BlueCross BlueShield of Vermont

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Allergy Testing, Including Selected Blood, Serum and Cellular Testing and Toxicity Testing Corporate Medical Policy

File Name: Allergy Testing, Including Selected Blood, Serum and Cellular Testing and Toxicity Testing
File Code: 1.02.VT201
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Description/Summary

This document addresses specific allergy testing as well as selected unproven blood, serum and cellular allergy and toxicity tests.

Allergy Testing is used to determine what types of allergens cause a particular allergy. Testing typically involves injecting a small amount of the allergen under the skin by scratching or puncturing the skin and watching the skin for a reaction.

Allergy Treatment or Immunotherapy is the treatment of allergies in which increasing amounts of allergic extract are injected until the patient becomes tolerant of the allergens. Based on a review of the medical literature and the position statements of scientific organizations in the field of allergy and immunology, Blue Cross VT considers the specific allergy testing described below medically necessary in accordance with the selection criteria noted.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.

Attachment I - CPT® Code Table & Instructions

Blue Cross VT will provide benefits for Allergy Testing when it is determined to be medically necessary when the medical criteria and guidelines below are met.

When a service may be considered medically necessary

The following allergy testing may be considered **medically necessary**:

- Epicutaneous (scratch, prick, or puncture) or Intradermal (Intracutaneous) allergy testing for diagnosing immunoglobulin E (IgE) mediated reactions to any of the following:
    - Inhalants
    - Foods
    - Hymenoptera (stinging insects)
    - Specific drugs (penicillins and macromolecular agents)

- Patch Testing for diagnosing contact allergic dermatitis and certain drug-induced cutaneous reactions. Photo Patch Testing for diagnosing photoallergy or photosensitization (e.g., photo-allergic contact dermatitis).

- Ingestion (Oral) Double Blind Challenge test to diagnose suspected IgE-mediated hypersensitivity, when history and physical findings are suggestive of hypersensitivity, but skin testing is negative or equivocal.

- Drug provocation/challenge test to diagnose suspected IgE-mediated hypersensitivity when **ALL** of the following are met:

    - History of allergy to a particular drug
    - Treatment with that drug class is essential
    - There is no effective alternative drug available

- Bronchial Challenge Test testing with methacholine, histamine, or antigens in defining asthma or airway hyperactivity when **ANY** of the following apply:

    - To identify causative or provocative occupational or other allergens for which skin testing is not reliable
    - To confirm diagnosis of asthma when the member is symptomatic but has abnormal pulmonary function test results and no response to a bronchodilator
    - To evaluate new allergens or to substantiate the role of allergens in members with significant symptoms.
    - Evaluation of occupational asthma

- Exercise Challenge Testing for exercise-induced bronchospasm.

- Skin Endpoint Titration (SET) for determining the starting dose for immunotherapy for members highly allergic to an inhalant allergy or Hymenoptera venom allergy (stinging insects).
  NOTE: SET is not appropriate for routine testing.

- Allergen-specific IgE immunoassays such as radioallergosorbent testing (RAST), multiple radioallergosorbent (MAST), paper radioimmunosorbent test (PRIST), radioimmunosorbent test (RIST), fluorescent allergosorbent (FAST), modified RAST (MRT), VAST, Enzyme Linked Immunoassay (ELISA) or ImmunoCAP when percutaneous testing of IgE-mediated allergies cannot be done for inhalant or food allergy due to **ANY** of the following reasons:
    - Testing of members with severe dermatographism, ichthyosis, or generalized atopic dermatitis
    - Testing of members who have been receiving long-acting antihistamines, tricyclic antidepressants, or medications that may put the member at undue risk if they are discontinued
    - Testing of uncooperative members with mental or physical impairments
    - Testing of infants and children who will not tolerate skin testing, or when severe reaction to skin testing is a concern
    - Serial testing of children with documented food allergies to assess whether an oral food challenge may occur
    - As adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases
    - The evaluation of cross-reactivity between insect venoms
    - 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
    - Direct skin testing is inconclusive

  NOTE: Intradermal skin tests, rather than in vitro tests, should generally be used for the definitive diagnosis of anaphylactic sensitivities to stinging insects and drugs.

