Clinical Trials (for Louisiana Only)

Policy Number: CS018LA.~~N~~O
Effective Date: TBD

➲ Instructions for Use

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Application

This ~~Coverage Determination Guideline~~**Medical Policy** only applies to the state of Louisiana.

Coverage Rationale

Indications for Coverage

associated with approved Clinical Trials are covered when the following criteria are met:

Approved Clinical Trial (Cancer or Life-Threatening Disease)

- An "Approved Clinical Trial" is defined as:
- ~~o~~ Phase I, Phase II, Phase III, or Phase IV clinical trial;
- ~~o~~ Being conducted in relation to the prevention, detection or treatment for Cancer or other life threatening disease or condition; **and**
- ~~o~~ Meets the requirements under **Criteria for Approved Clinical Trials.**~~Section II below~~

For purposes of this benefit, a "life-threatening disease or condition" is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Criteria for Approved Clinical Trials

The Clinical Trial must be described in one of the main bullets below.

- **The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:**

- **National Institutes of Health (NIH) [includes National Cancer Institute (NCI)]**
- **Centers for Disease Control and Prevention (CDC)**
- **Agency for Healthcare Research and Quality (AHRQ)**
- **Centers for Medicare and Medicaid Services (CMS)**
- **A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA)**
- **A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants**
- **The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:**
  - **Comparable to the system of peer review of studies and investigations used by the National Institutes of Health**
  - **Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review**

or

- **The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; or**
- **The study or investigation is a drug trial that is exempt from having such an investigational new drug application**

Additional Clinical Trials (Other Indications)

~~• Additional Clinical Trials:~~

~~Coverage of Routine Patient Costs incurred by members participating in the following types of Clinical Trials is not currently mandated by PPACA. However,~~ UnitedHealthcare's standard Clinical Trial benefit would also include coverage of the Routine Patient Costs when a member is participating in a:

~~o~~• Phase I, Phase II or Phase III **c**~~C~~linical **t**~~T~~rial;

~~o~~• Being conducted in relation to the detection or treatment of non-life threatening:

- ~~•~~o Cardiovascular disease (cardiac/stroke);
- ~~•~~o Surgical musculoskeletal disorders of the spine, hip and knees; **and/or**
- ~~•~~o Other Clinical Trials: Certain plans may allow Clinical Trials relating to other diseases or disorders which are not life-threatening

~~o~~ Meets the requirements under **Criteria for Approved Clinical Trials.** ~~Section II below~~

~~Criteria For Approved Clinical Trials~~

- ~~The Clinical Trial must be described in paragraph 1, 2 or 3 below.~~

~~1. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:~~

- ~~National Institutes of Health (NIH) [includes National Cancer Institute (NCI)]~~
- ~~Centers for Disease Control and Prevention (CDC)~~
- ~~Agency for Healthcare Research and Quality (AHRQ)~~
- ~~Centers for Medicare and Medicaid Services (CMS)~~
- ~~A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA)~~
- ~~A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants~~
- ~~The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:~~
  - ~~Comparable to the system of peer review of studies and investigations used by the National Institutes of Health~~
  - ~~Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review~~

~~**or**~~

~~2. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; **or**~~

~~3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application~~

- Additional Requirements~~:~~
  - The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant institutional review boards (IRBs) before participants are enrolled in the trial. We may, at any time, request documentation about the trial.
  - The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a Covered Health Care Service and is not otherwise excluded under the **p**~~P~~olicy.

