HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Allergy Testing

Policy MP-013

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

An allergy is the body's immune system response to certain items that it considers foreign and harmful, things as specific foods, animal dander, pollen, drugs, mold and many other substances. Substances that create allergic reactions are known as allergens. In people with allergies, their immune system overreacts to allergens by creating an antibody, a protein specially made to fight a particular substance, known as immunoglobulin E (IgE). Allergic reactions can cause several different types of symptoms such as a runny nose, watery eyes or hives. Serious reactions can range from breathing difficulties to life-threating swelling in the mouth or throat. Diagnosing allergies often involves testing the skin, measuring the ability to breathe or looking at IgE levels in the blood.

The American Academy of Allergy, Asthma and Immunology (AAAAI) in its allergy report cites that each year more than fifty million Americans suffer from allergic disease. Rhinitis, sinusitis, dermatitis, asthma, food allergy, and other allergic disorders negatively impact quality of life and escalate healthcare costs. Allergies are the 6th leading cause of chronic disease in the United States and are costing the healthcare system over $18 billion annually.

There are a variety of tests to identify the allergens that may be responsible for an individual's allergic disease. Allergy testing can be broadly subdivided into two methodologies:

- In vivo methodologies include skin allergy testing (i.e., skin prick testing, skin scratch testing, intradermal testing, skin patch testing, and skin endpoint titration), bronchial provocation tests, and food challenges.

- In vitro methodologies include various techniques to test the individual's blood for the presence of specific IgE antibodies to a particular antigen (i.e., RAST and ELISA tests).

The optimum management of the allergic individual should include a careful history and physical examination and may include confirming the cause of the allergic reaction by information from various testing methods. Once the offending allergen is identified, treatment is provided by avoidance, medication and/or immunotherapy. It is essential to the care of allergic individuals to determine which allergens may be inciting their disease because this information is used to direct allergy prevention and treatment.

Various types of allergy testing may be performed. These include:

Direct Skin Testing

Percutaneous (scratch, prick, or puncture)
Percutaneous (scratch, prick, or puncture) tests are performed for inhalant allergies and suspected food hypersensitivity. This is covered only in individuals if the adverse food reaction is suspected to be immune-related. This will require detailed documentation of the individual's history and a description of the reaction to the suspected foods, which should include documentation of the symptoms following ingestion of suspected foods and the modification of symptoms after the avoidance of these foods. Any additional testing would require the results of an initial screening and an individual's history. (CPT 95004, 95017, 95018)

Intracutaneous (intradermal)
Intracutaneous (intradermal) tests are usually performed following negative prick/puncture tests and are approximately 100 to 1000-fold more sensitive. This testing is not performed in the diagnosis of food or latex allergy due to an unacceptably high rate of both false positives and systemic reactions to testing. In contrast, intracutaneous testing is important in the diagnosis of drug and insect venom allergies. (CPT 95024, 95027, 95028)

Skin Patch Testing (application testing)
Skin patch testing (application testing) is a form of skin testing used to determine the cause of allergic contact dermatitis. Small disks or chambers containing different chemicals are taped to an individual's back for several days. Small areas of localized inflammation may appear within 2-4 days, or even up to a week, and confirm the presence of sensitivity to a variety of substances including: metals, rubber compounds, fragrances, preservatives and sometimes medications. This form of testing is looking for delayed skin reactions, also called type IV hypersensitivity reactions, and helps the provider determine if a person's skin inflammation is due to contact with something in their home or work environment. Skin patch testing is different from skin prick testing and is not used to diagnose immediate or acute hypersensitivity to foods and other allergens. (CPT 95044)

Photo Patch Testing
Photo patch testing reflects contact photosensitization. A patch of skin is applied with the suspected sensitizer 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. (CPT 95052)

Rebuck Skin Window Test
Rebuck Skin Window Test is a test of the inflammatory process. The skin is abraded and a cover applied to the abraded area. The cover is replaced at specified intervals and examined for the presence of immune response cells. This test is not useful in documenting allergies since other immunodeficiencies can be found in individuals with allergic conditions.

