Clinical Policy: Allergy Testing

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CPT Codes: 86001, 86003, 86005, 86008, 95004, 95012, 95017, 95018, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95071, 95076, 95079, 0178U, 94617, 94618
Document: BI111:00

Public Statement

Effective Date:

a) This policy will apply to all services performed on or after the above revision date which will become the new effective date.
b) For all services referred to in this policy that were performed before the revision date, contact customer service for the rules that would apply.

1) Allergy testing requires preauthorization except for the following:
   a) Percutaneous (scratch, prick or puncture) testing
   b) Intradermal testing
   c) Patch testing up to first 80 units.
   d) In vitro testing (certain types of blood tests) is covered when performed by Allergist, for one set, up to 70 tests; additional in vitro testing requires pre-authorization.

2) Other allergy tests that require preauthorization include patch testing for more than 80 units, intradermal dilution testing, oral challenge testing and pulmonary function testing.

3) For pulmonary function testing, please refer to BI542.

4) Tests that are considered Experimental and Investigational are not covered and are listed under the Limits section.

Medical Statement

For pulmonary function testing, please refer to BI542.

1) The following forms of allergy testing are considered medically necessary and do not require pre-authorization:
   A) **Percutaneous** (scratch, prick or puncture) skin testing (95004) has a maximum limit of 70 units per 12 months and is considered medically necessary when IgE-mediated reactions occur to **any** of the following:
      i. Inhalants; **or**
      ii. Foods; **or**
      iii. Hymenoptera (stinging insects); **or**
      iv. Specific drugs (penicillin's and macromolecular agents).

B) **Intradermal (Intracutaneous)** allergy testing (95024, 95028) is performed when percutaneous tests are negative. Intradermal allergy testing has a maximum combined limit of 40 units per 12 months; any additional units require pre-authorization. Intradermal allergy testing is considered medically necessary when IgE-mediated reactions occur to **any** of the following:
   i. Inhalants; **or**
   ii. Foods; **or**
   iii. Hymenoptera (stinging insects); **or**
   iv. Specific drugs (penicillin's and macromolecular agents).

C) **Allergen Specific IgE (in vitro) Testing** (86003 – 86008) requires evaluation by an Immunologist or Dermatologist and has a limit of up to 70 tests per year; any additional tests require pre-authorization. Allergen specific testing is considered medically necessary under the following guidelines:
   i. When percutaneous testing of IgE-mediated allergies cannot be done for:
      a. Inhalant allergy; **or**
      b. Food allergy;
         1. Due to **any** of the following reasons:
            - Member has severe Dermatographism, ichthyosis, or generalized eczema; **or**
            - Member is unable to discontinue antihistamines but is in need of allergy testing; **or**
            - Difficulty in testing uncooperative members (e.g., small children or individuals with mental or physical impairments); **or**
            - When clinical history suggests an unusually greater risk of anaphylaxis from skin testing than usual; **or**
            - Direct skin testing is inconclusive.

   ii. Also as an alternative to percutaneous testing for:
      a. The evaluation of cross-reactivity between insect venoms; **or**
      b. As adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis (ABPA) and certain parasitic diseases.

D) **Skin Patch Testing** (95044) for diagnosing contact allergic dermatitis. The first 80 units are covered without pre-authorization; any additional units require pre-authorization.

E) **Skin Endpoint Titration (SET) or Intradermal Dilutional testing (IDDT)** (95017, 95018, 95027) is covered for a cumulative total of 80 units per calendar year for determining the starting dose for immunotherapy for members highly allergic to:
   i. Inhalant allergy (95027); **or**
   ii. Hymenoptera venom allergy (95017); **or**
   iii. Drugs/biological allergy (95018).

It is inappropriate to use SET or IDDT (95027) in place of skin testing and it is not eligible for benefits unless skin testing has been performed.

2) The following tests require pre-authorization:
   A) **Photo Patch Testing** (95052) for diagnosing photo allergy (e.g., photo-allergic contact dermatitis to be requested by an Allergist or Dermatologist)
   B) **Photo Tests** (95056) for evaluating photosensitivity disorders, to be requested by an Allergist or Dermatologist.
   C) **Exercise Challenge Testing** (94617, 94618) for exercise-induced bronchospasm, to be requested by Allergist or Pulmonologist.
   D) **Bronchial Challenge Test** (95070 – 95071) for testing with methacholine, histamine or antigens in defining asthma or airway hyperactivity when any of the following conditions are met:
      i. Asthma is a serious possibility and spirometry performed before and after administration of a bronchodilator, have not established or eliminated the diagnosis; **or**
      ii. To identify new allergens for which skin or blood testing has not been validated; **or**
      iii. When skin testing is unreliable; **AND**
      iv. When requested by a Pulmonologist or Allergist.
   E) **Ingestion (Oral) Challenge Test** (95076 – 95079) for any of the following:
      i. Food or other substances (i.e., Metabisulfite); **or**
      ii. Drugs when all of the following are met:
         a. History of allergy to a particular drug; **and**
         b. Treatment with that drug class is essential; **and**
         c. There is no effective alternative drug; **and**
         d. Requested by an Allergist.
   F) Peanut allergen-specific quantitative assessment (0178U) for documented severe anaphylactic reaction to minimal peanut exposure.

