

Corporate Medical Policy

Allergy Testing

File Name:	allergy_testing
Origination:	7/1979
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	11/2011

Description of Procedure or Service

Management of the allergic patient may include identifying the offending agent by means of allergy testing. Allergy testing can be broadly grouped into in vivo and in vitro methodologies:

- In vivo testing - includes allergy skin testing such as the scratch, puncture or prick test (epicutaneous), intradermal test (intracutaneous) and patch test.
- In vitro testing - includes various techniques to test the blood for the presence of specific IgE antibodies to a particular antigen.

Once the agent is identified, treatment is provided by avoidance, medication or immunotherapy (allergy shots).

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as by localized reactions in any organ system of the body. The reactions may be acute, subacute, or chronic, immediate or delayed, and may be caused by numerous offending agents: pollen, molds, dust mites, animal dander, stinging insect venoms, foods, drugs, etc.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Allergy Testing when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Allergy Testing is covered

The following allergy testing modalities are considered eligible for coverage **when medically necessary**, and ordered by a physician:

1. **Direct Skin Testing** (for immediate hypersensitivity)

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- a. Percutaneous or epicutaneous (scratch, prick, or puncture) - The number of tests required may vary widely depending on the patient's age and the degree of hypersensitivity.
 - b. Intradermal testing is considered to be a more sensitive, but less specific, testing method than percutaneous testing for the detection of IgE antibodies. The number of intradermal tests may also vary from patient to patient.
 - c. The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture tests are negative. Under special circumstances and in certain geographic areas, a greater number of prick/puncture and/or intradermal tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required.
2. **Patch Testing** (also called application testing) is indicated for evaluation of possible allergic contact dermatitis. A limited series of patch tests may be an appropriate initial step. Standard panels of allergens for patch testing are available from various commercial sources, the most commonly used being the T.R.U.E. TEST® by Allerderm. Each T.R.U.E. TEST® patch test unit includes 28 common allergens and a negative control. In addition to the standard series of 29 patch tests, six (6) additional allergens targeted at the patient's most likely exposures may be performed initially. More comprehensive patch testing (greater than 35 patch tests) may be considered medically necessary when both a.) and b.) are met:
- a. The patient has persistent allergic contact dermatitis (ACD) after being previously evaluated and treated (including 6 weeks of avoidance of any allergens that were positive on initial patch testing, and use of topical steroid products if appropriate); **AND**
 - b. The dermatitis interferes with the patient's normal activities of daily living, such as occupational or work activities (use of hands), sleep patterns (due to itching), bathing or social interactions.
3. **Photo-patch test:** This test reflects contact photosensitization. A photosensitivity (sensitivity to sunlight) reaction may be suspected when a rash appears only in areas exposed to sunlight. The reaction may be caused by various drugs, substances applied to the skin (drugs or cosmetics), chemicals, etc. Photo-patch testing involves applying two identical sets of allergens to the back on day one. One of the sets is exposed to UVA light, and the sites are then examined as usual. A positive photo-patch test is recorded when an allergic reaction appears only on the light-exposed site.
4. **Specific IgE In Vitro Testing:** Radioallergosorbent Test (RAST), Multiple Radioallergosorbent Tests (MAST), Fluorescent Allergosorbent Test (FAST), Enzyme-linked Immunosorbent Assay (ELISA) and ImmunoCAP. These tests detect specific IgE antibodies in the patient's blood serum.
- a. Specific IgE in vitro tests for inhalant allergens (pollens, molds, dust, mites, animal danders) and foods are considered eligible for coverage when medically necessary because the following criteria are met:
 - i. Direct skin testing is impossible due to an extensive dermatitis or marked dermagraphism;
 - ii. Direct skin testing is impossible such as in young children less than four years of age; or
 - iii. Direct skin testing results are not consistent with a history of anaphylactic or other severe reaction to an allergen and further treatment decisions would be impacted by confirmation of sensitivity;

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- iv. Inability to discontinue medication (e.g., antihistamines) that impair skin test sensitivity.
- b. Specific IgE in vitro tests for insect sting and other allergens (for example, drugs) are considered eligible for coverage under the following circumstances:
 - i. Direct skin testing is impossible due to an extensive dermatitis or marked dermographism;
 - ii. Direct skin testing is impossible such as in young children less than four years of age; or
 - iii. Direct skin testing results are not consistent with a history of anaphylactic or other severe reaction to an allergen and further treatment decisions would be impacted by confirmation of sensitivity;
 - iv. Inability to discontinue medication (e.g., antihistamines) that impair skin test sensitivity.

