MEDICAL POLICY

POLICY TITLE	ALLERGY TESTING AND IMMUNOTHERAPY
POLICY NUMBER	MP-2.001

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I. POLICY

Allergy Testing

Specific allergy testing may be considered **medically necessary** for members with clinically significant allergic history of symptoms when all of the following criteria are met:

- Symptoms are not adequately controlled by empiric conservative therapy; **and**
- Testing must correlate specifically to the member's history, risk of exposure and physical findings; **and**
- Test technique and/or allergens tested must have proven efficacy demonstrated through scientifically valid studies published in the peer-review literature.

Allergy testing may be considered **medically necessary** in the diagnosis of allergies utilizing the following techniques:

- Direct Skin Test
  Percutaneous (scratch, prick, or puncture) and intra cutaneous (intradermal) allergy testing when used for the diagnosis, evaluation, and treatment of allergies when there are signs and symptoms or a diagnosis of an allergy (e.g., a history of hypersensitivity to animals, food, pollen, dust mites, mold, grass, insect venoms or asthma, allergic rhinitis, or urticaria).
  - A cumulative total of 70 percutaneous or 40 intracutaneous tests may be considered medically necessary per benefit period.
  - Quantity level limits (QLL) greater than 70 percutaneous or 40 intracutaneous tests will be considered **not medically necessary** per benefit period.
- Patch test (application test)
- Photo patch test
- Bronchial challenge test
- Double Blind Food Challenge.
- Serial Endpoint Testing (SET) when used in conjunction with immunotherapy to determine a safe starting dose for testing; or to determine a safe starting dose for immunotherapy.

  - A cumulative total of 80 endpoints (SET, SDET, IDT) allergy tests may be considered medically necessary per benefit period.
  - Quantity level limits (QLL) greater than 80 endpoint tests will be considered not medically necessary per benefit period.
- Specific IgE In Vitro tests including RAST, MAST, FAST, and ELISA when testing for the following allergens:
  - Inhalant allergens (pollens, molds, dust, mites, animal dander)
  - Foods
  - Insect stings
  - Other allergens, such as drugs, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism is present or in children five years of age or less, or with a diagnosis of a pervasive developmental disorder or an individual with an intellectual disability.
- Total Serum IgE Concentration for patients suspected of having one of the following diagnoses:
  - 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

Other allergy tests, including but not limited to the following, are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures:

- Antigen Leukocyte Cellular Antibody Test (ALCAT) automated food allergy testing
- Cytotoxic food testing (also known as Bryan's testing)
- Leukocyte histamine release test (LHRT)
- Provocative tests for food or food additive allergies (e.g. Rinkel method)
- Nasal challenge test
- Conjunctival challenge test (ophthalmic mucous membrane test)
- IgG ELISA indirect method or Elisa/Act qualitative antibody testing
- IgG4 allergy testing - IgG4 does not indicate imminent food allergy or intolerance, but rather a physiological response of the immune system after exposition to food components
- Mediator Release Testing (MRT), including any aspect of the Lifestyle Eating and Performance (LEAP) program.
- Complement Antigen Testing
- Food Immune Complex Assays (FICA)

Allergy Immunotherapy

Allergy immunotherapy may be considered **medically necessary** for patients with demonstrated hypersensitivity that cannot be managed by medication, avoidance or environmental control measures. Injections of airborne or insect venom allergens should be prepared for the patient individually.

Maintenance Phase

Individuals must be re-evaluated every 6 to 12 months while receiving allergy immunotherapy for **ALL** of the following:

- To determine efficacy; **and**
- To determine whether adjustments in the dosing schedule or allergen content are necessary; **and**
- To ensure compliance; **and**
- To monitor for the two types of adverse reactions: local (i.e., redness and swelling at the injection site) and systemic (i.e., sneezing, nasal congestion, or hives).

Allergy immunotherapy is considered **not medically necessary** after one year in the maintenance phase unless one of the following is documented:

- A noticeable decrease of symptoms; **or**
- An increase in tolerance to the offending allergen; **or**
- A reduction in medication usage; **or**
- A reasonable explanation for lack of improvement in spite of allergy immunotherapy, and why it is likely that allergies would worsen if immunotherapy were discontinued.

Other allergy immunotherapy, including but not limited to the following, are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

- Provocative and neutralization therapy for food allergies
- At home administration of allergy immunotherapy, including preparation of serum and any other related services.

