Allergy Testing

Number: 2.01.500
Effective Date: March 1, 2017
Revision Date(s): 02/14/17; 02/09/16; 12/16/15; 08/28/15; 04/24/15; 08/12/14; 05/02/14; 08/12/13; 10/05/12; 08/14/12; 07/12/11; 06/08/10; 08/11/09; 12/16/08; 02/12/08; 07/08/08; 04/08/08; 10/09/07; 11/15/16; 10/10/06; 06/16/16; 10/13/05; 05/10/05; 08/12/03; 08/13/02; 09/11/01; 08/17/09; 05/05/07
Replaces: 2.01.23

Policy

Diagnosing Allergy Disease
The following allergy tests may be considered medically necessary when performed to establish a diagnosis of allergy disease:

- Certain Bronchial Challenge Tests, as indicated in Policy Guidelines
- Direct Skin Test
  - Percutaneous (scratch, prick, or puncture)
  - Intracutaneous (intradermal)
- Oral Challenge Tests for any of the following:
  - Food or other substances (i.e. additives or preservatives)
  - Drugs when 1 of the following criteria is met:
    - An allergy to multiple classes of drugs within a drug category is suspected (i.e. allergic to penicillin, and cephalosporins)
    - There is a history of allergy to a particular drug; and treatment with that drug is essential.
- Patch Test (also known as application testing)
- Photo Patch Test
- Specific IgE In Vitro Tests as indicated in Policy Guidelines
  - Enzyme-linked immunosorbent assay (ELISA)
  - Fluorescent allergosorbent test (FAST)
  - Multiple radioallergosorbent tests (MAST)
  - Radioallergosorbent test (RAST)
- Total Serum IgE Concentration

Immunotherapy Dosage Determination
Skin/serial endpoint tests/titration (SET), also known as skin/serial dilution endpoint titration (SDET) as well as intradermal dilution testing (IDT), may be considered medically necessary when used to determine a safe starting dose for testing or immunotherapy when the specific allergen might cause a severe systemic allergic reaction or anaphylaxis.

Allergy tests that are considered not medically necessary when performed to establish a diagnosis of allergy disease include but are not limited to the following:
• Complement antigen testing
• Conjunctival challenge test (ophthalmic mucous membrane test)
• Cytotoxic food tests
• IgG allergen specific antibody or food test/concentration food allergy testing
• Lymphocyte response assay (LRA)
• Nambudripad's Allergy Elimination Technique (NAET)
• Nasal challenge test
• Re buck skin window test
• Passive transfer or P-X (Prausnitz-Küstner) test (test is obsolete-replaced by radioallergosorbent tests-RAST)
• Provocation-neutralization testing (Rinkel Test) either subcutaneously or sublingually

Related Policies

2.01.17 Sublingual Immunotherapy as a Technique of Allergen-Specific Therapy
5.01.513 Omalizumab (Xolair®)

Policy Guidelines

Allergy testing is used to determine if a symptom is the result of an allergic response that involves antibodies and the release of histamine in the body. There are various modalities that are used as diagnostic tools for allergy testing.

Modalities for Allergy Testing
The following guidelines should be considered when reviewing claims for specific medically necessary testing modalities:

• **Bronchial Challenge Test:** Histamine or methacholine is used to perform this test when it is necessary to determine if the patient has hyper-responsive airways. Volatile chemicals are used to perform the test when the allergy is encountered in an occupational setting. If dust, ragweed, or other common allergens are the suspected cause of the problem, this test is generally considered not medically necessary, since skin tests can be used in these situations. Infrequently, aerosol challenge is indicated for occupational exposures, e.g., plicatic acid for cedar workers and fish extracts for fishermen.

• **Direct Skin Test/Percutaneous and Intracutaneous (intradermal) Testing:** The number of tests required may vary widely from patient to patient, depending upon the patient’s history. Rarely are more than 40 percutaneous or 20 intracutaneous tests required.

• **Oral Challenge Testing:** With this test, a suspected allergen is administered in an attempt to reproduce symptoms. There may be some clinical situations in which the allergen must be confirmed. A food challenge test involves provoking an allergic reaction. Therefore, this test should always take place at a site that is well-equipped to deal with any sort of reaction. This service should be billed using the code 95075 which is specific to this procedure. An office visit billed in addition to this procedure will be denied unless documentation supports that a significant additional service was provided.