Codes Used In This BI:

86001	Allergen specific IgG; quantitative/semi quantitative, ea allergen
86003	Allergen specific IgE; quantitative/semi quantitative, ea allergen
86005	qualitative, multiallergen screen
86008	quantitative/semi quantitative, recombinant or purified component, each (new code 1/1/2018)
95004	Percut tests w/allergenic extracts, immed type reaction, incl test interpret & rpt, specify # of tests
95012	Nitric oxide expired gas determination
95017	Allergy Testing, any combo of percut & intracut, seq & incrmntl, w/venoms, immed type reaction, incl test interp & rpt, specify # tests
95018	Allergy Testing, any combo of percut & intracut, seq & incrmntl, w/drugs or biologicals, immed type reaction, incl test interp & rpt, specify # tests

95024	Intracut tests w/allergenic extracts, immed type reaction, incl test interpret & rpt, specify # of tests
95027	Intracut tests, sequential & incremental, w/allergenic extracts for airborne allergens, immed type reaction, incl test interpret & rpt, specify # of tests (SET or IDDT)
95028	Intracutaneous tests, w/allergenic extracts, delayed type reaction, incl reading, specify # of tests
95044	Patch or application test(s), specify # of tests
95052	Photo Patch Test(s), specify # of tests
95056	Photo tests
95060	Ophthalmic mucous membrane tests
95065	Direct nasal mucous membrane test
95070	Inhalation bronchial challenge testing; w/histamine, methacholine, or similar compounds
95071	w/antigens or gases, specify
95076	Ingestion challenge test; initial 120 mn of testing
95079	each addtl 60 mn
94617	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; with electrocardiographic recording(s)
94618	Pulmonary stress testing (eg, 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction (new code eff 7/1/2020)

Limits

The following tests are considered experimental and investigational as they have not been proven to be effective:

A. Exhaled nitric oxide measurement.
B. ALCAT test
C. IgG RAST/ELISA Testing
D. Candidiasis test
E. Chlorinated pesticides (serum)
F. Complement (total or components); (may be appropriate in autoimmune disorders, complement component deficiencies, hereditary angioedema, vasculitis)
G. C-reactive protein (may be appropriate in inflammatory diseases)
H. Cytotoxic food testing (Bryans Test, ACT)
I. Electrodermal acupuncture
J. ELISA/ACT
K. Food immune complex assays (FICA)
L. Immune complex assay (may be appropriate in autoimmune disorders, systemic lupus erythematosus, vasculitis)
M. Leukocyte histamine release test

N. Lymphocytes (B or T subsets); (may be appropriate for collagen vascular disease, immune deficiency syndromes, leukemia, lymphomas)
O. Mediator release test (MRT)
P. Testing for multiple chemical sensitivity syndrome (a.k.a., idiopathic environmental intolerance (IEI), clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease)
Q. Muscle strength testing or measurement (kinesiology) after allergen ingestion
R. Ophthalmic mucous membrane tests/conjunctival challenge tests
S. Direct nasal mucous membrane testing/provocative nasal test
T. Prausnitz-Kustner or P-K testing - passive cutaneous transfer test
U. Provocation-neutralization testing (Rinkel Test) either subcutaneously or sublingually
V. Pulse test (pulse response test, Reaginic pulse test)
W. Rebuck skin window test
X. Sublingual provocative neutralization testing and treatment with hormones
Y. Venom blocking antibodies
Z. Volatile chemical panels (blood testing for chemicals).

Background

In-Vivo Diagnostic tests of IgE Dependent Reactions

Percutaneous (Scratch, Prick or Puncture) and Intracutaneous In-Vivo Diagnostic Skin Tests
Skin testing to drugs is generally unreliable, except for the penicillin's and macromolecular agents, such as foreign antisera, hormone (e.g., insulin), enzymes (e.g., L-Asparaginase, streptokinase, Chymopapain), and egg-containing vaccines.