Repeat Allergy Skin Testing

- Repeat skin testing with multiple antigens may be considered **medically necessary** for children who are initially sensitive to food or indoor environmental exposures, but later develop pollen and outdoor mold sensitivities.
- Repeat skin testing may be considered medically necessarrt for adults who:
  - Have food allergy and require reevaluation to examine for resolution of their food allergy; **or**
  - Have received three to five years of venom immunotherapy and require reevaluation for the resolution of the venom allergy **or**
  - Develop increased atopic symptoms suggesting new sensitizations.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP: The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

FEP PPO - Refer to FEP Benefit Brochure for information on Allergy Care: https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms

Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

CHIP (aka Capital Cares 4Kids): Quantity level limits do not apply.

III. DESCRIPTION/BACKGROUND

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Allergy Testing

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions or localized reactions in any organ system of the body. Reactions may be acute, sub-acute, or chronic, immediate or delayed. Allergy testing can be broadly subdivided into in vivo and in vitro 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 allergy tests include various techniques to test the blood for the presence of specific IgE antibodies to a particular antigen (i.e., RAST and ELISA tests), and leukocyte histamine release test (LHRT). LHRT may also be referred to as basophil histamine release test.

Skin prick testing and in vitro analyses of IgE are the most commonly performed allergy tests. The number of tests required may vary widely from patient to patient, depending on the patient's history. Rarely are more than 40 percutaneous or 20 intracutaneous tests required.

Serial endpoint testing (SET), also known as serial endpoint titration, 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 is a potential alternative to other diagnostic tests such as skin prick testing or in vitro testing for this purpose. Also SET has been used to guide the initiation of immunotherapy by using the endpoint dilution as the starting antigen dose.

Mediator release testing (MRT) testing attempts to measure the release of chemical mediators from white blood cells and platelets in response to specific foods, chemicals, or additives. Mediator release testing has been advocated as a means to measure the reaction in the blood resulting from a food or chemical to which you have become sensitive or intolerant. When exposed to a food or chemicals that a person is sensitive to the cells release various chemical mediators. The Lifestyle Eating and Performance (LEAP) program is used along with MRT testing to try to identify delayed food allergies and treatments that include dietary manipulation with or without supplements.

In January 2003, the Board of Directors of the American Academy of Otolaryngic Allergy (AAOA) endorsed strategies for testing for inhalant allergy (Krouse and Mabry, 2003), stating

that "[m]embers should practice in ethical and fiscally responsible ways." The AAOA provided the following guidelines on the necessary number of tests for inhalant allergy (e.g., prick testing, intradermal testing, intradermal dilutional testing (IDT), and in vitro testing):

- Screening: Screen with no more than 14 relevant antigens plus appropriate controls.
- Antigen survey: If screening is positive and immunotherapy is contemplated, use no more than 40 antigens. More extensive testing may be justified in special circumstances.
- Quantification for safe starting point: Use no more than 80 IDT tests routinely. More extensive testing may be justified in special circumstances.

Allergy Immunotherapy

Allergy immunotherapy involves routine injections of escalating doses of an offending allergen over a period of months, with the goal of reducing symptoms. Once immunity is achieved the patient begins maintenance therapy. Maintenance immunotherapy may be administered continuously for several years and the interval between injections may range from two to six weeks.

Provocative and Neutralization Therapy

This procedure is purported to diagnose allergy to foods, chemicals, inhalant allergens, and endogenous hormones. Varying concentrations of test extracts of these substances are given to the patient by intracutaneous or subcutaneous injection or sublingually. The patient records all subjective sensations for 10 minutes afterward, and any reported sensation is taken as a positive test result for allergy. In the event of a positive test result, other doses of the same substance are given until the sensation has disappeared, at which point the action is said to be "neutralized." Some proponents recommend measuring increase in the size of the injected wheal in the intracutaneous provocation procedure, but the primary indication of a positive result is the provocation and neutralization of symptoms.

IV. RATIONALE

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Test	Description	Rationale
The Antigen Leukocyte Antibody Test (ALCAT)	**Considered Investigational** The Antigen Leukocyte Antibody Test (ALCAT) is intended to diagnose intolerance to foods and other environmental agents. It is a blood test that assesses the response of leukocytes and platelets to a panel of foods and/or other environmental agents, by measuring the change in size and number of cells following exposure to a specific agent	There is a lack of published research on the diagnostic accuracy of the test therefore it is not possible to determine the sensitivity, specificity, and/or predictive value of the test compared with alternatives. A few low-quality studies report improvement in outcomes following use of the ALCAT test, but it is not possible to determine whether these changes occur as a result of test itself, versus bias, variation in the natural history of the condition, and/or the placebo effect. Guidelines for the diagnosis of food allergy from the National Institute of Allergy and Infectious Disease (NIAID) do not discuss use of the ALCAT test.

