident)
0529	Free-standing clinic-other
0982	Professional fees-outpatient services
0983	Professional fees-clinic

CPT/HCPCS Codes

Allergy Testing

86003	Allergen specific IgE; quantitative, each panel of up to 12 allergens
86005	Qualitative, multi-allergen screen (dipstick, paddle or disk)
82785	IgE level
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95010	Percutaneous tests (scratch, puncture, prick) sequential and incremental, with drugs, biologicals, or venoms, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95015	Intracutaneous (intradermal) tests, sequential and incremental, with drugs, biologicals, or venoms, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95024	Intracutaneous (intradermal) test with allergenic extracts, immediate type reaction, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95027	Intracutaneous (intradermal) tests, sequential and incremental, with Allergenic extracts for airborne allergens, immediate type reaction, immediate type reaction, including test interpretation and report by a physician, 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
95065	Direct nasal mucous membrane test
95075	Ingestion Challenge Test (sequential and incremental ingestion of test items, e.g., food, drug or other substance such as metabisulfite)
95078	Provocative testing (e.g., Rinkel test)

Allergy Immunotherapy

95115	Professional services for allergen immunotherapy not including provision of extract; single injection
95117	---; two 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
95146	---; two stinging insect venoms
95147	---; three stinging insect venoms
95148	---; four stinging insect venoms
95149	---; five 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	---; whole body extract of biting insect or other arthropod (specify number of doses)
95180	Rapid desensitization procedure, each hour (e.g. insulin, penicillin, equine serum)
95199	Unlisted allergy/clinical immunologic service procedure

Note:

CPT/HCPCS Codes For 95120-95134 describe the “complete service” (injection and antigen provision). These codes are not valid for Medicare purposes.

Does the CPT 30% Rule Apply

No

ICD-9 Codes that Support Medical Necessity

Allergy Testing: 95004, 95010, 95024, 95027

ICD-9 code	Description
372.00	Acute conjunctivitis, unspecified
372.05	Acute atopic conjunctivitis
372.13	Vernal conjunctivitis
372.14	Other chronic allergic conjunctivitis
381.01	Serous otitis media, acute
381.3	Chronic allergic nonsuppurative otitis media
382.9	Unspecified otitis media
461.0 - 461.9	Acute sinusitis
462	Pharyngitis
463	Tonsillitis
464.00	Acute laryngitis without mention of obstruction
464.01	Acute laryngitis with mention of obstruction
464.50	Supraglottitis, unspecified without mention of obstruction
464.51	Supraglottitis, unspecified with obstruction
466.0	Acute bronchitis
471.0	Polyp of nasal cavity
471.8	Other polyp of sinus
471.9	Unspecified nasal polyp
473.0 - 473.2	Chronic sinusitis
477.0	Allergic rhinitis due to pollen
477.8	Allergic rhinitis due to other allergen
477.9	Allergic rhinitis; cause unspecified
478.0	Hypertrophy of nasal turbinates
478.19	Other diseases of nasal cavity and sinuses (Rhinorrhea, congestion)
493.00 - 493.92	Asthma
535.40	Gastritis, allergic
691.8	Other atopic dermatitis and related conditions
693.1	Food allergy, dermatitis
698.9	Unspecified pruritic disorder
708.0	Allergic urticaria
708.1	Idiopathic urticaria
708.8	Chronic urticaria and recurrent urticaria
708.9	Urticaria, unspecified
786.09	Reactive airway disease/dyspnea
786.2	Cough
995.0	Anaphylaxis

995.1 Angioneurotic edema, not elsewhere classified
 995.20, 995.27, Drug allergy or adverse effect of drug
 995.29
 995.3 Allergy, unspecified, not elsewhere classified
 V14.0 - V14.9 Allergy to medications, serums and vaccines
 V15.01-V15.09 Personal history of allergy, other than to medications

86003 Specific IgE in Vitro Test (RAST)
 691.8 Extensive Dermatitis
 708.0 Allergic urticaria
 708.3 Marked Dermographism
 691.8 Severe Eczema
 117.3 Aspergillosis
 989.5 Insect Venom Sensitivities
 Child Under Age of 4
 995.0; 995.60-995.69 History of severe Anaphylactic Reaction to Agents Including Food
 989.82 Toxic effects of Latex
 V67.59 Follow-up exam following other treatment. Use this code to indicate testing in patients who have been receiving long-acting antihistamines, tricyclic antidepressants, beta-blockers or medications that may put the patient at undue risk if they are discontinued.

