

Local Coverage Determination (LCD): Allergy Testing (L34313)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada

LCD Information

Document Information

LCD ID

L34313

LCD Title

Allergy Testing

Proposed LCD in Comment Period

N/A

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 10/01/2019

Revision Ending Date

N/A

Retirement Date

N/A

Source Proposed LCD

N/A

Notice Period Start Date

N/A

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Notice Period End Date

N/A

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), 1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Title XVIII of the Social Security Act, 1862(a)(7) and 42 Code of Federal Regulations, §411.15, exclude routine physical examinations.

Title XVIII of the Social Security Act, 1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations Manual*, Chapter 1, Part 2, §110.11; food allergy testing and treatment.

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 12, §200; allergy testing and immunotherapy.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Allergy refers to conditions in which immune responses to environmental antigens cause tissue inflammation and organ dysfunction. Allergy testing is performed to determine immunologic sensitivity or reaction to antigens for the purpose of identifying the cause of the allergic state. This policy addresses immediate (IgE-mediated) hypersensitivity and delayed (cell mediated) hypersensitivity. In vivo allergy sensitivity testing correlates the performance and evaluation of selective cutaneous and mucous membrane tests with the patient's history, physical examination, and other observations. Immediate hypersensitivity may also be tested in vitro by measurement of allergen-specific serum IgE. Under certain limited conditions, this is covered by Medicare Part B. Immediate hypersensitivity skin testing is important in the diagnosis of IgE mediated inhalant, food, venom; and penicillin allergies, delayed hypersensitivity testing is more often helpful in the diagnosis of contact dermatitis and the clinical evaluation of cell-mediated immunity.

INDICATIONS

Allergy testing is allowed when it has proven efficacy as demonstrated through scientifically valid peer reviewed published medical studies.

- A complete medical and immunologic history and appropriate physical examination must be done prior to performing diagnostic testing.
- The testing must be performed based on this history and a physical exam, which documents that the antigen being used for testing exists with a reasonable probability of exposure in the patient's environment.
- It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number of tests performed must be judicious and related to the history, physical findings, and clinical judgment specific to each individual.

General Information

In vivo immunologic tests have been shown to be reliable and valid diagnostic tools and include skin tests with standardized allergenic extracts by prick, puncture, and intradermal techniques, skin end-point titration, and patch testing.

- **Percutaneous Testing** remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected. Percutaneous tests require medical supervision, since there is a small but significant risk of anaphylaxis. Overall, skin testing is quick, safe, and cost-effective.
- **Intracutaneous/Intradermal Tests** are usually performed when increased sensitivity is the main goal such as when percutaneous tests are negative and there is a strong suspicion of allergen sensitivity. The usual testing program may include 2 concentrations of an extract: a weaker concentration and a stronger concentration. It would not be expected that 3 or more concentrations of one extract would be medically necessary.
- **Skin End Point Titration Testing** analyzes the highest dilution of a substance that produces a reaction, and

may be used to determine the starting dose(s) of allergen immunotherapy.

- **Delayed Hypersensitivity Skin Testing** has been commonly used in three ways: anergy testing, testing for infection with intracellular pathogens, and testing for sensitivity to contact allergens. Accurate testing for contact allergy requires careful attention to technique, and limitation of testing to the specific allergens known to be associated with a contact reaction.
- **Photo Testing** is skin irradiation with a specific range of ultraviolet light. Photo tests are performed for the evaluation of photosensitivity disorders.
- **Patch Testing** is indicated to evaluate a nonspecific dermatitis, allergic contact dermatitis, pruritus, and other dermatitis to determine the causative antigen.
- **Photo Patch Testing** uses two patches, with one of them being irradiated with ultraviolet light half way through the occlusive period. It is indicated to evaluate unique allergies resulting from light exposure.
- **Ophthalmic Mucous Membrane Tests and Direct Nasal Mucous Membrane Tests** are rarely indicated. They are allowed when skin testing cannot test allergens.
- **Inhalation Bronchial Challenge Testing** involves the inhalation of agents that can trigger respiratory responses. The agents include drugs that cause airway constriction, antigens and chemical sensitizers usually related to occupational breathing problems. Pulmonary function studies are not included in the bronchial challenge test. Generally three measures of each determination (e.g., spirometry, prolonged post exposure evaluation of bronchospasm) are performed. The best of the three is accepted and represents one unit of service. A unit is defined as each set of three measurements.
- **Ingestion Challenge Test** involves the administration of sequentially or incrementally larger doses of the test item. The test items may include food or antibiotics. The service is allowed once per patient encounter, regardless of the number of items tested, and includes evaluation of the patient's response to the test items.