Cytotoxic Food Testing (Leukocytotoxic Test)	**Considered Investigational** This test involves the response of specially collected white blood cells to the presence of food extracts to which the patient is allergic. The cytotoxic test is performed by placing a drop of whole blood or buffy coat as an unstained wet mount on a microscope slide precoated with a dried food extract. The technician observes the unstained cells for changes in shape and appearance of the leukocytes. Swelling, vacuolation, crenation, or other cytotoxic changes in leukocyte morphology are taken as evidence of allergy to the food	There is no proof that this is effective for foods or pollens. The test is time consuming and entirely subjective, and there are no standards for time of incubation, pH osmolarity, temperature, or other conditions of the test. Controlled studies have shown that results are not reproducible and do not correlate with clinical evidence of food allergy. It offers no reliable help in establishing a diagnosis of food allergy. The utility of these tests has not been validated for the diagnosis of food allergies and may result in false positive or false negative diagnoses, leading to unnecessary dietary restrictions or delaying the appropriate diagnostic workup, respectively. Quality of evidence is low.
Leukocyte histamine release test (LHRT)	**Considered Investigational** The leukocyte histamine release test (LHRT) is designed to provide an in vitro correlate to an in vivo allergic response (i.e., skin prick testing). An allergen is added to the peripheral blood leukocytes of the individual being tested and the in vitro release of histamine from basophils in response to exposure to the allergen is measured. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies (froRecently, a special type of glass fiber has been developed that binds histamine with high affinity and selectivity. These glass fibers can be used as a "solid phase" to absorb the histamine that is released directly into the blood. The recent commercial availability of simplified and automated methods of	The utility of basophil histamine release tests has not been validated for the diagnosis of food allergy and may result in false positive or false negative diagnoses, leading to unnecessary dietary restrictions or delaying the appropriate diagnostic workup, respectively. Quality of evidence is low.

	laboratory analysis (i.e., both ELISA and radioimmunoassays) have renewed interest in the clinical applications of LHRT in the evaluation of food, inhalant, and drug allergies m BCBS Idaho)	
Provocative tests for food or food additive allergies	**Considered Investigational** Provocative tests attempt to duplicate the individual's symptoms. There are three variations of provocative testing for food allergies that can be performed. The variations, which differ in the route of administration for the test allergen, are: intracutaneous, subcutaneous or sublingual. Aside from the route, each type of testing involves the same basic method. The method includes administration of the food extract, followed by observation for any of a broad variety of subjective and objective signs and symptoms that could be interpreted as the presence of a food allergy.	This procedure has been evaluated by double-blind, placebo-controlled trials, which showed that responses to test substances are no different from responses to placebo. Furthermore, there is no rational immunologic explanation for provocation and prompt neutralization of subjective symptoms under these conditions. The utility of provocative tests has not been validated for the diagnosis of food allergies and may result in false positive or false negative diagnoses, leading to unnecessary dietary restrictions or delaying the appropriate diagnostic workup, respectively. Quality of evidence is low.
Nasal Challenge Test (Also called nasal mucous membrane test or nasal challenge /provocation test	**Considered Investigational** This test has been proposed as a tool in the diagnosis of allergic rhinitis. It is performed to duplicate the patient's main symptoms or signs by controlled exposure to a suspected antigen and is delivered by direct application to the nasal mucous membranes. Evaluation of the patient's response is recorded	Although nasal allergen challenge can definitively establish the diagnosis, it is clinically impractical and rarely performed outside of research settings. While, this test is used in studies of allergic rhinitis, its utility in clinical practice has not been established. Non-specific hyperreactivity of the nasal mucosa due to inflammation from another etiology could be an alternative explanation.
Conjunctival challenge test (ophthalmic mucous membrane test)	**Considered Investigational** Allergenic extract is placed into the conjunctival sac of the eye, followed by observation for	These tests are often the tools of research protocols that require an objective gold standard for establishing clinical sensitivity.

