



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 12/06/22
LAST REVIEW DATE: 12/06/22
CURRENT EFFECTIVE DATE: 12/06/22
LAST CRITERIA REVISION DATE: 12/06/22
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2023

ALLERGY TESTING AND TREATMENT

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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ALLERGY TESTING AND TREATMENT (cont.)

Description:

Allergy or hypersensitivity disorders may be manifested by localized or systemic reactions. Reactions may be acute, subacute or chronic, immediate or delayed, and caused by numerous allergens, including venomous stinging insects (insects from the Hymenoptera family), foods, drugs, fur, inhalant allergens present in the environment (i.e., cockroaches, dust mites, grasses, mold spores, animal dander, trees and weeds). The offending allergen can be diagnosed/identified by history, physical exam and various types of allergy testing.

Treatment is provided by immunotherapy, medication or avoidance. The goal of immunotherapy is to reduce symptoms by administering regular injections of the offending allergen. Therapy begins with low doses once or twice a week. The dose gradually increases as immunity develops. After the maintenance dose is achieved, the interval between injections may range between 2 – 6 weeks. Immunotherapy can continue for several years.

Allergy Tests:

Antigen Leukocyte Antibody Test (ALCAT):

The Antigen Leukocyte Antibody Test (ALCAT) is intended to diagnose intolerance to foods and other environmental agents for which an individual may have intolerance. It is not intended to diagnose food allergy. 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.

Bronchial Challenge Test:

Use of histamine or methacholine to diagnose hyper-responsive airways. Volatile chemicals are used when symptoms are encountered in an occupational setting.

Challenge/Provocative Test:

Extract of the suspected allergen is applied directly to the conjunctiva or nasal mucosa. Degree of response is subjectively determined. Also known as Conjunctival or Nasal Challenge Test.

Cytotoxicity Test:

Extract of the suspected food allergen is added to specially collected white blood cells. If the cells react, an allergic response is said to have occurred. Also known as Bryan's Test, Leukocytotoxicity Test, Cytotoxic Leukocyte Test.

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ALLERGY TESTING AND TREATMENT (cont.)

Description: (cont.)

Allergy Tests: (cont.)

Direct Skin Test:

Extract of the suspected allergen is injected intracutaneously or applied percutaneously to a superficial scratch, prick or puncture on the skin of the arm or back. Can show immediate hypersensitivity. Number of tests required may vary. Rarely are more than 20 intracutaneous or 40 percutaneous tests needed.

Double Blind Food Challenge Test:

Individual is blinded and eats the food to which sensitivity is suspected (disguised within other food or beverage products or in a capsule form). This test is commonly done in the home setting. In some instances of extreme suspected hypersensitivity, it may be performed in the office setting.

E-95 Basic Food Panel:

Enzyme-linked immunosorbent assay technique (ELISA) to measure serum IgG4 and IGE antibodies for food allergy testing. IgG4 is a subclass of IgG. Serum is added to a 96-well plate containing different food antigens and then evaluated for classic antigen/antibody interactions. Accurate testing requires the individual to eat a wide range of foods within 3 weeks of assessment for IgG exposure to be present. The test provides a report of whether the levels of antibody to the various foods suggest that each one is "safe" to eat, best to eat in moderation, or to avoid entirely.

A-95 Extended Food Panel:

The A-95 panel is an extended food allergy test panel and consists of 95 additional foods to the E95 test (combined IgG4 and IgE levels are measured). IgG4 is a subclass of IgG.

IgE Concentration Test (Total Serum):

Detects total quantitative IgE antibodies in the serum.

IgE In Vitro Test (Specific):

Detects allergen-specific IgE antibodies in the serum. Includes the following:

- Enzyme-linked Immunosorbent Assay (ELISA)
- Fluorescent Allergosorbent Test (FAST)
- Multiple Radioallergosorbent Test (MAST)
- Radioallergosorbent Test (RAST)

IgG In Vitro Test (Specific):

Detects allergen-specific IgG antibodies in the serum.

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ALLERGY TESTING AND TREATMENT (cont.)

Description: (cont.)

Allergy Tests: (cont.)

Mediator Release Test:

Measures the aggregate release of inflammatory mediators in the blood after exposure to specific foods and food additives to help design individual-specific oligoantigenic diet. The Lifestyle Eating and Performance Programs (LEAP®) use the Mediator Release test as part of their evaluation of migraine headaches and irritable bowel syndrome (IBS).

Patch Test:

Extract of the suspected allergen is applied to the skin of the back and covered with a dressing for 48 hours. Area is then examined for a delayed reaction. Used to determine the offending allergen that is causing contact dermatitis (not mediated through IgE). Also known as Application Test.

Photo Patch Test:

Extract of the suspected allergen is applied to a patch of skin for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on surrounding skin.

Provocative and Neutralization Test:

Also known as Food and Chemical Allergy Test/Therapy. Used to diagnose (provoke) and treat (neutralize) food and food additive allergens.

