



BlueCross BlueShield of Vermont

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Selected Blood, Serum and Cellular Allergy and Toxicity Tests Corporate Medical Policy

File Name: Selected Blood, Serum and Cellular Allergy and Toxicity Tests

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Description/Summary

This document addresses selected unproven blood, serum and cellular allergy and toxicity tests.

Allergy testing is used to determine if a symptom could be the result of an allergic reaction (involving antibodies and histamine release). Generally accepted diagnostic tools include the percutaneous (scratch, prick, or puncture) tests, the allergen - specific serum IgE test, food elimination diets and oral food challenges (double-blind, placebo-controlled food challenge). Diagnosis of food related symptoms is often made based on history, elimination diet and/or food challenge. Treatment of food allergy is usually avoidance of that food (ACAAI, 2006; Boyce, 2010).

Policy

Coding Information

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

[Attachment I- CPT® Code Table & Instructions](#)

When a service may be considered medically necessary

The following blood, serum and cellular allergy or toxicity tests may be considered **medically necessary**.

- Antigen leukocyte cellular antibody test (ALCAT)
- Complement antigen testing for the diagnosis and management of inflammatory conditions.
- Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantative, multiple step method (ALCAT)

testing for the treatment and management of autoimmune disorders.

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

When a service is considered not medically necessary

The following blood, serum and cellular allergy or toxicity tests are considered **not medically necessary**. List may not be all inclusive:

- Basophil tests
- Basophil Histamine release assay (BHRA)
- Alpha gal allergy (meat allergy) testing
- Anti-Fc epsilon receptor antibodies testing
- Anti-IgE receptor antibody testing
- Body chemical analysis
- Candidiasis test
- Chlorinated pesticides (serum)
- Chronic Urticaria Index testing
- Clifford materials reactivity testing
- Complement (total or components); (unless meets medical necessity criteria above for autoimmune disorders, complement component deficiencies, hereditary angioedema or vasculitis)
- Component-Resolved diagnostics
- C-reactive protein (may be appropriate in inflammatory diseases)
- Conjunctival challenge test (ophthalmic mucous membrane test)
- Cytokine and cytokine receptor assay
- Cytotoxic food testing (Bryan's Test, ACT)
- Cytotoxic tests
- Electrodermal acupuncture
- Electrodermal testing
- ELISA/ACT
- Eosinophil cationic protein (ECP) test
- Food immune complex assays (FICA)
- Hair Analysis
- HEMOCODE Food Intolerance S system
- IgG food sensitivity test
- IgG RAST/ELISA testing
- Immune complex assay (may be appropriate in autoimmune disorders, systemic lupus erythematosus, vasculitis)
- Bloodprint Diagnostic Testing (Immuno Labs)
- ImmunoCAP ISAC Test (Thermo Fisher Scientific)
- In-vitro metal allergy testing (as known as lymphocyte transformation tests (LTT))
- Iridology
- Kinesiology and Applied Kinesiology
- Leukocyte antibodies testing
- Leukocyte histamine release test (LHRT)Lymphocytes (B or T subsets); (may be

appropriate for collagen vascular disease, immune deficiency syndromes, leukemia, lymphomas)

- Lymphocyte function assay
- Mediator release test (MRT)
- Muscle strength testing or measurement (kinesiology) after allergen ingestion
- Nasal Challenge
- Ophthalmic mucous membrane tests/conjunctival challenge tests
- Prausnitz-Küstner or P-K testing -- passive cutaneous transfer test
- Provocative nasal test (also known as nasal provocation testing)
- Provocation-neutralization testing (Rinkel Test) either subcutaneously or sublingually
- Pulse test (pulse response test, reaginic pulse test)
- Rebeck skin window test
- Serum immunoglobulin A (IgA) or immunoglobulin G (IgG) testing for allergies
- Sublingual provocative neutralization testing and treatment with hormones
- Testing for electromagnetic sensitivity syndrome/disorder (also known as allergy to electricity, electro-sensitivity, electrohypersensitivity, and hypersensitivity to electricity)
- 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)
- Venom blocking antibodies
- Volatile chemical panels (blood testing for chemicals).