	redness, itchiness, tearing of the eye, and other similar symptoms	
IgG ELISA indirect method or ELISA/Act qualitative antibody testing	**Considered Investigational** The enzyme-linked immunosorbent assay (ELISA) is a simple and rapid technique for detecting and quantitating antibodies or antigens attached to a solid surface. This technique utilizes an enzyme-linked antibody binding to a surface-attached antigen. Subsequently, a substrate is added to produce either a color change or light signal correlating to the amount of the antigen present in the original sample.	IgG antibodies to allergens such as foods can be detected and quantified by Unicap or ELISA techniques. The presence of IgG antibodies, however, does not indicate allergy to these environmental substances. Detection of IgG antibodies, IgG subclasses, or IgG/IgG4 antibody ratios were discredited as reliable diagnostic tools. IgG antibodies to common foods can be detected in health and disease. This reflects the likelihood that circulating immune complexes to foods occur in most normal individuals, particularly after a meal that would be considered a normal physiologic finding. It was therefore concluded that food specific IgG or IgG subclasses should not be used in the diagnostic evaluation of food allergy.
IgG4 allergy testing	**Considered Investigational** Serological tests for immunoglobulin G4 (IgG4) against foods are persistently promoted for the diagnosis of food-induced hypersensitivity. Since many patients believe that their symptoms are related to food ingestion without diagnostic confirmation of a causal relationship, tests for food-specific IgG4 represent a growing market. Testing for blood IgG4 against different foods is performed with large-scale screening for hundreds of food items by enzyme-linked immunosorbent assay-type and radioallergosorbent-type assays in young children, adolescents and adults	Food-specific IgG4 does not indicate (imminent) food allergy or intolerance, but rather a physiological response of the immune system after exposition 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.
Mediator Release Testing (MRT), including any aspect of the Lifestyle	**Considered Investigational** In vitro particle size measurement for screening hypersensitivity reactions	There is a lack of evidence demonstrating that any of these nonstandardized tests has any value in the diagnosis of FA. The utility

Eating and Performance (LEAP) program	involves the measurement of the aggregate release of inflammatory mediators from an individual's immunocytes after exposure to various food extracts and chemicals (e.g., food additives). A determination is made of the difference in volume of circulating immunocytes and plasma before and after an in vitro antigen challenge An example of this technology is the Mediator Release Test® or MRT®. For this test, portions of an individual's blood sample are incubated with various food extracts and food additives (typically 150 different substances). The degree of reactivity is determined by the degree of mediator release from the cells. A response, change in cellular and plasma volume, is thought to indicate a hypersensitivity reaction and results are used as a basis for modifying an individual's diet. The MRT® is one component of the Lifestyle Eating and Performance (LEAP®) Program of oligoantigenic dieting. This type of testing has been promoted for individuals with, among other conditions, irritable bowel syndrome, chronic fatigue syndrome, migraine headaches, and dermatologic conditions (e.g., eczema, dermatitis).	of these tests has not been validated for the diagnosis of food allergy and may result in false positive or false negative diagnoses, leading to unnecessary dietary restrictions or delaying the appropriate diagnostic workup, respectively. Quality of evidence is low.
Provocative and Neutralization Therapy for Food Allergies	**Considered investigational** This procedure has been evaluated by double-blind, placebo-controlled trials, which showed that responses to test	There is no rational immunologic explanation for provocation and prompt neutralization of subjective symptoms under these conditions.841 Application of neutralizing injections of milk and wheat in a

	substances are no different from responses to placebo	patient with unsuspected urticaria pigmentosa resulted in a potentially life-threatening reaction.
Home Allergy Immunotherapy	**Considered investigational** This method of immunotherapy involves the bi-weekly injection of a small dose of allergic extract. The dose is slowly increased until the person becomes tolerant to larger amounts of the same extract. These injections are initially given at the beginning of each new dilution under the supervision of a physician until a maintenance dose, or constant dose, is achieved. This usually takes approximately 30 weeks. Once the maintenance dosage is reached no more office visits for immunotherapy are required. The person continues to self- administer the maintenance dose.	According to guidelines from the American Academy of Asthma, Allergy and Immunotherapy (Cox, et al., 2011), allergen immunotherapy should be administered in a medical facility with trained staff and medical equipment capable of recognizing and treating anaphylaxis. Under rare circumstances, when the benefit of allergen immunotherapy clearly outweighs the risk of withholding immunotherapy (e.g., patients with a history of venom-induced anaphylaxis living in a remote region), at-home administration of allergen immunotherapy can be considered on an individual basis. There are a small number of studies of home-based allergy immunotherapy. One prospective study by Hurst, et al. (1999) reports during a 1-year period, 27 otolaryngic allergy practices recorded all systemic reactions to immunotherapy resulting from 635,600 patient visits and 1,144,000 injections. Sixty percent of injections were given at home. Major systemic reactions were observed after 0.005% of injections. There were no hospitalizations or deaths. Eighty-seven percent of major reactions began within 20 minutes of injection. Frequently observed risk factors for major reactions were buildup phase of immunotherapy, active asthma, and first injection from a treatment vial. The authors reported that home and office injections had similar rates of total systemic reactions, but home-based immunotherapy had far fewer major reactions. A major limitation of the study is that it was limited to otolaryngic allergy practices; the generalizability of the results to primary care practices is uncertain. A study presented at the World Allergy Organization's (WAO) Annual Symposium on Immunotherapy and Biologics in Chicago

