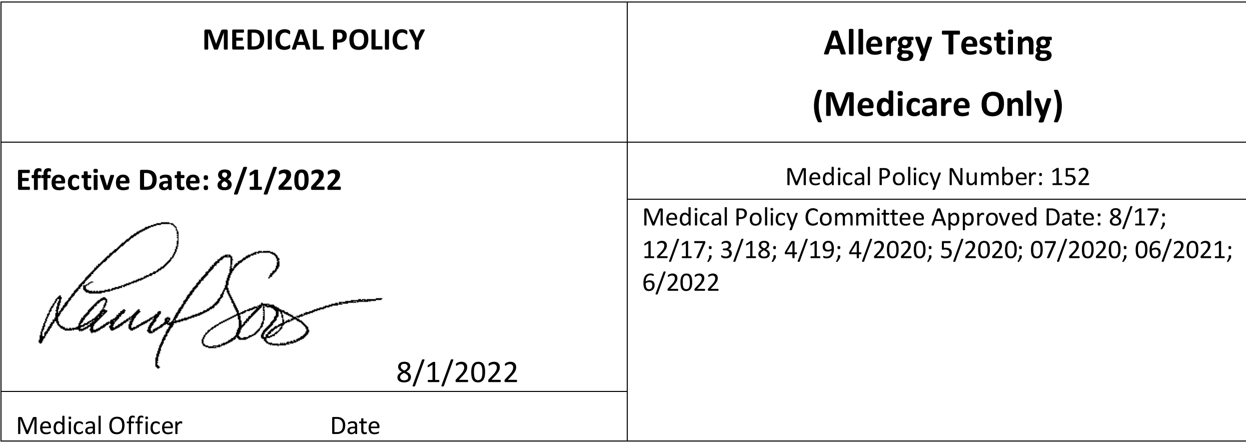

MEDICAL POLICY	Allergy Testing (Medicare Only)
Effective Date: 8/1/2022	Medical Policy Number: 152
8/1/2022	Medical Policy Committee Approved Date: 8/17; 12/17; 3/18; 4/19; 4/2020; 5/2020; 07/2020; 06/2021; 6/2022
Medical Officer Date	

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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*	Company medical policy for Allergy Testing (All Lines of Business Except Medicare)

(e.g., RAST/MAST/FAST/ELISA/ImmunoCAP®, CPT: 86003, 86008; or PRIST/RIST, CPT: 82785)	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 (All Lines of Business Except Medicare) 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 (All Lines of Business Except Medicare) 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 either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "investigational" by the Company policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members.* See *Policy Guidelines below.*

POLICY GUIDELINES

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

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.), 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)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, 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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

BILLING GUIDELINES

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.

CPT CODES

Medicare Only	
No Prior Authorization Required	
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)
Not Covered	
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)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed relative to services addressed in this policy then **prior-authorization is required.**	
95199	Unlisted allergy/clinical immunologic service or procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.