• **Patch Test:** This testing is used to identify allergens causing contact dermatitis. The suspected allergens are applied to the patient’s back under occlusive dressings and allowed to remain in contact with the skin for 48 – 96 hours. The area is then examined for evidence of delayed hypersensitivity reactions. The testing may require several office visits during a 1 week span of time.

• **Photo Patch Test:** This test reflects contact photosensitization. A patch of skin is applied with the suspected sensitizer 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.

• **Serial endpoint testing (SET,SDET,IDT):** 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.

- **Specific IgE in Vitro tests (RAST, MAST, FAST, and ELISA):** These tests detect antigen-specific IgE
  antibodies in the patient’s blood serum. They may be considered medically necessary when
  percutaneous testing cannot be done for inhalant allergens (pollens, molds, dust, mites, animal danders),
  foods, insect stings, and other allergens such as drugs due to any of the following reasons:
  - When direct skin-testing is impossible due to extensive dermatitis or marked dermatographism;
  - In children younger than 4 years of age or adults with mental or physical impairments;
  - When clinical history suggests an unusually greater risk of anaphylaxis from skin testing than
    usual;
  - The patient is on a beta-blocker which cannot be stopped prior to skin testing;
  - A standardized or commercial skin test is not available for the allergen in question;
  - Skin testing is negative in the face of a strong clinical suspicion for allergen/allergens.

- **Total Serum IgE Concentration:** This testing modality is not indicated for most allergic patients, but may
  be indicated for those patients suspected of having 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.

**Definition of Terms**

**Allergen:** Any substance that can cause an allergic reaction. (Common allergens include dust mites, mold, pollen and animal dander)

**Allergy:** An acquired potential for developing adverse reactions that trigger the immune system to produce an
antibody called immunoglobulin E (IgE).

**Antibody:** A type of protein produced by the immune system in response to substances called antigens. The IgE
antibodies trigger mast cells to release histamines into the bloodstream.

**Antigen:** Any substance that, when introduced into the body causes an immune response and stimulates the
production of antibodies.

**Histamine:** Mast cells release histamine when exposed to an allergen. The histamine response causes allergic
reactions/symptoms that can affect the eyes, nose, throat, skin, lungs and gastrointestinal tract.

**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>82785</td>
<td>Gammaglobulin; IgE</td>
</tr>
<tr>
<td>86001</td>
<td>Allergen specific IgG quantitative or semiquantitative, each allergen</td>
</tr>
<tr>
<td>86003</td>
<td>Allergen specific IgE; quantitative or semi-quantitative, each allergen</td>
</tr>
<tr>
<td>86005</td>
<td>Allergen specific IgE; quantitative or semi-quantitative, qualitative multiallergen screen (dipstick, paddle or disk)</td>
</tr>
<tr>
<td>86160</td>
<td>Complement, antigen, each component</td>
</tr>
<tr>
<td>95004</td>
<td>Percutaneous tests (scratch, puncture, and prick) with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests.</td>
</tr>
<tr>
<td>95010</td>
<td>Percutaneous tests (scratch, puncture, prick), sequential and incremental, with drugs, biological or venoms, immediate type reaction, specify number of tests</td>
</tr>
<tr>
<td>95015</td>
<td>Intracutaneous (intradermal) sequential and incremental, with drugs, biological, or venoms, immediate type reaction, specify number of tests</td>
</tr>
<tr>
<td>95024</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests</td>
</tr>
<tr>
<td>95027</td>
<td>Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report by a physician, specify number of tests</td>
</tr>
<tr>
<td>95028</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests</td>
</tr>
<tr>
<td>95044</td>
<td>Patch or application test(s), specify number of tests</td>
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</tbody>
</table>
Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions and/or localized reactions in any organ system of the body. This exaggerated immune response to a foreign antigen may be acute, subacute or chronic, immediate or delayed. Some of the agents that may cause a reaction include, but are not limited to, pollens (tree, grass, weed), molds, house dust, dust mites, animal dander, stinging insect venoms, foods, medications (both over-the-counter and prescription), and latex.

Allergy testing can be broadly subdivided into two methodologies:

1. 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.
2. In vitro methodologies include various techniques to test the patient’s blood for the presence (serum level) of specific IgE antibodies to a particular antigen (i.e., RAST and ELISA tests).

