Clinical Policy: Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

Reference Number: WNC.CP.115 Coding Implications
Last Review Date: 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.

Description[1]

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.

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that they shall provide coverage of routine patient costs (refer to Background II.E.) 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 Background II.D.) when:

A. The member must:

1. Meet all eligibility criteria of the qualifying clinical trial;
2. Be enrolled in the qualifying clinical trial;
3. Provide informed consent; **and**
4. Be treated according to the qualified clinical trials protocol. **AND**
5. The health care provider and principal investigator shall complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial (refer to Background III).

NOTE: *Routine costs associated with trials involving IDE, HUD, HDE, or IND will be covered as long as the trial meets the definition for "qualifying clinical trial" as defined in Background II.D.*

II. It is the policy of WellCare of North Carolina® shall **not** cover any clinical trial services for:

A. 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.

B. If the service provided includes a transplant, coverage is not provided for organs sold rather than donated to a Member.

C. The plan shall not cover the following clinical trial services:

1. Services that are not health care services;
2. Any item or services that is provided to the member solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the member and is not otherwise covered under the state plan, waiver, or demonstration project;
3. 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);
4. Investigational drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment;
5. 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;
6. Travel, lodging and meals.

Background[1]

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 members 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.

I. 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 Trials (formerly listed as Phase 0)
Pre-clinical studies are conducted to explore the effects of a drug on the body and determine whether it is safe for further testing. These studies precede traditional phase I trials and involve minimal human exposure to the drug, with no therapeutic or diagnostic objectives.

B. Phase I Trials
Phase I clinical trials are designed to evaluate the safety of a drug, typically using healthy volunteers as participants. The primary objective is to identify the most common and severe adverse effects of the drug, as well as its metabolism and elimination pathways. These trials typically involve a limited number of participants.

C. Phase II Trials

Phase II clinical trials are conducted to gather initial evidence on the efficacy of a drug in individuals with a specific condition or disease. Participants receiving the drug are typically compared to those receiving a placebo or an alternative treatment. These trials continue to evaluate safety and study short-term adverse events.

D. Phase III Trials
Phase III clinical trials are designed to gather extensive information about a drug's safety and efficacy by studying various dosages, populations, and combinations with other drugs. These studies usually involve a larger number of participants.

E. Phase IV Trials
Phase IV clinical trials refer to studies conducted after the FDA approves a drug for marketing. They typically include post-market requirements and commitment studies that the study sponsor is obligated to conduct or has agreed to perform. These trials are conducted to gather additional information on the drug's safety, efficacy, or optimal use.

F. Phase Not Applicable
Non-pharmacological trials refer to studies of devices or behavioral interventions that do not follow the FDA-defined phases used for drug clinical trials. These trials may involve different methodologies and evaluation criteria than traditional clinical trials.

G. 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 subcategories:

1. **Category A** (Experimental) 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.
2. **Category B** (Nonexperimental-non-investigational) 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.

II. Pertinent Definitions

A. Humanitarian Use Device (HUD) 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.

B. 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.

C. 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.

D. 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:

1. A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
    a. The National Institutes of Health (NIH);
    b. The Centers for Disease Control and Prevention (CDC);
    c. The Agency for Health Care Research and Quality (AHRQ);
    d. The Centers for Medicare & Medicaid Services (CMS);
    e. A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; or
    f. A qualified non-governmental research entity identified in the guidelines
    g. issued by the NIH for center support grants.
2. 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:
    a. The Department of Energy;
    b. The Department of Veterans Affairs; or
    c. The Department of Defense.
3. 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
4. A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

E. 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 member 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 member 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 member solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the member and is not otherwise covered under the state plan, waiver, or demonstration project. For example, if a member has a condition that typically requires monitoring through an annual medical imaging scan and the member 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 Member's routine patient costs to the extent they are not used for the direct clinical management of the member or are not otherwise covered under the state plan, waiver, or demonstration project

F. Serious Condition:

The term "serious," as defined in the Affordable Care Act, refers to a disease or condition:

1. Involving extreme physical pain; or
2. Involving a substantial risk of death; or
3. Involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; or
4. Requiring medical intervention such as surgery, hospitalization, or physical rehabilitation.

(Reference: Affordable Care Act language available at https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf)

G. Life-Threatening Condition

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

H. Informed Consent

1. The process by which a member 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.
2. Generally, requires the member or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment.

I. ClinicalTrials.gov Identifier (National Clinical Trial number)

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

J. Principal Investigator

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

III. Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial

WellCare of North Carolina will not require an attestation be submitted with claims associated with routine costs, however, a completed attestation form must be in the member'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 (refer to Background II.I.) and Health Care Provider (provider who has referred member to qualifying clinical trial) prior to participation in the study, all associated costs will be recouped. Electronic signatures will be allowed on the attestation form. The form is available at https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx.

IV. Prior Approval:

WellCare of North Carolina® shall not require prior approval for Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials, except if the underlying service, product, or procedure requires prior approval. The fact that the Medicaid member is enrolled in a qualifying clinical trial does not eliminate the requirement for prior approval for the underlying service, product, or procedure.

V. Compliance:

A. Provider(s) shall comply with the following in effect at the time the service is rendered:

1. All applicable agreements, federal, state, and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; **and**
2. 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).

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 2025, 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.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	01/21	06/21
Annual Review	02/22	05/22
Annual Review, NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Policy Title updated. **CRITERIA Addition**: I.D.5. Requirement added that "provider and principial investigator complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial." II.C.2."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." AND 3. "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" **CRITERIA Deleted**: II. C2 "services related to Phase 0-1 clinical trials." C3 "needs (protocol induced costs). And C3. The experimental intervention itself except medically necessary Category B investigational devices. And C.8. Services not provided for the direct clinical management of the beneficiary. **BACKGROUND Updates**: I.A-E. Phase definitions updated. I.A-E., III.D. 'qualifying clinical trial" III.E 'routine costs' **BACKGROUND Additions:** : "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. I.F. Phase Not Applicable. III.I "principal investigator." **BACKGROUND Deleted**: Institutional Review Board.	05/23	05/23
Criteria I. added, "they shall provide coverage of routine patient costs (refer to Background III.E.) 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 Background III.D.) when:" Deleted Criteria I. A,B.C 1-4, then Criteria D became A. Criteria E. became Criteria I.A.5. Criteria A.4. added "the qualified clinical trials" "and" Criteria A.5. Added "refer to Background IV." AND "Note Routine costs associated with trials involving IDE, HUD, HDE, or IND will be covered as long as the trial meets the definition for "qualifying clinical trial" as defined in Background III.D." Criteria II. Changed "that	10/23	10/23

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
routine costs in clinical trials services for life threatening conditions" to "shall not cover any clinical trial services for:" Criteria II. C.2. added "Any item or service" and "to the member" Criteria Change: Criteria D became Criteria C. changed "shall" to "must" Criteria II. Investigational Device Exemption (IDE) changed to Criteria I.G. Background Additions: II.F. "Serious Conditions" definition. IV. "Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial" V. "Prior Approval" VI. "Compliance" Removed ICD-10-CM table.		
Annual Review. Changed 'beneficiary' to member. Removed CPT and HCPCS tables. Removed "Medicaid and health choice" verbiage from References.	11/24	11/24
Annual Review. Under NC Guidance/Claims related information, updated state web address.		

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 1A-39 Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published July 1, 2023. Accessed July 1, 2025.

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

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/meetingsnotices/medicaid-state-plan-public-notices

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, 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.