95044, 95052, 95056 Patch Tests
 692.0 Due to detergents
 692.1 Due to oils and greases
 692.2 Due to solvents
 692.3 Due to drugs and medicines in contact with skin
 692.4 Due to other chemical products
 692.5 Due to food in contact with skin
 692.6 Due to plants (except food)
 692.81 Dermatitis due to cosmetics
 692.83 Dermatitis due to metals
 692.84 Dermatitis due to animal (cat) (dog) dander
 692.89 Dermatitis due to other
 692.9 Dermatitis unspecified

CPT code: 95075 Ingestion Challenge Test
 693.1 Food allergy, dermatitis
 995.60-995.69 Anaphylactic shock due to adverse food reaction
 V14.0-V14.8 Allergy to medicinal agents
 V15.01-V15.05 Allergy to foods

Allergen Immunotherapy

CPT codes: 95115, 95117, 95145, 95146, 95147, 95148, 95149, 95165, 95199:
 372.14, 477.0-477.9, Other chronic conjunctivitis
 493.0-493.1
 518.3 Pulmonary eosinophilia
 989.5 Toxic effects of venom
 995.0 Other anaphylactic shock
 995.3 Allergy unspecified
 V15.06 Personal history of allergy to insects

V15.09	Personal history of other allergy other than medicinal agents
CPT code: 95170 E905.5	Other venomous arthropods causing poisoning toxic reactions
CPT code: 95180: 995.20, 995.27, 995.29	Unspecified adverse effect of drug medicinal and biologic substance not elsewhere classified
999.4	Anaphylactic shock due to serum not elsewhere classified
V14.0	Personal history of allergy to penicillin
V14.1	Personal history of allergy to other antibiotic agent
V14.2	Personal history of allergy to sulfonamides
V14.3	Personal history of allergy to other infective agent
V14.4	Personal history of allergy to anesthetic agent
V14.7	Personal history of allergy to serum or vaccine
V15.03	Personal history of allergy to eggs

Note: ICD-9 codes must be coded to the highest level of specificity.

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Diagnoses that DO NOT Support Medical Necessity

Documentation Requirements

1. Documentation must be available to Medicare upon request.
2. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Allergy Testing

1. Prior to performance of allergy testing, there must be evidence on the patient's record that a history has been obtained, indicating the possible presence of allergy. This history should attempt to narrow the area of investigation so that the minimal number of necessary skin tests might deliver a diagnosis.
2. The selection of antigens should be individualized based on the history and physical examination. The number of tests performed should be judicious. All patients should not necessarily be tested for the same antigens or receive the same number of tests. Claims with excessive numbers of tests (2 standard deviations above the national mean) will be reviewed for medical necessity.
3. Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include young children with negative skin tests or older children and adults with negative skin tests, but persistent symptoms suggestive of allergic disease where skin tests may be repeated one year later. Claims for retesting within a three-year period should be submitted with documentation of the medical necessity. Testing done on separate days for different antigens is acceptable as long as the total number of tests done within any three-year period is not excessive (2 standard deviations above the national mean).

Allergen Immunotherapy

1. Include in the record the following information: Medical history, examination, and results of diagnostic testing (including allergy testing) upon which the need for the treatment is based.
2. A plan of treatment and dosage regimen must be documented in the patient's medical record. The record should be prepared so that the data regarding injection and responses can be appreciated in a logical and sequential sense.
3. When an evaluation and management service is billed on the same day as allergen immunotherapy (by the same physician) a separately identifiable service must be documented in the medical record.
4. Documentation must support the use of the code (e.g., number of venoms, number of vials).

Utilization Guidelines

Other Comments

For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare's possible denial of payment. A waiver of liability should be signed when a provider/supplier does not want to accept financial responsibility for the service.

Sources of Information and Basis for Decision

Practice Parameters for Allergy Diagnostic Testing; Annals of Allergy, Asthma, & Immunology. Volume 75 (6), December 1995; March 15, 1996

Allergen immunotherapy: a practice parameter; Annals of Allergy, Asthma, & Immunology. Volume 90, January, 2003

Trevino, Richard J., Veling, Maria C.; The importance of quantifying skin reactivity in treating allergic rhinitis with immunotherapy; Ear, Nose & Throat Journal, May, 2000

Krouse JH, et al. Efficacy of immunotherapy based on skin endpoint titration. Otolaryngol - Head and Neck Surg. 2000. 123;3:183-187.

Hurst, DS, Gordon, BR, Fornadley, JA, Hunsaker, DH. Safety of home-based and office allergy immunotherapy: A multicenter prospective study. Otolaryngol - Head and Neck Surg. 1999. 121;5:553 - 561.

Mabry RL, et al. AAOA Monograph Series: Skin Endpoint Titration. Second Edition, 1994.

