NC Medicaid
~~Routine Costs in Clinical Trial Services for Life Threatening Conditions~~
Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

Medicaid and Health Choice
Clinical Coverage Policy No: 1A-39
Amended Date:

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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

DRAFT

Related Clinical Coverage Policies
Refer to NC Medicaid's clinical coverage policies listed at https://medicaid.ncdhhs.gov/ to determine if Prior Approval is required.

1.0 Description of the Procedure, Product, or Service

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.

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.

Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions:

a. **Early Phase 1 (formerly listed as Phase 0)**
   A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (screening studies, micro dose studies).

b. **Phase I trials**
   A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

   ~~Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.~~

c. **Phase II trials**
   A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

~~The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.~~

d. **Phase III trials**

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

~~The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.~~

e. **Phase IV trials**

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include post market requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

~~Post-marketing studies, which are conducted after a treatment is approved for use by the U.S. Food and Drug Administration (FDA), provide additional information including the treatment or drug's risks, benefits, and best use.~~

f. **Phase Not Applicable**

Describes trials without FDA-defined phases, including trials of devices or behavioral interventions

An **Investigational Device Exemption (IDE)** is an unphased trial in which an investigational device is used in a clinical study in order to collect safety and effectiveness data required to support submission for approval to the FDA. This classification is divided into two sub-categories:

a. **Category A** (experimental) device refers to a device for which the risk of the device has not been established and the FDA is unsure whether the device type can be safe and effective.
b. **Category B** (nonexperimental-non-investigational) device refers to a device for which the incremental risk is the primary risk in question and questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval (PMA) or clearance for that device type.

A **Humanitarian Use Device (HUD)** is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

A **Humanitarian Device Exemption (HDE)** is a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

DRAFT

An **Investigational New Drug (IND)** application is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics Product License Application.

1.1 Definitions

1.1.1 Qualifying Clinical Trial

Section 1905(gg)(2) of the Act defines the term "qualifying clinical trial" for purposes of section 1905(a)(30) of the Act as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act. Therefore, to meet the statutory definition, the "qualifying clinical trial" must also be one or more of the following:

a. A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
   1. The National Institutes of Health (NIH);
   2. The Centers for Disease Control and Prevention (CDC);
   3. The Agency for Health Care Research and Quality (AHRQ);
   4. The Centers for Medicare & Medicaid Services (CMS);
   5. A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; or
   6. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants;

b. A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
   1. The Department of Energy;
   2. The Department of Veterans Affairs; or
   3. The Department of Defense;

c. A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or

d. A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

~~a. The subject or purpose of the trial must be the evaluation of an item or service that falls within a NC Medicaid or Health Choice benefit category and is not statutorily excluded from coverage;~~

~~b. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent;~~

~~c. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group;~~
~~d. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;~~
~~e. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;~~
~~f. The trial does not unjustifiably duplicate existing studies;~~
~~g. The trial design is appropriate to answer the research question being asked in the trial;~~
~~h. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;~~
~~i. The trial is in compliance with Federal regulations relating to the protection of human subjects; and~~
~~j. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.~~

1.1.2 Routine Costs

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service. Some examples of routine costs in a clinical trial could include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

As described under section 1905(gg)(1) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act **do not** include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project. Similarly, routine patient cost **does not** include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project. For example, if a beneficiary has a condition that typically requires monitoring through an annual medical imaging scan and the beneficiary is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the

investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the beneficiary's routine patient costs to the extent they are not used for the direct clinical management of the beneficiary or are not otherwise covered under the state plan, waiver, or demonstration project.

~~Routine costs of a clinical trial include all items and services that are otherwise generally available to NC Medicaid and Health Choice beneficiaries that are provided in either the experimental or the control arms of a clinical trial ***except*:**~~
~~a. The investigational item or service, itself unless otherwise covered outside of the clinical trial;~~
~~b. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the beneficiary; and~~
~~c. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.~~

~~Routine costs in clinical trials **include**:~~
~~a. Items or services that are typically provided absent a clinical trial;~~
~~b. Items or services required for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and~~
~~c. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.~~

~~1.1.3 Life-Threatening Condition~~

~~Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.~~

1.1.4 Informed Consent

The process by which a beneficiary learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Informed consent generally requires the beneficiary or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment.

1.1.5 ClinicalTrials.gov Identifier (National Clinical Trial number)

The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

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1.1.6 Principal Investigator

The person who is responsible for the scientific and technical direction of the entire clinical study.

~~1.1.7 Institutional Review Boards (IRB)~~

~~Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of doctors, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected. This includes making sure that research risks are minimized and are reasonable in relation to any potential benefits, among other responsibilities. The IRB also reviews the informed consent document.~~

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.