Skin Endpoint Titration (SET)
While allowing that SET is a valid method for obtaining semi-quantitative information about a person's sensitivity and for determining a safe beginning dose for immunotherapy, the American College of Physicians (ACP) advises that the primary use of SET is to identify hymenoptera venom (yellow jacket, honey bee, hornet, wasp, fire ant) sensitivity and to determine the safe starting dose for venom immunotherapy.

Provocation (Challenge) Testing
In provocation or challenge testing, a suspected allergen in a clinically relevant exposure is administered in an attempt to reproduce symptoms. Challenge tests have been broadly applied under research conditions for many years, but there are some clinical situations in which they can be useful for confirmation of clinical disease. Considerable experience with these methods is required for proper interpretation and analysis.

Patch Testing
Patch testing is an accepted method of differentiating allergic contact dermatitis and irritant contact dermatitis. Twenty to thirty antigens are used in the usual routine screening panel of patch tests. The patches are removed after 48 hours and an initial reading is taken 1 hour later. The final reading is taken a further 48 hours later.

Photo Patch Testing
Some chemicals or medications (e.g., lomefloxacin, Ofloxacin, ciprofloxacin, and Norfloxacin) produce an allergic reaction only when exposed to light (usually ultraviolet type A, UVA). Patients who are over-sensitive to light and those with a rash that appears on parts of the body normally exposed to light but that does not appear in areas shielded from the light should have a photo-patch test. With photo patch testing, two identical sets of allergens are placed onto the patient`s back on day-1. One of the sets is exposed to UVA light, and the sites are then examined as described above for patch testing. A positive photo patch test is recorded when an allergic reaction appears only on the light-exposed site.

Photo Tests
Photo testing is skin irradiation with a specific range of ultraviolet light. Photo tests are performed for the evaluation of photosensitivity disorders.

Exercise Challenge Testing
Exercise challenge testing is an accepted method of diagnosing exercise induced bronchospasm in asthmatic and non-asthmatic patients.

Ingestion (Oral) Challenge Testing
Ingestion (oral) challenge testing is an accepted method of diagnosing allergies to food, drug or other substances (i.e., Metabisulfite). Drug challenge testing should not be confused with cutaneous or sublingual provocation and neutralization therapy, which is a non-covered modality.

Nasal or Conjunctival Provocative or Challenge Tests
Nasal or conjunctival provocative or challenge tests employed for the diagnosis of either food or inhalant allergies, involve the direct administration of the allergen to the mucosa. The patient is then observed for signs and symptoms and the presence of symptoms is interpreted as a positive indication of allergies. These tests are time consuming; only one antigen may be administered per session, a non-standardized quantity of allergen is administered, and they have the potential of inducing severe symptoms. There is currently no standard technique for nasal or conjunctival challenge tests that can be applied to clinical practice.

Prausnitz-Kustner or P-K Testing
Prausnitz-Kustner testing has been used in patients with Dermatographia or generalized skin eruptions. A control site on the forearm of a non-allergic recipient is selected. This site is injected intradermally with allergy serum from a patient on whom direct skin tests cannot be done. Allergenic extract is later injected intradermally into the initial injection site of the

recipient and observed for the development of a wheal and flare. **Because of the risk of transmitting hepatitis or AIDS, this test is contraindicated**.

Provocation-Neutralization (Rinkel Test)
Provocation-neutralization is a method of testing for the presence of food, inhalant or environmental chemical allergies by exposing the individual to test doses of these substances intradermally, subcutaneously, or sublingually with the purpose of either producing or preventing subjective symptoms.

Both the ACP and the American Academy of Allergy and Immunology (AAAI) consider provocation-neutralization therapy an unproven modality. In a Training Program Directors` Committee Report on Controversial Practices published by the AAAI, provocation-neutralization testing and neutralization therapy are listed as unproven. The AMA`s Council on Scientific Affairs, based on the reports in the peer-reviewed scientific literature, stated that there are no well-controlled studies establishing a clear mechanism or cause for multiple chemical sensitivity syndromes. More importantly, there are no well-controlled studies that have demonstrated either diagnostic or therapeutic value for provocation-neutralization therapy.

Provocation-neutralization must not be confused with the recognized forms of target-organ challenge testing (bronchial, ingestion, patch testing), which are covered modalities.