Diagnose: Diluted extracts of the suspected food allergen are administered intradermally, subcutaneously or sublingually to “provoke” the allergy symptoms to appear.

Treatment: Immediately after symptoms appear, weaker or stronger dilutions are administered until the “provoked” symptoms subside. The dose at which the symptoms subside is considered the “neutralizing dose” that will be used in future treatment of the food allergy.

Rebuck Skin Window Test:

Extract of the suspected allergen is applied directly to skin that has been abraded. Lab cover slips are placed over the area for 24 hours and then analyzed for a reaction.

Sage ELISA Test:

The SAGE Systems' Food Allergy Test uses an Enzyme Linked Immunosorbant Assay (ELISA) to measure the presence of both IgG and immune complexes against a wide variety of food, food additive and dye antigens in serum in an attempt to identify food allergies or food related chronic illnesses.

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ALLERGY TESTING AND TREATMENT (cont.)

Description: (cont.)

Allergy Treatment - Immunotherapy:

Intravenous Nutrient Therapy and Intravenous Vitamin Therapy:
Nutrient and vitamin solutions administered intravenously.

Repository Emulsion Therapy:
Certain materials are placed inside the body to improve allergies.

Rhinophototherapy:
Intranasal application of ultraviolet and visible light to the nasal cavities investigated for allergic rhinitis as an immunosuppressive to inhibit hypersensitivity reactions.

Subcutaneous Immunotherapy:
Offending allergen is administered through the skin.

Urine Auto-injection:
Also known as Autogenous Urine Immunization. Substance from an individual's own urine is injected into the skin.

Criteria:

Antigen Leukocyte Antibody Test (ALCAT):

- ALCAT test is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

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ALLERGY TESTING AND TREATMENT (cont.)

Criteria: (cont.)

Bronchial Challenge Test:

- Bronchial Challenge Test to diagnose/identify hyper-responsive airways is considered **medically necessary**.
- Bronchial Challenge Test is considered **not medically necessary** if dust, ragweed, or other common allergens are the suspected cause. (Direct skin test can be used.)

IgE Concentration Test (Total Serum):

- IgE Concentration Test is considered **medically necessary**.

IgE In Vitro Test (Specific):

- IgE In Vitro Test (i.e., inhalant allergens) is considered **medically necessary**.
- IgE as a component of a food panel (which can include the subclass IgG4), to diagnose/identify an offending food allergen is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

These tests include, *but are not limited to:*

- E95 Basic Food Panel (test includes IgE and IgG4)
- A95 Basic Food Panel (test includes IgE and IgG4)

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ALLERGY TESTING AND TREATMENT (cont.)

Criteria: (cont.)

IgG In Vitro Test (Specific):

- IgG In Vitro Test to diagnose/identify the offending IgG antibody titer of a stinging insect (a member of the Hymenoptera family) when performed on an individual who has been on stinging insect immunotherapy for an extended period of time is considered **medically necessary**.
- IgG as a specific In Vitro Test and/or IgG as a component of a food panel (which is the subclass IgG4), to diagnose/identify an offending food allergen is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

These tests include, *but are not limited to:*

- E95 Basic Food Panel (test includes IgE and IgG4)
- A95 Extended Food Panel (test includes IgE and IgG4)
- Immuno 1 Bloodprint™
- Allergy Smarts Food Intolerance Test
- FoodScan IgG ELISA Food Intolerance Test

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ALLERGY TESTING AND TREATMENT (cont.)

Criteria: (cont.)

IgG In Vitro Test (Specific): (cont.)

- IgG In Vitro Test for all other indications not previously listed is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

These tests include, *but are not limited to*:

- Stachybotrys chartarum (black mold) exposure

Other Allergy Tests:

- The following allergy tests to diagnose/identify an offending allergen are considered **medically necessary**:
 1. Direct Skin Test
 2. Double Blind Food Challenge Test
 3. Patch Test
 4. Photo Patch Test
- The following allergy tests to diagnose/identify an offending allergen are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
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ALLERGY TESTING AND TREATMENT (cont.)

Criteria: (cont.)

Other Allergy Tests: (cont.)

These tests include, *but are not limited to*:

- Challenge/Provocative Test (Conjunctival Challenge Test, Nasal Challenge Test)
- Cytotoxicity Test (Bryan's Test, Leukocytotoxicity Test, Cytotoxic Leukocyte Test)
- Mediator Release Test for oligoantigenic food sensitivity (includes testing/treatment for irritable bowel syndrome and/or migraine headaches as part of the LEAP® program)
- Provocative and Neutralization Test (includes treatment of the offending food allergen)
- Rebuck Skin Window Test
- Sage ELISA Test, for delayed food allergy/sensitivity

Allergy Treatment – Immunotherapy:

- Subcutaneous immunotherapy is considered **medically necessary** when administered by a professional for inhalant or insect venom allergens with demonstrated hypersensitivity and inability to be managed by avoidance or medication with the limit of 150 units maximum allowed for any rolling twelve (12) month period.
- The following treatments/immunotherapy are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

These treatments/immunotherapy include, *but are not limited to*:

- Intravenous Nutrient Therapy and Intravenous Vitamin Therapy
- Repository Emulsion Therapy
- Urine Auto-injection

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ALLERGY TESTING AND TREATMENT (cont.)

