

## Clinical Policy: Allergy Immunotherapy

Reference Number: WNC.CP.221

Last Review Date: 08/24

Coding Implications

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

**Note:** When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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### Description<sup>1</sup>

This policy describes the medical necessity criteria for Allergy Immunotherapy.

### Definitions:

- **Rapid Desensitization**  
An allergy treatment that increases doses over a short period of time allowing for several months of build-up to be completed in one day.
- **Hymenoptera Sensitivity**  
An allergic reaction to the venom of stinging insects, including wasps, hornets, bees, and fire ants.

### Policy/Criteria<sup>1</sup>

- I. WellCare of North Carolina® shall cover *allergy immunotherapy* when the member meets the following criteria :
  - 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*, at <https://medicaid.ncdhhs.gov/>, AND
  - C. The member 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.
- II. WellCare of North Carolina® shall **cover rapid desensitization** for any **ONE** of the following:
  - A. Hymenoptera sensitivity;
  - 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.

III. WellCare of North Carolina® **shall not** cover allergy immunotherapy for:

- A. Intrinsic (non-allergic) asthma;
- B. Angioedema;
- C. Chronic urticaria;
- D. Migraine headaches;
- E. Non-allergic vasomotor rhinitis; **AND**
- F. 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
- G. 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.
- H. **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 **Non-Covered CPT Codes below** for the list of non-covered codes.

IV. Allergy Immunotherapy must be individualized, specific, and consistent with the member's symptoms or confirmed diagnosis. Treatment beyond a two-year period is **NOT covered** when **ANY** of the following are true:

- A. The member does not experience a noticeable decrease of symptoms;
- B. The member 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.

### **Background<sup>1</sup>**

Allergy immunotherapy (a.k.a., desensitization, hypo sensitization, 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 in vivo or in vitro testing (Refer to Clinical Coverage Policy *WNC.CP.220 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.

### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Administration of Antigen(s) by Injection		
CPT®* Codes	Description	Testing Limitations
95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection	1 unit per date of service
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections	1 unit per date of service

Allergy Treatments		
CPT®* Codes	Description	Testing Limitations
95180	Rapid desensitization procedure, each hour	6 units per date of service

Preparation of Antigen(s)		
CPT®* Codes	Description	Testing Limitations
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s)	10 units per date of service
95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single stinging insect venom	10 units per date of service

Preparation of Antigen(s)		
CPT®* Codes	Description	Testing Limitations
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; 2 single stinging insect venoms	10 units per date of service
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; 3 single stinging insect venoms	10 units per date of service
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; 4 single stinging insect venoms	10 units per date of service
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; 5 single stinging insect venoms	10 units per date of service
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens	180 units per 365 days
95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod	10 units per date of service

**NOTE: Preparation of Antigen(s)**

*CPT code 95165 represents the supervision of preparation and provision of the build-up and maintenance concentrate vial. A billable unit dose of antigen is defined as 1 mL (cubic centimeter) aliquot. This does not mean that 1 mL aliquot must be removed but the professional may not bill for this vial preparation code for more than 10 doses per 10 mL vial. This applies to venom and non-venom antigen codes.*

NON-COVERED CPT®* CODES						
95120	95125	95130	95131	95132	95133	95134

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	04/21	05/21
Reviewed CPT codes.	08/21	11/21
Reviewed CPT codes.	08/22	08/22
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual review. Moved CPT codes 95120 95125 95130 95131 95132 95133 95134 to Non Covered Codes.	08/23	08/23
Annual Review. HCPCS and CPT-10 code boxes removed.	05/24	05/24
Added Definitions for Rapid Desensitization and Hymenoptera Sensitivity. Criteria I.B. added “as described in clinical coverage policy 1N-1, <i>Allergy Testing</i> , at <a href="https://medicaid.ncdhhs.gov/">https://medicaid.ncdhhs.gov/</a> ” Criteria II.A. deleted “allergic reaction to the venom of stinging insects, including wasps, hornets, bees, and fire ants.” Added criteria III.H. Combined Supply Procedure Codes. Unit limitations have been changed for the following CPT codes: 95180 changed from 12 to 6u/date of service. 95145 95146 95147 95148 95149 95170 changed from 1 to 10 U/date of service. Under CPT code box, added “Note: Preparation of Antigen”	08/24	08/24

## References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 1N-2 Allergy Immunotherapy. [Program Specific Clinical Coverage Policies | NC Medicaid \(ncdhhs.gov\)](https://medicaid.ncdhhs.gov/). Published July 1, 2024. Accessed July 11, 2024.

## North Carolina Guidance

### *Eligibility Requirements*

- 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.

### *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.

#### **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/>

#### *Provider(s) Eligible to Bill for the Procedure, Product, or Service*

To be eligible to bill for the procedure, product, or service 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.

#### *Compliance*

**CLINICAL POLICY WNC.CP.221**  
**ALLERGY IMMUNOTHERAPY**



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).

*Claims-Related Information*

Provider(s) shall comply with the NC Tracks 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 - as applicable to the service provided:  
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.

*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 - Providers shall follow applicable modifier guidelines.
- e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -  
For Medicaid refer to Medicaid State Plan:  
<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>



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

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



**CLINICAL POLICY WNC.CP.221**  
**ALLERGY IMMUNOTHERAPY**



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