In-Vitro Testing (Allergen Specific IgE Testing)

ELISA/FEIA/RAST/MAST/PRIST/RIST/FAST/MRT/VAST/ImmunoCAP
For most allergens, in-vitro allergen - specific immunoassays detect IgE antibody in the serum of most but not all patients who respond clinically to those allergens. The precise sensitivity of these immunoassays compared with skin tests has been reported to range from < 50% to > 90% with the average being about 70 to 75%. **In a joint statement, the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma, and Immunology, and the Joint Council of allergy, Asthma and Immunology (the Joint Council) concluded that allergen skin testing is the most sensitive method for detecting specific IgE antibody**. Therefore, skin tests are presently the preferred tests for the diagnosis of IgE-mediated sensitivity. Because of the inherent pitfalls in the sensitivity and reliability of IgE specific immunoassays, clinical applications are not completely defined and are still evolving.

According to the Joint Council, although skin tests are presently the preferred method of testing in making the diagnosis of allergy, in vitro tests may also be useful in specific clinical situations. Specific IgE immunoassays may be preferable to skin testing under special clinical circumstances: 1) testing of patients with severe Dermatographism, ichthyosis, or generalized eczema; 2) testing in patients who have been receiving long-acting antihistamines, tricyclic antidepressants, beta blockers, systemic corticosteroids or other medications that interfere with skin testing and may put the patient at undo risk if they are discontinued; 3) testing of

uncooperative patients with mental or physical impairments; 4) the evaluation of cross-reactivity between insect venoms; 5) postmortem examination for IgE antibodies to identify allergens responsible for lethal anaphylaxis; 6) as adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases; 7) when clinical history suggests an unusually greater risk of anaphylaxis from skin testing than usual; and 8) direct skin testing is inconclusive.

Intradermal skin tests, rather than in-vitro tests, should be used for the definitive diagnosis of anaphylactic sensitivities to stinging insects and drugs.

Total Serum IgE

An elevated serum IgE level is one of the diagnostic criteria of allergic bronchopulmonary aspergillosis (ABPA). IgE levels can be used to follow the course of the disease. Serum IgE levels will fall when the disease is successfully treated with corticosteroids; rising IgE levels indicate disease exacerbations.

Total serum level of IgE is correlated with allergic disease in only a general way. Elevated levels are associated with the presence of allergy, while normal levels are not. However there are many individuals with clinical symptoms and allergen-specific IgE who have serum IgE levels within the normal range. Because of this, routine measurement of serum IgE is not a useful screening test for allergy.

IgG RAST/ELISA Testing

There is no evidence that IgG antibodies are responsible for delayed allergic symptoms or intolerance to foods.

ALCAT

ALCAT food allergy testing utilizes an indirect method of measuring mediator releases and the effects of other pathogenic mechanisms of allergy and delayed hypersensitivity. It employs semi-automated Coulter Electronics and fully automated computer analysis. **This automated testing has not been validated and has not been established as a useful allergy test in clinical practice**.

Cytotoxic Testing (Bryans Test)

Cytotoxic testing is based on the theory that the addition of a specific allergen to either whole blood or a serum leukocyte suspension from a suspected allergic patient will result in reduction of the white blood cell count or death of the leukocytes, thereby indicating the presence of an immune response. Controlled studies have failed to substantiate the value of cytotoxic testing for the diagnosis of allergies, whether they are airborne, foods, or chemicals.

ELISA/ACT

ELISA/ACT tests lymphocytes in a laboratory culture for their reaction to up to 300 purified foods, preservatives, chemicals and minerals. **This test is not FDA approved and is not established as a useful test in clinical practice**.

Food Immune Complex Assays (FICA)
FICA are based on the standard solid phase radioimmunoassay methodology. These assays have not yet been subjected to rigorous study of potential false-negative and false-positive results. Clinical studies to date indicate that circulating immune complexes can be found in a normal population of people having no food allergy. **The value of the measurement of FICA toward the diagnosis of food allergy remains unproven and does not have a place in current clinical practice**.

Rebuck Skin Window Test
Rebuck skin window test is an immunologic test in which the skin is abraded with a scalpel. Laboratory cover slips are placed over the abraded areas for 24 hours. The coverslips are then stained and analyzed. An immune deficiency may be present if there is an abnormality of monocytes displayed either by their absence or their inability to migrate to intracellular sites of antigen within 12 hours. **This test is not useful in documenting allergies since other immunodeficiency's can be found in patients with allergic conditions.**

Leukocyte Histamine Release Test
The leukocyte histamine release test is a measurement of the amount of histamine released in-vitro. Varying concentrations of an allergen extract are added to the patient`s peripheral blood leukocytes. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies. If an individual is atopic to a specific antigen, the leukocytes will not release the histamine in-vitro. **Only a limited number of allergens can be tested from a single aliquot of blood and quality control studies have shown considerable variability in the measurement of histamine results**.

