

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1
1.1 Definitions 1

2.0 Eligibility Requirements 1
2.1 Provisions..... 1
2.1.1 General..... 1
2.1.2 Specific 2
2.2 Special Provisions..... 2
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age 2
2.2.2 EPSDT does not apply to NCHC beneficiaries 3
2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age 3

3.0 When the Procedure, Product, or Service Is Covered..... 3
3.1 General Criteria Covered 3
3.2 Specific Criteria Covered..... 3
3.2.1 Specific criteria covered by both Medicaid and NCHC 3
3.2.2 Rapid Desensitization 4
3.2.3 Medicaid Additional Criteria Covered..... 4
3.2.4 NCHC Additional Criteria Covered 4

4.0 When the Procedure, Product, or Service Is Not Covered..... 4
4.1 General Criteria Not Covered 4
4.2 Specific Criteria Not Covered..... 5
4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC..... 5
4.2.2 Medicaid Additional Criteria Not Covered..... 5
4.2.3 NCHC Additional Criteria Not Covered..... 6

5.0 Requirements for and Limitations on Coverage 6
5.1 Prior Approval 6
5.2 Prior Approval Requirements 6
5.2.1 General..... 6
5.2.2 Specific 6
5.3 Office Visits..... 6
5.4 Duration of Treatment 6
5.5 Limitations or Requirements..... 7

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 7
6.1 Provider Qualifications and Occupational Licensing Entity Regulations..... 7
6.2 Provider Certifications 7

7.0 Additional Requirements 7
7.1 Compliance 7
7.2 Documentation..... 7

8.0 Policy Implementation/Revision Information..... 8

Attachment A: Claims-Related Information 12

- A. Claim Type 12
- B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) 12
- C. Code(s)..... 12
- D. Modifiers..... 13
- E. Billing Units..... 13
- F. Place of Service 13
- G. Co-payments 14
- H. Reimbursement 14

Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policy listed below:
1N-1, *Allergy Testing*

1.0 Description of the Procedure, Product, or Service

Allergy immunotherapy (a.k.a., desensitization, hyposensitization, allergy injection therapy, or "allergy shots"), is an effective treatment for allergic rhinitis, allergic asthma, and Hymenoptera sensitivity. Immunotherapy is indicated in patients whose triggering allergens have been determined by appropriate skin or in vitro testing (Refer to Policy titled, Allergy Testing). The goal is to reduce the allergy patient's sensitivity when exposed to the offending allergen in the future. Treatment begins with low doses to prevent severe reactions. Gradually the doses are increased and are given once or twice a week until the body becomes tolerant of the allergen. After the maintenance dose is achieved, the interval between injections may range between two and six weeks. Immunotherapy may be administered continuously for several years

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. Medicaid
None Apply.
- b. NCHC
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 practitioner).

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/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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 or NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall cover allergy immunotherapy when **all of the following** criteria apply:

- a. The hypersensitivity cannot be managed by medications or allergen avoidance;
- b. The triggering allergens must have been determined by appropriate skin testing or blood tests, as described in clinical coverage policy 1N-1, *Allergy Testing*, on NC Medicaid's website at <https://medicaid.ncdhhs.gov/>; and

- c. The beneficiary selected for immunotherapy shall have clinically significant allergic symptoms or a chronic allergic state caused by **any** of the following:
1. hymenoptera sensitivity;
 2. inhalants;
 3. allergic (extrinsic) asthma;
 4. allergic rhinitis or conjunctivitis; or
 5. dust mite atopic dermatitis.

3.2.2 Rapid Desensitization

Medicaid and NCHC shall cover rapid desensitization for any **one** of the following:

- a. hymenoptera sensitivity (allergic reaction to the venom of stinging insects, including wasps, hornets, bees, and fire ants);
- b. the presence of IgE antibodies to a medically necessary drug for which substitution with an alternative medicine is not an effective option;
or
- c. moderate to severe allergic rhinitis requiring treatment during or immediately before the season of the affecting allergy.

3.2.3 Medicaid Additional Criteria Covered

None Apply.

3.2.4 NCHC 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 or NCHC 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 both Medicaid and NCHC

Medicaid and NCHC shall not cover allergy immunotherapy for

- a. intrinsic (non-allergic) asthma;
- b. food allergy;
- c. angioedema;
- d. chronic urticaria;
- e. migraine headaches;
- f. non-allergic vasomotor rhinitis; and
- g. the following antigens:
 1. newsprint
 2. tobacco smoke
 3. dandelion
 4. orris root
 5. phenol
 6. formalin
 7. alcohol
 8. sugar
 9. yeast
 10. grain mill dust
 11. pyrethrum
 12. marigold
 13. soybean dust
 14. honeysuckle
 15. wool
 16. fiberglass
 17. green tea
 18. chalk

Allergen Proof Supplies

Allergen proof supplies, including mattresses, mattress casings, pillows, pillow casings, and other supplies that are commonly used in the management of allergy patients—are not covered. These supplies can be used for non-medical purposes and may be considered personal convenience items. They are not considered medically necessary for the treatment of illness.