		in Dec 2013 reported on a study of 24,892 subcutaneous immunotherapy (SCIT) patient records. 2.182 million injections were examined for systemic reactions (SR). 74 identifiable reactions occurred and were graded by two different qualified individuals according to the WHO grading system for reporting AR published in the 2011 ITPP.2 Basic survey techniques were utilized to show efficacy and changes in medications scores. Statistical analysis and summaries were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC). Comparisons were measured using frequencies and paired t-tests. The results reported by UAS indicate an SR rate of 0.3% in 24,892 patients (2.182 million injections) and concludes that the risk of systemic, or adverse, reaction is less with UAS treatment protocol than traditional dosage and fast-build up RUSH methods that involve immunotherapy shots administered at a physician's office. The UAS protocol in the study was administered by primary care physicians and utilized self (home) administration. These results are reportedly due to UAS' slower, more incremental, immunotherapy build up phase as a self-administered treatment for patients suffering from seasonal and perennial allergies. Patients that receive allergy shots according to UAS protocols are under the care of primary care physicians
Complement Antigen Testing	**Considered Investigational** Complement Antigen Testing is a test that has been used to identify delayed food allergies. This test employs a unique patented process that measures Type II and III reactions thought to provide a more complete picture than by measuring IgG alone.	The use of this test for the purpose of identifying delayed food allergies has yet to be studied and validated.

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Food Immune Complex Assays (FICA)	**Considered Investigational** An allergen- and isotype-specific assay to quantify the presence of serum immune complexes.	Immune complex assays were once thought to be a promising diagnostic technique. However, they have generally been replaced with tests that are more specific, more standardized, and less expensive.

V. DEFINITIONS

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ALLERGEN – Any substance that causes a hypersensitivity reaction. Among common allergens are inhalants (dusts, pollens, fungi, smoke, perfumes, and odors of plastics), foods (wheat, eggs, milk, chocolate and strawberries), drugs (aspirin, antibiotics, and serums), infectious agents (bacteria, viruses and fungi), contactants (chemicals, animals, plants and metals), and physical agents (heat, cold, light and pressure).

ALLERGY – An immune response to a foreign antigen that results in inflammation and organ dysfunction. Allergies range from the life threatening to the annoying, and include systemic anaphylaxis, laryngeal edema, transfusion reaction, urticaria, hay fever and rhinitis.

ANTIGEN – A protein that induces the formation of antibodies, which interact specifically with it. This antigen–antibody reaction forms the basis of immunity.

ANTIBODY – A protein substance produced in response to a unique antigen. The substance developed combines with a specific antigen to destroy or control it.

BRONCHIAL CHALLENGE TEST uses histamine or methacholine to perform the test when it is necessary to determine if the patient has hyper-responsive airways. Volatile chemicals can be used to perform the test when the allergy is encountered in an occupational setting.

DOUBLE BLIND FOOD CHALLENGE TEST involves the patient ingesting the food to which sensitivity is suspected. Both the patient and physician are unaware of the food the patient is to ingest. This is done to eliminate the risk of prejudgment by the patient.

ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) is an in vitro method of allergy testing for specific IgE antibodies against allergens.

IGE refers to immunoglobulin E; an immunoglobulin that attaches to mast cells in the respiratory and intestinal tracts and plays a major role in allergic reactions.

INTRADERMAL refers to intracutaneous, or more specifically, within the dermis.

PATCH TEST is used to identify allergens causing contact dermatitis. The suspected allergens are applied to the patient's back, covered by a dressing and allowed to remain in contact with the skin for forty-eight (48) hours. The area is then examined for evidence of delayed hypersensitivity reactions.

