Allergy Tests of Uncertain Efficacy

Policy # 00350
Original Effective Date: 06/25/2013
Current Effective Date: 09/13/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the following allergy tests as the scientific evidence does not permit conclusions regarding their effects on health outcomes to be **investigational:***

1. Antigen leukocyte cellular antibody (ALCAT) automated food test
2. Applied kinesiology allergy test
3. Conjunctival challenge test (ophthalmic mucous membrane test)
4. Cytotoxic food tests
5. Electrodermal testing (also known as electro-acupuncture)
6. Hair analysis
7. IgA food panel tests
8. IgG/IgG4 allergen specific antibody test and food tests
9. Iridology
10. Lifestyle Eating and Performing-Mediator Release Test (LEAP-MRT®‡)
11. Leukocyte histamine release test (LHRT)
12. Nasal challenge test
13. Passive transfer or P-X (Prausnitz-Küstner) test (now considered obsolete-and replaced by Radioallergosorbent tests)
14. Provocation-neutralization food or food additive allergy test
15. Rebuck skin window test (no longer in use)

Background/Overview

Allergy refers to an acquired potential for developing adverse reactions that are mediated by the immune system (via immunoglobulin E [IgE] antibodies). Allergic disease represents the clinical manifestations of these adverse immune responses. An allergen is any substance that can cause an

allergic reaction. Allergens are often common, usually harmless substances such as pollens, mold spores, animal danders, dust, foods, insect venoms, latex, and drugs.

The optimum management of the allergic patient should include a careful history and physical examination and may include confirming the cause of the allergic reaction by information from allergy tests. The following allergy tests are considered clinically useful for allergy confirmation by the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) in the diagnosis and management of the allergic patient

- Bronchial challenge test
- Double-blind food challenge test
- Intradermal skin testing
- Patch test
- Percutaneous skin tests such as the scratch, prick, or puncture tests
- Photo patch test
- Specific IgE in vitro tests such as Radioallergosorbent Test (RAST), Multiple Radioallergosorbent Tests (MAST), Fluorescent Allergosorbent Test (FAST), Enzyme-linked Immunosorbent Assay (ELISA), and the ImmunoCAP IgE test
- Total serum IgE concentration

Once an allergy-causing agent is identified, treatment is provided by avoidance, medication, or immunotherapy.

ALLERGY TESTS OF UNCERTAIN EFFICACY

This policy addresses only allergy tests of uncertain efficacy and those used primarily in research settings. Tests which may be considered useful in the clinical setting, as noted above, are not addressed in this policy.

Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Test

The ALCAT automated food test measures whole blood leukocytes by a proprietary process that identifies allergens which cause an increase in leukocyte activity. An electronic counter measures the change in number and size of white blood cells which have been incubated with purified food or mold extracts. A histogram is produced based on cell count and cell size. Individually processed test

samples are compared with a "Master Control" graph. Scores are generated by relating these effective volumetric changes in white blood cells to the control curve.

Applied Kinesiology (or Muscle Strength Test)
Muscle strength in the extremities is measured before and after a person is exposed to an allergen. Strength in the opposing arm is measured as a person holds a container of allergen extract in the opposite hand or ingests an allergen. A decrease in strength is used to indicate the presence of disease and various nutritional supplements may be recommended.

Cytotoxic Food Tests
This test involves the response of collected white blood cells to the presence of food extracts to which the patient may be allergic. A technician observes the unstained cells for changes in shape and appearance of the leukocytes. Swelling, vacuolation, crenation, or other cytotoxic changes in cell morphology are taken as evidence of allergy to the food.

Electrodermal Testing (Also Known as Electro-acupuncture)
Electrodermal testing measures changes in skin resistance while a person is exposed to an allergen, either food or inhalant. This allergy-testing device uses a galvanometer to measure the electrical resistance of the skin. A drop in the resistance of the skin is believed to indicate the presence of allergy.

Hair Analysis
Hair is analyzed for the presence (or lack) of various minerals and toxins. Findings are correlated to nutritional deficiencies or disease. Recommendations for diet and supplements are provided based on the analysis.

