

**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.**

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**NC Medicaid  
Routine Costs In  
Clinical Trial Services for  
Life Threatening Conditions**

**Medicaid and Health Choice  
Clinical Coverage Policy No: 1A-39  
Amended Date: March 15, 2019**

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## **1.0 Description of the Procedure, Product, or Service**

### **1.1 Definitions**

#### **1.1.1 Clinical Trials**

Clinical trials are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients.

Refer to the Glossary of Clinical Trials Terms at <http://www.clinicaltrials.gov/ct2/info/glossary> for definition of clinical trial phases.

**Qualifying clinical trials** are patient research studies designed to evaluate new treatments, including prescription drugs, that:

- a. involve the treatment of life-threatening medical conditions,
- b. are medically indicated and preferable for that patient compared to available non-investigational treatment alternatives, and
- c. have clinical and preclinical data demonstrating that the trial will likely be more effective for that patient than available non-investigational alternatives.

Medicaid and NCHC do not cover procedures, products, or services that are experimental or investigational (see section 4.1(d)). The only costs covered by Medicaid and NCHC in a qualifying clinical trial (Phases II, III, and IV) are routine costs.

#### **1.1.2 Routine Costs**

- a. Routine costs are items or services covered by Medicaid and NCHC and furnished to a beneficiary while evaluating and treating the beneficiary's underlying diagnosis. These items or services are:
  1. subject to all terms, conditions, restrictions, exclusions, and limitations set forth in the clinical coverage policy applicable to the beneficiary's underlying diagnosis; and
  2. furnished to the beneficiary regardless of whether or not the beneficiary is participating in a clinical trial.

- b. Routine costs in clinical trials include items or services satisfying the requirements in **Subsection 1.2 (a)**, and are necessary for the following:
1. Providing the investigational item or service.

**Example:** Medicaid and NCHC cover the standard mechanism needed to administer a chemotherapeutic agent for a beneficiary requiring chemotherapy. Medicaid and NCHC do not cover the experimental delivery system nor the experimental chemotherapeutic agent.

**Example:** Medicaid and NCHC covers the standard surgical procedure necessary to implant a pacemaker for a beneficiary requiring a pacemaker. However, Medicaid and NCHC do not cover the experimental pacemaker.

**Example:** Medicaid and NCHC cover the standard surgical procedure necessary to remove a tumor for a beneficiary requiring this procedure. During the procedure, an experimental radiological device provided by a clinical trial may be implanted. However, Medicaid and NCHC do not cover the surgical procedure required to remove the experimental device.

**Note:** Medicaid and NCHC do not cover a procedure performed solely for an experimental or investigational treatment specific to a clinical trial. This includes administering, implanting, or removing the experimental or investigational treatment.

2. Monitoring (in a clinically appropriate manner) the effects of the investigational item or service.
3. Preventing complications from the investigational item or service. This includes the items or services needed for the treatment (conforming to standard of care) of side effects caused by the investigational item or service.

**Example:** The treatment of nausea symptoms associated with a chemotherapy regimen.

4. The items or services needed to furnish the reasonable and necessary care due to the provision of the investigational item or service. In particular, the diagnosis or treatment of complications resulting from the investigational item or service may be covered.

**Note:** The clinical trial is responsible for treating complications that are reasonably foreseeable or unique to the experimental item or service provided.

## 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 and NCHC shall cover the procedure, product, or service related to this policy when 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 routine costs in clinical trial services for life-threatening conditions when all of the following criteria are met:

- a. The beneficiary, who is a potential clinical trial enrollee, has a current diagnosis with a grave prognosis (life expectancy less than 2 years):
  1. even if treated with currently accepted treatment options; or
  2. standard therapies have not been effective in significantly improving the condition of the beneficiary, and
- b. The proposed treatment is likely to benefit the beneficiary based on at least two independent documents of medical and scientific evidence; and
- c. The beneficiary is to be treated as part of a qualifying clinical trial satisfying **all** of the following criteria:
  1. The investigational drug, device, therapy or procedure is under current review by the FDA and has an Investigational New Drug (IND) number (when applicable) or is classified as an Investigational Device Exemption (IDE);
  2. The clinical trial has passed independent scientific review and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation;
  3. The clinical trial must be a phase II, phase III, or phase IV patient research study approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, or the Department of Veterans Affairs; and
  4. The clinical trial must be conducted in a setting and by personnel who maintain a high level of expertise because of their training, experience, and volume of patients; and

- d. The beneficiary shall:
  1. be enrolled in the qualifying clinical trial;
  2. provide informed consent; and
  3. be treated according to protocol.

#### **3.2.2 Medicaid Additional Criteria Covered**

None Apply.

#### **3.2.3 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 and NCHC shall not cover the procedure, product, or service 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 routine costs associated with clinical trial services for life-threatening conditions when the criteria in **Section 3.0** of this policy are not met.

Coverage is not allowed for any clinical trial services for which the costs have been or are funded by governmental or national agencies, foundations, commercial manufacturers, distributors, charitable grants or other such research sponsors of participant's individual trials. If the service provided includes a transplant, coverage is not provided for organs sold rather than donated to a beneficiary.

In addition, the following clinical trial costs are not covered:

- a. services that are not health care services;
- b. services provided solely to satisfy data collection and analysis needs (protocol induced costs);
- c. services related to investigational drugs and devices; and
- d. services not provided for the direct clinical management of the beneficiary.

#### **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 routine costs in clinical trial services for life threatening conditions, except if a service, product or procedure requires prior approval. The fact that the Medicaid or NCHC beneficiary is enrolled in a qualifying clinical trial does not eliminate the requirement for prior approval.

#### **5.2 Prior Approval Requirements**

##### **5.2.1 General**

None Apply.

##### **5.2.2 Specific**

None Apply.

#### **5.3 Limitations or Requirements**

None Apply.

### **6.0 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 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).

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** January 1, 2004 – Phases III and IV

**Revision Information:**

Date	Section Revised	Change
09/01/2013	All sections and attachment(s)	New policy, effective June 1, 2013, documenting current Medicaid and NCHC coverage of routine costs in clinical trials for life threatening conditions in Phases III and IV of qualifying clinical trials. The policy developed according to SL 2011-145 Section 10.31.(d).
09/01/2013	All sections and attachment(s)	Coverage of routine costs in clinical trials for life threatening conditions for Phase II qualifying clinical trials effective November 15, 2010.
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.
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.

## 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)

Institutional (UB-04/837I 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.

Refer to the applicable clinical coverage policy or manual linked from <https://medicaid.ncdhhs.gov/>.

#### 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 applicable modifier guidelines.

### E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

**F. Place of Service**

Inpatient, Outpatient, Office.

**G. Co-payments**

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

**H. Reimbursement**

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

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

In the event a claim contains charges related to covered clinical trial services but those charges have not been or cannot be separated from costs related to non-covered services, those charges will not be reimbursed.