

## MEDICAL POLICY – 2.01.500

## Allergy Testing

Effective Date:	March 1, 2020	RELATED MEDICAL POLICIES:
Last Revised:	Feb. 4, 2020	2.01.17 Sublingual Immunotherapy as a Technique of Allergen-Specific Therapy
Replaces:	2.01.23	5.01.513 Xolair® (omalizumab)

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## Introduction

The immune system is the body's defense against harmful substances. An allergy is the immune system's response to certain items that the immune system considers foreign and harmful—things like specific foods, animal dander, pollens, drugs, mold, and many other substances. The substances that create allergic reactions are known as allergens. In people with allergies, their immune system overreacts to allergens by creating an antibody (a protein specially made to fight a particular substance) known as immunoglobulin E (IgE). Allergic reactions can cause several different types of symptoms, such as a runny nose, watery eyes, or hives. Serious reactions can range from breathing difficulties to life-threatening swelling in the mouth or throat. Diagnosing allergies often involves testing the skin or measuring the ability to breathe, or looking at IgE levels in the blood. This policy describes which allergy tests are considered medically necessary and when they should be done. It also lists types of allergy tests that are considered not medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

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## Policy Coverage Criteria

Service	Medical Necessity
<b>Diagnosing allergy disease</b>	<p><b>The following allergy tests may be considered medically necessary when performed to establish the presence of an allergy:</b></p> <ul style="list-style-type: none"> <li>• Certain Bronchial Challenge Tests, as indicated in <b>Modalities for Allergy Testing</b> (below)</li> <li>• Direct Skin Test <ul style="list-style-type: none"> <li>○ Percutaneous (scratch, prick, or puncture)</li> <li>○ Intracutaneous (intradermal)</li> </ul> </li> <li>• Oral Challenge Tests for any of the following: <ul style="list-style-type: none"> <li>○ Food or other substances (ie, additives or preservatives)</li> <li>○ Drugs when one of the following criteria is met: <ul style="list-style-type: none"> <li>▪ An allergy to multiple classes of drugs within a drug category is suspected (ie, allergic to penicillin and cephalosporins)</li> <li>▪ There is a history of allergy to a particular drug, and treatment with that drug is essential.</li> </ul> </li> </ul> </li> <li>• Patch Test (also known as application testing)</li> <li>• Photo Patch Test</li> <li>• Specific IgE In Vitro Tests as indicated in <b>Modalities for Allergy Testing</b> <ul style="list-style-type: none"> <li>○ Enzyme-linked immunosorbent assay (ELISA)</li> <li>○ Fluorescent allergosorbent test (FAST)</li> <li>○ Multiple radioallergosorbent tests (MAST)</li> <li>○ Radioallergosorbent test (RAST)</li> </ul> </li> <li>• Total Serum IgE Concentration</li> </ul>
<b>Immunotherapy dosage determination</b>	<p><b>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.</b></p>
<b>Testing to establish a diagnosis of allergy disease</b>	<p><b>Allergy tests that are considered not medically necessary when performed to establish the presence of an allergy include, but are not limited to, the following:</b></p> <ul style="list-style-type: none"> <li>• Complement antigen testing</li> </ul>



Service	Medical Necessity
	<ul style="list-style-type: none"> <li>• Conjunctival challenge test (ophthalmic mucous membrane test)</li> <li>• Cytotoxic food tests</li> <li>• IgG allergen specific antibody or food test/concentration food allergy testing</li> <li>• Lymphocyte response assay (LRA)</li> <li>• Nambudripad's Allergy Elimination Technique (NAET)</li> <li>• Nasal challenge test</li> <li>• Rebeck skin window test</li> <li>• Passive transfer or P-X (Prausnitz-Küstner) test (this test is obsolete and was replaced by radioallergosorbent tests [RAST])</li> <li>• Provocation-neutralization testing (Rinkel Test) either subcutaneously or sublingually</li> </ul>

### Modalities for Allergy Testing

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, eg, plicatic acid for cedar workers and fish extracts for fishermen.
- **Direct skin test/percutaneous and intracutaneous (intra-dermal) 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



## Modalities for Allergy Testing

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 time span.
- **Photo patch test:** This test reflects contact photosensitization. A patch containing the suspected sensitizer is applied to the 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.
- **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. SET has also 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 for inhalant allergens (pollens, molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs when percutaneous testing cannot be done due to any of the following reasons:
  - When direct skin-testing is impossible due to extensive dermatitis or marked dermatographism
  - OR**
  - In children younger than 4 years of age or adults with mental or physical impairments
  - OR**
  - When clinical history suggests a greater than usual risk of anaphylaxis from skin testing
  - OR**
  - The patient is on a beta-blocker which cannot be stopped prior to skin testing
  - OR**
  - A standardized or commercial skin test is not available for the allergen in question
  - OR**
  - 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



## Modalities for Allergy Testing

bronchopulmonary aspergillosis, immune deficiency disease characterized by increased IgE levels (eg, Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma, or pemphigoid.

## Coding

Code	Description
<b>CPT</b>	
82785	Gammaglobulin; IgE
86001	Allergen specific IgG quantitative or semiquantitative, each allergen
86003	Allergen specific IgE; quantitative or semi-quantitative, each allergen
86005	Allergen specific IgE; quantitative or semi-quantitative, qualitative multiallergen screen (dipstick, paddle or disk)
86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
86160	Complement, antigen, each component
95004	Percutaneous tests (scratch, puncture, and prick) with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests.
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergic extracts for airborne allergens, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95028	Intracutaneous (intradermal) tests with allergic extracts, delayed type reaction, including reading, specify number of tests



Code	Description
95044	Patch or application test(s), specify number of tests
95052	Photo patch test(s), specify number of tests
95060	Ophthalmic mucous membrane tests
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds
95071	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with antigens or gases, specify
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing
95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### 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 response to a trigger that makes the immune system 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.



