MEDICAL POLICY DRAFT

MEDICAL POLICY DETAILS	
Medical Policy Title	**Allergy Testing**
Policy Number	**2.01.10**
Category	**Technology Assessment**
Original Effective Date	**01/20/00**
Committee Approval Date	**10/18/01, 10/16/02, 10/15/03, 09/16/04, 11/17/05, 09/21/06, 12/20/07, 09/18/08, 09/17/09, 09/16/10, 09/15/11, 09/20/12, 09/19/13, 09/18/14, 09/17/15, 9/15/16, 11/16/17, 01/17/19, 01/16/20, 08/20/20, 02/18/21, 01/20/22, 01/19/23, 6/XX/23**
Current Effective Date	**~~01/19/23~~ 10/15/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the following tests are considered **medically appropriate** in the diagnosis of the allergic patient:

CODE	DESCRIPTION	GUIDELINE
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests	The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 70 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	Usually used when percutaneous testing is not considered to be sensitive enough to be the cause of an allergic reaction. The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 40 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	

CODE	DESCRIPTION	GUIDELINE
	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	This code may be used to represent serial endpoint testing (SET). A physician or other qualified health care provider uses intracutaneous tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, to determine a patient's specific allergies. The number of tests must be specified *(each sequential test = 1 unit).* This code includes test interpretation and provider report.
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests	Used as a part of an evaluation of the status of immune function. The number of tests is usually small, under 10 tests.
95044	Patch or application test(s) (specify number of tests)	Also known as delayed hypersensitivity testing, this testing modality identifies allergens causing contact dermatitis. The suspected allergens are applied to the patient's back under dressings and allowed to remain in contact with the skin for 48 to 72 hours. The area is then examined for evidence of delayed hypersensitivity reactions.
95052	Photo patch test(s) (specify number of tests)	This test reflects contact photosensitization. The suspected sensitizer is applied to a patch of skin for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on the surrounding skin.
95056	Photo tests	Photo, or photosensitivity, tests are performed for the evaluation of photosensitivity disorders by irradiating the skin with a specified range of ultraviolet light.
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds	Histamine or methacholine is used to perform this test, when it is necessary to determine whether the patient has hyper-responsive airways. Volatile chemicals are used to perform the test, when the allergy is encountered in an occupational setting. If dust, ragweed, or other common allergens are the suspected cause of the problem, this test is **not medically appropriate**, as skin tests can be used in these situations.
95076	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug, or other substance); initial 120 minutes of testing	With these tests, the patient ingests a food, drug or other substance to which sensitivity is suspected. This may be done in an open or blinded manner. Testing may be done at home, but in some instances of extreme suspected hypersensitivity, it may be performed in the office setting.
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.)	

CODE	DESCRIPTION	GUIDELINE
82785	Gammaglobulin (immunoglobulin), IgE	Total serum IgE concentration testing is not indicated in most allergic patients but may be indicated for patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease characterized by increased IgE levels (e.g., Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma, pemphigoid, or a poorly controlled moderate-to-severe asthmatic patient being considered for possible anti-IgE treatment.
86003	Allergen-specific IgE; quantitative or semiquantitative, crude allergen extract, each	Commonly known as RAST (radioallergosorbent) testing, these tests detect antigen specific IgE antibodies in the patient's serum. They are considered **medically appropriate** *only* when testing for allergens (e.g., inhalant, food, insect, drug) under the following circumstances: • When direct skin testing is impossible due to extensive dermatitis or marked dermatographism; • For patients unable to discontinue use of interfering medications (e.g., antidepressants, antihistamines, or beta-blocking agents); • For patients who have had a near fatal reaction to an allergen; • In children younger than four years of age; • In patients who will not or cannot cooperate with percutaneous testing due to mental or physical disease (e.g., Down syndrome, intellectual disability, dementia); • To follow patients with food allergies and/or insect sting allergies previously documented by history and in-vivo or in-vitro testing; • For patients with suspected latex allergy; • For patients with suspected insect sting allergy with prior negative skin testing; or • For patients with suspected penicillin allergy.
86005	Allergen-specific IgE; qualitative, multi-allergen screen (e.g., disk, sponge, card)	
86008	Allergen-specific IgE; quantitative or semiquantitative, recombinant or purified component, each	

II. Based upon our criteria and assessment of the peer-reviewed literature, the following allergy tests have not been medically proven to be effective and, therefore, are considered **investigational**:

CODE	DESCRIPTION
86001 **(E/I)**	Allergen-specific IgG; quantitative or semiquantitative, each allergen
86343 **(E/I)**	Leukocyte histamine release test (LHR)
95060 **(E/I)**	Ophthalmic mucous membrane tests
95065 **(E/I)**	Direct nasal mucous membrane test
0165U **(E/I)**	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0178U **(E/I)**	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction

CODE	DESCRIPTION
No specific code(s)	Cytotoxicity, Provocative testing (e.g., Rinkel test), Rebuck skin window test

III. **Based upon our criteria and assessment of the peer-reviewed literature, allergy and laboratory testing for a treatment program that has not been medically proven to be effective and, therefore, is considered investigational (e.g., Southern California Food Allergy Tolerance Induction Program) will also be considered investigational.**

Refer to Corporate Medical Policy # 2.01.11 Allergen Immunotherapy.