IgG/IgG4 Antibody Test and Food Specific IgG/IgG4 Tests
There are four subclasses of immunoglobulin G (IgG). Selective deficiencies in one or more of the four IgG subclasses are seen in some patients with repeated infections. Measurements of IgG and specifically IgG4 antibodies have been used in research settings as diagnostic and prognostic tests to determine response to allergy treatments.

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Iridology
According to the AAAAI, iridology attempts to relate the anatomical features in the iris to various systemic diseases.

LEAP-MRT®‡
This procedure involves two test components. The first component, Lifestyle Eating and Performing (LEAP®)‡, tests patients for multiple food and additive/chemical allergies. The patient is tested and then given a tailored eating plan. In the second component, the Mediator Release Test (MRT®)‡ measures non-IgE mediated immune pathways using a blood test.

Provocative-neutralization Tests for Food (or Food Additive Allergy Test)
This procedure is performed by injecting (intradermal or subcutaneous), or placing under the tongue (sublingual), dilute extracts of the suspected food or inhalant allergen and observing the patient's response or reaction. A symptomatic response indicates an allergy to that food or inhalant, and the reaction can be neutralized by application of a similar extract of a lesser dilution.

ALLERGY TESTS IN THE RESEARCH SETTING
The following tests are primarily used in the research setting:

Conjunctival Challenge Test
With conjunctival testing, an allergenic extract is placed into the conjunctival sac of the eye followed by observation for redness, itchiness, tearing of the eye, and other similar symptoms. According to the AAAAI, these tests are often used in research protocols that require an objective standard for evaluating clinical sensitivity to an allergen.

Leukocyte Histamine Release Test (LHRT)
In this testing, leukocytes from the serum of an allergic individual are observed for histamine release in the presence of an antigen. The commercial availability of simplified and automated methods of laboratory analysis have renewed interest in the clinical applications of LHRT in the evaluation of food, inhalant, and drug allergies. The AAAAI guidelines for this test indicate it is primarily used in a research setting.

Nasal Challenge Test
This test provides precise measurements of changes in nasal airway resistance along with observations such as number of sneezes and measurement of inflammatory mediators in the nasal secretions after exposure to an allergen. The more commonly known "sniff test," uses a visual assessment of mucosal swelling and rhinorrhea after a small amount of dry pollen is inhaled.

IgA Food Panel Tests
Immunoglobulin A (IgA) is secreted by mucous membranes. Testing for a specific type of IgA, called tissue transglutaminase antibodies, can be useful in diagnosing celiac disease. Measurement of IgA antibodies have been used in research settings as diagnostic tests for various food allergies and prognostic tests to determine response to allergy treatments for other food types.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. ALCAT is available under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. FDA has chosen not to require any regulatory review of this test.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines

Supplemental Information

Practice Guidelines and Position Statements
No clinical practice guidelines were identified on the diagnosis and management of food intolerance.

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The National Institute of Allergy and Infectious Disease (2010) published guidelines on the diagnosis and management of food allergy. These guidelines defined and distinguished food intolerance from food allergy but did not provide recommendations for diagnosis and management of intolerance. For the diagnosis of food allergy, the guidelines stated that "tests selected to evaluate food allergy should be based on the patient's medical history and not comprise large general panels of food allergens."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in August 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Regence Medical Policy Manual Laboratory Policy No. 1, Allergy and Sensitivity Tests of Uncertain Efficacy, Effective 09:2020.
2. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Antigen Leukocyte Antibody Test ", 2.01.93, 11:2020.

Policy History

Original Effective Date: 06/25/2013
Current Effective Date: 09/13/2021
06/06/2013 Medical Policy Committee review
06/25/2013 Medical Policy Implementation Committee approval. New policy.
06/05/2014 Medical Policy Committee review
06/18/2014 Medical Policy Implementation Committee approval. No change to coverage.
06/04/2015 Medical Policy Committee review

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06/17/2015	Medical Policy Implementation Committee approval. Added LEAP-MRT to the policy.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. No change to coverage.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. IgA food panel tests added as investigational.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 08/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	86353
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.