### Description

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 (ie, 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 (ie, 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.

## Summary of Evidence

### ***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.<sup>1</sup> 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.

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

The American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology jointly published guidelines in 2008 on allergy diagnostic testing. Their recommendations on intracutaneous tests are:<sup>2</sup>

- "...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."

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.<sup>3,4</sup> 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.<sup>4</sup>

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.<sup>5</sup> 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 measure 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.<sup>6</sup> 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.<sup>7</sup>

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 to either suggestibility, muscle fatigue (from repeated testing) or variations in the test technique.<sup>8</sup>



## ***Food Allergy Testing***

The Food Allergy practice parameter<sup>9</sup> 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<sup>10</sup> performed a retrospective medical record review of open food challenges, administered in a university-based pediatric allergy-immunology clinic during a 3-year period. 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.<sup>11</sup>

## ***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.<sup>12</sup>



## 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.<sup>13</sup> It 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".<sup>14</sup> 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 (AAAAI)***

The AAAAI 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

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Additional historical references used to create this policy:

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13. Policy reviewed in August 2001 by practicing board-certified allergist.

## History

Date	Comments
05/05/97	Add to Medicine Section - New Policy
08/17/99	Replace Policy - Reviewed; policy unchanged.
09/11/01	Replace Policy - Scheduled update; latex added to allergic conditions and statement about inhalant testing added.
08/13/02	Replace with BC Policy - Policy regarding skin end point titration reviewed; policy statement unchanged; references added to 2002 TEC assessment. Policy replaces



Date	Comments
	P2.01.100.
08/12/03	Replace Policy - Policy reviewed with focus on leukocyte histamine release assay; policy statement unchanged.
05/10/05	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.
10/13/05	Replace policy - Description and Rationale sections on LHRT updated (BCBSA policy 2.04.42 not adopted); no change to policy statement.
06/16/06	Update Scope and Disclaimer - No other changes.
10/10/06	Replace Policy - Policy updated with literature search; no change in policy statement.
11/15/06	Update Codes - No other changes.
10/09/07	Replace Policy - Policy updated with literature search; no change to policy statement.
04/08/08	Code Updated - Added 95060, no other changes.
07/08/08	Replace Policy - Policy updated with literature search. Policy statement revised to include NAET as investigational. Policy guidelines regarding RAST updated. References added.
08/12/08	Code Updated - 95078 deleted no other changes.
12/16/08	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.
08/11/09	Replace Policy - Policy updated with literature search; no change to policy statement.
06/08/10	Replace Policy - Policy updated with literature search; no change to policy statement. Reference added.
07/12/11	Replace Policy - Policy updated with literature search; no change to policy statement.
08/14/12	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.
10/05/12	Implementation extended to April 1, 2013.
08/12/13	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.



Date	Comments
05/02/14	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.
08/12/14	Update Related Policies. Change title to 2.01.01.
04/24/15	Annual Review. Policy updated with literature review through February, 2015; no references added. Policy statements unchanged.
08/28/15	Update Related Policies. Remove 2.01.01 as it was archived.
12/16/15	Update Related Policies. Remove 2.01.93 as it was archived.
02/09/16	Annual Review. Policy reviewed with literature review through January 2016; reference 22 added. Definition of Terms added to Guidelines section. Policy statements unchanged.
03/01/17	Annual Review, approved February 14, 2017. Policy reviewed with literature review through December 2016; reference 13 deleted. Policy statements unchanged.
11/10/17	Policy moved to new format. No changes to policy statement.
01/23/18	Coding update, added CPT code 86008 (new code effective 1/1/18).
02/01/18	Annual Review, approved January 30, 2018. No change to policy statement.
02/01/19	Annual Review, approved January 22, 2019. Policy reviewed with literature review through January 2019. Reference 21 added. Reference removed. No change to policy statement.
03/01/20	Annual Review, approved February 4, 2020. Policy reviewed. References updated. Policy statements unchanged.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**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.



**Discrimination is Against the Law**

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera 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:

Civil Rights Coordinator - Complaints and Appeals  
PO Box 91102, Seattle, WA 98111  
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357  
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the 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, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)  
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**Getting Help in Other Languages**

**This Notice has Important Information.** This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

**አማርኛ (Amharic):**

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታወቅ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

**العربية (Arabic):**

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

**中文 (Chinese):**

**本通知有重要的訊息。**本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

**Oromoo (Cushite):**

**Beeksisni kun odeeffannoo barbaachisaa qaba.** Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

**Français (French):**

**Cet avis a d'importantes informations.** Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

**Kreyòl ayisyen (Creole):**

**Avi sila a gen Enfòmasyon Enpòtan ladann.** Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

**Deutsche (German):**

**Diese Benachrichtigung enthält wichtige Informationen.** Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

**Hmoob (Hmong):**

**Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hns ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

**Iloko (Ilocano):**

**Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion.** Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

**Italiano (Italian):**

**Questo avviso contiene informazioni importanti.** Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

**日本語 (Japanese):**

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

**한국어 (Korean):**

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងរបស់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ដុល្លារចេញផ្លូវ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).