Background

The standard of care in the medical community for diagnosing food allergies includes a medical history, a physical examination and diagnostic tools such as the percutaneous (scratch, prick, or puncture) tests, the allergen-specific serum IgE test, food elimination diets and oral food challenges (double-blind, placebo-controlled food challenge).

This document addresses selected blood, serum and cellular allergy and toxicity tests that are considered unproven.

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.

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.

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.

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.

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.

Rationale/Scientific Background

According to the National Institute of Allergy and Infectious Diseases (NIAID), food allergies should be suspected in the following: (1) individuals presenting with anaphylaxis or select symptoms that occur within minutes to hours of ingesting food, especially in young children and/or if symptoms have followed the ingestion of a specific food on more than one occasion; (2) infants, young children and selected older children diagnosed with conditions such as moderate to severe atopic dermatitis (AD), eosinophilic esophagitis (EoE), enterocolitis, enteropathy, and allergic proctocolitis (AP); and (3) adults diagnosed with EoE (Boyce, 2010).

As mentioned above, generally accepted tests to diagnose food allergies include the percutaneous (scratch, prick, or puncture) tests, the allergen-specific serum IgE test, food elimination diets and oral food challenges (double-blind, placebo-controlled food challenge [Boyce, 2010]). *ALCAT*

The antigen leukocyte cellular antibody test (ALCAT) measures whole blood leukocyte activity to identify allergens which cause an increase in the leukocyte activity. The ALCAT has been promoted as a diagnostic test for food allergy or intolerance (chemical sensitivity) and as a tool to establish elimination diets.

Mylek and colleagues (1995) explored the use of the ALCAT results as the base for elimination diet treatment in several conditions considered to be the result of food allergy (intolerance). A total of 72 participants (45 children and 27 adults), suffering from various symptoms of unproven etiologies and who had undergone a variety of treatments without improvement, were enrolled in the study. An ALCAT with 50 foods, skin prick test with 11 common inhalants and 28 foods and a detailed history were performed. Clinicians assessed whether the diet tailored on the basis of the ALCAT results achieved an improvement in symptoms after 1 month of an individual elimination diet. Emotional disturbances were assessed after the participants had been on the elimination diet for 4 months. The best results (83% improvement) were seen in symptoms related to arthritis. A 75% improvement was reported in urticaria, bronchitis and gastroenteritis. Less favorable results (32% improvement) were reported in childhood hyperactivity. The researchers concluded that "using the ALCAT Test in the course of allergologic diagnosis helps to describe less common foods that may cause reactions similar to that of apple, beetroots, lettuce, leek, pears, millet, oat or rice, etc." Some of the limitations of the Mylek study include a lack of a definition of "emotional disturbances", and the fact that detailed study methods and results were not published. The authors indicate that the study participants were assessed for symptom improvement after 1 month on the elimination diet and for improvement in emotional disturbances after 4 months on the elimination diet. However, the authors failed to report exactly what was evaluated during the clinical assessment, how the severity of symptoms were measured and failed to provide a breakdown of the results at the 1- and 4-month intervals.

Wuthrich (2005) reviewed of a number of tests including cytotoxic food testing, ALCAT test, bioresonance, electrodermal testing (electroacupuncture), reflexology and applied kinesiology for the diagnosis and treatment of allergies. The author concluded that "there is little or no scientific rationale for these methods. Results are not reproducible when subject to rigorous testing and do not correlate with clinical evidence of allergy." In a review article by Beyer and colleagues (2005), both scientific and unproven methods to

diagnose food allergies are discussed. While the review does not specifically address ALCAT, the authors concluded that controlled oral food challenges remain the most important diagnostic tools in suspected food allergy. The evidence-based allergy testing guidelines by the American Academy of Allergy, Asthma and Immunology and the National Institute of Allergy and Infectious Diseases do not mention ALCAT as one of the recognized tests for the evaluation of potential allergy (Bernstein, 2008; Boyce, 2010).