Skin prick testing and in vitro analyses of IgE are the most commonly performed allergy tests.

**Nambudripad’s Allergy Elimination Technique (NAET)**

NAET is based on the theory that allergies are caused by "energy blockage" that can be diagnosed with muscle-testing and permanently cured with acupressure and/or acupuncture treatments.

Some theories suggest that IgG antibodies may be responsible for delayed symptoms or vague intolerance to foods. RAST and similar technologies are capable of detecting minute quantities of such antibodies, and it is known that low-level IgG antibodies to foods circulate normally in the system, but they have no known pathogenic significance.

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**

N/A
This policy was originally created in 1997 and updated regularly with searches of the MEDLINE database. The most recent literature search was through December 2016. Following is a summary of the key literature to date.

**Skin/serial Endpoint Tests/Titration (SET) or Intradermal Dilution Endpoint Tests/Titration (IDT)**

Much of the available literature on the accuracy of IDT and SET was written during the 1970s and 1980s. None of these studies showed improvement in allergy-related symptoms and/or quality of life based on the testing and, therefore, systematic review is difficult for this type of allergy testing. Nevertheless, IDT has become an established approach to allergy testing by the American Association of Otolaryngology, as reported by Krouse and Mabry. (1) SET, in particular, is generally considered the method of choice for life-threatening and antibiotic-related allergies in which other testing techniques may not be available or may be dangerous.

<table>
<thead>
<tr>
<th>The advantages of IDT over other allergy testing</th>
<th>The disadvantages of IDT over other allergy testing</th>
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<tbody>
<tr>
<td>• Determination of a safe starting dose</td>
<td>• Less specific than skin prick testing or serum IgE</td>
</tr>
<tr>
<td>• Reliability of testing greater in many drug-related allergies</td>
<td>• More extensive procedure that can require up to 6 rounds of intradermal injections before the diagnosis is established</td>
</tr>
<tr>
<td>• Higher sensitivity than skin prick testing for allergies</td>
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</table>

The American Academy of Allergy, Asthma and Immunology and American College of Allergy, Asthma and Immunology state in their 2008 guideline on allergy diagnostic testing recommendations on intracutaneous tests (2):

- “...When compared with specific nasal challenge, skin endpoint titration (SET) is equivalent to prick/puncture skin tests.”
- “Intracutaneous tests should be performed with small volumes (approximately 0.02 to 0.05 mL) of allergens injected intracutaneously with a disposable 0.5- or 1.0-mL syringe.”
- “As a general rule, the starting dose of an intracutaneous allergen test ranges from 100- to 1,000-fold more dilute than the allergen concentration used for prick/puncture tests.”

A 2011 article reported on the author’s experience conducting allergy testing in 52 patients with a history of allergic rhinitis. (3) Patients underwent SET testing, as well as in vitro and prick testing. All 52 patients were positive for one or more allergens on SET testing. Twenty-two of the 52 (42%) patients had no reaction to either of the other 2 types of testing. Of the remaining patients, 11 of 52 (21%) had positive reactions in vitro testing, 5 (10%) had positive reactions to prick testing, and 14 (27%) patients had positive reactions to both in vitro and prick testing. The author did not report treatment outcomes in the group of 52 patients. However, he stated that all of 230 patients in his practice who were given immunotherapy based on their response to SET testing said that they had either complete or significant relief of symptoms after treatment. The study was not designed prospectively to evaluate the accuracy or clinical utility of SET.

Although there is little primary literature on SET and health outcomes, guidelines and publications have discussed the need for this more intensive type of testing for certain drug allergies in particular. (3, 4) For example, the Centers for Disease Control and Prevention (CDC) recommend the use of SET testing in the management of patients with secondary syphilis or neurosyphilis and a history of penicillin allergy. (4)

In 1987, the American Medical Association’s Council on Scientific Affairs Allergy Panel published a report on in vivo diagnostic testing and immunotherapy for allergy. (5) Skin endpoint titration was addressed in this report, and the following conclusion was offered:

“Skin end point titration provides a safe and effective measure of patient sensitivity. Controlled studies have shown that the intradermal method of skin end-point titration is effective in quantifying sensitivity to ragweed extract and for identifying patients highly susceptible to ragweed. The method provides reliability comparable to that of in vitro leukocyte histamine release and radioallergosorbent test. Controlled studies have shown that the prick test methods of skin end-point titration can be used as a
measures of response to immunotherapy of cat extract."

