Medicare Medical Policy

Allergy Testing

MEDICARE MEDICAL POLICY NUMBER: 152

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Provocation & neutralization testing (includes intradermal or subcutaneous, and sublingual)	National Coverage Determination (NCD) for Food Allergy Testing and Treatment (110.11)
Cytotoxic Food Tests (e.g., Cytotoxic Leukocyte Tests)	NCD for Cytotoxic Food Tests (110.13)
Challenge Ingestion Food Testing/Oral Food Challenge Testing (CPT 95076, 95079)	NCD for Challenge Ingestion Food Testing (110.12)
Hair Analysis	NCD for Hair Analysis (190.6)
Conjunctival or nasal challenge tests (CPT 95060, 95065)	Ophthalmic mucous membrane challenge tests and direct nasal mucous membrane challenge tests may be considered **medically necessary** for Medicare Plan members. *See Policy Guidelines for information.*

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Medicare does not have criteria for allergy testing in a coverage manual (billing guidance can be found in Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, §200, but this does not provide medical necessity criteria).
- **National Coverage Determination (NCD):** With the exception of the NCDs called out above, Medicare does not have any other NCD for certain types of allergy testing.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, several Medicare Administrative Contractors (MACs) have LCDs for allergy testing. Noridian Healthcare Solutions (Noridian) **Jurisdiction F** (J-**F**) is the designated MAC with oversight over the states of Oregon and Washington. While Noridian does not have

an LCD or LCA for their J-F contract service area, they **do** have an LCD/LCA for their **J-E** contract service area (LCD L34313 and LCA A57181). • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. The below Company evidence-based policy criteria are generally consistent with the Noridian J-E coverage policy. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
In Vitro *Allergy Testing* *(e.g., RAST/MAST/FAST/ELISA/ImmunoCAP®, CPT: 86003, 86008; or PRIST/RIST, CPT: 82785)*	Company medical policy for Allergy Testing I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare when the Company medical policy criteria are not met. *See Policy Guidelines below.*
Medically Necessary ***In Vivo*** *Allergy Tests Not Otherwise Addressed* *(e.g., percutaneous tests [scratch, prick, or puncture] [95004, 95017, 95018], intradermal tests [95024, 95027, 95028], skin patch [95044], photo test [95052, 95056], bronchial challenge [95070])*	Company medical policy for Allergy Testing I. These services may be considered **medically necessary** based on the Company medical policy.
Allergy Tests Not Otherwise Addressed *Examples:* • Antigen leukocyte cellular antibody (ALCAT) automated food test • Applied kinesiology test • Bead-based epitope assays (BBEA) (e.g., VeriMAP™ Peanut Diagnostic and Sensitivity tests from AllerGenis™; 0165U and 0178U) • Iridology • IgG/IgG4 allergen-specific antibody test • Leukocyte histamine release test (LHRT)	Company medical policy for Allergy Testing I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members when the Company medical policy criteria are **not** met See *Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member

EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

General

In order for a laboratory service (including allergy testing) to be considered for coverage, Medicare requires that the test in question meet all of the following:

- **Not be excluded from coverage** by statute, regulation, National Coverage Determination, (NCD), or Local Coverage Determination (LCD);[1]
- **Be ordered by a physician or qualified practitioner** who is treating the beneficiary;[2,3]
- Provide data that will be **directly used in the management** of a beneficiary's specific medical problem;[2,3]
- **Be considered medically reasonable and necessary**, as required per the Social Security Act, §1862(a)(1)(A). This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected diagnosis because the patient has signs and/or symptoms.[4,5]

In addition to the above general Medicare requirements, under Chapter 13 of the Medicare Program Integrity Manual, Medicare allows contractors to consider a service "reasonable and necessary" when the service is appropriate for the member's condition. This includes appropriateness in duration, frequency, and that the service is furnished in accordance with accepted standards of medical practice for the condition, furnished in a setting appropriate to the medical needs and condition, ordered and furnished by qualified personnel, that the service meets, but does not exceed, the medical need; and is at least as beneficial as an existing and available medically appropriate alternative.[6] It would not be expected that all patients receive the same specific tests or the same number of tests (e.g., same number of sensitivity tests for all patients). The type and quantity of tests performed must be relevant to the individual patient based on their history and physical findings, and the clinical judgment by the physician, with a reasonable probability of exposure to the allergen in the patient's environment.[7]

