Clinical Policy Title: Allergy testing

Clinical Policy Number: CCP.1075

Effective Date: June 1, 2014
Initial Review Date: December 18, 2013
Most Recent Review Date: September 10, 2019
Next Review Date: January 2021

ABOUT THIS POLICY
AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

This policy addresses immediate (immunoglobulin E-mediated) hypersensitivity and delayed (cell-mediated) hypersensitivity allergy testing.

Allergy testing is clinically proven and, therefore, medically necessary for members age 2 years and older when the following general and test-specific criteria are met (Boyce, 2010; Fonacier, 2015; Golden, 2017; Joint Task Force, 1995; Sampson, 2014; Seidman, 2015):

- General criteria (all criteria must be met):
  - Clinically significant symptoms documented in an allergy-focused history.
  - Test correlates to the member’s allergy-focused clinical presentation (i.e., testing for antigens to which it is reasonably possible for the member to be exposed).
  - Test method and/or allergens tested have been scientifically validated.
  - Tests are performed by a licensed provider acting within their scope of practice to perform allergy and immunology services.

- Medically necessary allergy tests and specific criteria:
  - Percutaneous (skin scratch or prick) tests for suspected immunoglobulin E-mediated allergies to foods, inhaled allergens, stinging insect venom, or specific drugs (Bernstein, 2008; Golden, 2017).
- Skin endpoint titration for members highly allergic to stinging insect venom or inhaled allergens, with both of the following:
  - Determination of starting dose for testing or immunotherapy.
  - Testing in facility equipped to manage anaphylaxis.
- Intradermal testing for inhalant allergens, either:
  - When percutaneous tests are negative.
  - When using delayed hypersensitivity of the tuberculin type.
- Patch testing for suspected contact allergy.
- Repeated open application testing for a negative or inconclusive patch test.
- Photo testing or photo-patch testing for suspected contact allergy resulting from light exposure.
- Specific immunoglobulin E in vitro testing, either:
  - After inconclusive percutaneous tests.
  - In lieu of percutaneous skin testing for one of the following:
    - Inability to temporarily discontinue skin test suppressive medication therapy (e.g., antidepressants or beta blockers).
    - Presence of widespread skin disease (e.g., dermatographism or generalized eczema).
    - Uncooperative members.
    - Clinical history suggesting an unusually elevated risk of anaphylaxis from skin testing.
- Total serum immunoglobulin E testing for:
  - Presence of allergic bronchopulmonary aspergillosis.
  - Select immunodeficiencies (hyper-immunoglobulin E).
  - Eczematous or atopic dermatitis.
  - Suitability and dosing for omalizumab therapy.
- Double-blind, placebo-controlled oral challenge test (Sampson, 2014).
- Inhalation challenge for suspected immunoglobulin E-mediated hypersensitivity, either (Joint Task Force, 1995):
  - To establish a causative agent to an occupational exposure.
  - To evaluate therapeutic effectiveness of medications and immunotherapy.
  - When skin tests cannot be performed.
  - In combination with in vitro tests to evaluate specific immunoglobulin E-mediated sensitivity.

**Limitations:**

The number of allergens to be tested per member over a 12-month period is limited to (Bernstein, 2008; Centers for Medicare & Medicaid Services local coverage article A54842):

- Skin prick/puncture tests — 70 allergens. An additional 70 prick/puncture tests may be approved if the initial tests are negative or inconclusive.
• Intracutaneous tests — 40 allergens.
• Patch tests — 55 allergens.
• In vitro immunoglobulin E testing — 30 allergens.

In vitro allergy testing is not medically necessary for members:
• With no contraindications to skin testing.
• Who respond successfully to empiric therapy for allergy.
• With mild symptoms.
• In combination with a skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both tests may be indicated.

Routine or annual use of a large number of skin tests in the absence of a definitive clinical indication is not medically necessary, except venom skin tests, which may require a repeat test at three- to six-month intervals when the initial test is negative (Golden, 2017).

Routine use of in vitro tests for delayed hypersensitivity to contact allergens (e.g., metals and bone cement) is not medically necessary.

If photo patch tests (CPT 95052) are performed for the same antigen and in the same session with patch or application tests (CPT 95044), only the photo patch tests should be reported.

