

# Regence

## Allergy and Sensitivity Tests of Uncertain Efficacy

Published: 10/01/2024

Next Review: 06/2025

Last Review: 08/2024

Medicare Link(s) Revised: 10/01/2024

### IMPORTANT REMINDER

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

### DESCRIPTION

The term "allergy" refers to an acquired potential for developing adverse reactions that are mediated by the immune system (via immunoglobulin E [IgE] antibodies). Allergic disease represents the clinical manifestations of these adverse immune responses. An allergen is any substance that can cause an allergic reaction, and are generally common, harmless substances such as pollens, mold spores, animal danders, dust, foods, insect venoms, latex, and drugs. Several allergy tests are considered clinically useful for allergy confirmation or sensitivity to an allergen and for the diagnosis and management of the allergic patient. However, other allergy and sensitivity tests are of uncertain efficacy and are used primarily in research settings.

## MEDICARE ADVANTAGE POLICY CRITERIA

Procedure(s):	CMS Coverage Manuals and National Coverage Determinations (NCDs)	Noridian Local Coverage Determinations (LCD) and Articles	Medical Policy Manual
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**Note:** The following allergy tests are considered clinically useful for allergy confirmation by the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) in the diagnosis and management of the allergic patient.

- Bronchial challenge test
- Double-blind food challenge test
- Intradermal skin testing
- Patch test
- Percutaneous skin tests such as the scratch, prick, or puncture tests
- Photo patch test
- Specific IgE in vitro tests such as Radioallergosorbent Test (RAST), Multiple Radioallergosorbent Tests (MAST), Fluorescent Allergosorbent Test (FAST), Enzyme-linked Immunosorbent Assay (ELISA), and the ImmunoCAP IgE test
- Total serum IgE concentration

This policy addresses only allergy or sensitivity tests of uncertain efficacy and those used primarily in research settings. Tests which may be considered useful in the clinical setting, as noted above, are not addressed in this policy.

<b><i>Cytotoxic food testing</i></b>	<a href="#"><u>110.13</u></a>
<b><i>Hair analysis</i></b>	<a href="#"><u>190.6</u></a>
<b><i>Provocation &amp; neutralization testing (includes intradermal or subcutaneous, and sublingual)</i></b>	<a href="#"><u>110.11</u></a>

Procedure(s):	CMS Coverage Manuals and National Coverage Determinations (NCDs)	Noridian Local Coverage Determinations (LCD) and Articles	Medical Policy Manual
<b><i>Antigen leukocyte cellular antibody (ALCAT) automated food test</i></b>			
<b><i>Applied kinesiology allergy test</i></b>			
<b><i>Electrodermal testing (also known as electro-acupuncture)</i></b>			
<b><i>IgA food panel tests</i></b>			<i>Medicare coverage guidance is not available in the health plan's service area (Jurisdiction F) for most types of allergy or sensitivity testing. Therefore, the health plan's medical policy is applicable for these services. The health plan's medical policy is consistent with the Noridian Jurisdiction E (J-E) LCD for allergy testing.<sup>[1]</sup></i>
<b><i>IgG/IgG4 allergen specific antibody test and food tests</i></b>			
<b><i>Iridology</i></b>			
<b><i>Leukocyte Histamine Release Test (LHRT)</i></b>			
<b><i>Nasal challenge test</i></b>			
<b><i>Ophthalmic mucous membrane test (conjunctival challenge test)</i></b> (Note: <i>The Schirmer tear test is not considered a conjunctival challenge test; however, it is considered an incidental procedure and is not separately reportable or reimbursed. It is included as part of the general ophthalmologic examination.</i> )			Allergy and Sensitivity Tests of Uncertain Efficacy, Laboratory, <a href="#">Policy No. 01</a> (see "NOTE" below)
<p><b>NOTE:</b> If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (<a href="#">Medicare IOM Pub. No. 100-04, Ch. 23, §30 A</a>). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an <b>objective, evidence-based process, based on authoritative evidence</b>. (<a href="#">Medicare IOM Pub. No. 100-16, Ch. 4, §90.5</a>). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).</p>			

## CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

## REFERENCES

1. Noridian Healthcare Solutions Jurisdiction E (J-E) LCD for *Allergy Testing* ([L34313](#))

## CODING

**NOTE:** It is not appropriate to report CPT 95060 for the Schirmer test for dry eye, as this test is included as a part of a general ophthalmologic exam and is not separately reimbursable.

Codes	Number	Description
CPT	83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
	86001	Allergen specific IgG quantitative or semiquantitative; each allergen
	86003	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
	86005	Allergen specific IgE; qualitative, multiallergen screen (eg, disk, sponge, card)
	86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
	86343	Leukocyte Histamine Release Test (LHR)
	86486	Skin test; unlisted antigen, each
	95060	Ophthalmic mucous membrane tests
	95065	Direct nasal mucous membrane test
	95199	Unlisted allergy/clinical immunologic service or procedure
HCPCS	None	

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.