Medicare Medical Policy

Allergy Testing

MEDICARE MEDICAL POLICY NUMBER: 152

Effective Date: 9/1/2023

Last Review Date: 6/2023

Next Annual Review: 6/2024

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	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.*
***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*	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	Company medical policy for Allergy Testing

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)	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

Noridian Healthcare Solutions (Noridian) Jurisdiction F (J-F) is the designated Medicare Administrative Contractor (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 and LCA for their **J-E** contract service area (LCD L34313 and LCA A57181). The above criteria are mostly consistent with this Noridian coverage policy. While there is no LCD or LCA for the Company service area, Medicare Contractors which do have allergy testing LCDs 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.

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)*.

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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.

- A cumulative total of 70 percutaneous (scratch, prick, or puncture) allergy tests (CPT: 95004, 95017, 95018) are eligible for reimbursement per calendar year.
- A cumulative total of 40 intracutaneous allergy tests (CPT: 95024, 95027, 95028) are eligible for reimbursement per calendar year.
- A cumulative total of 80 skin patch allergy tests (CPT: 95044) are eligible for reimbursement per calendar year.
- A cumulative total of 40 allergen specific IgE serum tests (CPT: 86003 and 86008, each) for inhalant allergies are eligible for reimbursement per calendar year.
- A cumulative total of 12 allergen specific IgE serum tests (CPT: 86003 and 86008, each) for food allergies are eligible for reimbursement per calendar year.

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

None

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"