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 or food intolerances is an in vitro technique purported to be useful for diagnosing food allergies. 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. This test involves the exposure of leukocytes to the presence of food extracts to which the individual is allergic. A technician then observes the unstained cells for changes in the size, shape, appearance or integrity. Swelling, vacuolation or other cytotoxic changes in cell morphology are taken as evidence an allergic reaction to food.

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

The Health Care Financing Administration (HCFA) and the Federal Trade Commission (FTC) requested that the United States Food and Drug Administration (FDA) assess the validity, accuracy, and effectiveness of "in vitro" cytotoxic testing as a diagnostic tool. The FDA concluded that the cytotoxic test is "an unproven diagnostic procedure unsupported by the scientific literature or well-controlled studies and clinical trials" (FDA, 1985).

Several other organizations and scientific groups have reviewed the literature related to cytotoxic testing and have concluded that the test is unproven. The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination which states "cytotoxic leukocyte tests for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective" (CMS, 1985). A position statement by the American Academy of Allergy, Asthma, and Immunology (AAAAI) concluded cytotoxic testing is either disproved or unproven and therefore is not recommended for the diagnosis of food allergy (2006). A joint report of the Royal College of Physicians and the British Nutrition Foundation (1984) concluded that the results of cytotoxic testing are of no diagnostic value. NIAID does not recommend non-standardized tests (cytotoxic testing) for the routine evaluation of IgE-mediated food allergies (Boyce, 2010).

Cytotoxic testing has been identified by a variety of names, including but not limited to, Bryan's Test, the leukocytotoxicity test, the leukocytic food allergy test, the cytotoxic leukocyte test and the CYTOTOXIC test.

IgG-Mediated Food Sensitivity Testing

Immunoglobulin G (IgG) is frequently divided into four subclasses. Selective deficiencies in one or more of the four IgG groups may be seen in some individuals with repeated infections. IgG and IgG subclasses can be measured in a manner similar to those for allergen specific IgE. Controversy exists regarding whether increases of IgG4 are valid indicators of either diagnosis of a food allergy or clinical efficacy after immunotherapy. Specific IgG/IgG4 results do not correlate with oral food challenges and are not recommended for diagnosing food allergies. Measurements of IgG and specifically IgG4 antibodies is frequently carried out in the research settings as diagnostic and prognostic tests to determine response to allergy treatments. The guidelines published by the AAAAI state that "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" (Bernstein, 2008).

The European Academy of Allergy and Clinical Immunology (EAACI) notes that testing for blood IgG4 against different foods is being more frequently performed with large- scale screening for hundreds of food items by ELISA-type and radioallergosorbent-type tests. However, many serum samples show positive IgG4 results in the absence of corresponding clinical symptoms. These findings, in conjunction with the lack of convincing evidence for the histamine-releasing properties of IgG4 in humans, and lack of any controlled studies on the diagnostic value of IgG4 testing in food allergy, do not provide any basis for the hypothesis that food-specific IgG4 results in food hypersensitivity. To the contrary, elevated IgG4 levels may indicate that an individual has been repeatedly exposed to food components, recognized as foreign proteins by the immune system. Its presence should not be considered as a factor which causes hypersensitivity, but rather as an indicator for immunological tolerance, linked to the activity of regulatory T cells. Food-specific IgG4 does not indicate (imminent) food allergy or intolerance, but rather a physiological response of the immune system after exposure to food components. Therefore, "testing of IgG4 to foods is considered as irrelevant for the laboratory work-up of food allergy or intolerance and should not be performed in case of food-related complaints" (Stapel, 2008).