- Lymphocyte transformation testing in any of the following:
    - The medical surveillance of beryllium sensitivity and chronic beryllium disease (CBD)
    - The evaluation of members suspected of having congenital or acquired immunodeficiency diseases affecting cell-mediated immunity
    - To predict allograft compatibility in the transplant setting

  NOTE: Lymphocyte transformation tests for evaluation of persons with allergies or other hypersensitivities are considered experimental and investigational.

- Total Serum IgE for diagnostic evaluation in members with known or suspected:
    - Allergic bronchopulmonary aspergillosis (ABPA)
    - Certain stages of HIV infection

    - Drug-induced interstitial nephritis
    - Eczema and the hyper-IgE syndrome (dermatitis and recurrent pyogenic infections),
    - Graft versus host disease
    - Parasitic diseases such as immune deficiency diseases such as Hyper- IgE syndrome, Wiskott-Aldrich syndrome, and IgE Myeloma

- Complement antigen testing for the diagnosis and management of inflammatory conditions.

- Immunoglobulin subclasses (eg, IgG1, 2, 3, or 4) testing for the diagnosis and management of autoimmune disorders.

- Mutational analysis of KIT D816V to aid in the diagnosis of suspected Systemic Mastocytosis in a member with compatible symptoms.

When a service is considered not medically necessary

Routine allergy re-testing that will not change clinical management is considered **not medically necessary**.

Leukocyte Histamine Release Test (LHRT) is considered **not medically necessary.**

When a service is considered investigational

The following allergy testing is unproven and therefore **investigational**. (This list may not be all-inclusive):

- Advanced cell test (ACT) qualitative antibody testing- ELISA methodology
- Adrenal stress index
- Alpha gal allergy (meat allergy) testing
- Anti-Fc epsilon receptor antibodies testing
- Antigen leukocyte cellular antibody test (ALCAT)
- Applied kinesiology (allergy testing through muscle relaxation)
- Basophil tests
- Basophil Histamine release assay (BHRA)
- Body chemical analysis
- Candida hypersensitivity test
- Chemical analysis of body tissues, such as hair
- Chlorinated pesticides (serum)
- Circulating immune complexes to foods
- Component-Resolved diagnostics
- Conjunctival challenge test (ophthalmic mucous membrane test)

- Cytokine and cytokine receptor assay
- Cytotoxic food test (i.e.: Bryan's Test, Metabolic Intolerance test)
- Electrodermal diagnostic testing (VEGA test)
- Electrodermal acupuncture
- Eosinophil cationic protein (ECP) test Food immune complex assay (FICA)
- Hair Analysis
- HEMOCODE Food Intolerance System
- Iridology Kinesiology and Applied Kinesiology
- Leukocyte Histamine Release Test (LHRT)Lymphocyte function assay
- Mediator release test (MRT)
- Muscle strength testing or measurement (kinesiology) after allergen ingestion
- Nasal mucous membrane challenge test
- Passive transfer or P-X (Prausnitz-Kustner) test
- Provocation-neutralization tests (subcutaneous or sublingual)
- Pulse test or Reaginic pulse test (Reaginic Pulse test that measures the increase of pulse rates after ingestion of a suspected allergic food substance)
- Rebuck Skin Window test
- SAGE test for food delayed hypersensitivity
- Saliva testing
- Serum IgG Antibodies (measurement of circulating allergen-specific IgG or IgG4 antibodies)
- Serum immunoglobulin A (IgA) or immunoglobulin G (IgG) testing for allergy
- Skin titration (Rinkel method)
- Sublingual provocative neutralization testing and treatment with hormones
- Urine autoinjection (autogenous urine immunization)
- Venom blocking antibodies
- Volatile chemical panels (blood testing for chemicals)
- Laboratory testing for electromagnetic sensitivity syndrome/disorder (also known as allergy to electricity, electro-sensitivity, electrohypersensitivity, and hypersensitivity to electricity)
- Laboratory testing for multiple chemical sensitivity syndrome (also known as idiopathic environmental intolerance (IEI), clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease)
- Laboratory testing designed to affirm the diagnosis of idiopathic environmental intolerance
- Treatments for idiopathic environmental intolerance, including but not limited to IVIG, neutralizing therapy of chemical and food extracts, avoidance therapy, elimination diets, and oral nystatin (to treat Candida)

Policy Guidelines

Background

Environmental illness refers to a physiologic reaction that is triggered by an exogenous agent, which can be ingested, inhaled, or exposed through direct contact with skin. The physiologic reaction can be an immunologic response or a non-immunologic response. An adverse physiologic reaction to exogenous antigens has been proposed to play a causative role in a wide variety of illnesses, including allergies, gastrointestinal (GI) tract disorders such as irritable bowel syndrome, eczema, chronic fatigue, and migraine headache.