Qualified Individual

A qualified individual must be:

- Covered under the health plan; **and**
- Eligible to participate in an approved clinical trial according to the trial protocol when the individual:

- Was referred to the clinical trial by an in-network health care professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol; **or**
- Provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol

Routine Patient Costs During Clinical Trials Include Covered Health Care Services:

- For which benefits are typically provided absent a clinical trial
- Required solely for:
  - The provision of the Experimental or Investigational Service(s) or item (e.g., the infusion administration services to deliver an investigational drug); **and/or**
  - The clinically appropriate monitoring of the effects of the service or item (e.g., lab tests and imaging done at a frequency consistent with signs and symptoms and other standards of care for that diagnosis or treatment type); **and/or**
  - The prevention of complications
- Needed for reasonable and necessary care arising from the provision of an Experimental or Investigational Service(s) or item

Network Plans

If one or more network providers are participating in a clinical trial, then UnitedHealthcare may require that the Qualified Individual participate in the clinical trial using a network provider, as long as the network provider will accept the qualifying individual as a participant in the trial. However, if an Approved Clinical Trial is conducted outside of the Qualified Individual's state of residence, then UnitedHealthcare may not deny or otherwise limit payment for Routine Patient Services solely on the basis that the trial is conducted out-of-state.

Coverage Limitations and Exclusions

Benefits for Clinical Trials do not include:

- The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following:
  - Certain Category B Devices. **Only certain FDA-designated Category B Devices are covered. In order to be covered, all of the following criteria must be met:**
    - **The device must be used within the context of an FDA-approved clinical trial.**
    - **The device must be used according to the clinical trial's approved protocols.**
    - **Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines.**
    - **The device is medically necessary for the member, and the amount, duration and frequency of use or application of the service is medically appropriate.**
    - **The device is furnished in a setting appropriate to the member's medical needs and condition.**
  - Certain promising interventions for members with terminal illnesses
  - Other items and services that, in our determination, meet specified criteria in accordance with our medical and drug policies
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member. Examples include, but are not limited to:
  - Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type.

- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
- Items and services provided by the research sponsors free of charge for any person enrolled in the trial.
- Travel and transportation expenses are excluded from coverage. These include, but are not limited to:
  - Fees for all types of transportation. Examples include, but are not limited to: personal vehicle, taxi, medical van, ambulance, commercial airline, and train.
  - Rental car expenses
  - Mileage reimbursement for driving a personal vehicle
  - Lodging
  - Meals
- Routine patient costs obtained out-of-network where non-network benefits do not exist under the plan.
- Clinical Trials that do not meet the requirements listed in the **Indications for Coverage** ~~*Indications for Coverage*~~ section above~~. An example includes, but is not limited to, Phase 0 drug Clinical Trials.~~

Definitions

Check the definitions within the federal, state, and contractual requirements that supersede the definitions below. ~~Check the definitions within the member benefit plan document that supersede the definitions below.~~

Category B Devices: As determined by the FDA, non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying 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 approval for that device type. (CFR, 1995)~~Only certain FDA-designated Category B Devices are covered. In order to be covered, all of the following criteria must be met:~~

- ~~The device must be used within the context of an FDA-approved clinical trial.~~
- ~~The device must be used according to the clinical trial's approved protocols.~~
- ~~Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines.~~
- ~~The device is medically necessary for the member, and the amount, duration and frequency of use or application of the service is medically appropriate.~~
- ~~The device is furnished in a setting appropriate to the member's medical needs and condition.~~

Clinical Trials/Studies Involving Investigational New Drugs:

- **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 (for example, screening studies, microdose studies).**
- **Phase 1: 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.**

- **Phase 2: 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.**
- **Phase 3: 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.**
- **Phase 4: 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. (ClinicalTrials.gov, 2022)**

~~(National Institutes of Health) (https://clinicaltrials.gov/ct2/about-studies/home - About Clinical Studies > Glossary of Common Site Terms > P)~~

- ~~**Phase 0:** Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).~~
- ~~**Phase 1:** Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.~~
- ~~**Phase 2:** Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with 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.~~
- ~~**Phase 3:** Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.~~
- ~~**Phase 4:** Studies occurring after the US Food and Drug Administration (FDA) has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.~~

Covered Health Care Service(s): Health care services, including supplies or Pharmaceutical Products, which we determine to be all of the following:

- **Provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms.**
- **Medically Necessary.**
- **Described as a Covered Health Care Service in the Certificate under Section 1: Covered Health Care Services and in the Schedule of Benefits.**
- **Not excluded in the Certificate under Section 2: Exclusions and Limitations.**