IgG antibody testing for food intolerance is generally offered by CLIA (Clinical Laboratory Improvement Amendments) approved laboratories. The BloodPrint™ test (Immuno Laboratories, Fort Lauderdale, FL) is an example of a laboratory test that measures IgG response. There are several types of BloodPrint tests which vary by number. The numbers (154, 115, 88, 108 and 104) are indicative of how many different foods are being tested. Samples for the BloodPrint test can be drawn at a local laboratory or a physician's office and sent to Immuno Laboratories for processing at a CLIA certified facility.

A search of the peer-reviewed, scientific literature did not reveal any published studies for the BloodPrint test. A search of the Clinical Trials.gov database identified the completion of a clinical trial (NCT01592071) which included the use of the BloodPrint test. The study sought to evaluate the effect of an IgG-mediated food sensitivity test in combination with a food elimination diet on body composition and secondary outcomes in people who were overweight. At the time of this review, we were unable to identify any published results of the study.

The HEMOCODE™ Food Tolerance System (Gemoscan, Ontario, Canada) is marketed as more than an IgG test. In addition to the test, it includes a "comprehensive program", supervised by Doctors of Naturopathic Medicine. The system includes a preliminary face-to-face consultation and follow-up review of the test results with a health professional. The HEMOCODE Food Tolerance System is not available online but can be purchased through participating retailers.

A search of the peer-reviewed, scientific literature did not reveal any publications related to the HEMOCODE test.

The US BioTek Laboratories IgG antibody assays (IgA and IgG) measure all 4 subclasses (IgG1 through IgG4) and are reported as a total IgG value on a semi-quantitative scale for each antigen. Information on the US BioTek Laboratories web site indicates that the panel is not available online but can be requested via a healthcare practitioner.

A search of the peer-reviewed, scientific literature did not reveal any publications related to the US BioTek Laboratories antibody assessment panel.

The Complement Antigen Test (Sage Medical Laboratories) measures IgG and components of complement to identify delayed food allergies. However, search of the peer-reviewed, scientific literature did not reveal any publications related to the Complement Antigen Test.

Leukocyte histamine release test

The leukocyte histamine release test (LHRT, basophil histamine release test) measures the amount of histamine released in the presence of an antigen. Varying concentrations of an allergen extract are added to the peripheral blood leukocytes of the individual being tested. Histamine is normally released as a result of the interaction of allergen with cell-bound IgE antibodies. If the individual is allergic to a specific antigen, the leukocytes should release histamine in -vitro upon stimulation of said antigen, unless the individual has recently been exposed and his/her cells are in a refractory state. A limited number of allergens can be tested using a single aliquot of blood.

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).

Reference Resources

Blue Cross and Blue Shield Association Medical Policy Reference Manual; Antigen Leukocyte Antibody Test, MPRM 2.01.93. Reviewed November 2020. Accessed January 2021.

Peer Reviewed Publications:

1. Benson TE, Arkins JA. Cytotoxic testing for food allergy: evaluation of reproducibility and correlation. *J Allergy Clin Immunol.* 1976; 58(4):471-476.
2. Beyer K, Teuber SS. Food allergy diagnostics: scientific and unproven procedures. *Curr Opin Allergy Clin Immunol.* 2005; 5(3):261-266.
3. Buczyłko K, Obarzanowski T, Rosiak K. Prevalence of food allergy and intolerance in children based on MAST CLA and ALCAT tests. *Rocz Akad Med Białymst.* 1995; 40(3):452-456.
4. Golbert, T. A review of controversial diagnostic and therapeutic techniques employed in allergy. *J Allergy Clin Immunol.* 1975; 56(3):170-190.
5. Grieco MH. Controversial practices in allergy. *JAMA.* 1982; 247(22):3106-3111.
6. Griese, M., Kusenbach, G., Reinhardt, D. Histamine release test in comparison to standard tests in diagnosis of childhood allergic asthma. *Ann Allergy.* 1990; 65(1):46-51.
7. Kleine-Tebbe J, Galleani M, Jeep S, et al. Basophil histamine release in patients with birch pollen hypersensitivity with and without allergic symptoms to fruits. *Allergy* 1992; 47(6):618-623.
8. Kleine-Tebbe J, Werfel S, Roedsgaard D et al. Comparison of fiberglass -based histamine assay with a conventional automated fluorometric histamine assay, case history, skin prick test, and specific serum IgE in patients with milk and egg allergic reactions. *Allergy* 1993; 48(1):49-53.
9. Lieberman P, Crawford L, Bjelland J. Controlled study of the cytotoxic food test. *JAMA.* 1975; 231(7):728-730.
10. Myłek D. ALCAT Test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system. *Rocz Akad Med Białymst.* 1995; 40(3):625-629.
11. Niggemann B, Gruber C. Unproven diagnostic procedures in IgE-mediated allergic diseases. *Allergy.* 2004; 59(8):806-808.
12. Nolte H, Schiøtz PO, Kruse A, Stahl Skov P. Comparison of intestinal mast cell and basophil histamine release in children with food allergic reactions. *Allergy.* 1989; 44(8):554-565.
13. Nolte H, Schiøtz O, Skov PS. A new glass microfibre-based histamine analysis for allergy testing in children. Results compared with conventional leukocyte histamine release assay, skin prick test, bronchial provocation test and RAST. *Allergy.* 1987; 42(5):366-373.
14. Ostergaard PA, Ebbensen F, Nolte H, et al. Basophil histamine release in the diagnosis of house dust mite and dander allergy of asthmatic children. Comparison between prick test, RAST, basophil histamine release and bronchial provocation. *Allergy.* 1990; 45(3):231-235.
15. Prahł P, Krasilnikof F, Stahl Skov P, Norn S. Basophil histamine release in children with adverse reactions to cow milk. Comparison with RAST and skin prick test. *Allergy.* 1988; 43(6):442-448.
16. Ruokonen J, Holopainen E, Palva T, Backman A. Secretory otitis media and allergy. With special reference to the cytotoxic leucocyte test. *Allergy.* 1981; 36(1):59-68.
17. Skov PS, Mosbech M, Norn S, et al. Sensitive glass microfibre-based histamine analysis for allergy testing in washed blood cells. Results compared with

- conventional leukocyte histamine release assay. *Allergy*. 1985; 40(3):213-218.
18. Terr AI. The cytotoxic test. *West J Med*. 1983; 139(5):702-703.
 19. Wanich N, Nowak-Wegrzyn A, Sampson HA, Shreffler WG. Allergen-specific basophil suppression associated with clinical tolerance in patients with milk allergy. *J Allergy Clin Immunol*. 2009; 123(4):789-794.e20.
 20. Wuthrich B. Unproven techniques in allergy diagnosis. *J Investig Allergol Clin Immunol*. 2005; 15(2):86-90.
 21. UpToDate: Diagnostic evaluation of food allergy. Literature review current through December 2021. Accessed January 2021.
 22. UpToDate: Unproven and disproven tests for Food Allergy. Literature review current through December 2020. Accessed January 2021.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Allergy: position statements--controversial techniques. *J Allergy Clin Immunol*. 1981; 67(5):333-338.
2. American College of Allergy, Asthma, & Immunology. Food allergy: a practice parameter. *Ann Allergy Asthma Immunol*. 2006; 96(3 Suppl 2): S1-S68.
3. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol*. 2008; 100(3 Suppl 3):S1-S148.
4. Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol*. 2010; 126(6Suppl):S1-S58.
5. Centers for Medicare and Medicaid Services. National Coverage Determination for Cytotoxic Food Tests. NCD #110.13. Effective August 5, 1985. Available at: <http://www.cms.gov/>. Accessed on June 10, 2015.
6. Food intolerance and food aversion. A joint report of the Royal College of Physicians and the British Nutrition Foundation. *J R Coll Physicians Lond*. 1984; 18(2):83-123.
7. New York Academy of Medicine Committee on Public Health. Statement on cytotoxic testing for food allergy (Bryan's test). *Bull N Y Acad Med*. 1988; 64(1):117-119.
8. Stapel SO, Asero R, Ballmer-Weber BK, et al. Testing for IgG4 against foods is not recommended as a diagnostic tool: EAACI Task Force Report. *Allergy*. 2008; 63(7):793-796.
9. U.S. Food and Drug Administration. Inspections, Compliance, Enforcement, and Criminal Investigations. CPG Sec. 370.100 Cytotoxic Testing for Allergic Diseases. Revised 3/95. Page updated 03/20/2015. Available at: <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm123806.htm>. Accessed on June 10, 2015.