Combined Supply Procedure Codes

Procedure codes that describe the complete service code for the combined supply of antigen and allergy injection provided during a single encounter will not be covered. Please see **Attachment A, Section C, 4**, for the list of non-covered codes.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

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 and NCHC shall not require prior approval for Allergy Immunotherapy.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Office Visits

An office visit must not be billed in conjunction with an allergy injection unless the office visit represents another significant separately identifiable service.

Note: Providers shall append Modifier 25 to the office visit procedure code to indicate that a separately identifiable service was provided.

5.4 Duration of Treatment

As indicated in **Subsection 3.1**, Allergy Immunotherapy must be individualized, specific, and consistent with the beneficiary’s symptoms or confirmed diagnosis. Treatment beyond a two-year period is **not** covered when *any* of the following are true:

- a. The beneficiary does not experience a noticeable decrease of symptoms;
- b. The beneficiary does not demonstrate an increase in tolerance to the offending allergen;
- c. There is not a reduction in medication usage; or
- d. There is no documented clinical benefit.

5.5 Limitations or Requirements

Refer to **Attachment A, Section C, Codes** for Testing limitations for CPT codes covered in 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 or NCHC 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).

7.2 Documentation

Health record documentation must:

- a. confirm that allergy immunotherapy is medically necessary and clinically reasonable;
- a. demonstrate that indications for immunotherapy were determined by appropriate diagnostic procedures;
- b. include reactions to injections, if any; and
- c. include continuing evaluation of the effectiveness of treatment; and reflect the number of vials and doses prepared and the injection schedule.

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-2 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.
07/01/2012	Subsection 1.3	Removed statement: “Note: NCHC does not cover the complete service code, which describes the combined supply of antigen and allergy injection provided during a single encounter, as described in Subsection 4.3.”
02/01/2013	Attachment A Section C. Billing Code(s), Subsection 4. Non-covered Codes	Revisions made to CPT codes description 95120-95134 per the American Medical Association during CPT Code Update 2013.
02/01/2013	All sections and attachment(s)	Replaced “recipient” with “beneficiary.”
05/03/2015	All sections and attachment(s)	Policy name changed from Allergen Immunotherapy to Allergy Immunotherapy
05/03/2015	All sections and attachment(s)	Template updates incorporating latest standard policy wording and numbering
05/03/2015	Section 1.0	Revised and clarified “Description of the Procedure, Product, or Service
05/03/2015	Subsection 1.1	Removed definitions. Replaced with “None Apply.”

Date	Section Revised	Change
05/03/2015	Subsection 3.2.1	<p>Statements changed as listed below: “Allergen immunotherapy is considered medically necessary when all of the following criteria apply:” changed to: “Medicaid and NCHC shall cover allergy immunotherapy when all of the following criteria apply:” “ b. Skin testing or blood tests must have determined the presence of allergies, as described in Clinical Coverage Policy 1N-1 NCHC, Allergy Testing” changed to: “b. The triggering allergens must have been determined by appropriate skin testing or blood tests, as described in clinical coverage policy 1N-1, Allergy Testing, on DMA’s website at http://www.ncdhhs.gov/dma/mp/; and” Numbered list under item c. “1. stinging insect hypersensitivity 2. inhalant allergies 3. allergic asthma 4. allergic rhinitis or conjunctivitis 5. dust mite atopic dermatitis” changed to: “1. hymenoptera sensitivity; 2. inhalants; 3. allergic (extrinsic) asthma; 4. allergic rhinitis or conjunctivitis; or 5. dust mite atopic dermatitis.”</p>