*Specific IgE in vitro testing is considered medically necessary only after physician determination that one of the aforementioned conditions precludes the use of direct skin testing. Specific IgE in vitro tests should be used judiciously and include testing only for those allergens that could be reasonably suspected regardless of test kit packaging. Initial diagnostic screening is limited to 36 allergen specific antibodies. Additional testing beyond this number will require individual review for medical necessity.

- 5. **Total Serum IgE Concentration** - This testing modality is not indicated in all allergic patients, but should be reserved for those patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease (for example, Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma or pemphigoid or for consideration of Xolair administration in patients with moderate to severe asthma.
- 6. **Bronchial Challenge Testing** - This procedure is performed with aeroallergens or other chemical substances such as histamine, methacholine, and volatile chemicals encountered at home, school, or work. Such testing is generally reserved for the difficult asthmatic patient in whom routine skin testing is not sufficient to isolate the factors responsible for the asthma.
- 7. **Double-blind Food Challenge Testing** - The patient is required to eat the food to which sensitivity is suspected. The food is randomized by a noninterested party (i.e., dietitian) so that neither the patient nor physician are aware of the specific food (blinded). The food may be lyophilized (freeze dried) and blended in liquid or placed in a capsule.
- 8. **Serial Dilution Endpoint Titration (SDET)** - Also known as skin endpoint titration (SET), intradermal dilutional testing (IDT), 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 to 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. Use of SET is considered advantageous in specific situations, i.e., when there is a high likelihood for a severe allergic reaction to specific agents such as antibiotics or other high-risk allergens.

When Allergy Testing is not covered

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Allergy testing is not covered when the medical criteria and guidelines shown above are not met.

Allergy testing is not covered when it is considered investigational. The following allergy tests are considered **investigational**.

Test	Description	Rationale
Nasal Challenge Test (Also called nasal mucous membrane test; nasal challenge/provocation test)	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 to the allergen is recorded.	This test is used in studies of allergic rhinitis, but its utility in clinical practice has not been established. The role of nasal challenge testing in the diagnosis and management of allergic diseases has not been established.
Leukocyte Histamine Release Test (LHRT)	Measures the amount of histamine released from the white blood cells in response to exposure to an allergen.	The published literature is not sufficient to permit conclusions on the diagnostic accuracy of LHRT.
Rebuck Skin Window Test	A test of the inflammatory process in which the skin is abraded and a cover slip is applied to the abraded area. The cover slips are removed and replaced at intervals and examined for the presence of cells involved in the immune response.	This test is not useful in documenting allergies since other immunodeficiencies can be found in patients with allergic conditions.
Passive Transfer of P-X (Prausnitz-Kustner Test)	Performed by injecting serum intradermally from a suspect allergic patient into a non-allergic patient and later challenging the injection site with antigens.	Danger of transferring infections. Considered obsolete. (It has been replaced by RAST.)
Cytotoxic Food Testing (Leukocytotoxic Test)	This test involves the response of specially collected white blood cells to the presence of food extracts to which the patient is allergic.	There is no proof that this is effective for foods or pollens. AAAAI*, NCHCT**
Provocation Neutralization Testing (sometimes referred to as the Rinkel Test)	This is a procedure that evolved from serial endpoint titration and has been proposed as a test for allergies to foods, inhalants and environmental chemicals. Patients are exposed to test doses of substances intradermally, subcutaneously or sublingually, with the goal of either producing or preventing symptoms.	It is an unproven test. AAAAI*, NCHCT**
Serum IgG levels, as part of allergy evaluation	This is a blood test for certain antibodies.	Considered to be investigational due to incomplete and conflicting