Policies from other carriers including NHIC, Noridian, Empire

Advisory Committee Meeting Notes

Meeting Date:

Wisconsin: 09/25/2009

Illinois: 09/16/2009

Michigan: 09/09/2009

Minnesota: 09/24/2009

Iowa, Kansas, Missouri, 10/08/2009

Nebraska

Jurisdictional Open Meeting 08/19/2009

Meeting

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from Allergy, Otolaryngology , Primary Care, Dermatology and Laboratory.

Start Date of Comment Period

10/08/2009

End Date of Comment Period

11/23/2009

Start Date of Notice Period

(Published)

Revision History Number/Explanation

Last Reviewed On

Related Documents

[There is a coding article associated with this LCD.](#)

Does this LCD contain a "Least Costly Alternative" Provision?

No

Local Coverage Determination Coding Guidelines

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302, 05402, 52280

LCD Title

Allergy Testing and Allergy Immunotherapy

LCD Database ID Number

Contractor's Determination Number

ALRG 001

Medicare Regulations and Coding Guidelines

1. *Evaluation and management codes reported with allergy testing or allergy immunotherapy are appropriate only if a significant, separately identifiable service is administered. When appropriate, use modifier -25 with the E&M code to indicate it as a separately identifiable service. Obtaining informed consent is included in the immunotherapy. If E & M services are reported, medical documentation of the separately identifiable service should be in the medical record.*
2. 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.

Allergy Testing

1. *The MPFSDB fee amounts for allergy testing services billed under codes 95004-95078 are established for single tests. Therefore, the number of tests must be shown on the claim.*

EXAMPLE

If a physician performs 25 percutaneous tests (scratch, puncture, or prick) with allergenic extract, the physician must bill code 95004 and specify 25 in the units field of Form CMS-1500 (paper claims or electronic format). To compute payment, the Medicare carrier multiplies the payment for one test (i.e., the payment listed in the fee schedule) by the quantity listed in the units field.

2. Part B providers indicate the number of tests (one for each antigen) in Box 24G of the HCFA 1500 claim form. On EMC claims enter the number in the service field.
3. Interpretation of CPT codes: 95004 - 95078; use the code number which includes the number of tests which were performed and enter 1 unit for each test performed. For example, if 18 scratch tests are done, code 95004 with 18 like services. If 36 are done, code 95004 with 36 like services.

4. When photo patch tests (e.g. CPT code 95052) are performed (same antigen/same session) with patch or application tests, only the photo patch testing should be reported. Additionally, if photo testing is performed including application or patch testing, the code for photo patch testing (CPT code 95052) is to be reported, not CPT code 95044 (patch or application tests) and CPT code 95056 (photo tests).
5. **Non-covered testing:**
Non-covered services include, but are not limited to, the following services (some are not represented by specific CPT-4 codes). Some of these are based on statute and this is noted in italics.
 - a. CIM 50-53
*Food Allergy Testing and Treatment--NOT COVERED-- (Effective for services furnished on or after October 31, 1988.)
Effective October 31, 1988, sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded from Medicare coverage because available evidence does not show that these tests and therapies are effective. This exclusion was published as a Final Notice in the **Federal Register** on September 29, 1988.*
 - b. CIM 50-2
*Cytotoxic Food Tests--NOT COVERED (Effective for services performed on or after August 5, 1985).
Prior to August 5, 1985, Medicare covered cytotoxic food tests as an adjunct to in vivo clinical allergy tests in complex food allergy problems. Effective August 5, 1985, cytotoxic leukocyte tests for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective. This exclusion was published as a HCFA Ruling in the **Federal Register** on July 5, 1985.*

Allergen Immunotherapy

Coding

1. *Always use the component codes (95115, 95117, 95144-95170) when reporting allergy immunotherapy services to Medicare. Report the injection only codes (95115 and 95117) and/or the codes representing antigens and their preparation (95144-95170). Do not use the complete service codes (95120-95134)!*
2. *Use CPT component procedure codes 95115 (single injection) and 95117 (multiple injections) to report the allergy injection alone, without the provision of the antigen.*
3. *Use CPT component procedure codes 95144-95170 (provision of antigens) to report the antigen/antigen preparation service when this is the only service rendered by the physician.*
4. *Use CPT procedure codes 95115/95117 and the appropriate CPT procedure code from the range 95145-95170 when reporting both the injection and the antigen/antigen preparation service (complete service). These instructions also apply to allergists who provide both services through the use of treatment boards.*
5. *The provision of antigens must be coded based on the specific type of antigen provided:*