Food allergy is the most well-defined type of environmental illness and is estimated to affect 8% of children. In most cases, true food allergy is characterized by a classic immunologic response, i.e., an immunoglobulin E–mediated reaction in response to a specific protein allergen. Reactions can range from mild symptoms to life -threatening anaphylaxis. Current guidelines for the diagnosis and management of food allergies have been developed by NIAID.

Food intolerance is a broader term that overlaps with food allergy but is less well-defined. Food intolerance refers to physiologic reactions that are triggered by a particular food, but which are not immune-mediated. It is hypothesized that physiologic reactions to food may manifest as a range of nonspecific symptoms, such as GI complaints, headache, fatigue, and musculoskeletal complaints and that these symptoms may become chronic with repeated exposure. An example of food intolerance, distinguished from a true food allergy, is lactose intolerance, in which dairy products incite non-immunologic reaction that can lead to a constellation of GI symptoms. Treatment of environmental illness primarily involves avoidance of the inciting agent. Acute allergic reactions are treated in the same way as other types of allergies with antihistamines, steroids, and supportive measures. In cases of severe allergy where an agent cannot be definitively avoided, patients can carry and self- administer auto-injectable epinephrine when needed. Prophylactic antihistamines can also be used to prevent or lessen reactions. Allergy immunotherapy may be appropriate for selected allergens.

For patients with food intolerance that is not allergic in nature, identification of the inciting agent(s) can be difficult because the symptoms are chronic in nature. Use of an elimination diet is considered the best way to identify intolerant agents. In an elimination diet, one specific food or food group is eliminated from the diet for a specified period of time and symptoms observed. Following the elimination period, a re-challenge can be performed to ascertain whether symptoms return. Elimination diets often need to be done sequentially with a large number of items, so that the process can be lengthy and cumbersome.

ALCAT
ALCAT measures whole blood leukocyte activity to identify allergens which cause an increase in leukocyte activity. An electronic counter measures the change in number and size of leukocytes which have been incubated with purified food or mold extracts. A histogram is produced which reflects the cell count and cell size. The test samples are

then compared with a "Master Control" graph. The ALCAT has been promoted as a diagnostic test for food allergy or intolerance (chemical sensitivities) in conditions such as, but not limited to arthritis, urticaria, bronchitis, gastroenteritis, childhood hyperreactivity, rhinitis, and atopic dermatitis. Typically, the results are used to establish elimination diets for these diseases.

The ALCAT is manufactured by Cell Science Systems, Corp. (CSS), located in Deerfield Beach, Florida. All specimens submitted for ALCAT testing are processed at the CSS CLIA certified lab.

Currently, there is insufficient evidence in the peer-reviewed, published, scientific literature to support the use of this testing in the diagnosis or management of chemical or food allergies. Articles listed on the manufacturer's website consisted primarily of abstracts of papers presented at industry congresses or articles published in non-peer-reviewed journals.

Cytotoxic testing
Cytotoxic testing for food allergies is purported to be useful for diagnosing food allergies and food intolerances. The premise of cytotoxic testing is based on the theory that mixing an individual's white blood cells with an antigen to which that individual is allergic, results in injury to the cells.

The peer-reviewed scientific published literature on cytotoxic testing consisted primarily of review articles, small case studies and uncontrolled, non-randomized studies.

Leukocyte histamine release test
In the leukocyte histamine release test, leukocytes from the serum of an allergic individual are observed for the release of histamine in the presence of an antigen.

The peer-reviewed scientific published literature on LHRT consists primarily of small case studies and uncontrolled, non-randomized studies.

The AAAAI guidelines for allergy diagnostic testing indicate that this test is a valuable research tool for in vitro investigations of allergy (Bernstein, 2008). The guidelines published by the NIAID indicate that although the basophil histamine release/activation test is not a routine diagnostic test for IgE-mediated food allergies, it is commonly used in the research setting (Boyce, 2010).

IgG-Mediated Food Sensitivity Testing
IgG antibody testing for food intolerance is based on the premise that elevated levels of IgG antibodies are an indicator of food intolerances.

