ALLERGY TESTING

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply.

UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BACKGROUND

Allergy is the fifth leading chronic disease in the United States, and allergy and asthma affects one in five Americans. Allergy is a type I hypersensitivity response mediated by immunoglobulin E (IgE). Following exposure to an allergen which binds to IgE on mast cells and basophils, these cells release mediators such as histamine that elicit an immediate response. Manifestations of this response include cutaneous, respiratory, cardiovascular, and gastrointestinal symptoms in addition to anaphylaxis, a potentially lethal reaction. IgE-mediated clinical conditions include hypersensitivity reactions to foods, insects, drugs, and latex; allergic rhinitis; asthma; urticaria; angioedema; atopic dermatitis; and allergic bronchopulmonary aspergillosis. Allergy tests are a crucial step in the management of these conditions.
The two most clinically utilized tests for allergy are office-based skins tests (in vivo testing) and laboratory tests that measure specific IgE antibodies (in vitro testing). Skin tests involve the introduction of an allergen extract into the skin by a prick or puncture technique or by an intradermal technique. The patient’s wheal-and-flare response is immediately measured. In studies using controlled provocation challenges, the sensitivity of prick/puncture tests has been reported to be 85-87% with a specificity of 79-86%. Intracutaneous tests are more sensitive than prick/puncture tests and are preferred for drug and venom anaphylaxis but are not recommended for food allergy testing due to potential dangers.

In vitro tests were first used in the late 1960s and were termed radioallergosorbent tests or RASTs. These tests used a gamma counter to quantify radioactively labeled IgE antibody bound to a solid-phase antigen on a paper disc. The radioactive assay has been replaced by a colorimetric assay, a fluoroimmunoassay, and a chemiluminescent assay. These assays are all calibrated against the World Health Organization 75/502 international human serum IgE reference preparation. The sensitivity of these assays compared to skin tests averages 70-75%, but it is notable that there is no gold standard for allergen-specific IgE testing by which to assess skin tests or in vitro tests. The three enzymatic assays may not yield the same results, and IgE levels from differing assays may not be interchangeable. For this reason, it is desirable to use the same assay over time for a patient.

Skin tests are more often utilized than serologic tests for the diagnosis of allergy, but there are certain situations where skin tests are not preferable. Histamine antagonists, antidepressants, and long-term, high-dose glucocorticoid therapy affect skin test results. Skin tests should not be performed at the site of active dermatitis, severe dermatographism or topical application of corticosteroids. Other situations where serologic tests may be more appropriate include patients with a history of dangerous allergic reactions, patients who have discordance between exposure history and skin test results, and uncooperative patients or those preferring in vitro testing. Neither of the tests will detect drug-induced allergies that are not mediated by type I hypersensitivity, such as Stevens-Johnson syndrome, which is mediated by immune complexes. These tests will not detect celiac disease.

Allergy testing is indicated when the clinical history suggests allergic rhinitis, asthma, hypersensitivity, atopic dermatitis or urticarial disorders. Screening of the general population is not recommended. Symptoms of allergy include sneezing, postnasal drip, nasal discharge, and conjunctivitis, and complications include otitis media and sinusitis. Food allergies can present with urticaria (hives), angioedema (swelling under the skin), cough, wheezing, nausea/vomiting, and anaphylaxis. Fifty percent of asthma cases are attributed to an allergic etiology, and national guidelines recommend that patients with persistent asthma should be evaluated for allergy. In these cases a multiallergen test with up to fifteen allergens bound to a linear solid-phase system can be used to screen for atopy, with follow-up for allergen-specific tests. The multiallergen screen has the highest negative predictive value of any single laboratory test for atopy.