**Lymphocyte Response Assay (LRA)**

Lymphocyte response assay tests, also known as ELISA/ACT, analyze lymphocytes in a laboratory culture for their reaction to over 300 foods, minerals, preservatives, and other environmental substances. The ELISA/ACT Biotechnologies website states that the test identifies the reactive substances of delayed hypersensitivity by providing a comprehensive “immunologic fingerprint” of delayed reactive substances. However, there are no published scientific studies to show how this testing is useful in the diagnosis or management of allergic disease.

**Nambudripad's Allergy Elimination Technique (NAET)**

The NAET muscle-testing procedure is an offshoot of applied kinesiology, a system based on the concept that every organ dysfunction is accompanied by a specific muscle weakness. Although Dr. Nambudripad recommends taking a standard allergy history, her principal diagnostic method is muscle-testing in which substances are placed in the patient's hand and the opposite arm is pulled by the practitioner (usually a chiropractor or acupuncturist) to measure the amount of resistance. The theory is that decreased muscle strength indicates the substance is a cause of allergy.

There is no scientific evidence to validate the claim that allergies are caused by energy blockages; and test-to-test variations are most likely due either suggestibility, muscle fatigue (from repeated testing) or variations in the test technique.

**Food Allergy Testing**

The Food Allergy practice parameter states that for the Diagnosis of Food Allergy – “The primary tools available to diagnose adverse reactions to foods include history (including diet records), physical examination, skin prick or puncture tests, serum tests for food specific IgE antibodies, trial elimination diets, and oral food challenges.” (Summary Statement 61) The practice parameters are endorsed by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology.

**Oral Challenge Test**

In 2008, Mankad and colleagues performed a retrospective medical record review of open food challenges, administered in a university-based pediatric allergy-immunology clinic during a 3-year period. They report on a total of 109 patients who underwent 150 open food challenges, most of which were to milk (n=39), peanuts (n=37) and egg (n=29). There were 40 positive challenges in 33 patients. Reactions were mild to moderate in 92% of positive challenges. Cutaneous reactions occurred in 68% of positive challenges, followed by GI tract reactions (45%) and upper respiratory reactions (38%). No patient had cardiovascular involvement. No patient received epinephrine or required hospitalization. The authors concluded that open food challenges are a safe procedure in the office setting.

**Complement Antigen Testing**

Complement Antigen Testing is a test that has been used to identify delayed food allergies. However, this application has yet to be studied and validated. This test is considered investigational.

**Serum IgG Testing - Radioallergosorbent Test (RAST) or Enzyme-linked Immunosorbent Assay (ELISA)**

The role of RAST or ELISA measurement of serum IgG in the diagnosis and management of allergic disease has not been established. There are no randomized controlled trials documenting outcomes or impact on treatment decisions. Several evidence-based guidelines have been published which conclude that IgG testing is not recommended to diagnose food allergies or intolerance.

**Practice Guidelines and Position Statements**

*European Academy of Allergy and Clinical Immunology (EAACI)*
The EAACI Task Force published a position paper in 2008 regarding testing for IgG4 against foods.(13) They stated: “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. However, many serum samples show positive IgG4 results without corresponding clinical symptoms. These findings, combined with the lack of convincing evidence for histamine-releasing properties of IgG4 in humans, and lack of any controlled studies on the diagnostic value of IgG4 testing in food allergy, do not provide any basis for the hypothesis that food-specific IgG4 should be attributed with an effector role in food hypersensitivity. In contrast to the disputed beliefs, IgG4 against foods indicates that the organism has been repeatedly exposed to food components, recognized as foreign proteins by the immune system. Its presence should not be considered as a factor which induces hypersensitivity, but rather as an indicator for immunological tolerance, linked to the activity of regulatory T cells. In conclusion, 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.”