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		data. AAAAI*
Conjunctival Challenge Testing (ophthalmic mucous membrane test)	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.	This test is qualitative, and not objectively interpreted.
Mediator Release Test (MRT)	The MRT has primarily been used to detect intolerance to foods and additives in patients with irritable bowel syndrome (IBS). It has also been promoted for use in patients with, but not limited to: chronic fatigue syndrome, migraine headaches, rheumatologic disorders, and dermatologic conditions. The results of the MRT have been used to design a patient-specific diet.	There are no studies of MRT reported in peer-reviewed published medical literature that demonstrate improvements in clinical outcomes by incorporating the MRT and associated dietary modifications into the clinical management of patients with these conditions.
In Vitro Metal Allergy Testing	In vitro metal allergy tests, known as lymphocyte transformation tests (LTT) are commercially available. These have been used to test for allergies to metals in jewelry and dental implants and could potentially be used to test individuals who have or are considering metal orthopedic implants.	There is insufficient evidence that in vitro metal allergy testing improves patient management decisions or health outcomes for total joint replacement patients. No national organizations have issued recommendations regarding in vitro metal allergy testing and orthopedic implants.
Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Allergy Testing	Antigen leukocyte cellular antibody testing (ALCAT) is an automated method of testing for food allergies that is purported to identify food sensitivity by using a modified Coulter counter linked to a computer program to measure the change in white blood cells incubated with purified food and mold extract.	There is insufficient evidence in the published peer-reviewed scientific literature to support the use of this testing in the diagnosis or management of allergic disease.

*AAAAI = American Academy of Allergy, Asthma, and Immunology

**NCHCT = National Center for Health Care Technology

Policy Guidelines

A thorough history should be taken before allergy tests are ordered. The medical record should document the medical necessity, based on the patient's history, for each allergy test ordered.

Requirements of intradermal testing for delayed hypersensitivity of the tuberculin type should not usually exceed six to eight tests.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 83516, 83518, 83519, 83520, 86001, 86003, 86005, 86343, 86353, 95004, 95010, 95015, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95071, 95075

The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture and/or intradermal tests are negative. Specific IgE in vitro initial diagnostic screen is limited to 36 allergen specific antibodies. Additional testing beyond this number will require individual review for medical necessity. Greater than 35 patch tests will be reviewed by individual consideration. Documentation of medical necessity for over 35 tests will be necessary.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

Plan Consultant - 12/96 (Rush Immunotherapy)

Medical Policy Advisory Group Review - 3/99

Specialty Matched Consultant Advisory Panel - 7/2000

Specialty Matched Consultant Advisory Panel - 8/00

Medical Policy Advisory Group Review - 10/00

Specialty Matched Consultant Advisory Panel - 1/2001

BCBSA Medical Policy Reference Manual - Policy 2.01.23 - 5/12/02

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual, Policy 2.01.23; 4/29/03

Specialty Matched Consultant Advisory Panel - 7/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.23, 6/27/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.42, 6/27/05.

Specialty Matched Consultant Advisory Panel - 7/2006

Joint Council of Allergy, Asthma and Immunology. Practice Parameters for Allergy Diagnostic

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Testing Ann Allergy 1995; 75:543-625. Retrieved on December 7, 2006 from http://www.jcaai.org/pp/adt_toc.asp

Specialty Matched Consultant review 1/14/08

Giuseppe Militello; Denise K. Woo; Jonathan Kantor; Christine L. Egan; Stephen A. Solotoff; Elizabeth M. Spiers; et. al. (October 2006) The Utility of the TRUE Test in a Private Practice Setting. *Dermatitis*. 2006;17(2):77-84. Retrieved on January 22, 2008 from <http://www.medscape.com/viewarticle/546030>

BCBSNC Internal Medical Directors' review 1/30/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.23, 10/10/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.42, 12/12/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.23, 6/10/10

Bernstein IL, Li JT, Bernstein DI et al. American Academy of Allergy, Asthma and Immunology and American College of Allergy, Asthma and Immunology. Allergy diagnostic testing: an updated practice parameter. Part 1. *Ann Allergy Asthma Immunol* 2008; 100 (Suppl 3): S15-S66. Retrieved October, 27, 2011 from http://www.guideline.gov/summary/summary.aspx?view_id=1&doc_id=13114