Date	Section Revised	Change
05/03/2015	Subsection 3.2.2	<p>“Rapid desensitization is considered medically necessary for either:</p> <ul style="list-style-type: none"> a. insect sting hypersensitivity (Hymenoptera—e.g., wasps, hornets, bees, fire ants), or b. IgE antibodies to a medically necessary drug for which substitution with an alternative medic. <p>or</p> <ul style="list-style-type: none"> c. moderate to severe allergic rhinitis who need treatment during or immediately before the season of the affecting allergy.” <p>changed to:</p> <p>“ Medicaid and NCHC shall cover rapid desensitization for any one of the following:</p> <ul style="list-style-type: none"> a. hymenoptera sensitivity (allergic reaction to the venom of stinging insects, including wasps, hornets, bees, and fire ants); b. the presence of IgE antibodies to a medically necessary drug for which substitution with an alternative medicine is not an effective option; <p>or</p> <ul style="list-style-type: none"> c. moderate to severe allergic rhinitis requiring treatment during or immediately before the season of the affecting allergy”
05/03/2015	Subsection 4.2.1	<p>“Allergen immunotherapy will not be covered for non-allergic asthma or for the following antigens:”</p> <p>changed to:</p> <p>“Medicaid and NCHC shall not cover allergy immunotherapy will not be covered for</p> <ul style="list-style-type: none"> a. intrinsic (non-allergic) asthma; b. food allergy; c. angioedema; d. chronic urticaria; e. migraine headaches; f. non-allergic vasomotor rhinitis; and”
05/03/2015	Subsection 4.2.1	<p>Phrase, “Allergen proof supplies—such as mattresses”</p> <p>changed to:</p> <p>“Allergen proof supplies, including mattresses”</p>
05/03/2015	Subsection 4.2.1	<p>Deleted, “Note: These lists are not all inclusive.”</p>

Date	Section Revised	Change
05/03/2015	Subsection 4.2.1	<p>“Procedure codes which describe the complete service code for the combined supply of antigen and allergy injection provided during a single encounter will not be covered. Please see Attachment A, Section C, 4. for the list of non-covered codes”</p> <p>changed to: Combined Supply Procedure Codes Procedure codes that describe the complete service code for the combined supply of antigen and allergy injection provided during a single encounter will not be covered. Please see Attachment A, Section C, 4, for the list of non-covered codes.</p>
05/03/2015	Subsection 5.3	<p>Statement, “However, treatment beyond a two-year period is not covered ...”</p> <p>changed to: “ Treatment beyond a two-year period is not covered ...”</p>
05/03/2015	Subsection 5.4	<p>Added “Limitations or Requirements Refer to Attachment A Section C, Codes for testing limitations for CPT codes covered in this policy.”</p>
05/03/2015	Attachment A Section C: Codes	<p>Added Testing Limitations” CPT codes 95115, 95117, 95145, 95146, 95147, 95148, 95149 and 95170 are limited to 1 unit per date of service. CPT code 95180 is limited to 12 units. CPT code 95144 is limited to 10 units per date of service. CPT code 95165 is limited to 180 units per 365 days</p>
10/01/2015	All Sections and Attachments	<p>Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.</p>
01/01/2019	Attachment A E. 3(a)	<p>Clarification of CPT code 95165. Reimbursement is for the maintenance concentrate vial and is based on the number of 1 cc (cubic centimeter) that it contains in the multi-dose vials. Maximum of 10 doses are allowed per multi-dose vial.</p>

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 and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

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.

1. Administration of Antigen(s) by Injection

Code(s)	Testing Limitations
95115	1 unit per date of service
95117	1 unit per date of service

2. Allergy Treatments

Code(s)	Testing Limitations
95180	12 units per date of service

3. Preparation of Antigen(s)

Code(s)	Testing Limitations
95144	10 units per date of service
95145	1 unit per date of service
95146	1 unit per date of service
95147	1 unit per date of service
95148	1 unit per date of service
95149	1 unit per date of service
95165	180 units per 365 days
95170	1 unit per date of service

4. Non-Covered Codes

CPT Code(s)
95120
95125.
95130
95131
95132
95133
95134

Note: The supply (preparation) of antigen (s) and the administration of the antigen(s) must be billed separately, using two different CPT codes.

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).

1. Administration of Antigen(s) by Injection
 - a. For 95115, one unit is billed when only one injection is given on the same day.
 - b. For 95117, one unit is billed when two or more injections are given on the same day of service.
2. Allergy Treatments
For 95180, rapid desensitization must be billed **as one hour equals one unit.**
3. Preparation of Antigen(s)
 - a. CPT code 95165 represents the preparation of the maintenance concentrate vial. A billable unit dose of antigen is defined as 1 cc (cubic centimeter) aliquot. This does not mean that 1 cc aliquot must be removed but the professional may not bill for this vial preparation code for more than 10 doses per vial. This applies to venom and non-venom antigen codes.
 - b. The supply (preparation) of antigen(s) and the administration of the antigen(s) **must be billed separately**, using two different CPT codes.

F. Place of Service

Outpatient, Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at <https://medicaid.ncdhhs.gov/>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>