If photo tests are performed with patch or application tests, only the photo tests should be reported.

Tests considered not medically necessary due to insufficient evidence of efficacy include, but are not limited to (Bernstein, 2008; Boyce, 2010; Golden, 2017; Local coverage article A54842):
• Antigen leukocyte cellular antibody automated food allergy testing.
• Applied kinesiology (Nambudripad’s allergy elimination test).
• Atopy patch test, except in patients with pediatric eosinophilic esophagitis to assess potential food triggers.
• Basophil/histamine release or activation.
• Candidiasis test.
• Chemical analysis of body tissue (e.g., hair).
• Chlorinated pesticides (serum).
• Component-resolved testing.
• Conjunctival challenge.
• C-reactive protein.
• Cytokine and cytokine receptor assay.
• Cytotoxicity assays.
• Electrodermal test (vega).
• ELISA/Act qualitative antibody testing.
• Endoscopic allergen provocation.
• Facial thermography.
• Food immune complex assay.
• Gastric juice analysis.
• Ingestion challenge food testing for diagnosing rheumatoid arthritis, depression, or respiratory disorders not associated with anaphylaxis or similar systemic reactions.
• Iridology.
• Lymphocytes (B or T subsets).
• Lymphocyte function assay.
• Lymphocyte stimulation.
• Mediator release assay.
• Prausnitz-Kustner or P-K testing (passive cutaneous transfer test).
• Provocation neutralization tests (subcutaneous or sublingual) for food allergies.
• Pulse test (pulse response test, reaginic pulse test).
• Rebut skin window test.
• Sage complement antigen test.
• Testing and desensitization for poison ivy, oak, or sumac.
• Multiple chemical sensitivity testing (a.k.a., idiopathic environmental intolerance, clinical ecological illness, clinical ecology, environmental illness, chemical autoimmune deficiency syndrome, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease).
• Specific immunoglobulin G testing (e.g., by radioallergosorbent or enzyme-linked immunosorbent assay).
• Total serum immunoglobulin G, immunoglobulin A, or immunoglobulin M testing.

Tests for the following allergens are not clinically proven or medically necessary, including (Bernstein, 2008; Local coverage article A54842):
• Cornstarch.
• Cotton.
• Formaldehyde.
• Newsprint.
• Non-pollen producing flowers (e.g., marigold, dandelion, honeysuckle).
• Orris root.
• Poison ivy, oak, or sumac.
• Smog.
• Sugar.
• Tobacco smoke.

**Alternative covered services:**
Physical examination.

**Background**

Allergies are acquired, rapid, usually predictable, and exaggerated immune system responses to otherwise harmless environmental allergens that are ingested, inhaled, or contacted. They affect as many as 30 percent of adults and 40 percent of children in the United States (Asthma and Allergy Foundation of America, 2015a). The most common allergens include drugs, food, insects, latex, pollen, pets, and mold.

Hypersensitivity to allergens may be immediate (i.e., immunoglobulin E-mediated) or delayed (cell-mediated). Most allergic reactions, such as hay fever or hypersensitivity to animal dander, are relatively mild and non-life-threatening, although accompanied by unpleasant symptoms (sneezing, eye irritation, or itching). Other reactions, such as anaphylaxis or severe asthma attacks, may be much more serious.

Diagnosis of allergies comprises personal and medical history to identify the causative allergen and allergy testing when diagnosis remains uncertain. Diagnostic modalities test for immediate (immunoglobulin E-mediated) and delayed (non-immunoglobulin E- or cell-mediated) hypersensitivity or reaction to rule in or rule out specific allergens. Allergy tests include skin patches or prick tests and intradermal tests with candidate allergens, tests involving cell types or chemicals that mediate hypersensitivity reactions (basophils, lymphocytes, or histamines), serologic tests (serum or allergen-specific immunoglobulin E), and physician-supervised challenge tests (Asthma and Allergy Foundation of America, 2015b).

**Searches**

We searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on July 10, 2019. Search terms were: “Immunologic tests” (MeSH), “Hypersensitivity” (MeSH), “Immune system diseases/chemistry” (MeSH), “Immune system diseases/diagnosis” (MeSH), “Immune system diseases/immunology” (MeSH), and free text terms “allergy test” and “allergy diagnosis.”