Refer to Corporate Medical Policy # 11.01.03 Experimental or Investigational Services.

DESCRIPTION

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions and/or localized reactions in any organ system of the body. The reactions may be acute, subacute, or chronic, and immediate or delayed, and they may be caused by numerous offending agents (e.g., pollen, molds, dust, mites, animal dander, stinging insect venoms, foods, and drugs).

The optimum management of the allergic patient should include a careful history and physical examination and may include confirming the cause of allergic reaction by information from various testing methods. Once the offending allergenic agent(s) is (are) identified, treatment is provided by avoidance, medication, and/or immunotherapy.

RATIONALE

Although in vivo (e.g., percutaneous, intracutaneous) testing is presently the preferred method of diagnostic allergy testing for IgE-mediated sensitivity, in vitro (e.g., RAST) tests are useful when used as stated in the situations identified in the above table.

According to a November 2006 American Academy of Allergy, Asthma, and Immunology (AAAAI) work group report addressing Allergy Diagnosis in Clinical Practice, IgE antibody assay technology has improved, with new high-binding capacity, solid-phase matrices, non-isotopic labels for detection antibodies, and standards calibrated to the World Health Organization IgE reference preparation. These enhancements have led to an evolution in assay methods from the first generation qualitative assays (e.g., RAST, MAST, EAST), through the second generation semi-quantitative IgE assays (e.g., AutoCAP, Alastat, HYTech, Matrix, MagicLite), to the present state-of-the-art quantitative third generation autoanalyzers. Two third-generation immunoassays are the ImmunoCAP System (Phadia) and the Immulite 2000 (Diagnostic Products Corp.), the chemistry of which is similar to the original RAST, but which employ non-isotopic labels and have more rapid throughput with improved precision, accuracy, and analytical sensitivity. Their automated chemistries report out allergen specific IgE antibody quantitatively.

Serial endpoint testing (SET), or *intradermal dilutional testing (IDT)*, is a form of intradermal skin testing that uses increasing doses of antigen to determine the concentration at which the reaction changes from negative to positive (the "endpoint"). The test has been used for diagnosing allergic disorders and to guide the initiation of immunotherapy by using the endpoint dilution as the starting antigen dose.

Ferastraoaru et al. (2017) reported, in an independent analysis of 75 patients with over 1600 tests between January 2014 and May 2015, for comparison of skin-prick (SPT), intradermal (IDST), and serum-specific immunoglobulin E (ssIgE) testing, that IDST detected more additional environmental sensitizations, compared with ssIgE testing. The authors concluded that IDST may be useful when the SPT and/or ssIgE testing results are negative, but the exposure history indicates relevant allergic sensitization. Serology added only a little more information when both SPT and IDST results were negative, but may be useful in combination with SPT, if IDST cannot be performed.

In a prospective, comparative clinical study (Peltier 2007), 134 subjects were tested for a comparison of intradermal dilutional testing, skin prick testing, and modified quantitative testing for common allergens. The researchers found poor correlation between endpoint and wheal size, as graded on a 1 to 4 system, and concluded that, although a correlation existed, the use of SPT to determine endpoint was inaccurate and dangerous. Modified quantitative testing (MQT) appears

to be a safe alternative to IDT for determining starting doses for immunotherapy. The data support the safety and efficacy of MQT (combination SPT and IDT).

In a retrospective review of clinical data (random accrual), Seshul et al. (2006) concluded that IDT is an important step in determining the strongest starting dose of immunotherapy that may safely be administered. Initiating immunotherapy in this manner may potentially create significant health care savings by shortening the time required for a patient to reach the patient's individual, maximally tolerated dose. The use of a relatively large screening panel is cost-effective and does not increase the average number of antigens treated by immunotherapy. Blended allergy testing techniques that include IDT in their protocol are comparable in cost with commonly used allergy testing protocols. Otolaryngologists often favor IDT (SET) because of its well-documented sensitivity, specificity, safety, and reproducibility. IDT has been compared with many testing modalities used by other physicians to validate the technique as a part of mainstream allergy care.

In a 2010 publication on Practice Parameters for Drug Allergy, a joint task force of the AAAAI, the American College of Allergy, Asthma and Immunology (ACAAI), and the Joint Council of Allergy, Asthma & Immunology included in its executive summary a statement validating the use of intracutaneous (intradermal) tests, which are generally used for specific allergens (e.g. Hymenoptera venoms and penicillin), but may also be applied if prick/puncture test results are negative, and there is a strong historical likelihood of clinical allergy to specific allergens.

