To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:
1N-2, *Allergen Immunotherapy*

1.0 Description of the Procedure, Product, or Service

The term “allergy” indicates an abnormally hypersensitive immune reaction in response to exposure to certain foreign substances. Allergy-producing substances are called "allergens.” When an allergic individual comes in contact with an allergen, the immune system mounts a response through the immunoglobulin E (IgE) antibody.

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as by localized reactions in any organ system of the body. The reaction may be acute, subacute or chronic, immediate or delayed and may be caused by numerous offending agents including pollen, molds, foods, and drugs.

The management of an allergy or hypersensitivity may include identifying the offending substance (allergen) by means of various testing methods. Immunoglobulin E (IgE)-mediated allergy testing is evaluated by measuring allergen-specific IgE. This can be done through skin testing (in vivo) testing or with serological tests (in vitro). Allergy testing includes the performance, evaluation, and reading of the tests.

It is important to note that skin prick tests, and tests that measure total serum levels of IgE or allergen-specific IgE, only detect the presence of allergic sensitization. They do not, by themselves, make a diagnosis of allergy. For instance, almost one-half of the U.S. population has detectable allergen-specific IgE against a food allergen, but the overall prevalence of clinical food allergy is only about 4 to 6 percent.

Treatment options for allergies are avoidance of the allergen, pharmacological therapy, and immunotherapy.

1.1 Definitions

None Apply.

2.0 Eligible Beneficiaries

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid policies*)

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover procedures, products, and services related to this policy when they are medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid shall cover allergy testing when the physician or qualified non-physician practitioner completes all of the following requirements, prior to performing the allergy test:

a. Completes a medical and immunologic history, along with a physical exam;
b. Determines, upon completion of the history and physical exam, one of the following:
    1. that the signs and symptoms are suggestive of an allergy: or
    2. a diagnosis indicates an allergy, such as asthma.
c. Documents in the health record all tried and failed allergy treatments;
d. Selects the appropriate allergy test with proven efficacy published in peer-reviewed literature; and
e. Orders the allergy test based on findings from (a) through (d) above, that document the antigen being used for testing exists with a reasonable probability of exposure in the beneficiary's environment.

3.2.2 Allergy Tests Covered

After all requirements in **Subsection 3.2.1** are met, the physician or qualified non-physician practitioner performs the appropriate allergy test from the list below. Specific IgE tests as described in "g." can be performed by a clinical laboratory:

a. Direct skin testing (for immediate hypersensitivity):
    1. Percutaneous or epicutaneous (scratch, prick, or puncture);
    2. Intradermal;
b. Patch or application test;
c. Photo patch test;
d. Photo test;
e. Bronchial challenge testing;
f. Ingestion (oral) challenge test; and
g. specific IgE in vitro tests for inhalant allergens (pollens, molds, dust mites, and animal dander), foods, insect stings, and drugs.

3.2.3 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover procedures, products, and services related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**

c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid shall not cover investigational allergy tests including:

a. Leukocyte histamine release;
b. Rebuck skin window;
c. Prausnitz-Kustner test;
d. Cytotoxic food testing (leukocytotoxic test, Bryans test);
e. Conjunctival challenge testing (ophthalmic mucous membrane test);
f. Nasal challenge (provocative) test;
g. Kinesiology testing;
h. Provocation-neutralization testing; or
i. Electrodermal testing.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid shall not require prior approval for Allergy Testing.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Limitations or Requirements

Refer to **Attachment A: Section C, Codes,** for testing limitations related to this policy.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;

b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:
a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1974

Revision Information:

Date	Section Revised	Change
01/01/2009	All sections and attachment(s)	Initial promulgation of current coverage.
07/01/2010	All sections and attachment(s)	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
03/12/2012	All sections and attachment(s)	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 1N-1 under Session Law 2011-145 § 10.41.(b)
03/12/2012	All sections and attachment(s)	Technical changes to merge Medicaid and NCHC current coverage into one policy.
02/01/2013	Attachment A: Subsection C Billing Codes	CPT codes 95010, 95015 and 95075 deleted and replaced with 95017, 95018, 95076 and 95079 due to the American Medical Association during CPT Code Update 2013.
02/01/2013	All sections and attachment(s)	Replaced "recipient" with "beneficiary."
02/01/2015	All Sections and Attachments	Updated template language
02/01/2015	All Sections and Attachments	Checked and amended grammar, numbering and readability as needed
02/01/2015	Section 1.0	Updated "Description of the Procedure, Product or Services" to provide more details
02/01/2015	Subsection 3.2.1	Moved all of Subsection 5.2 (Allergy Testing Requirements) to Subsection 3.2.1, Revised wording of section to better reflect current standards of coverage
02/01/2015	Subsection 4.2.1	Statement, "Medicaid and NCHC shall not cover the following allergy tests:" changed to "Medicaid and NCHC shall not cover investigational allergy tests including:" Added "and" after item "e." Deleted "**Note**: This list is not all inclusive."
02/01/2015	Subsection 4.2.3.a	Statement, "None apply" changed to "None apply for Allergy Testing for NCHC."
02/01/2015	Subsection 5.2	Moved all of Subsection 5.2 (Allergy Testing Requirements) to Subsection 3.2.1, Revised wording of section to better reflect current standards of coverage
02/01/2015	Subsection 5.2	Added a new Subsection 5.2 "**Limitations or Requirements** Refer to **Attachment A, Section C, Codes,** for testing limitations related to this policy."
02/01/2015	Subsection 7.1	Changed "agent" to "contractor"

Date	Section Revised	Change
02/01/2015	Attachment A: Section C, Codes	Added Testing Limitations for the following CPT Codes 95004 - 75 units per year. 95024, 95027 and 95028 - 20 units per year 86003 and 95044 - 36 units per year 95070, 95071 and 95076 - Limited to 1 unit per date of service 95079 - Limited to 8 units per date of service 95017 and 95018 – Limited to 30 units per date of service
09/01/2015	Attachment A: Section C, Codes	Unit limitations changed for the following CPT codes: 95018 is being changed from 30 units per date of service to 19 units per date of service, and 95079 is being changed from 8 units per date of service to 2 units per date of service
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
10/01/2015	Attachment A: Section C, Codes	Unit limitations changed for the following CPT codes: 95018 is being changed from 30 units per date of service to 19 units per date of service, and 95079 is being changed from 8 units per date of service to 2 units per date of service
02/01/2017	Subsection 3.2.1	Updated coverage criteria related to Direct skin testing and specific IgE in vitro testing
02/01/2017	Subsection 3.2.2	Deleted the listing of specific IgE in vitro tests and criteria
02/01/2017	Subsection 4.2.1	Added additional non-covered tests
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”
03/15/2019	All Sections and Attachments	Updated policy template language.
01/03/2020	Table of Contents	Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
01/03/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
4/15/2023	All Sections and Attachment(s)	Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 4/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Codes	Testing Limitations
86003	36 units per year
86005	
95004	75 units per year
95017	30 units per date of service
95018	19 units per date of service
95024	20 units per year
95027	20 units per year
95028	20 units per year
95044	36 units per year
95052	
95056	
95070	1 unit per date of service
95071	1 unit per date of service
95076	1 unit per date of service
95079	2 units per date of service

Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow the applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used, which determines the billing unit(s).
a. For CPT 86003, each specific allergen tested (one test) must be billed as one unit.
b. Each antigen tested (one test) must be billed as one unit, even if more than one injection or scratch or prick of the antigen is used on the same day.
c. For CPT 95027, one unit equals one allergen tested (not the number of dilutions of each antigen).

F. Place of Service

Outpatient, Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/