LIMITATIONS

- **Ingestion challenge food testing** performed by the patient in the home, and not in the office setting, will not be covered.
- **Provocative testing** will be denied as not medically necessary.
- **Quantitative or semi-quantitative in vitro allergen specific IgE testing** is covered under conditions where skin testing is not possible or is not reliable. In vitro testing is covered as a SUBSTITUTE for skin testing; it is usually not necessary in addition to skin testing. The number of tests done, frequency of retesting and other coverage issues, are the same as for skin testing. The indications for using in vitro testing instead of in vivo methods must be documented with the claim.
- **Qualitative multiallergen screens for allergen specific IgE** have insufficient literature to support clear-cut clinical utility and will be denied as not medically necessary.

Examples of indications for in vitro testing include the following:

- Patients with severe dermatographism, ichthyosis or generalized eczema;
- Patients at increased risk for anaphylactic response to skin testing based on clinical history (e.g., when an unusual allergen is not available as a licensed skin test extract);
- Patients unable to discontinue long-acting antihistamines, tricyclic antidepressants, or medications that may put the patient at undue risk if they are discontinued long enough to perform skin tests;
- Patients with mental or physical impairments, who are uncooperative; or
- Evaluation of cross-reactivity between insect venoms.

The following are noncovered antigens: newsprint, tobacco smoke, dandelion, orris root, phenol, alcohol, sugar, yeast, grain mill dust, soybean dust (except when the patient has a known exposure to soybean dust such as a food processing plant), honeysuckle, fiberglass, green tea, or chalk.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation Requirements

It is expected that supportive documentation evidencing the condition and treatment will be documented in the medical record and be available to the Contractor upon request.

Documentation, such as ICD-10-CM codes, supporting the medical necessity of the service must be submitted with each claim. Claims submitted without such evidence will be denied as not medically reasonable and necessary.

Utilization Guidelines

The evaluation of an inhalant may require up to 90 prick-puncture tests followed by up to 40 intracutaneous tests which are usually performed when prick/puncture tests are negative. Sometimes 60 intracutaneous tests performed via multi test, in lieu of prick puncture, may be appropriate for selected patients (for example young children, older adults and needle phobic individuals.)

The number of percutaneous tests performed for the evaluation of food sensitivity may require up to 40 tests.

The total number of tests, i.e. prick or intracutaneous, should not exceed generally accepted standards of testing set forth by professional associations. Exceeding these parameters may be justified if preliminary testing failed and immunotherapy failed to control symptoms.

In California, for percutaneous allergy testing, among patients treated by Allergists, over half required fewer than 100 tests. The great majority required less than 120-130 tests, and only 5% required more than 200 tests. Some of the high-test group includes repeat testing necessitated by unsatisfactory response to clinical treatment and a clinical need for further investigation. For intracutaneous (intradermal) allergy testing, among patients treated by Allergists,

over half required only 12 tests, and only 5% required 70 or more tests. High-utilization testing may be selected for medical review when inconsistent with clinical practice norms.

Sources of Information

2005 ICD-9-CM, copyright 2004, Ingenix, Inc.

Contractor Medical Consultants

Contractor Medical Director

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2019	R3	<p>10/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage.</p> <p>ICD10 Update to add: T50.915A; T50.915S; T50.915D to Group I/II/III/IV Coding</p> <p>LCD was converted to the "no codes" format.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes • Revisions Due To Code Removal
10/01/2015	R2	<p>The LCD is revised under "General Information" to correct the bullet format for "Percutaneous Testing", removed "2005 Current Procedural Terminology (CPT), copyright 2004 American Medical Association" and added the link to the NCD Food Allergy Testing and Treatment.</p>	<ul style="list-style-type: none"> • Typographical Error • Other (Added the NCD link to Food Allergy Testing and Treatment.)
10/01/2015	R1	<p>Approved FU annual update.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57181 - Billing and Coding: Allergy Testing

Related National Coverage Documents

NCD(s)

110.11 - Food Allergy Testing and Treatment

Public Version(s)

Updated on 09/18/2019 with effective dates 10/01/2019 - N/A

Updated on 09/09/2015 with effective dates 10/01/2015 - 09/30/2019

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- Food Allergy Testing