Leukocyte histamine release testing (LHRT) is a technique to evaluate the in vitro release of histamine from leukocytes in response to an allergen. It provides an in vitro correlate to an in vivo allergic response. Published literature reflects that commercially available LHRT studies suffer from not having been performed in a blinded manner or do not indicate whether or not there were blinded interpretations of the tests. Some studies included patients with known allergies, which did not represent the same population with equivocal allergy histories that would undergo testing. Studies of LHRT are potentially prone to spectrum, referral, and ascertainment bias, and are not sufficient to permit conclusions on the diagnostic accuracy of the tests. It has been suggested that LHRT may be a valuable test in those patients with discordant results of skin prick testing and RAST testing, but studies focusing on this subgroup of patients have not been identified.

A number of procedures have been shown to be invalid for any clinical purpose. Studies of cytoxic tests and provocation-neutralization tests have demonstrated that results are not reproducible. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. The "reaginic" pulse test and chemical analysis of body tissues have not been substantiated as valid allergy tests. These tests are considered to be **investigational**.

According to the 2008 AAAAI and the ACAAI joint practice parameter addressing allergy diagnostic testing, IgG and IgG subclass antibody tests for food allergy do not have clinical relevance, are not validated, lack sufficient quality control, and should not be performed. In addition, although a number of investigators have reported modest increases of IgG4 during venom immunotherapy, confirmation, and validation of the predictive value of IgG4 for therapeutic efficacy of venom immunotherapy are not yet proven. There is insufficient evidence in the published, peer-reviewed, scientific literature to support the use of specific IgG antibody testing by RAST or ELISA in the diagnosis or treatment of allergic disease and, therefore, is considered **investigational**.

There is a lack of published research on the diagnostic accuracy of peanut allergen-specific quantitative assessment of multiple epitopes using ELISA (e.g., VeriMAP Peanut Diagnostic and VeriMAP Peanut Sensitivity, AllerGenis). The evidence is insufficient to determine the effects of the technology on health outcomes.

There is lack of published research showing the efficacy of Tolerance Induction Programs (e.g. Southern California Food Allergy Institute's Tolerance Induction Program) to treat food allergies. These treatment programs and the extensive testing required to participate in the treatment is considered investigational. Please see 2.01.11 Allergen Immunotherapy.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code
Refer to the tables in the policy statement section.

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HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
B44.0-B44.9	Aspergillosis (code range)
B48.4	Penicillosis
D80.3	Selective deficiency of immunoglobulin G (IgG) subclasses
D82.0	Wiskott-Aldrich syndrome
H10.411-H10.419	Chronic giant papillary conjunctivitis (code range)
H10.45	Other chronic allergic conjunctivitis
J30.0	Vasomotor rhinitis
J30.1-J30.9	Allergic rhinitis (code range)
J45.20-J45.998	Asthma (code range)
L23.0-L23.9	Allergic contact dermatitis (code range)
L24.0-L24.9	Irritant contact dermatitis (code range)
L25.0-L25.9	Unspecified contact dermatitis (code range)
L27.0-L27.9	Dermatitis due to substances taken internally (code range)
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L30.9	Dermatitis, unspecified
L50.0	Allergic urticaria
L50.3	Dermatographic urticaria
T36.0X5A-T36.0X5S	Adverse effect of penicillins (code range)
T36.1X5A-T36.1X5S	Adverse effect of cephalosporins and other beta-lactam antibiotics (code range)
T39.015A-T39.015S	Adverse effect of aspirin (code range)
T39.095A-T39.095S	Adverse effect of salicylates (code range)

Code	Description
T63.001A-T63.94XS	Toxic effect of contact with venomous animals and plants (code range)
T65.811A-T65.814S	Toxic effect of latex (code range)
T78.00XA-T78.09XS	Anaphylactic reaction due to food (code range)
T78.2xxA	Anaphylactic shock, unspecified, initial encounter
T78.3xxA	Angioneurotic edema, initial encounter
T78.40XA	Allergy, unspecified, initial encounter
T78.41xA	Arthus phenomenon, initial encounter
T78.49xA	Other allergy, initial encounter
T88.2xxA	Shock due to anesthesia, initial encounter
T88.52XA	Failed moderate sedation during procedure, initial encounter
T88.59xA	Other complications of anesthesia, initial encounter
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter
Z91.010-Z91.09	Allergy status other than drugs & biologicals (code range)

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*Key Article

KEY WORDS

Allergy tests: Allergen specific IgE, Allergen specific IgG, Challenge, Cytotoxic, Dipstick, Disk, Intracutaneous, Intradermal, Leukocyte histamine release, Mucous membrane, Paddle, Percutaneous, Phadiatop, Prick, Provocation-neutralization, RAST, Rinkel, Scratch, Serial endpoint titration, Skin test.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) addressing Food Allergy Testing and Treatment and Cytotoxic Food Tests. There is also a Local Coverage Determination (LCD) addressing RAST Type Tests. Please refer to the following websites for Medicare Members:
NCD:
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=266&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=allergy+testing&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=110.11&ncd_version=1&basket=ncd%25253A110%25252E11%25253A1%25253AFood+Allergy+Testing+and+Treatment&bc=gAAAABAAAAAA&

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=161&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=allergy&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=187&ncdver=1&keyword=110.12&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

LCD:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33591&ver=18&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=allergy&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACABAAAA&