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.

Table of Contents

1.0	Description of the Procedure, Product, or Service					
	1.1	Definitions				
		Immunoglobulin E (IGE) Antibody	1			
		Serological Testing (In Vitro)				
		Testing (In Vivo)	2			
2.0	E1: 1		~			
2.0	_	ble Beneficiaries				
	2.1	Provisions				
		2.1.1 General				
	2.2	2.1.2 Specific				
	2.2	2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid				
		Beneficiary under 21 Years of Age				
		Deficitedly under 21 Tears of Age				
3.0	When the Procedure, Product, or Service Is Covered.					
	3.1	General Criteria Covered				
	3.2	Specific Criteria Covered	4			
		3.2.1 Specific criteria covered by Medicaid	4			
		3.2.2 Medicaid Additional Criteria Covered	4			
4.0		the Procedure, Product, or Service Is Not Covered				
	4.1	General Criteria Not Covered				
	4.2	Specific Criteria Not Covered				
		4.2.1 Specific Criteria Not Covered by Medicaid				
		4.2.2 Medicaid Additional Criteria Not Covered	5			
5.0	Regu	Requirements for and Limitations on Coverage				
5.0	5.1	Prior Approval				
	5.2	Prior Approval Requirements				
	0.2	5.2.1 General				
		5.2.2 Specific				
	5.3	Limitations or Requirements				
		1				
6.0		ders Eligible to Bill for the Procedure, Product, or Service				
	6.1	Provider Qualifications and Occupational Licensing Entity Regulations				
	6.2	Provider Certifications	6			
7.0	٨٨٨	tional Requirements	6			
7.0	7.1	Compliance				
	/.1	Соприанс	C			
8.0	Polic	y Implementation/Revision Information				
Attacl	hment A	A: Claims-Related Information				
	A.	Claim Type	10			

25A6 i

NC Medicaid Allergy Testing

Medicaid Clinical Coverage Policy No: 1N-1 Amended Date: February 1, 2025

В.	International Classification of Diseases and Related Health Problems, Tenth Revision	ns,
	Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)	10
C.	Code(s)	10
D.	Modifiers	11
E.	Billing Units	11
F.	Place of Service	11
G.	Co-payments	11
	Reimbursement	

25A6 ii

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 allergen, pharmacological therapy, and immunotherapy.

1.1 Definitions

Immunoglobulin E (IGE) Antibody

Immunoglobulin E Antibodies is a type of protein in the body. As part of the immune system, the IGE Antibody plays a role in allergic reactions by causing symptoms in the body, commonly the nose, throat, lungs, and skin.

Serological Testing (In Vitro)

Serological testing occurs outside of a living organism such as a test tube and laboratory. These are blood tests to detect the presence of antibodies against a microorganism or potential allergen and can determine if individuals have been exposed to a particular allergen.

Testing (In Vivo)

Skin testing occurs within a living organism. These tests rely on the reactivity and sensitivity to exposure of specific allergens through various percutaneous and intradermal routes to identify allergic reactions.

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 beneficiary meets the following specific criteria:

- a. Services are provided by a physician or qualified non-physician practitioner after **ALL** the following are completed;
 - 1. Completes a medical and immunologic history, along with a physical exam:
 - 2. Determines, upon completion of the history and physical exam, one of the following:
 - A. that signs and symptoms are suggestive of an allergy: or
 - B. a diagnosis indicates an allergy, such as asthma.
 - 3. Establishes reasonable probability of exposure in the beneficiary's environment:
 - 4. Documents in the health record that symptoms are not controllable by empiric conservative therapy;
 - 5. Documents in the health record all tried and failed allergy treatments;
 - 6. Selects the appropriate allergy test with proven efficacy published in peer-reviewed literature; and
 - 7. Orders the allergy test based on findings from (1) through (6) above that document and appropriately support the antigen being used for testing.

3.2.2 Medicaid Additional Criteria Covered

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.

