



**IN VITRO IgE ANTIBODY  
ALLERGY TESTING  
HS-190**



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**In Vitro IgE Antibody  
Allergy Testing**

**Policy Number: HS-190**

**Original Effective Date: 9/23/2010**

**Revised Date(s): 9/1/2011**

**DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## BACKGROUND

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 National Asthma Education Program Expert Panel Report (2007) recommends the use of skin testing or in vitro IgE antibody testing to determine the presence of specific IgE antibodies to the allergens to which the patient is exposed. The Expert Panel concluded that allergy skin or in vitro IgE antibody tests are reliable in determining the presence of specific IgE. The Expert Panel Report stated that either skin tests or in vitro IgE antibody tests can be used to assess specific IgE sensitization to *Aspergillus* in persons suspected of having allergic bronchopulmonary aspergillosis.

According to the National Asthma Education and Prevention Program *Guidelines for the Diagnosis and Management of Asthma*, advantages of RAST and other in vitro tests over skin tests include the fact that they do not require knowledge of skin testing technique, they do not require availability of allergen extracts, they can be performed on patients who are taking medications that suppress the immediate skin test (e.g., antihistamines, antidepressants), they carry no risk of systemic reactions, and they can be done on patients with extensive eczema. Despite the advantages, there are two major concerns limiting the use of in-vitro tests for allergen-specific IgE in the United States. The first limitation is the rather consistent finding that in-vitro tests are not as sensitive as skin tests for detecting allergen-specific IgE. The second limitation is that on a per test basis skin tests have lower time and reagent costs. Other advantages of skin tests are that they are faster (results are available within an hour), and the results are visible to the patient (this may enhance patient compliance). A variety of modifications have been made to tests related to RAST (such as MAST, PRIST, RIST, FAST, MRT, VAST, ELISA, and ImmunoCAP).

ImmunoCAP (Pharmacia Diagnostics, Clayton, N.C.) is an in vitro-specific immunoglobulin E test that uses a three-dimensional cellulose solid allergen phase; by contrast, the older modified Phadezym-Rast (Pharmacia Diagnostics) uses a two-dimensional solid phase. The ImmunoCAP provides more rapid results (available in 6 hours) compared to traditional RAST tests (Phadezym-RAST results take 3 days to obtain). With the ImmunoCAP, solid-phase bound allergens are allowed to react with IgE antibodies in the sample; the IgE antibodies are detected by labeled anti-IgE. To minimize handling and increase safety, the system includes instrumentation and computer software that handles the technical manipulations, the measurements and the data management. The assays is calibrated against the WHO standard for IgE and includes two sets of calibrators, one for specific IgE Ab and low range total IgE, and the other for wide range total IgE. Results from published studies report the overall sensitivity and specificity of different allergens compared to expert clinical diagnosis range from 78-94% and 77-94% respectively.

### *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.

A 2011 update by Hayes stated the result of a literature review of 5 abstracts, including clinical and case studies and results from the National Health and Nutrition Examination Survey (NHANES). Information further establishes the efficacy of testing (Ciprandi, De Amici, Giunta & Marseglia, 2010; Ciprandi, DeAmici, & Marseglia 2011;

Gadisseur, Chapelle, & Cavalier, 2010; Linden et al., 2011).

The NHANES studied levels of serum total and allergen-specific IgE in the American population and found a strong correlation between self-reported allergy symptoms and high levels of plant-, pet-, and mold-specific IgE (Salo et al., 2011).

## **POSITION STATEMENT**

In Vitro IgE Antibody Tests (RAST, MAST, FAST, ELISA, ImmunoCAP) **are considered medically necessary** for:

- **516.8** Allergic bronchopulmonary aspergillosis (ABPA and certain parasitic diseases); **OR**,
- **693.1** Food allergy; **OR**,
- **989.5** Stinging insects (hymenoptera venom allergy); **OR**,
- **477.0 - 477.9** Inhalant allergy; **OR**,
- **995.27** Drug Allergy; i.e. adverse effect of specific drug(s) correct medicinal substance properly administered

NOTE: In vitro tests MAY BE medically necessary for the initial allergy screen in lieu of skin testing in certain situations (i.e. member has serious skin condition, skin tests are inconclusive). An initial allergy screen is comprised of 12 tests. Additional tests may be medically necessary if any of the initial test results are positive. If all test results are negative, additional testing beyond the initial allergy screen of 12 tests/allergens is not considered medically necessary.

NOTE: Routine allergy re-testing is NOT considered medically necessary.

## **CODING**

### **Covered CPT® Codes**

- 86003** Allergen specific IgE; quantitative or semiquantitative, each allergen  
**86005** Allergen specific IgE; qualitative, multiallergen screen (dipstick, paddle or disk)

**ICD-9-CM Procedure Code** - No applicable code

**HCPCS Level II® Codes** - No Applicable code

### **Covered ICD-9-CM Diagnosis Codes**

- 477.0 - 477.9** Allergic rhinitis due to pollen, food, animal hair and dander, other allergen and unspecified cause  
**518.6** Allergic bronchopulmonary aspergillosis  
**691.8** Other atopic dermatitis and related conditions  
**692.3** Contact dermatitis and other eczema due to drugs and medicines in contact with skin  
**692.5** Contact dermatitis and other eczema due to food in contact with skin  
**693.1** Dermatitis due to food taken internally  
**708.0** Allergic urticaria  
**989.5** Toxic effect of venom; Bites of venomous snakes, lizards and spiders; tick  
**995.27** Other drug allergy  
**995.60 - 995.69** Anaphylactic shock due to adverse food reaction  
**995.7** Other adverse food reactions, not elsewhere classified

\*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

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## **HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
12/1/2011	<ul style="list-style-type: none"><li>• New template design approved by MPC.</li></ul>
9/1/2011	<ul style="list-style-type: none"><li>• Approved by MPC.</li></ul>