Medica Coverage Policy

Policy Name:	**Food Allergy / Intolerance Testing (in vitro)**
Effective Date:	**11/18/2019**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Note: This policy is no longer scheduled for routine review of the scientific literature.

Food allergy testing (in vitro) of food allergen specific serum IgE, is **COVERED** in patients with clinically suspected food allergy.

Food allergy testing (in vitro) of food allergen specific serum IgG or IgG4 is investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Food allergy/intolerance testing (in vitro) of serum or saliva IgA is investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See related Medica coverage policies: *Cytotoxic Testing for Allergy Diagnosis; Sublingual, Oral or Intranasal Allergenic Extracts for Allergy Diagnosis and/or Immunotherapy; Antigen Leukocyte Cellular Antibody Test (ALCAT Test) for Food & Chemical Allergies; Salivary Hormone Tests.*

Description

Food allergy (FA) has no universally accepted definition. It has been suggested that a FA may be defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food and is distinct from other adverse responses to food, such as food intolerance, pharmacologic reactions, and toxin-mediated reactions. FA is usually mediated by IgE antibody directed to specific food proteins, but other immunologic mechanisms can also play a role. The primary target organs for food allergic reactions are the skin, the gastrointestinal tract and the respiratory system. Both acute reactions (hives and anaphylaxis) and chronic disease (asthma, atopic dermatitis and gastrointestinal disorders) may be caused or exacerbated by FA. The diagnosis of FA remains a clinical exercise dependent upon a careful history, selective skin tests or *in vitro* measurement of food-specific IgE, appropriate exclusion diet and blinded food challenge test.

Allergy testing can be grouped into *in vivo* and *in vitro* methodologies. *In vivo* methodologies include allergy skin testing such as the prick test (percutaneous), the patch test (epicutaneous), and the intradermal test (intracutaneous). Two additional *in vivo* tests are available for food allergies: the food challenge test (patients are given small amounts of potential food allergens and monitored for a response) and the elimination test (patients eliminate from their diet foods that they suspect are causing an allergic reaction and then re-introduce these foods one by one to see which ones cause a reaction). *In vitro* tests may include various techniques to test the blood for the presence of specific immunoglobulin antibodies (e.g. IgE) to a particular antigen or the ability of certain blood components to react in the presence of certain antigens. The presence of antigen-specific IgE antibody can be determined using *in vitro* methodology such as the radioallergosorbent test (RAST) or a quantitative enzyme-linked immunosorbent assay that measure the amount of circulating allergen-specific IgE in the serum in kilounits of allergen-specific IgE per liter. Food allergen-specific IgE levels aid in predicting the likelihood of a reaction, but do not predict reaction severity. *In vitro* tests offer the advantages of safety (no danger of anaphylaxis), they are not dependent on skin condition, and patients on antihistamines do not need to discontinue their medications.

Some clinical laboratories offer quantitative measurements of circulating IgG antibodies to food and mold allergens. Low-level IgG antibodies to foods may circulate normally, but they are of no known pathogenic significance in atopic disease. Although some researchers have postulated that IgG antibodies may be responsible for delayed symptoms or vague intolerance to foods, there is as yet no proof of this claim.

Food intolerance, known as non-allergic food hypersensitivity, is a term used for varied physiological responses associated with a particular food. It is not a true food allergy. A food intolerance, e.g., lactose intolerance, can cause some of the same signs and symptoms as a food allergy, but the symptoms generally come on gradually, are less serious, are limited to digestive problems, and do not involve an immune system reaction. A person may be able to eat the offending food without trouble. Some clinical laboratories offer quantitative measurements of IgA antibodies to food. Some researchers have theorized that IgA antibodies may be responsible for intolerance to foods.

FDA Approval
Multiple food allergy tests have received FDA approval, including but not limited to:
1. ImmunoCAP Allergen f338, Scallop (Phadia US Inc, Portage, MI).
2. IMMULITE® 2000 3g Allergy™ Specific IgE Assay (Siemans Healthcare Diagnostics Inc. CA).
3. HY*TEC™ Extended Specific IgE EIA, MCS Assay using the Tecan Freedom EVO® RSP 200.

Saliva tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) or 1988. FDA market approval is not required so long as the assay is performed in a laboratory facility that observes the CLIA regulations and does not market the test for distribution.

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT codes:
- **82784** - Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
- **86001** - Allergen specific IgG quantitative or semiquantitative, each Allergen
- **86003** - Allergen specific IgE; quantitative or semiquantitative, each allergen
- **86005** - Allergen specific IgE; qualitative, multiallergen screen (dipstick, paddle, or disk)

- **86008** - Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each

Original Effective Date:	12/1/2010
Re-Review Date(s):	8/27/2013 9/21/2016 1/1/2018 – administrative update; codes added 9/18/2019 – Clinical Review Reserve 2/10/2020 – administrative update; format.