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 RegulationsNone 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	Initial promulgation of current coverage.
	attachment(s)	
07/01/2010	All sections and	Policy Conversion: Implementation of Session Law 2009-451,
	attachment(s)	Section 10.32 "NC HEALTH CHOICE/PROCEDURES
		FOR CHANGING MEDICAL POLICY."
03/12/2012	All sections and	To be equivalent where applicable to NC DMA's Clinical
	attachment(s)	Coverage Policy # 1N-1 under Session Law 2011-145 §
		10.41.(b)
03/12/2012	All sections and	Technical changes to merge Medicaid and NCHC current
	attachment(s)	coverage into one policy.
02/01/2013	Attachment A:	CPT codes 95010, 95015 and 95075 deleted and replaced with
	Subsection C	95017, 95018, 95076 and 95079 due to the American Medical
	Billing Codes	Association during CPT Code Update 2013.
02/01/2013	All sections and	Replaced "recipient" with "beneficiary."
	attachment(s)	
02/01/2015	All Sections and	Updated template language
	Attachments	
02/01/2015	All Sections and	Checked and amended grammar, numbering and readability as
	Attachments	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	Statement, "None apply" changed to "None apply for Allergy
	4.2.3.a	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:	Added Testing Limitations for the following CPT Codes
	Section C, 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
00/01/2015	A 441 A .	Heitelinitedian dense de cada e disconsissa CDT e de c
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
	Section C, Codes	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	Updated policy template language and added ICD-10 codes to
10/01/2015	Attachments	comply with federally mandated 10/1/2015 implementation
		where applicable.
10/01/2015	Attachment A:	Unit limitations changed for the following CPT codes:
	Section C, 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
02/01/2017	Subsection 3.2.1	units per date of service Updated coverage criteria related to Direct skin testing and
02/01/2017	Subsection 3.2.1	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
00/15/2010		after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and	Updated policy template language.
01/03/2020	Attachments Table of Contents	Updated policy template language, "To all beneficiaries
01/03/2020	Table of Contents	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.
	1	All claims must comply with National Coding Guidelines".
4/15/2023	All Sections and	Updated policy template language due to North Carolina Health
	Attachment(s)	Choice Program's move to Medicaid. Policy posted 4/15/2023
02/01/2025	Section 1.1	with an effective date of 4/1/2023. Added definitions for the following terms; Immunoglobulin
02/01/2023	Section 1.1	antibody, In Vivo Testing and In Vitro Testing.
02/01/2025	Section 3.2.1	Specific Criteria Covered by Medicaid was reformatted such as
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Date	Section Revised	Change
02/01/2025	Section 3.2.1 (d)	Added language to follow current policy guidelines; section 4. Documents in the health record that symptoms are not controllable by empiric conservative therapy;
02/01/2025	Section 3.2.1 (c) and (g)	Moved part of (e) to create 3 and 7 for clarity; 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. Changed to 3. Establishes reasonable probability of exposure in the beneficiary's environment; and 7. Orders the allergy test based on findings from (1) through (6) above, that document and appropriately support the
02/01/2025	Attachment A, Section C	Unit limitations changed for the following CPT codes: 86003 changed from 36 units per year to 30 units per 365 days 86005 2 units per day up to 30 allergens per 365 days 95004 changed from 75 units per year to 80 units per 365 days 95017 changed from 30 units per date of service to 27 units per date of service 95024 changed from 20 units per year to 30 units per 365 days 95027 changed from 20 units per year to per 365 days 95028 changed from 20 units per year per 365 days 95044 changed from 36 units per year to 80 units per 365 days 95052 36 units per date of service 95056 1 unit per date of service 95071 removed due to obsoletion

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	30 units per 365 calendar days	
86005	2 units per day up to 30 allergens per 365 calendar days	
95004	80 units per 365 calendar days	
95017	27 units per date of service	
95018	19 units per date of service	
95024	30 units per 365 calendar days	
95027	20 units per 365 calendar days	
95028	20 units per 365 calendar days	
95044	80 units per 365 calendar days	
95052	36 units per date of service	
95056	1 unit per date of service	
95070	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/