PHOTO PATCH TEST reflects contact photosensitization. The suspected sensitizer is applied to the skin and is allowed to remain in contact with the skin for forty-eight (48) hours. If there is no reaction, 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 surrounding skin.

RADIOALLERGOSORBENT TEST (RAST)/MULTIPLE RADIOALLERGOSORBENT TESTS (MAST)/FLUORESCENT ALLERGOSORBENT TEST (FAST) are in vitro (test tube) techniques for determining whether a patient's serum contains IgE antibodies against specific allergens of clinical importance.

SERIAL ENDPOINT TESTING (SET) 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). SET has also been used to guide the initiation of immunotherapy by using endpoint dilution as a starting antigen dose.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational and therefore not covered:

CPT Codes®							
83516	84600	86001	86160	86332	86343	86807	86808
86849	95060	95065	95199				

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HCPCS Code	Description
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Covered when Medically Necessary

CPT Codes ®							
0165U	86008	95027	95070	95120	95133	95147	95180
0178U	95004	95028	95076	95125	95134	95148	95199
82785	95017	95044	95079	95130	95144	95149	
86003	95018	95052	95115	95131	95145	95165	
86005	95024	95056	95117	95132	95146	95170	

ICD-10-CM Diagnosis Code	Description
B44.81	Allergic bronchopulmonary aspergillosis
C90.0	Multiple myeloma
D82.0	Wiskott-Aldrich syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
H65.411	Chronic allergic otitis media, right
H65.412	Chronic allergic otitis media, left
H65.413	Chronic allergic otitis media, bilateral
J30.0	Vasomotor rhinitis
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89	Other allergic rhinitis
J30.9	Allergic rhinitis, unspecified
J31.0	Chronic rhinitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.8	Other chronic sinusitis
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated

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ICD-10-CM Diagnosis Code	Description
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.991	Cough variant asthma
J45.998	Other asthma
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L27.2	Dermatitis due to ingested food
L29.9	Pruritus, unspecified
L30.9	Dermatitis, unspecified
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria
L50.9	Urticaria, unspecified
R05	Cough
R06.00	Dyspnea, unspecified
R06.02	Shortness of breath
R06.09	Other forms of dyspnea
R06.83	Snoring
R06.89	Other abnormalities of breathing
R09.81	Nasal congestion
T63.421D	Toxic effect of venom of ants, subsequent encounter
T63.424D	Toxic effect of venom of ants, undetermined, subsequent encounter
T63.431D	Toxic effect of venom of caterpillars, accidental (unintentional), subsequent encounter
T63.434D	Toxic effect of venom of caterpillars, undetermined, subsequent encounter
T63.441D	Toxic effect of venom of bees, accidental (unintentional), subsequent encounter
T63.444D	Toxic effect of venom of bees, undetermined, subsequent encounter
T63.451D	Toxic effect of venom of hornets, accidental (unintentional), subsequent encounter
T63.454D	Toxic effect of venom of hornets, undetermined, subsequent encounter
T63.461D	Toxic effect of venom of wasps, accidental (unintentional), subsequent encounter
T63.464D	Toxic effect of venom of wasps, undetermined, subsequent encounter
T63.481D	Toxic effect of venom of other arthropod, accidental (unintentional), subsequent encounter
T63.484D	Toxic effect of venom of other arthropod, undetermined, subsequent encounter
T65.811D	Toxic effect of latex, accidental (unintentional), subsequent encounter
T78.00XD	Anaphylactic reaction due to unspecified food, subsequent encounter
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter
T78.02XD	Anaphylactic reaction due to shellfish (crustaceans), subsequent encounter

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ICD-10-CM Diagnosis Code	Description
T78.03XD	Anaphylactic reaction due to other fish, subsequent encounter
T78.04XD	Anaphylactic reaction due to fruits and vegetables, subsequent encounter
T78.05XD	Anaphylactic reaction due to tree nuts and seeds, subsequent encounter
T78.06XD	Anaphylactic reaction due to food additives, subsequent encounter
T78.07XD	Anaphylactic reaction due to milk and dairy products, subsequent encounter
T78.08XD	Anaphylactic reaction due to eggs, subsequent encounter
T78.09XD	Anaphylactic reaction due to other food products, subsequent encounter
T78.40XD	Allergy, unspecified, subsequent encounter
T78.49XD	Other allergy, subsequent encounter
Z01.82	Encounter for allergy testing
Z01.89	Encounter for other specified special examinations
Z88.0	Allergy status to penicillin
Z88.1	Allergy status to other antibiotic agents status
Z88.2	Allergy status to sulfonamides status
Z88.3	Allergy status to other anti-infective agents status
Z88.4	Allergy status to anesthetic agent status
Z88.5	Allergy status to narcotic agent status
Z88.6	Allergy status to analgesic agent status
Z88.7	Allergy status to serum and vaccine status
Z88.8	Allergy status to other drugs, medicaments and biological substances status
Z91.010	Allergy to peanuts
Z91.011	Allergy to milk products
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.018	Allergy to other foods
Z91.030	Bee allergy status
Z91.038	Other insect allergy status
Z91.040	Latex allergy status
Z91.041	Radiographic dye allergy status
Z91.048	Other nonmedicinal substance allergy status
Z91.09	Other allergy status, other than to drugs and biological substances