Selection of extracts for allergy testing is based on patient history and symptomology in addition to possible environmental exposures. Animal allergies rarely cause dermatologic symptoms; food allergies generally do not cause respiratory symptoms. Patients with perennial allergies are usually tested for sensitivity to house dust mite, fungus, cockroach, and animal dander or urine. Seasonal allergy testing should take into account the regional flora. Selection of testing for food allergies can be aided by information gleaned from the patient’s history and food diary.
Results of skin and serologic allergy tests are considered in combination with the clinical findings. With some exceptions, allergen-specific serum IgE levels greater than 0.35 kU/L suggest sensitization. Although individuals with positive tests to certain allergens sometimes do not react when exposed to the allergen, studies suggest a strong reaction could predict future allergies. Nonetheless, treatment is only indicated for those patients with allergies with a basis in the clinical history. Allergy immunotherapy is not driven solely by laboratory tests.

Allergen immunotherapy (known in lay parlance as allergy shots) is based on the findings of skin or serum allergy testing in combination with the clinical history. This therapy exposes patients in a controlled fashion to specific allergens with the aim of achieving symptom remission. Studies have shown that allergy immunotherapy may prevent asthma in patients with allergic rhinitis. Patients receiving immunotherapy for allergy usually experience an initial increase in specific IgE antibody levels with a subsequent decrease in these levels over time. Patients note improvement of symptoms before the levels decrease, and a decrease in specific IgE levels is not necessary for immunotherapy to be efficacious.

Another therapy that has been approved by the FDA for allergic asthma is omalizumab, a monoclonal anti-immunoglobulin E antibody. Because omalizumab-bound IgE has a longer half-life, omalizumab elevates patients’ IgE from baseline. Nonetheless, total and allergen-specific antibody can be reliably measured during omalizumab therapy with the ImmunoCAP assay but not with the other two commercially available assays.

The measurement of total serum IgE has several clinical uses. In patients on omalizumab therapy, the total serum IgE is used to determine if therapy is indicated for the patient and to determine the starting dose. Levels between 70 and 800 IU/mL are suitable for treatment with omalizumab. This level and the patient’s weight are used to establish the initial dose. Repeat testing after a month of therapy is used to monitor therapy. Total serum IgE is also used in the diagnosis and management of allergic bronchopulmonary aspergillosis (ABPA).

Diagnostic criteria for ABPA include the total IgE level, and a normal IgE level excludes diagnosis of ABPA. Total IgE levels are followed to assess efficacy of treatment and to diagnose remission.

Other causes for increased total IgE include HIV, parasitic disease, nephrotic syndrome, systemic lupus erythematosus, dermatologic conditions such as alopecia areata, and neoplasia. IgE myeloma tends to occur at an advanced age and has a more accelerated course to death than the other myelomas. IgE levels are elevated and serum protein electrophoresis detects a monoclonal spike. Total IgE is also elevated in hyper-immunoglobulin E syndrome, characterized by eczematous dermatitis and recurrent pyogenic infections. In contrast to these examples of increased total serum IgE, there is a condition of IgE deficiency associated with sinopulmonary disease, autoimmune disease, and arthralgias.

**POLICY**

For the following CPT code(s) in Table 1, the patient should have a diagnosis (ICD-10-CM) code(s) listed in the attached files below.
Table 1. HCPCS Codes (Alphanumeric, CPT® AMA)

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>86003</td>
<td>Allergy specific IgE; quantitative or semiquantitative, crude allergen extract, each</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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ICD-10 Diagnosis Codes (Proven)
REFERENCES


2. Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma, and Immunology; American College of Allergy, Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. J Allergy Clin Immunol. 2007;129:525-85.


<table>
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<tr>
<th>Date</th>
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<tr>
<td>12/07/2017</td>
<td>Annual Policy Review Completed: Added 2018 CPT code 86008. Updated description for CPT 86003 as per AMA. Updated ICD10 codes as per CMS recommendations.</td>
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<tr>
<td>01/21/2017</td>
<td>Updated ICD10 codes as per CMS recommendations. Removed ICD9 code file.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>Removed ICD9 table. Embedded ICD9/ICD10 PDF files.</td>
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