Skin Endpoint Titration Testing
Skin endpoint testing (Serial Endpoint Titration [SET], Serial Dilution Endpoint Titration [SDET], Intradermal 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"). 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. SET has also been used to guide the initiation of immunotherapy by using the endpoint dilution as the starting antigen dose. (CPT 95027)

Inhalation Bronchial Testing
Methacholine challenge test does not include necessary pulmonary function tests. Histamine, cold air or methacholine is used to perform this test when it is necessary to determine if the individual 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 since skin tests can be used in these situations. Infrequently, aerosol challenge is indicated for occupational exposures (e.g., plicatic acid for cedar workers and fish extracts for fishermen). (CPT 95070)

Oral Food/Ingestion Challenge Testing
Oral Food/Ingestion challenge test is a sequential and incremental ingestion of test items (e.g., food, drug or other substance), also known as the "Double Blind Food Test". The physician has the individual ingest specific substances, such as food or drugs to determine which sensitivity is suspected, to show that a hypersensitivity no longer exists and to determine a sensitivity when a history is vague or allergy testing is equivocal. The individual is observed by qualified medical staff during the challenge. The observation and any reactions are documented. Truly double-blinded challenges are rarely performed in clinical practices and are usually done in research studies. (CPT 95076, 95079)

Gamma Globulin/Immunoglobulin E (IgE) Testing
Gamma Globulin/Immunoglobulin E (IgE) is a testing modality not indicated in most allergic individuals but may be indicated for those individuals suspected of having an allergic bronchopulmonary aspergillosis immune deficiency disease characterized by increased IgE levels (e.g., Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome, IgE myeloma or pemphigoid). (CPT 82785)

Allergen-Specific Immunoglobulin E (IgE) Testing
Allergen-specific immunoglobulin E (IgE) test detects specific IgE antibodies in an individual's serum. This Test is medically appropriate only when testing for allergens (e.g., inhalant, food, insect, drug) when direct skin testing is impossible due to extensive dermatitis or marked

dermatographism, individuals unable to discontinue use of antihistamines or other interfering medications (e.g., antidepressants, beta blocking agents) or those who have had a near fatal reaction to an allergen. (CPT 86003, 86005)

In Vitro Allergy Testing

In vitro testing is done when the history is suggestive of an allergy, but skin testing is negative or equivalent. It is also done to follow individuals with food allergies for prognostic purposes and for confirmation of the loss of an allergy before an oral challenge. After a careful history is obtained, the individual's symptoms must indicate a possibility of a hypersensitivity reaction. Medical necessity is not established for in-vitro testing if there are no allergy symptoms. These tests include radioallergosorbent test (RAST), multiple radioallergosorbent tests (MAST), fluorescent allergosorbent test (FAST), and enzyme-linked immunosorbent assay (ELISA).

Conjunctival Challenge Testing /Ophthalmic Mucous Membrane Test

Conjunctival challenge test, also known as an ophthalmic mucous membrane test, is done by placing an allergenic extract into the conjunctival sac of the eye followed by observation for redness, itchiness, tearing of the eye, and other similar symptoms.

Direct Nasal Mucous Membrane Test/Nasal Challenge Test

Direct nasal mucous membrane test, also known as nasal challenge test, provides precise measurements of changes in nasal airway resistance and is seldom used because of the instrumentation required. This test is used in studies of allergic rhinitis, but its utility in clinical practice has not been established. The role of nasal challenge testing in the diagnosis and management of allergic diseases has not been established.

Provocative Neutralization Testing

Provocative testing (e.g., Rinkel test) is a procedure that evolved from serial endpoint titration and has been proposed as a test for allergies to foods, inhalants and environmental chemicals. Individuals are exposed to test doses of substances intradermally, subcutaneously or sublingually, with the goal of either producing or preventing symptoms.

Cytotoxic Food Testing, Leukocytotoxic Test

Cytotoxicity, Leukocytotoxic test (Bryan's test, Metabolic Intolerance Test or cytotoxic testing) is a test in which leukocytes from the serum of an allergic individual are observed for histamine release in the presence of an antigen. This test is rarely done except in a research setting. There is no proof that this is effective for foods or pollens.