**National Institute of Allergy and Infectious Diseases (NIAID)**
In December 2010, the NIAID, a division of the National Institutes of Health (NIH), published “Guidelines for the Diagnosis and Management of Food Allergy in the United States”.(14) In section 4.2.2.9.Nonstandardized and Unproven Procedures, Guideline # 12 states: “The Expert Panel recommends not using any of the following nonstandardized tests for the routine evaluation of IgE-mediated food allergy”:

- Allergen-specific IgG4
- Applied kinesiology
- Basophil histamine release/activation
- Cytotoxicity assays
- Electrodermal test (Vega)
- Endoscopic allergen provocation
- Facial thermography
- Gastric juice analysis
- Hair analysis
- Lymphocyte stimulation
- Mediator release assay (LEAP diet)
- Provocation neutralization

**American Academy of Allergy, Asthma & Immunology (AAAIA)**
The AAAIA website (2014) lists several tests which it believes “are not useful, effective or may lead to inappropriate diagnosis and treatment”. These tests include:

- Allergy screening tests done in supermarkets or drug stores,
- Applied kinesiology (allergy testing by testing muscle strength or weakness),
- Cytotoxicity testing for food allergy,
- Home testing,
- Immunoglobulin G (IgG) testing for food allergy,
- Rinkel skin titration method/ provocative neutralization testing,
- Sublingual provocation.

**References**

2. Bernstein IL, Li JT, Bernstein DI, et al. American Academy of Allergy, Asthma and Immunology,


16. Reynolds TM, Twomey PJ. Can we manage demand for allergy testing by restricting requests to a small number of prime target allergens? Ann Clin Biochem. 2007; 44(Pt 5):467-470. PMID 17761033


Additional historical references used to create this policy:

1. 2002 TEC Assessment: Tab 6; Serial Endpoint Testing for the Diagnosis and Treatment of Allergic Reactions.


release and bronchial provocation. Allergy 1990; 45(3):231-5.
6. Griese M, Kusenbach G, Reinhardt D. Histamine release tests in comparison to standard tests in
7. Skov PS, Mosbech M, Norn S, et al. Sensitive glass microfibre-based histamine analysis for allergy
testing in washed blood cells. Results compared with conventional leukocyte histamine release assay.
conventional automated fluorometric histamine assay, case history, skin prick test, and specific serum
11. Nolte H, Storm K, Schiotz PO. Diagnostic value of a glass fibre-based histamine analysis for allergy
12. BlueCross BlueShield Association (BCBSA). Serial Endpoint Testing for the Diagnosis and Treatment of
13. Policy reviewed in August 2001 by practicing board-certified allergist.

Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/05/97</td>
<td>Add to Medicine Section - New Policy</td>
</tr>
<tr>
<td>08/17/99</td>
<td>Replace Policy - Reviewed; policy unchanged.</td>
</tr>
<tr>
<td>09/11/01</td>
<td>Replace Policy - Scheduled update; latex added to allergic conditions and statement about inhalant testing added.</td>
</tr>
<tr>
<td>08/13/02</td>
<td>Replace with BC Policy - Policy regarding skin end point titration reviewed; policy statement unchanged; references added to 2002 TEC assessment. Policy replaces P2.01.100.</td>
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<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy reviewed with focus on leukocyte histamine release assay; policy statement unchanged.</td>
</tr>
<tr>
<td>05/10/05</td>
<td>Replace with PR Policy - Indication regarding Lymphocyte Response Assay (LRA) added to investigational causing policy to revert back to PR. Policy replaces BC.2.01.23.</td>
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<tr>
<td>10/13/05</td>
<td>Replace policy - Description and Rationale sections on LHRT updated (BCBSA policy 2.04.42 not adopted); no change to policy statement.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>10/10/06</td>
<td>Replace Policy - Policy updated with literature search; no change in policy statement.</td>
</tr>
<tr>
<td>11/15/06</td>
<td>Update Codes - No other changes.</td>
</tr>
<tr>
<td>10/09/07</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement.</td>
</tr>
<tr>
<td>04/08/08</td>
<td>Code Updated - Added 95060, no other changes.</td>
</tr>
<tr>
<td>07/08/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement revised to include NAET as investigational. Policy guidelines regarding RAST updated. References added.</td>
</tr>
<tr>
<td>08/12/08</td>
<td>Code Updated - 95078 deleted no other changes.</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement updated to include Oral Challenge Testing with criteria as medically necessary. Policy reviewed with focus on leukocyte histamine release assay and oral food challenge. Description and code removed for LHRT. References added.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement.</td>
</tr>
<tr>
<td>06/08/10</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement. Reference added.</td>
</tr>
<tr>
<td>07/12/11</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement.</td>
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</table>
Replace policy. Policy updated: Complement antigen testing, Antigen leukocyte cellular antibody test (ALCAT) and IgG, previously not addressed, are added as investigational indications; references added. Codes 83516, 86001 and 86160 added. Policy has a 90-day hold for provider notification and will be effective February 1, 2013.