IX. REFERENCES

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Allergy Testing

1. *Bernstein IL, LI J, Bernstein DI. Allergy diagnostic testing: an updated practice parameter, part 1. 2008. [Website]: http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/allergydiagnostictesting.pdf Accessed May 14, 2020.*
2. *Mosby's Medical, Nursing, and Allied Health Dictionary 6th edition.*

3. *Lieberman P. Chronic Nonallergic Rhinitis. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated March 15, 2018. [Website] : www.uptodate.com . Accessed May 14, 2020.*
4. *deShazo R, Kemp S. Allergic Rhinitis: Clinical Manifestations, Epidemiology and Diagnosis. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated January 15, 2018. [Website] : www.uptodate.com . Accessed May 14, 2020.*
5. *Stapel, S, Asero, R., Ballmer-Weber, B. et al (July 2008), Testing for IgG4 Against Foods is Not Recommended as a Diagnostic Tool: EAACI Task Force Report. Allergy, 63: 793–796. doi: 10.1111/j.1398-9995.2008.01705.x [Website]: http://onlinelibrary.wiley.com/doi/10.1111/j.1398-9995.2008.01705.x/full. Accessed May 14, 2020.*
6. *Krouse JH, Mabry RL. Skin testing for inhalant allergy 2003 : Current strategies. Otolaryngol Head Neck Surg. 2003 ;129(4) : S33-S49*
7. *Baron M, Oleske J, LaBrico J, controversial Techniques in Allergy Treatment. J Natl Med Assoc. 1983 Aug; 75(8): 831–834. PMID: 6355491*

Antigen Leukocyte Antibody Test

1. *Solomon B.A. The ALCAT Test - A guide and barometer in the therapy of environmental and food sensitivities. Environmental Medicine. 1992;9(2):1-6.*
2. *Gupta RS, Dyer AA, Jain N, et al. Childhood food allergies: current diagnosis, treatment, and management strategies. Mayo Clin Proc. May 2013;88(5):512-526. PMID 23639501*
3. *NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, 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. Dec 2010;126(6 Suppl):S1-58. PMID 21134576*
4. *ALCAT test [Website]: https://cellsciencesystems.com/ Accessed May 14, 2020.*
5. *Wuthrich B. Unproven techniques in allergy diagnosis. J Investig Allergol Clin Immunol. 2005;15(2):86-90. PMID 16047707*
6. *Buczylko K, Obarzanowski T, Rosiak K, et al. Prevalence of food allergy and intolerance in children based on MAST CLA and ALCAT tests. Rocz Akad Med Bialymst. 1995;40(3):452-456. PMID 8775289*
7. *Kaats GR PD, Parker LK. The Short Term Efficacy of the ALCAT Test of Food Sensitivities to Facilitate Changes in Body Composition and Self-reported Disease Symptoms: A Randomized Controlled Study. The Bariatrician. 1996; Spring:18-23.*
8. *Mylek D. ALCAT Test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system. Rocz Akad Med Bialymst. 1995;40(3):625-629. PMID 877531*
9. *Cell Sciences Systems. Alcat Test. n.d.; https://cellsciencesystems.com/patients/alcat-test/. Accessed May 14, 2020.*
10. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.93, Antigen Leukocyte Antibody Test. October 17, 2019.*

Allergy Immunotherapy

Provocative and neutralization therapy for food allergies

1. *American Academy of Allergy Asthma Immunology, American College of Allergy Asthma Immunology, Joint Council of Allergy Asthma Immunology. Allergen immunotherapy: a practice parameter third update. August 2012. Available online at: https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Allergen-immunotherapy-Jan-2011.pdf Accessed May14, 2020. .*