- CPT code 95144 is used to report regular antigens, other than stinging insect. Use this code to report single dose vials. Use this code only when the allergist actually prepares the extract. Code 95144 (single dose vials of antigen) should be reported only if the physician providing the antigen is providing it to be injected by someone other than himself/herself. If this code is mistakenly reported in conjunction with an injection (95115 or 95117), payment will be made under code 95165.
 - CPT procedure code 95165 is used to report multiple dose vials of non-venom antigens. Effective January 1, 2001, for CPT code 95165, a dose is now defined as a one- (1) cc aliquot from a single multidose vial. When billing code 95165, providers should report the number of units representing the number of 1 cc doses being prepared. A maximum of 10 doses per vial is allowed for Medicare billing, even if more than ten preparations are obtained from the vial. In cases where a multidose vial is diluted, Medicare should not be billed for diluted preparations in excess of the 10 doses per vial allowed under code 95165.
 - CPT procedure codes 95145-95149 and 95170 are used to report stinging insect venoms. Venom doses are prepared in separate vials and not mixed together -except in the case of the three vespid mix (white and yellow hornets and yellow jackets). Use the code within the range that is appropriate to the number of venoms provided. If a code for more than one venom is reported, some amount of each of the venoms must be provided. Use of a code below the venom treatment number for the particular patient should occur only for the purpose of “catching up” (see coding guideline # 7).
 - The antigen codes (95144-95170) are considered single dose codes. To report these codes, specify the number of doses provided.
 - If a patient’s doses are adjusted (e.g., due to reaction), and the antigen provided is actually more or fewer doses than originally anticipated, make no change in the number of doses billed. Report the number of doses actually anticipated at the time of the antigen preparation. These instructions apply to both venom and non-venom antigen codes.
6. The physician should make no change in the number of doses for which he/she bills even if the patient’s doses are adjusted. The number of doses anticipated at the time of the antigen preparation is the number of doses that should be billed. If the patient actually receives more doses than originally planned (due to a decrease in the amount of antigen administered during treatment) or fewer doses (due to an increase in the amount of antigen administered), no change should be made in the billing.
 7. When a venom regimen requires that antigens be mixed from more than one vial for administration and, due to a dose adjustment of one of the antigens, one vial is depleted before the other, the physician may bill for “catch-up” doses of the short antigen. This must be done in a manner that synchronizes the preparation back to the highest venom code possible in the shortest amount of time. To catch up, the physician would bill only the amount of the depleted vial needed to catch-up with the other vials. This will permit the physician to get back to preparing the full number of venoms at one time and billing the doses of the “cheaper” higher venom codes. Use of a code below the venom treatment number for the particular patient should occur only for the purpose of “catching up”
 8. A visit to an allergist, which yields a diagnosis of specific allergy sensitivity but does not include immunotherapy, should be coded according to the level of care rendered.

9. Use CPT procedure code 95180 (rapid desensitization) when sensitivity to a drug has been established and treatment with the drug is essential. This procedure will also require frequent monitoring and skin testing. The number of hours involved in desensitization must be reported in the unit's field.
10. *Allergy Shots and Visit Services on Same Day*
Effective for services provided on or after January 1, 1995, visits may not be paid with allergy injection services 95115 through 95199 unless the visit represents another separately identifiable service. Modifier code -25 is used with the visit code to report the patient's condition required a significant, separately identifiable visit service above and beyond the allergen immunotherapy service provided.
11. **Place of Service**
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 and hospital settings (21, 22, 23).

Hospital Inpatient Claims:

- The hospital should report the patient's principal diagnosis in Form Locator (FL) 67 of the UB-04. *The principal diagnosis is the condition established after study to be chiefly responsible for this admission.*
- *The hospital enters ICD-9-CM codes for up to eight additional conditions in FLs 67A-67Q if they co-existed at the time of admission or developed subsequently, and which had an effect upon the treatment or the length of stay. It may not duplicate the principal diagnosis listed in FL 67.*
- For inpatient hospital claims, the admitting diagnosis is required and should be recorded in FL 69. (See CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 25, Section 75 for additional instructions.)

Hospital Outpatient Claims:

The hospital should report the full ICD-9-CM code for the diagnosis shown to be chiefly responsible for the outpatient services in FL 67. If no definitive diagnosis is made during the outpatient evaluation, the patient's symptom is reported. The hospital enters the full ICD-9-CM codes in FLs 67A-67Q for up to eight other diagnoses that coexisted in addition to the diagnosis reported in FL 67.

Antigens

1. **Supply of Antigen:**

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient when:

- *The antigens are prepared by a physician who is a doctor of medicine or osteopathy; and*
- *The physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.*

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person under the supervision of the doctor.

Effective January 1, 2001, the Health Care Financing Administration (HCFA) has revised the regulation limiting the supply of antigens that can be prepared by a physician for a particular patient at one time. The limitation is changed from a 12-week supply to a 12-month supply. This regulation is revised with the stipulation that it is a physician's responsibility to furnish only a supply that would remain stable and potent over the time period for which they are administered.

2. *For antigens provided to patients on or after November 17, 1996, Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. Antigens are covered only if they are administered by injection.*

Note:

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