Medicare and Medical Necessity

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for certain allergy tests available in applicable Medicare statutes, regulations, NCDs or LCDs for the MAO service area, then Company medical policy criteria for select allergy tests will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

Ophthalmic Mucous Membrane Challenge Tests and Direct Nasal Mucous Membrane Challenge Tests

While there is no LCD or LCA for the Company service area, Medicare Contractors which do have allergy testing LCDs all consistently consider ophthalmic mucous membrane challenge tests and direct nasal mucous membrane challenge tests to be medically indicated in some situations. Therefore, these tests may be considered medically necessary by the Company for Medicare Plan members.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

FREQUENCY LIMITS FOR MEDICALLY NECESSARY TESTS

High utilization testing may be subject to medical review or audit.

CMS has established medically unlikely edits (MUEs) for many of the services addressed by this medical policy. MUEs represent the maximum number of units for a service that would reasonably be reported for a service by the same provider, for the same member, on the same date of service. However, MUEs do **not** guarantee that those number of units are always going to be considered medically necessary. It is not expected that all patients will have the same medical need for this maximum number of units at every visit, or even collectively over the course of an entire year. Repeat testing with the same antigen(s) is rarely considered medically necessary, and the total number of tests performed should not exceed generally accepted standards of testing set forth by professional associations. Therefore, all units reported on any claim must be justified, and documentation must support the units of services rendered, that the services have been coded correctly, **and** that the services were medically reasonable and necessary for the individual.

CODING FOR MISCELLANEOUS NOT MEDICALLY NECESSARY TESTS

When CPT code 83516 is billed to represent ALCAT or cytotoxic food testing, it is considered not medically necessary and not covered per this policy.

CODES*		
Miscellaneous Allergy Tests		
CPT	0165U	Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and interpretation *(Used for the VeriMAP™ Peanut Dx–Bead–based Epitope Assay test, by AllerGenis)*
	0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction *(Used for the VeriMAP Peanut Sensitivity – Bead–based Epitope Assay test, by AllerGenis)*
	86001	Allergen specific IgG quantitative or semiquantitative, each allergen
	86005	Allergen specific IgE; qualitative, multiallergen screen (eg, disk, sponge, card)
Total Serum IgE Testing (e.g., PRIST/RIST)		
	82785	Gammaglobulin (immunoglobulin); IgE
Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Test or Cytotoxic Food Test This code is considered not medically necessary when used for a non-covered test in this policy.		
	83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
Allergen Specific IgE Testing (e.g., RAST/MAST/FAST/ELISA/ImmunoCAP®)		
	86003	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each

	86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
Miscellaneous Antigen Skin Tests		
	86486	Skin test; unlisted antigen, each
Percutaneous Test (Scratch, Prick, or Puncture Test)		
	95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests
	95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests
	95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests
Intracutaneous Test		
	95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests
	95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests
	95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests
Skin Patch Test		
	95044	Patch or application test(s) (specify number of tests)
Photo Test		
	95052	Photo patch test(s) (specify number of tests)
	95056	Photo tests
Ophthalmic Mucous Membrane and Direct Nasal Mucous Membrane Tests		
	95060	Ophthalmic mucous membrane tests
	95065	Direct nasal mucous membrane test
Bronchial Challenge Test		
	95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds
Oral (Ingestion) Food Challenge Test		
	95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing
	95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)
Unlisted/Non-Specific Code		
	95199	Unlisted allergy/clinical immunologic service or procedure
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database

(MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Coverage Determination Process. https://www.cms.gov/medicare/coverage/determinationprocess. Accessed 5/6/2025.
2. 42 CFR §410.32(a). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.32. Accessed 5/6/2025.
3. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf. Accessed 5/6/2025.
4. Title XVIII of the Social Security Act, §1862(a)(1)(A). https://www.ssa.gov/OP_Home/ssact/title18/1862.htm. Accessed 5/6/2025.
5. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf. Accessed 5/6/2025.
6. Centers for Medicare and Medicaid Services (CMS). Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 - Reasonable and Necessary Provision in an LCD. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf. Accessed 5/6/2025.
7. Noridian Jurisdiction E (J-E) LCD for Allergy Testing. 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34313. Accessed 5/6/2025.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2022	Annual review (converted to new format 2/2023)
9/2023	Annual review; Language revision due to Company policy change from "investigational" to "not medically necessary"
8/2024	Annual review; Update frequency limits, clarify intent of medically necessary testing
7/2025	Annual review; No change to criteria