Home Allergy Immunotherapy

1. *Epstein TG, et al. AAAAI/ACAAI Surveillance Study of Subcutaneous Immunotherapy, Years 2008-2012: An Update on Fatal and Nonfatal Systemic Allergic Reactions. J Allergy Clin Immunol Pract. 2014 Mar-Apr; 2(2):161-7.e3.*
2. *Hurst DS, Gordon BR, Fornadley JA, Hunsaker DH. Safety of home-based and office allergy immunotherapy: A multicenter prospective study. Otolaryngol Head Neck Surg. 1999; 121(5):553-561. [Website]: http://www.ncbi.nlm.nih.gov/pubmed/10547469. Accessed May 14, 2020..*
3. *Garner L. The Safety and Efficacy of the United Allergy Services Immunotherapy protocol. Poster Presentation ACAAI annual conference. Dec 2013.*

X. POLICY HISTORY

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MP 2.001	**CAC 2/25/03**
	CAC 12/2/03
	CAC 10/26/04
	CAC 10/25/05
	CAC 9/26/06
	CAC 7/31/07
	CAC 5/27/08
	CAC 11/25/08
	CAC 9/29/09 Serial endpoint testing now considered medically necessary for the determination of a safe starting dose for testing or immunotherapy for specific indications.
	CAC 3/30/10 Mediator Release Testing (MRT) and LEAP (Lifestyle Eating and Performance) program were added as investigational indications.
	CAC 4/26/11 Medicare Variation added
	CAC 10/25/11 Consensus Review
	2013 Codes added-12/20/2013
	CAC 6/4/13 Consensus review. References updated. No changes to the policy statements. FEP variation added to refer to FEP medical policy manual for serial endpoint testing. Codes reviewed 12/13/12
	8/1/14 Administrative update. Added reference to NCD 110.12 Challenge Ingestion Food Testing for the Medicare variation.
	CAC 5/20/14 Minor review.

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	• Added investigational statement related to home immunotherapy and related services. • Rationale added for the testing and immunotherapy that is listed as investigational. • Deleted section on Rebuck skin window test. • Deleted section on Autogenous urine immunization (urine auto injections) • Deleted section on Repository emulsion therapy. Coding reviewed.
	CAC 7/22/14 Minor revision. Sublingual immunotherapy is being removed from this policy and will now be addressed in MP-2.184 "Sublingual Immunotherapy as a Technique of Allergen Specific Therapy."
	CAC 7/21/15 Consensus review. No changes to the policy statements. References updated. Medicare variation updated to reflect two new LCDs L35771 Allergy Testing and L35759 Allergen Immunotherapy effective 8/13/15**.** Codes reviewed. Deleted reference to LCD L30524 Rast Type Testing – LCD retired effective 8/12/15.
	11/2/15 Administrative update. LCD number changed from L35759 and L35771 to L36240 and L36241 due to Novitas update to ICD-10. LCD L34855 Rast Type Tests added to the policy.
	CAC 9/27/16 Consensus review. No changes to the policy statements. References updated. Variations reformatted. Coding updated. New diagnosis code Z51.6 added effective 10/1/16
	1/1/18 Administrative update. Added new code 86008; effective 1/1/18. Medicare information removed.
	1/17/18 Administrative update. Coding corrections to errors in ICD-10 diagnosis codes
	CAC 1/30/2018 Minor revision. Benefit limits for skin endpoint titration testing, percutaneous and intracutaneous testing added to the policy. The Antigen Leukocyte Antibody Test (ALCAT) was added as an example of another, but not limited to test considered investigational. Criteria for the maintenance phase of immunotherapy was added to the policy. Rationale and references updated. A product variation was added for CHIP-Capital Cares for Kids. Coding reviewed.
	8/1/18 Administrative update. Benefit limit information removed.
	1/18/19 Consensus review. No change to the policy statements. References reviewed.
	6/3/19 Major review. Limits for percutaneous, intracutaneous, and end point allergy tests added. Added Complement Antigen Testing and Food Immune Complex Assays (FICA) as investigational. Rationale and references updated. Coding updated.
	4/1/20 Administrative update. Coding updated. Added new code 0165U.

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	5/14/20 Consensus Review. Policy Statement unchanged. Coding reviewed with no changes. References reviewed and updated.
	5/29/20 Administrative update. New code 0178U added.
	8/11/20 Minor Review. Policy statement changed and criteria added for repeat testing.
	1/28/2021 Administrative update. Deleted code 95071 removed.

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