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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 provide coverage of routine patient costs **(refer to Section 1.1.2**) for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial (**refer to Section 1.1.1**) when:

a. The beneficiary meets all eligibility criteria of the qualified clinical trial;
b. The beneficiary is enrolled in the qualified clinical trial;
c. The beneficiary has provided informed consent;

DRAFT

d. The beneficiary is treated according to the qualified clinical trial's protocol; **AND**

e. The health care provider and principal investigator completes the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial (refer to **Subsection 7.2**).

~~Medicaid and NCHC shall cover routine costs in clinical trial services for life-threatening conditions when **ALL** the following criteria are met:~~

~~a. The beneficiary, who is a potential clinical trial enrollee, has a life-threatening condition (refer to **Subsection 1.1**):~~

~~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 or would not be medically appropriate, and~~

~~b. The proposed treatment is likely to benefit the beneficiary based on at least two independent documents of medical and scientific evidence;~~

~~c. The beneficiary is to be treated as part of a **qualifying** clinical trial (refer to **Subsection 1.1**) satisfying **ALL** 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, refer to **Section 1.0**) or is classified as an Investigational Device Exemption (IDE) (when applicable, refer to **Section 1.0**);~~

~~2. The clinical trial has passed independent scientific review and has also been approved by an Institutional Review Board (IRB) (refer to **Subsection 1.1.6**) that oversees 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. meet all eligibility criteria of the qualifying clinical trial;~~

~~2. be enrolled in the qualifying clinical trial;~~

~~3. provide informed consent (refer to **Subsection 1.1**); and~~

~~4. be treated according to protocol.~~

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

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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 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 participants individual trials. If the service provided includes a transplant, coverage is not provided for organs sold rather than donated to a beneficiary.

In addition, Medicaid and NCHC shall not cover the following clinical trial services:

a. services that are not health care services;
~~b. services related to Phase 0 I clinical trials;~~

b. any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project ~~services provided solely to satisfy data collection and analysis needs (protocol induced costs)~~;
c. any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project ~~the experimental intervention itself (except medically necessary Category B investigational devices~~);
d. investigational drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment;
e. after the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a qualifying clinical trial; and
f. travel, lodging and meals; ~~and~~
~~g. services not provided for the direct clinical management of the beneficiary.~~

DRAFT

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 Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials ~~routine costs in clinical trial services for life threatening conditions~~, **except** if the underlying 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 for the underlying service, product, or procedure.

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).

7.2 Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial

NC Medicaid will not require an attestation be submitted with claims associated with routine costs, however, a completed attestation form must be in the beneficiary's health record. Records are subject to audit for compliance at any time. If a completed attestation form is not in the record and signed by the Principal Investigator and Health Care Provider prior to participation in the study, all associated costs will be recouped. The form is available at https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx.

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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.
07/01/2019	Section 1.0	Added descriptions for clinical trials, clinical trial phases, investigational device exemptions, investigational new drug applications, humanitarian use device, and humanitarian device exemption.
07/01/2019	Subsection 1.1	Added or updated definitions for qualifying clinical trial, routine costs, life-threatening conditions, informed consent, ClinicalTrials.gov identifier, and Institutional Review Boards.
07/01/2019	Subsection 3.2.1(a)	Removed criteria that beneficiary must have a current diagnosis with a grave prognosis (life expectancy less than 2 years) and replaced with "beneficiary must have a life-threatening condition."
07/01/2019	Subsection 3.2.1(d)	Added criteria that beneficiary must meet all eligibility criteria of qualifying clinical trial.
07/01/2019	Subsection 4.2.1	Added the following to non-coverage: after the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a qualifying clinical trial; services related to Phase 0-I clinical trials; travel, lodging and meals; the experimental intervention itself (except medically necessary Category B investigational devices).
07/01/2019	Subsection 4.2.1(e)	Removed "services related to investigational drugs and devices" from non-coverage and replaced with "investigational drug costs for drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment."
12/12/2019	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

DRAFT

Date	Section Revised	Change
		implementation, please contact your PHP."
12/12/2019	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.
	Section 1.0	Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.
	Section 1.0	Phase definitions updated.
	Section 1.1.1	Definition of "qualifying clinical trial" updated based on Section 1905(gg)(2) of the Act.
	Section 1.1.2	Definition of "routine costs" updated based on Section 1905(a)(30) and 1905(gg)(1) of the Act.
	Section 1.1.6	Definition added for "principal investigator."
	Section 3.2.1	Section revised to meet new criteria in the Act. Requirement added that provider and principial investigator complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.
	Section 4.2.1	Section revised to meet new criteria in the Act.
	Section 7.2	Requirement added that the provider and principal investigator must complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial and maintain in the beneficiary's health record.

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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)

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.

Refer to the applicable clinical coverage policy or manual on NC Medicaid's website 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.

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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 are not reimbursable.