Leukocyte Histamine Release Test (LHRT)

LHRT is a test which measures the amount of histamine released from the white blood cells in response to exposure to an antigen. The published literature is not sufficient to permit conclusions on the diagnostic accuracy of LHRT.

Passive Transfer of P-X (Prausnitz-Kustner Test)

Passive Transfer of P-X (Prausnitz-Kustner Test) is performed by injecting a serum intradermally from an allergic individual into a non-allergic individual and later challenging the injection site with antigens or danger of transferring infections.

Mediator Release Test (MRT)

The MRT has primarily been used to detect intolerance to foods and additives in individuals with irritable bowel syndrome. It has also been promoted for use in individuals with, but not limited to chronic fatigue syndrome, migraine headaches, rheumatologic disorders and dermatologic conditions. The results of the MRT have been used to design a patient-specific diet.

Peanut Allergen Epitope Assessment/Mapping

The VeriMAP Peanut Dx is a peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA) combined with Luminex's bead-based xMAP® Technology to measure the reactivity of an individual's antibodies to each epitope in order to generate a detailed reactivity profile.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans may cover allergy testing if the following criteria are met:

A. Immunotherapy is covered when performed by providers with a specialty in Allergy/Immunology or ENT;

B. Inadequate control of symptoms through conservative therapy;

C. Test technique and/or allergens must have proven efficacy demonstrated through scientifically and valid medical studies published in peer-reviewed literature;

D. Testing correlates to the member's history, risk of exposure and physical findings;

E. The antigens should generate an IgE mediated response and exist in the individual's environment with a reasonable probability of exposure.

The following allergy testing modalities are considered eligible for coverage when the above medical criteria are met:

A. Inhalation Bronchial Challenge Test

B. Direct skin testing (percutaneous and intracutaneous)

C. Oral Food/Ingestion Challenge Test

D. Photo Patch Test

E. Serial/Skin Endpoint Titration Test (SET)

F. Specific IgE in vitro tests (RAST, MAST, FAST, & ELISA)

G. Total Serum IgE Concentration Test (only for suspected allergic bronchopulmonary, aspergillosis, immune deficiency disease characterized by elevated IgE levels, IgE myeloma, or pemphigoid)

For the above allergy testing modalities, excluding Patch and Photo Patch testing, a combination or a total of sixty (65) tests every 3 years (based on dates of service) may be considered as medically necessary. Testing beyond these quantities has not been determined to be medically necessary and is considered investigational[#].

Patch/Photo Patch allergy testing will be limited to a series of patch tests as an appropriate initial step. Standard panels of allergens for patch testing are available from various commercial sources. The most used patch test unit includes thirty-five (35) common allergens and 1 negative control. In addition to the standard series of thirty-six patch tests, fourteen (14) additional allergens targeted at the individual's most likely exposures may be performed. Testing beyond these quantities has not been determined to be medically necessary and is considered investigational[#].

[#] Testing done on a separate day for different antigens is acceptable if the number of tests does not exceed the screening limits.

A combination or a total of fifty (50) Patch/Photo Patch tests every 3 years (based on dates of service) may be considered medically necessary.

Greater than fifty patch tests within 3 years may be reviewed for individual consideration. Documentation of medical necessity for over fifty tests is required.

Retesting with the same antigen is NOT considered medically necessary within 3 years unless member has a poor response* to immunotherapy.

*Poor response is considered persistent symptoms that interfere with activities of daily living despite optimal therapy.

More comprehensive patch testing, greater than fifty patch tests, may be considered medically necessary when BOTH (A or B and C) are met:

A. The individual has persistent allergic contact dermatitis (ACD) after being previously evaluated and treated (including 6 weeks of avoidance of any allergens that were positive on initial patch testing and use of topical steroid products if appropriate).