We included:
• **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

• **Guidelines based on systematic reviews.**

• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Consensus opinion suggests that (Bernstein, 2008; Boyce, 2010; Lieberman, 2010; National Institute for Health and Care Excellence, 2011):

- Available reviews cover all types of allergies in people of all ages, and generally concur that allergy testing should follow an allergy-focused history.
- Cost-effective testing strategies should begin with in vivo tests and progress to in vitro only when initial results are negative or equivocal.

The research literature on allergy testing is restricted to diagnostic accuracy studies. No reviews covered randomized controlled trials or other study types documenting improved outcomes with testing.

**Policy updates:**

The findings from a systematic review and meta-analysis of seven studies (n = 430 participants) (Nevis, 2016) suggest that skin-prick testing is accurate in discriminating subjects with or without allergic rhinitis, with a sensitivity and specificity of 85 percent and 77 percent, respectively. However, the diagnostic accuracy of intradermal testing for confirming skin-prick testing or as a stand-alone test is not as well established with only four studies identified.

In 2018, we added one systematic review of the diagnosis of food allergy (Soares-Weiser, 2014) and several evidence-based guidelines that represent the standard of care for allergy testing (Fonacier, 2015; Golden, 2017; Joint Task Force on Practice Parameters, representing 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, 1995; Sampson, 2014; Seidman, 2015). The policy ID was changed from CP# 17.01.03 to CCP.1075.

In 2019, we updated one guideline by the American College of Allergy, Asthma, & Immunology (Lieberman, 2015, replaces 2010) with no policy changes.

**References**
Professional society guidelines/other:


**Peer-reviewed references:**


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

110.11 Food allergy testing and treatment.

**Local Coverage Determinations:**

L33261 Allergy Testing.
L33417 Allergy Skin Testing.
L36241 Allergy Testing.
L36402 Allergy Testing.

A56320 Allergy testing revision to the Part A and Part B LCD (L33261).
A56559 Billing and Coding: Allergy Skin Testing (L33417).
A56558 Billing and Coding: Allergy Testing (L36241).
A54842 Response to Comments: Allergy Testing (L36402).

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>86001</td>
<td>Allergen specific IgG quantitative or semiquantitative, each allergen</td>
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<tr>
<td>86003</td>
<td>Allergen specific immunoglobulin E; quantitative or semiquantitative, each allergen</td>
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<tr>
<td>86005</td>
<td>Allergen specific immunoglobulin E; qualitative, multiallergen screen (dipstick, paddle, or disk)</td>
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<tr>
<td>86008</td>
<td>Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each</td>
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<tr>
<td>95004</td>
<td>Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<tr>
<td>95012</td>
<td>Nitric oxide expired gas determination</td>
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<tr>
<td>95017</td>
<td>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</td>
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<tr>
<td>95018</td>
<td>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</td>
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<td>95024</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<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, specify number of tests</td>
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<td>95028</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests</td>
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<td>95044</td>
<td>Patch or application tests(s) (specify number of tests)</td>
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<td>95052</td>
<td>Photo patch test(s) (specify number of tests)</td>
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<td>95056</td>
<td>Photo tests</td>
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<tr>
<td>95060</td>
<td>Ophthalmic mucous membrane tests</td>
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<td>95065</td>
<td>Direct nasal mucous membrane test</td>
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<td>95070</td>
<td>Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds</td>
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<td>95071</td>
<td>Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with antigens or gases, specify</td>
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<td>95115</td>
<td>Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection</td>
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<th>ICD-10 Code</th>
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<td>D69.0</td>
<td>Allergic purpura</td>
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<td>H10.45</td>
<td>Other chronic allergic conjunctivitis</td>
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<td>J30.1 - J30.9</td>
<td>Vasomotor and allergic rhinitis</td>
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<td>L20.84</td>
<td>Intrinsic (allergic) eczema</td>
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<td>L23.0-L23.9</td>
<td>Allergic contact dermatitis</td>
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<td>L27.0-L27.9</td>
<td>Dermatitis due to substances taken internally</td>
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<tr>
<td>L50.0</td>
<td>Allergic urticaria</td>
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<tr>
<td>Z91.010- Z91.09</td>
<td>Allergy status, other than to drugs and biological substances</td>
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<th>HCPCS Level II Code</th>
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