

Allergy Testing

CPT: 86003, 86008

CMS Policy for Delaware, Maryland, New Jersey, Pennsylvania, Virginia (Suburbs), and Washington, D.C.

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier. Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and Subsequent medical review audits.

Allergy Testing

In order for allergy testing to be considered reasonable and necessary by Medicare, antigens must meet all the following criteria;

- Skin testing must be performed based on history and physical exam,
- Proven efficacy as demonstrated through scientifically valid medical studies published in peer-review journal, and
- Exist in the patient's environment with a reasonable probability of exposure.

.In Vivo Testing:

1. Allergy Sensitivity Testing

These tests include the performance and evaluation of selective cutaneous and mucous membrane tests in correlation with history, physician examination, and other observations of the patient. The tests are performed to determine body sensitivity and reaction to the antigen for the purpose of diagnosing the presence of allergic reaction to antigenic stimuli.

The number of tests performed should be judicious and dependent upon the history, physical findings and clinical judgment. All patients should not necessarily receive the same tests or the same number of sensitivity tests. Rather testing should be patient specific based on the history and physical examination. These tests are injection of small amounts of antigen into the superficial layers of the skin. This is the preferred method for allergy testing. Medicare considers percutaneous (scratch, prick or puncture) testing medically reasonable and necessary when IgE-Medicated reactions occur to any of the following

- Inhalants
- Foods
- Hymenoptera (stinging insects)
- Specific drugs (such as penicillin or macromolecular agents)

2. Patch Testing

Patch testing is the gold standard method of identifying the cause of allergic contact dermatitis. This testing is indicated to evaluate a nonspecific dermatitis, allergic contact dermatitis, pruritus, and other dermatitis to determine the causative antigen. It is a diagnostic test reserved for patients with skin eruptions for which a contact allergy source is likely.

The patch test procedure can induce an eczematous reaction in miniature by applying suspect allergens to normal skin, allowing the physician to determine a specific patient allergy. Patch tests are applied to the skin on the patient's back and left in place for 48 hours. The test is interpreted after 48 hours, and typically once again at 72 hours or 96 hours, and the reactions are systemically scored and recorded. The patient is then informed and educated regarding specific allergies and avoidance of exposure. Avoidance of the identified allergen(s) is critical to patient improvement and resolution of the dermatitis.

Allergy patch testing is a covered procedure only when used to diagnose allergic contact dermatitis after the following exposures: dermatitis due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other chemical products, food in contact with skin, plants (except food), cosmetics, metals, other and unspecified.

Examples of contact allergens (antigens) include nickel, rubber additives, and topical antibiotics.

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CPT: 86003, 86008

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3. *Provocative Tests.*

Provocative tests for which there is limited or no evidence of validity include: the cytotoxic test, the provocation-neutralization procedure, electrodermal diagnosis, applied kinesiology, the 'reaginic' pulse test and chemical analysis of body tissues. Controlled studies for the cytotoxic and provocation-neutralization tests demonstrated that the results are not reproducible and do not correlate with clinical evidence of allergy. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. Similarly, the 'reaginic' pulse test and chemical analysis of body tissues for various exogenous chemicals have not been substantiated as valid tests for allergy.

- a. Organ challenge test material may be applied to the mucosae of the conjunctivae, nares, GI tract, or bronchi. Considerable experience with these methods is required for proper interpretation and analysis
- b. All organ challenge tests should be preceded by a control test with diluent and, if possible, the procedure should be performed on a double blind or at least single, blind basis.
- c. Direct nasal mucus membrane challenge testing may be informative provided that the patient's nasal mucosa does not manifest nonspecific irritative responses and the results can be interpreted by objective measurements. Ophthalmic mucous membrane test and direct nasal mucous membrane tests are considered reasonable and necessary if levels of allergic mediators (such as histamine and tryptase) are measured and a placebo control is performed. This is usually performed in the office setting if the physician is there to observe objective measurement of reactions which might include redness of the eyes, tearing and sneezing.
- d. Inhalation bronchial challenge tests are often used to evaluate new allergens and may be used to substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples.
 - Inhalation bronchial challenge tests should be performed as dose-response assays wherein provocation concentration thresholds can be determined on the basis of allergen concentration required to cause a significant decrease in pulmonary function measurements.
 - Inhalation bronchial challenge tests with occupation allergens need to be carefully controlled with respect to dose and duration of exposure. When industrial small molecular weight agents are assessed, tests should be performed under continuous monitoring of the specific chemical being assessed so as not to exceed the threshold limit level permitted in the workplace.
- e. Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure, when considered reasonable and necessary for the individual patient, is covered on an outpatient basis. Please refer to CMS Pub. 100-03, Medicare National Coverage Determination Manual, Chapter 1, Part 2, Section 110.12.

Medicare will consider challenge ingestion food testing reasonable and necessary for the following indications:

- *Food allergy dermatitis;
- *Anaphylactic shock due to adverse food reaction;
- *Allergy to medicinal agents;
- *Allergy to foods.

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of Section 1862 (a)(1) of Medicare law. Therefore, this service is considered non-covered.

4. *Intracutaneous testing, delayed reaction*

More than 6 tests may be covered but requires additional justification and case-by-case review for the number of tests performed and the medical necessity except when the skin test is used for collagen implant therapy: A collagen sensitivity test must be administered prior to collagen implant therapy (injectable bulking agent implantation) for Urinary Incontinence, and it must be evaluated over a four week period. Coverage Issues Section 65-9.