OR

B. The individual has ANY of the following:
    i. At least 8 weeks of dermatitis without resolution with treatment.
    ii. Has dermatitis that may be implanted device-related.
    iii. Is undergoing pre-testing for medical or dental device placement.

iv. Requires extensive patch testing to determine if persistent dermatitis is allergic contact dermatitis.

v. Has seen at least one other physician who has requested specialty patch testing.

AND

C. Dermatitis interferes with the individual's normal activities of daily living such as: occupational or work activities (use of hands), sleep patterns (due to itching), bathing or social interactions.

Food allergy testing is covered only in individuals with documented symptoms following ingestion of certain foods and avoidance of those foods has been proven to alleviate the symptoms. An initial screening of no more than twenty foods is covered with documented medical necessity.

Allergy testing performed by the following methods is considered investigational (may not be an all-inclusive list):

- Applied kinesiology (allergy testing by testing muscle strength or weakness)
- Conjunctival Challenge Testing /Ophthalmic mucous membrane test (CPT 95060)
- Cytotoxic Food Testing, Leukocytotoxic test (Bryan's test)
- Direct nasal mucous membrane test/ Nasal challenge test (CPT 95065)
- Home testing
- Immunoglobulin G (IgG) testing for food allergy
- Leukocyte Histamine Release Test (LHRT)
- Mediator Release Test (MRT)
- Passive Transfer of P-X (Prausnitz-Kustner) test (this test is obsolete and was replaced by radioallergosorbent tests [RAST])
- Peanut allergen epitope assessment (e.g., VeriMAP™ peanut sensitivity)
- Provocative Neutralization Testing (e.g., Rinkel test)
- Rebuck Skin Window Test
- Sage Allergy Testing
- Sublingual Provocation

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies

and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

American Academy of Allergy, Asthma & Immunology (AAAAI):
In 2014, the AAAAI website listed several tests that it believes "are not useful, effective, or may lead to inappropriate diagnosis and treatment." These tests include:

- Allergy screening tests done in supermarkets or drugstores
- Applied kinesiology (allergy testing by testing muscle strength or weakness)
- Cytotoxicity testing for food allergy
- Home testing
- Immunoglobulin G (IgG) testing for food allergy
- Rinkel skin titration method
- Provocative neutralization testing
- Sublingual provocation

National Institute of Allergy and Infectious Diseases (NIAID):
In 2017, the NIAID published addendum guidelines for the prevention of peanut allergy in the United States. These guidelines note that the expert panel (EP) "recommends that evaluation with peanut-specific IgE (peanut IgE) measurement, SPTs, or both be strongly considered before introduction of peanut to determine if peanut should be introduced and, if so, the preferred method of introduction.

The American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI):
Updated Practice Parameter states: 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.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative (2014):
The Choosing Wisely initiative includes the following recommendations from the American Academy of Asthma, Allergy, and Immunology regarding allergy testing:

- Don't perform unproven diagnostic tests, such as immunoglobulin G (IgG) testing or an indiscriminate battery of immunoglobulin E (IgE) tests, in the evaluation of allergy
- Don't routinely do diagnostic testing in patients with chronic urticaria.
- Don't perform food IgE testing without a history consistent with potential IgE-mediated food allergy.

U.S. Preventive Services Task Force (USPSTF) Recommendations
The USPSTF currently has no recommendations for allergy testing.

Applicable Coding

CPT Codes

82785	Gammaglobulin (immunoglobulin); IgE
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen, qualitative or semiquantitative; multiple step method
86003	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
86005	Allergen specific IgE; qualitative, multi allergen screen (disk, sponge, card)
86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
86486	Skin test; unlisted antigen, 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
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds
95076	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing
95079	; each additional 60 minutes of testing (List separately in addition to code for primary procedure)
95199	Unlisted Allergy/Clinical Immunologic Service or Procedure

Not Covered Codes:

0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction
82784	Gammaglobulin (immunoglobulin); IgG
86001	Allergen specific IgG quantitative or semiquantitative, each allergen
86343	Leukocyte Histamine Release Test (LHR)
95060	Ophthalmic mucous membrane tests
95065	Direct nasal mucous membrane test

HCPCS Codes

No Applicable Codes

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