Criteria: (cont.)

Allergy Treatment – Immunotherapy: (cont.)

- Rhinotherapy is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 12/06/22. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 12/06/22 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Ahlbeck L, Ahlberg E, Björkander J, et al. Intralymphatic immunotherapy with one or two allergens renders similar clinical response in patients with allergic rhinitis due to birch and grass pollen. *Clin Exp Allergy*. Jun 2022;52(6):747-759. doi:10.1111/cea.14138
2. Alcat Test. Cell Sciences Systems. n.d. Accessed Accessed September 20, 2022, <https://cellsciencesystems.com/patients/alcat-test/>
3. Andrae DA, M.D, PhD, Shreffler WG, MD, PhD. Future diagnostic tools for food allergy. In: Sicherer SH, MD, FAAAAI, TePas E, MD, MS, ed. *UpToDate*. UpToDate; 2022. Accessed November 8, 2022. <https://www.uptodate.com/contents/future-diagnostic-tools-for-food-allergy>
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*. Dec 2010;126(6 Suppl):S1-58. doi:10.1016/j.jaci.2010.10.007
5. Buczylo 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):452-6.

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ALLERGY TESTING AND TREATMENT (cont.)

Resources: (cont.)

6. Burks W M. Diagnostic evaluation of IgE-mediated food allergy. *UpToDate*. UpToDate; 2021. Accessed November 8, 2022. <https://www.uptodate.com/contents/diagnostic-evaluation-of-ige-mediated-food-allergy>
7. Calderon MA, Casale TB, Nelson HS, et al. Extrapolating Evidence Based Medicine of AIT into Clinical Practice in the US. *J Allergy Clin Immunol Pract*. Nov 4 2022;doi:10.1016/j.jaip.2022.10.033
8. Commins SP, MD, PhD. Food intolerance and food allergy in adults: An overview. In: Sicherer SH, MD, FAAAAI; Feldweg AM, MD, ed. *UpToDate*. UpToDate; 2022. Accessed November 8, 2022. <https://www.uptodate.com/contents/food-intolerance-and-food-allergy-in-adults-an-overview>
9. Gupta RS, Dyer AA, Jain N, Greenhawt MJ. Childhood food allergies: current diagnosis, treatment, and management strategies. *Mayo Clin Proc*. May 2013;88(5):512-26. doi:10.1016/j.mayocp.2013.03.005
10. Kaats GP, D; 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.
11. Kelso JM, MD. Unproven and disproven tests for food allergy. In: Sicherer SH, MD, FAAAAI, TePas E, MD, MS, ed. *UpToDate*. UpToDate; 2022. Accessed November 8, 2022. <https://www.uptodate.com/contents/unproven-and-disproven-tests-for-food-allergy>
12. Kowal K, MD, PhD, DuBuske L, MD. Overview of in vitro allergy testing. In: Bruce S Bochner M, Anna M Feldweg, MD, ed. *UpToDate*. UpToDate; 2021. Accessed November 8, 2022. <https://www.uptodate.com/contents/overview-of-in-vitro-allergy-tests>
13. Krzych-Fałta E. The conjunctival allergen provocation test and the nasal allergen provocation test as specific alternatives to the oral food challenge. *Postepy Dermatol Alergol*. Apr 2022;39(2):245-250. doi:10.5114/ada.2021.105362
14. Mårtensson A, Nordström FU, Cervin-Hoberg C, et al. Nasal administration of a probiotic assemblage in allergic rhinitis: A randomised placebo-controlled crossover trial. *Clin Exp Allergy*. Jun 2022;52(6):774-783. doi:10.1111/cea.14098
15. Mylek 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):625-9.
16. Solomon B. The ALCAT Test - A guide and barometer in the therapy of environmental and food sensitivities.



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Coding:

CPT: 82785, 83516, 83518, 83519, 83520, 86001, 86003, 86008, 86160, 86486, 86807, 86808, 86828, 86830, 86831, 86832, 86833, 86834, 86835, 95004, 95024, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95076, 95079, 95115, 95117, 95120, 95125, 95130, 95131, 95132, 95133, 95134, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, 95180, 95199

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	12/06/22	Approved guideline
Medical Director (Dr. Deering)	11/10/22	Review with revisions
Pediatric Advisory Subcommittee	08/18/22	Review with no revisions

Policy Revisions:



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ALLERGY TESTING AND TREATMENT (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínígíí Blue Cross Blue Shield of Arizona haada yit'éego bína'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idíílkidgo beehaz'ánii hólg díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo baq̄h ílínígóó. Ata' halne'ígíí kojį' bich'į' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