5. *Intradermal Dilutional Testing (IDT) (also known as Skin Endpoint Titration (SET))*

Intradermal dilutional testing is intradermal testing of sequential and incremental dilutions of a single antigen. The endpoint is determined by intradermal testing with the use of approximately 0.1ml of generally serial five-fold dilution extract. It is the weakest dilution that produces a positive skin reaction and initiates progressive increase in the diameter of the wheals with each stronger dilution.

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- ***In Vitro Testing:***

Specific IgE In Vitro Test (for example RAST, MAST, FAST, ImmunoCap)

These tests detect antigen-specific IgE antibodies in the patient's serum. They are useful when testing for inhalant allergens (pollens, molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs or latex, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism or in children younger than four years of age. In-vitro testing is considered reasonable and necessary when skin testing is not possible or would be unreliable as indicated below. In-vitro testing is not considered reasonable and necessary when done in addition to skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed. The number of tests done, choices of antigens, frequency of repetition and other coverage issues are the same as for skin testing.

Control testing is essential for proper interpretation. It is rarely necessary to test for more than 50 allergens and, if food allergy is not suspected, fewer than 30 are usually sufficient. Testing must be based on a careful history/physical examination which suggests IgE-mediated disease. If testing is inconclusive, and contraindications have been resolved, then skin testing may be done and is considered reasonable and necessary. The medical records must document this rationale.

In-vitro allergen specific IgE testing is limited to the following:

- Direct skin testing is not possible due to extensive dermatitis, dermatographism, ichthyosis, generalized eczema or the necessary continued use of H-1 blockers (antihistamines), or in the rare patient with a persistent unexplained negative histamine control;
- Testing in patients who have been receiving long acting antihistamines, tricyclic antidepressants, beta-blockers or medication that may put the patient at undue risk if they are discontinued;
- Testing of uncooperative patients with mental or physical impairments;
- The evaluation of cross-reactivity between insect venoms;
- As adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases; and
- When clinical history suggests an unusually greater risk of anaphylaxis from skin testing than usual (e.g., when an unusual allergen is not available as a licensed skin test extract).
- Total serum IgE: Measurements of total IgE levels (CPT code 82785-gammaglobulin {immunoglobulin}; IgE) are not appropriate in most general allergy testing which is performed to determine a patient's immunologic sensitivity or reaction to particular allergens for the purpose of identifying the cause of the allergic state. It would not be expected that total serum IgE levels would be billed unless evidence exists for the following:
 - follow-up of bronchopulmonary aspergillosis,
 - to diagnose atopy in small children,
 - select immunodeficiency, such as the syndrome of hyper-IgE,
 - eczematous dermatitis,
 - recurrent pyogenic infections, or
 - in the evaluation of omalizumab therapy.
- Serial, repeat testing of total IgE will be subject to medical review. It is not appropriate in most general allergy testing. Instead, individual IgE tests are performed against a specific antigen.

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Limitations

1. The following tests are considered not medically reasonable and necessary

- Provocative testing other than those mentioned above
- Blood, Urine or Stool micronutrient assessments
- Qualification of Nutritional Assessments
- IgG (ELISA) test
- Environmental Cultures and Chemicals
- Live Cell Analysis
- Passive Transfer
- Rebeck Skin Window
- Leukocyte Histamine Release
- Metabolic Assessments
- General Immune System Assessments
- Secretory IgA (Saliva)
- Qualitative multi-allergen screen
- Food Allergenic Extract Immunotherapy
- Cytotoxic Food Testing

2. Allergen specific IgE; qualitative, multiallergen screen is a non-specific screen that does not identify a specific antigen. This is a screening tool and therefore not covered by Medicare.

3. NCD 110.11 outlines limitations for food allergy testing and treatment. Refer to CMS Manual System, Pub 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, Section 110.11 for details.

4. In-vitro testing is covered when medically reasonable and necessary as a substitute for skin testing; it is not usually necessary in addition to skin testing.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862 (a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary);
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical needs;
 - At least as beneficial as an existing and available medically appropriate alternative.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

The number of tests performed should be judicious. All patients should not necessarily be tested for the same antigens.

In-vitro testing (CPT 86003) is covered when medically reasonable and necessary as a substitute for skin testing; it is not usually necessary in addition to skin testing.

CPT code 86005 is considered screening and will be denied.

CPT code 86001 is considered not medically reasonable and necessary as it is considered experimental and investigational.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

***Note—Bolded diagnoses below have the highest utilization**

| Code | Description |
|---------------|---|
| J30.1 | Allergic rhinitis due to pollen |
| J30.2 | Other seasonal allergic rhinitis |
| J30.81 | Allergic rhinitis due to animal (cat) (dog) hair and dander |
| J30.89 | Other allergic rhinitis |
| J31.0 | Chronic rhinitis |
| J45.20 | Mild intermittent asthma, uncomplicated |
| J45.30 | Mild persistent asthma, uncomplicated |
| J45.40 | Moderate persistent asthma, uncomplicated |
| J45.50 | Severe persistent asthma, uncomplicated |
| J45.998 | Other asthma |
| L20.84 | Intrinsic (allergic) eczema |
| L20.89 | Other atopic dermatitis |
| L27.2 | Dermatitis due to ingested food |
| L50.0 | Allergic urticaria |
| L50.1 | Idiopathic urticaria |
| L50.8 | Other urticaria |
| T78.02XA | Anaphylactic reaction due to shellfish (crustaceans), initial encounter |
| T78.04XA | Anaphylactic reaction due to fruits and vegetables, initial encounter |
| T78.05XA | Anaphylactic reaction due to tree nuts and seeds, initial encounter |
| T78.49XA | Other allergy, initial encounter |

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Disclaimer:

This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Quest Diagnostics does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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