Mediator Release Test
The mediator release test (MRT) (Signet Diagnostic Corporation) has primarily been used to detect intolerance to foods and additives in patients with irritable bowel syndrome.
The MRT-directed patient-specific diet is one component of the Lifestyle Eating and Performance (LEAP) Disease Management Program (Don Self & Associates, Inc., Whitehouse, TX). The LEAP program is based on the theory that symptoms irritable bowel syndrome and other certain conditions are caused by the physiological effects of non-IgE mediated immune reactions in response to sensitivities to specific foods and food additives.
According to the manufacturer, the LEAP program has been successful in reducing or eliminating symptoms in 84 percent of patients with irritable bowel syndrome, functional diarrhea, and related conditions. **However, there is no evidence in the peer-reviewed published medical literature to substantiate these claims**.

The mediator release test has also been promoted for use in patients with chronic fatigue syndrome, metabolic conditions (e.g., diabetes, obesity), gastrointestinal disorders (e.g., gastro esophageal reflux disease, chronic ulcerative colitis, and Crohn`s disease), neurologic disorders (e.g., migraine headaches, cluster headaches), rheumatologic disorders (inflammatory arthritis, arthralgia's, fibromyalgia), Otolaryngologic disorders (e.g., perennial rhinitis, chronic sinusitis,

chronic otitis media with effusion), dermatologic conditions (e.g., eczema, urticarial, dermatitis), and in patients with behavioral conditions (e.g., attention deficit disorder, hyperactivity, frequent mood swings, inability to concentrate). There are, however, no studies of the mediator release test reported in the peer-reviewed published medical literature that demonstrate improvements in clinical outcomes by incorporating the mediator release test and associated dietary modifications into the clinical management of patients with these conditions. **Thus, the mediator release test is considered experimental and investigational.**

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Addendum:

1) **Effective 04/01/2017**: Specified coverage limits for percutaneous and intracutaneous allergy testing. Clarified under limits that IgG testing (86001) is considered experimental and investigational. Added coverage for Bronchial Challenge testing with pre-authorization.

   Removed CPT codes 95010 & 95015 from policy. These codes were deleted 1/1/13 & replaced with 95017 & 95018. Also added the following CPT codes corresponding with Bronchial Challenge Testing coverage: 94070, 94150, 94200, 94350, 94360, 94620, 94621, 94680, 94681, 94690, 94720, & 94770.

   Retroactive to 01/01/2017 – No PA needed for the following CPT codes: 94010, 94060, and 94375.

2) **Effective 09/01/2017**: Removed CPT codes for PFT from BI and added the following statement: “For pulmonary function testing, please refer to BI542. Also updated “Codes Used in This BI” section to reflect updated changes.

3) **Effective 11/01/2017**: Skin Patch Testing: first 80 units is covered without prior authorization. Additional units require pre-authorization.

4) **Effective 3/8/2018**: Added new code for 2018.

5) **Effective 10/01/2018**: 95024 and 95028 have a maximum combined limit of 40 units per 12 months. Any additional units require prior authorization. Removed PA requirements for 95017, 95018 and 95027 (Skin serial endpoint titration (SET) for determination of a safe

starting dose for testing or immunotherapy): are covered for a cumulative total of 80 units per calendar year. Some types of allergy testing require evaluation by specialists.

6) **Effective 02/01/2019**: Updated codes in *Medical Policy Statement* section to align with system configuration.

7) **Effective 07/01/2020**: Added new code (0178U) with pre-authorization.

8) **Deleted code 95071** (eff 01-01-2021), **updated** revised code 95070 (eff 01-01-2021) and **added** codes 94617 and 94618 that were in the medical statement requiring PA and added to search box as well as description of codes in the codes used in this BI.

Application to Products

This policy applies to all health plans and products administered by QualChoice, both those insured by QualChoice and those that are self-funded by the sponsoring employer, unless there is indication in this policy otherwise or a stated exclusion in your medical plan booklet. Consult the individual plan sponsor Summary Plan Description (SPD) for self-insured plans or the specific Evidence of Coverage (EOC) or Certificate of Coverage (COC) for those plans or products insured by QualChoice. In the event of a discrepancy between this policy and a self-insured customer's SPD or the specific QualChoice EOC or COC, the SPD, EOC, or COC, as applicable, will prevail. State and federal mandates will be followed as they apply.

Changes: QualChoice reserves the right to alter, amend, change or supplement benefit interpretations as needed.