Total serum IgE testing in patients with allergic disease has no established clinical role. Substantial proportions of individuals with IgE-mediated allergic disease have normal serum IgE levels, and many nonallergic diseases are associated with elevated serum IgE.

Measurement of serum IgE may be indicated in adults with conditions such as suspected allergic bronchopulmonary aspergillosis and hyper- IgE syndromes (dermatitis and recurrent pyogenic infections), certain stages of HIV infection, IgE myeloma, drug-induced interstitial nephritis, graft-versus-host disease, several parasitic diseases and specific immune deficiency diseases. In children, serum concentrations of IgE increase slowly with development, with highest levels typically found in late adolescence. High concentrations of serum IgE measured in the first year of life have been shown to correlate with future development of atopic disease. However, in clinical situations when presenting signs of allergic disease are evident, total IgE levels do not provide additional diagnostic information. Furthermore, normal IgE levels do not exclude the diagnosis of allergic disease in infants or children.

Total serum IgG, IgA and IgM testing is not typically clinically useful, since their levels are not altered by allergic diseases. Based on a review of the literature, the role of routine quantitative measurement of serum IgG, IgA and IgM in the diagnosis and management of allergic disease has not been established.

Serum IgG antibodies are not involved in the pathogenesis of atopic disease. Although it has been suggested that IgG antibodies may be responsible for delayed symptoms or vague intolerance to foods, there is no evidence available that validates this contention. RAST and similar technologies are capable of detecting minute quantities of such antibodies, and it is known that low-level IgG antibodies to foods circulate normally but have no known pathogenic significance. The measurement of specific IgG antibodies is of no diagnostic value in the management of patients with atopic (allergic) disease. 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 without suspected immunodeficiency.

Reference Resources

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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

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Document Precedence

Blue Cross and Blue Shield of Vermont (Blue Cross VT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, Blue Cross VT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, Blue Cross VT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Benefits are subject to all terms, limitations and conditions of the subscriber contract.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

09/2016	New Policy
12/2017	Reviewed policy statements remain unchanged.
01/2019	Updated to include sublingual therapy for dust mites. Otherwise policy statements remain unchanged.
01/2020	Policy reviewed no changes to policy statements. Updated references.
02/2021	Policy reviewed. Not medically necessary allergy tests reclassified as investigational. Updated references.
01/2022	Policy reviewed. References updated. Minor formatting changes. Removed criteria for sublingual immunotherapy for treatment of allergies- see Pharmacy Policy for current criteria.
09/2022	Policy merged with BCBSVT Corporate Medical Policy: Selected Blood, Serum and Cellular Allergy and Toxicity Tests. Name changed to Allergy Testing, Including Selected Blood, Serum and Cellular Testing and Toxicity Testing. Formatting changes.

01/2023	Policy reviewed. No change to policy statement. Minor formatting changes. References updated.
01/2024	Policy reviewed. No change to policy statement. References updated.
01/2025	Policy reviewed. No change to policy statement. References updated.
02/2026	Policy reviewed. References updated. Medical necessity criteria for mutational analysis of KIT D816V to aid in the diagnosis of suspected Systemic Mastocytosis added. Minor formatting changes. Updated coding table adding code 81273 as requiring prior approval and changing code 83516 from 'not medically necessary for all diagnoses except may be indicated for the treatment and management of autoimmune disorders' to investigational.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by Blue Cross VT Medical Director(s)

Tom Weigel, MD, MBA
Vice President & Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I
CPT® Code Table & Instructions

Code Type	Number	Brief Description	Policy Instructions
CPT®	81273	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)	Prior Approval Required
CPT®	82787	Immunoglobulin subclasses (eg, IgG1,2, 3, or 4	Not medically necessary for all diagnoses except may be indicated for the treatment and management of autoimmune disorders.

CPT®	83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method [When specified as ALCAT]	Investigational
CPT®	86001	Allergen specific IgG quantitative or semiquantitative, each allergen	Not medically necessary for all diagnoses.
CPT®	86160	Complement; antigen, each component	Not medically necessary for all diagnoses except may be indicated for diagnosis and management of inflammatory conditions. Limit 4 units per day.
CPT®	86343	Leukocyte histamine release test (LHR)	Not Medically necessary for all diagnoses
CPT®	95199	Unlisted allergy/clinical immunologic service or procedure [when specified as cytotoxic testing for allergies]	Not medically necessary for all diagnoses. This code will suspend for medical record review.