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Thyssen JP, Menne T, Schalock PC et al. Pragmatic approach to the clinical work-up of patients with putative allergic disease to metallic orthopedic implants before and after surgery. *Br J Dermatol* 2011; 164(3):473-8.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.23, 6/9/11

Specialty Matched Consultant Advisory Panel review 11/2011

Policy Implementation/Update Information

7/79 Original Policy

5/81 Reaffirmed

6/83 Reaffirmed

6/84 Reaffirmed

7/87 Evaluated: Investigational for provocative testing for food allergies. Eligible for coverage for serial dilution endpoint titration (Rinkel).

5/90 Evaluated: Eligible for coverage for specific IgE in vitro tests (RAST, MAST, FAST, ELISA) for inhalant and food allergens. Eligible for coverage for insect stings and other allergens when direct skin testing is not possible.

8/90 Revised: Total serum IgE concentration indications

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- 1/93 Reviewed: PCP Physician Advisory Group (Local)
- 11/94 Reviewed: PCP Physician Advisory Group (Local)
- 11/95 Reviewed: PCP Physician Advisory Group (Local)
- 12/96 Revised: Added Rush Immunotherapy as investigational
- 3/99 Revised: Deleted the comment, "Rush" or "Cluster" immunotherapy. This type of immunotherapy is not considered medically necessary when compared with standard immunotherapy. This comment has been added to the Allergy Immunotherapy (95115.MED) policy and will be reviewed on an Individual Consideration basis.
- 5/99 Revised based on feedback from the MPAG. Nasal Challenge moved to investigational as it is obsolete. SDET or Rinkel is considered investigational.
- 8/99 Reformatted, Medical Term Definitions added.
- 7/00 Specialty Matched Consultant Advisory Panel. No changes to policy.
- 9/00 System coding changes.
- 10/00 Specialty Matched Consultant Advisory Panel. Criteria clarification of Specific IgE In Vitro Testing under When Allergy Testing is covered section. Four criteria applied to both inhalant allergens and insect sting and other allergens. Medical Policy Advisory Group review. Approved. No further changes to criteria.
- 02/01 Specialty Matched Consultant Advisory Panel review. Added additional information related to SDET or classic Rinkel method.
- 6/01 Serial Dilution Endpoint Titration is now listed as a covered service.
- 9/01 Codes 86001, 86003, and 86005 added to Billing/Coding section. Changed statement in Billing/Coding section to state, "Reimbursement for Specific IgE In Vitro Testing and Serial Dilution Endpoint Titration is based on the number of anitgens tested, not the number of dilutions/injections performed." System coding changes.
- 7/02 Specialty Matched Consultant Advisory Panel review. Under "When Allergy Testing is Covered" 3.a.ii. and 3.b.ii. revised to state "If direct skin testing is impossible such as in young children less than four years of age;". Under "When Allergy Testing is not Covered" added Serum IgG levels, as part of allergy evaluation
- 09/02 System coding changes.
- See Also: Allergy Immunotherapy.
- 10/02 System coding changes. Clarified excessive number of patch tests to be greater than 30.
- 1/03 Disclaimer added. Added "such as recalcitrant contact dermatitis" to clarify when more than 30 patch tests may be allowed on an IC basis.
- 10/03 Benefits Application and Billing/Coding sections revised.
- 11/03 Acronym for American Academy of Allergy, Asthma, and Immunology corrected from AAAI to AAAAI.

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10/14/04 Specialty Matched Consultant Advisory Panel review 7/23/04. Under "When Covered": 1.a added "Rarely are more than 40 percutaneous tests required in a three year period."; 1.b added "Rarely are more than 20 intracutaneous tests required in a three year period."; added photo-patch test and double-blind food challenge test; added "or for consideration of Xolair administration in patients with moderate to severe asthma." to #5. Under "When Not Covered", added Conjunctival Challenge Testing as investigational. Sources added. Notice given 10/14/04. Effective date 12/23/04.