Implementation extended to April 1, 2013.

Replace policy. Policy statement has Serial endpoint testing [SET] moved from investigational to medically necessary based on updated research. All tests put in alphabetic order. Rationale section reformatted for usability. Rationale updated based on a literature review through June 2013. Medicare coverage LCD added. References 1, 3, 4, 13 added; others renumbered/removed. Policy statement changed as noted.

Annual Review. Policy updated with literature review. Policy statement changed: 1) ALCAT information and policy statement as investigational deleted. ALCAT information now contained in new medical policy “Antigen Leukocyte Antibody Test” and considered not medically necessary. 2) Remaining list of investigational tests now considered not medically necessary. References added. CPT code 83516 removed; this now applies to 2.01.93 (ALCAT testing specific policy); ICD-9 diagnosis codes removed – these are not utilized in administration of the policy.

Update Related Policies. Change title to 2.01.01.

Annual Review. Policy updated with literature review through February, 2015; no references added. Policy statements unchanged.

Update Related Policies. Remove 2.01.01 as it was archived.

Update Related Policies. Remove 2.01.93 as it was archived.

Annual Review. Policy reviewed with literature review through January 2016; reference 22 added. Definition of Terms added to Guidelines section. Policy statements unchanged.

Annual review. Policy reviewed with literature review through December 2016; reference 13 deleted. Policy statements unchanged.

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يحيى هذا الإشعار معلومات هامة. قد يحيى هذا الإشعار معلومات مهمة في الوصول على مدار 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的讯息。本通知可能有关於您透过 Premera Blue Cross 提交的申请或保险的重要讯息。本通知可能有重要日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或者费用补贴。您有权利免费以您的母语得到本讯息和帮助。请拨电话 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi siila a gen Enfòmasyon Enpòtan ladan. Avi siila a kapab genyen enfòmasyon enpòtan konèsan aplikasyon y lwa osa konèsan kouvèti asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi siila a. Ou ka gen pou pou kòk aksyon avan sèten dat limit pou ka kente kouvèti asirans sante w la osa pou yo ka ede w avèk depans yo. Se dwa w pou resevwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Francais (French):
Bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Ilokano (Illoko):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar malabin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyon wenyong coverage banaan iti Premera Blue Cross. Daytoy ket malabin dagiti importante a pelsa iti daytoy a pakdaar. Malabin nga adda rumbeng nga aramidenyi nga addang sakkay dagiti partikular a naitudding nga alawina tapno maipangtalinayo ti coverage ti salain-ayo wenyong tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross has sent you this notice because it contains information important to you. The notice may contain information about your coverage or benefits under your plan that you need to know to protect your health. This notice may also include information about your rights and responsibilities under your health plan.

Premera Blue Cross is a leading health benefits company in the United States. We believe that everyone should have access to quality health care and we are committed to helping people make the most of their health resources.

Please contact Premera Blue Cross if you have any questions about your health care coverage or benefits. You can reach us at 1-800-722-1471 (TTY: 1-800-842-5357) or visit our website at www.premerablue.com.

If you need to file a claim, you can do so online at www.premerablue.com or by calling 1-800-722-1471 (TTY: 1-800-842-5357).

If you have any questions about your health care coverage or benefits, please contact Premera Blue Cross at 1-800-722-1471 (TTY: 1-800-842-5357) or visit our website at www.premerablue.com.

You can also contact Premera Blue Cross to check the status of your claim or to get information about your coverage.

We are required to provide this notice to you in accordance with federal and state laws. This notice does not change your health care coverage or benefits under your plan. It is simply a reminder of certain rights and responsibilities you have under your health plan.

Thank you for choosing Premera Blue Cross as your health care provider. We are committed to providing you with the best possible care and service.

Premera Blue Cross

P.O. Box 4040
Renton, WA 98058-4040

800-722-1471 (TTY: 800-842-5357)

Premera Blue Cross

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This notice is not a substitute for your health care coverage or benefits under your plan. It is simply a reminder of certain rights and responsibilities you have under your health plan.