Websites for Additional Information

1. American Academy of Allergy, Asthma, and Immunology (AAAAI). Available at: <http://www.aaaai.org/home.aspx>. Accessed on June 10, 2015.
2. Department of Health and Human Services. Centers for Medicare and Medicaid Services. CLIA, Clinical Laboratories Improvements Amendments (CLIA). ICN # 006270 July 2014. Available at: <https://www.cms.gov/Outreach-and->

[Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CLIABrochure.pdf](#). Accessed on June 10, 2015.

3. U. S. Food and Drug Administration. Regulatory Information. Guidance. Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration. Page last updated 08/05/2014. Available at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm144657.htm>. Accessed on June 10, 2015.

Related Policies

Diagnosis and Management of Idiopathic Environmental Illness/Intolerance (IEI)
Nutrient/Nutritional Panel Testing & Intracellular Micronutrient Analysis

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) 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, BCBSVT 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

BCBSVT 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, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

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

06/2016	New Policy
10/2017	External input received. Revised medical necessity criteria and eligible diagnoses for the following Codes: 83516, 86160, 82787.
11/2018	Code 83516 from not medically necessary to not medically necessary <u>except</u> may be indicated for the treatment and management of autoimmune disorders. Code 86160 changed from not medical necessary for all diagnoses <u>except</u> may be indicated for diagnosis and management of rheumatoid arthritis and systemic lupus erythematosus (4 units per day maximum M32.0-M32.9; M05. 9 to not medically necessary for all diagnoses <u>except</u> may be indicated for diagnosis and management of inflammatory conditions - Limit 4 units per day. The old mapping was only mapped to the examples in the policy not the whole class. Code 82787 changed from not medically necessary for all diagnoses to not medically necessary for all diagnoses <u>except</u> may be indicated in treatment and management of autoimmune conditions. Code 86343 moved to medically necessary.
11/2019	Reviewed policy updated references and added blood, serum and cellular allergy or toxicity tests are considered not medically necessary to policy section.
01/2021	Policy reviewed. Updated references. No change to policy statement.

Eligible providers

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

Approved by BCBSVT Medical Directors

Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP
Senior Medical Director

Attachment I
CPT® Code Table & Instructions

Code Type	Number	Brief Description	Policy Instructions
CPT® ⁻	83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method [when specified as ALCAT]	Not medically necessary for all diagnoses <u>except</u> may be indicated for <u>diagnosis and management of autoimmune disorders.</u>
CPT® ⁻	86001	Allergen specific IgG quantitative or semiquantitative, each allergen	Not Medically necessary for all diagnoses
CPT® ⁻	86343	Leukocyte histamine release test (LHR)	Not Medically necessary for all diagnoses
CPT®	86160	Complement; antigen, each component	Not medically necessary for all diagnoses <u>except</u> may be indicated for <u>diagnosis and management of inflammatory conditions. Limit 4 units per day.</u>
CPT® ⁻	82787	Immunoglobulin subclasses (eg, IgG1,2, 3, or 4	Not medically necessary for all diagnoses <u>except</u> may be indicated for <u>the treatment and management of autoimmune disorders.</u>
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.