5/7/07 Description section revised to explain in vivo and in vitro testing. Under "When Covered", #1.a. removed statement "Rarely are more than 40 percutaneous tests required in a three year period."; #1.b. removed statement "Rarely are more than 20 intracutaneous tests required in a three year period."; added 1.c. "The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture and/or intradermal tests are negative. Under special circumstances and in certain geographic areas, a greater number of prick/puncture and/or intradermal tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required."; #4. "Specific IgE In Vitro Testing: clarified that the testing should only be done when the listed criteria precludes the use of direct skin testing, that initial diagnostic screen is limited to 36 allergen specific antibodies, additional testing will require individual review; #8. Serial Dilution Endpoint Titration (SDET) now reads "Also known as skin endpoint titration (SET), intradermal dilutional testing (IDT), Serial endpoint titration. Allergy testing using this method is similar to conventional intradermal testing differing only in the number of dilutions of allergen administered. SDET is eligible as a variant of conventional intradermal skin testing." Under "When not Covered", additional information provided for: nasal challenge test, leukocyte histamine release test, Rebuck skin window test, passive transfer of P-X, and provocative testing. Under "Billing and Coding", revised to have same information as indicated in the "When Covered" section re: number of tests. Reference sources and Definitions added. (pmo)

6/18/07 Under "When Covered", 1.c. removed error- "...which are ordinarily performed when prick/puncture and/or intradermal tests are negative. Under "When not Covered", added Mediator Release Test (MRT) as investigational. "The MRT has primarily been used to detect intolerance to foods and additives in patients with irritable bowel syndrome (IBS). It has also been promoted for use in patients with, but not limited to: chronic fatigue syndrome, migraine headaches, rheumatologic disorders, and dermatologic conditions. The results of the MRT have been used to design a patient-specific diet." Reason it is investigational: "There are no studies of MRT reported in peer-reviewed published medical literature that demonstrate improvements in clinical outcomes by incorporating the MRT and associated dietary modifications into the clinical management of patients with these conditions." Reference source added. Notification given 6/18/07. Effective 8/27/07. (pmo)

8/27/07 Under "Billing/Coding section, added CPT codes 83516, 83518, 83519, 83520; removed deleted CPT code 95078. (pmo)

2/25/08 Under "When Covered" 2. Patch Testing-Additional information provided. Coverage for initial number of patch tests increased to 35 tests. Clarified indications for more comprehensive patch testing. Added CPT code 86343 to Billing/Coding section. Reference sources added. Under "Policy Implementation/Update Information", date 5/2/07, removed "added mediator release test as investigational" and "added CPT codes 83516, 83518, 83519, 83520". The mediator release test information was actually added to the policy and listed in the 6/18/07 implementation date. The CPT codes were actually added with the 8/27/07 update and are now listed with the 8/27/07 implementation date. (pmo)

8/25/08 References updated. Specialty Matched Consultant Advisory Panel review 7/14/08. No change to policy statement. (adn)

10/12/09 Description of Item 8 (Serial Dilution Endpoint Titration) in the When Allergy

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Testing is Covered section was reworded. Corrected typo regarding the number of Patch Testing (Item 2 in the When Allergy Testing is Covered section). Greater than 35 patch tests will be reviewed by individual consideration. Documentation of medical necessity for over 35 tests will be necessary. (adn)

6/22/10 Policy Number(s) removed. (amw)

12/21/10 Specialty Matched Consultant Advisory Panel review 11/2010. References updated. Added additional information regarding Serial Endpoint Titration. (mco)

12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. Added "ImmunoCAP" as a Specific IgE In Vitro Test. Added the following tests to the "When not Covered" table: "Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Allergy Testing. There is insufficient evidence in the published peer-reviewed scientific literature to support the use of this testing in the diagnosis or management of allergic disease." "In Vitro Metal Allergy Testing. There is insufficient evidence that in vitro metal allergy testing improves patient management decisions or health outcomes for total joint replacement patients. No national organizations have issued recommendations regarding in vitro metal allergy testing and orthopedic implants." References updated. Added CPT code 86353 to "Billing/Coding" section. References updated. Notice given on 12/20/11 for effective date 03/20/12. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.