Exceptions:

- **Clinical Trials for which Benefits are available as described under Clinical Trials in Section 1: Covered Health Care Services.**
- **If you are not a participant in a qualifying clinical trial, as described under Clinical Trials in Section 1: Covered Health Care Services and have a Sickness or**

condition that is likely to cause death within one year of the request for treatment we may, as we determine, consider an otherwise Experimental or Investigational Service to be a Covered Health Care Service for that Sickness or condition. Prior to such a consideration, we must first establish that there is sufficient evidence to conclude that, albeit unproven, the service has significant potential as an effective treatment for that Sickness or condition.

Experimental or Investigational Service(s): Medical, surgical, diagnostic, psychiatric, mental health, substance related and addictive disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time we make a determination regarding coverage in a particular case, are determined to be any of the following:

- Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use.
- Subject to review and approval by any institutional review board for the proposed use. (Devices which are FDA approved under the Humanitarian Use Device exemption are not Experimental or Investigational.)
- The subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: Clinical Trials claims are not limited to these modifiers. However, if a claim has one of these modifiers it is considered to be a Clinical Trials claim.

Modifier Code	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

HCPCS Code	Description
~~**Covered When Criteria Are Met**~~	
***G0276**	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
***G0293**	Non-covered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day

HCPCS Code	Description
*G0294	Non-covered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day
*G2000	Blinded administration of convulsive therapy procedure, either electroconvulsive therapy (ECT, current covered gold standard) or magnetic seizure therapy (MST, non-covered experimental therapy), performed in an approved IDE-based clinical trial, per treatment session
*S9988	Services provided as part of a Phase I clinical trial
*S9990	Services provided as part of a Phase II clinical trial
*S9991	Services provided as part of a Phase III clinical trial
Not Covered	
*S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
*S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion
*S9996	Meals for clinical trial participant and one caregiver/companion

Codes labeled with an asterisk(*) are not on the state of Louisiana Fee Schedule and therefore not covered by the State of Louisiana Medicaid Program.

Coding Clarification: Clinical Trials claims are not limited to this diagnosis code. However, if a claim has this code, it is considered to be a Clinical Trials claim.

Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Description of Services

Clinical trials are studies involving human volunteers (also called participants) that add to medical knowledge. Participants receive specific interventions according to a research protocol created by the trial investigators. These interventions may be medical devices, drugs, procedures, or changes to participant's behavior. Clinical trials may compare a new medical approach to one that is already available, to a placebo, or to no intervention. A clinical trial may also compare existing interventions to each other. Clinical trials aim to determine safety and efficacy of interventions. (ClinicalTrials.gov, 2022)

Clinical Evidence

In a cross-sectional study, Huey et al. (2021) conducted a survey regarding economic burden and financial toxicity in patients with cancer enrolled in phase I clinical trials for >1 month. Financial toxicity score was assessed using the Comprehensive Score for Financial Toxicity survey. Patients also reported monthly out-of-pocket (OOP) costs. Two hundred and thirteen patients completed the survey (72% non-Hispanic White; 45% with annual income ≤$60,000; 50% lived >300 miles from the clinic; 37% required air travel). Forty-eight percent of patients had monthly OOP costs of at least $1,000. Fifty-five percent and 64% of patients reported unanticipated medical and nonmedical expenses,

respectively. Worse financial toxicity was associated with yearly household income <$60,000 (odds ratio [OR]: 2.7; p = .008), having unanticipated medical costs (OR: 3.2; p = .024), and living >100 miles away from the clinical trial hospital (OR: 2.3; p = .043). Non-White or Hispanic patients (OR: 2.5; p = .011) and patients who were unemployed or not working outside the home (OR: 2.5; p = .016) were more likely to report high unanticipated medical costs. The authors concluded that among patients with cancer participating in clinical trials, economic burden is high, and most of patients' OOP costs were nonmedical costs. The authors notes financial toxicity was disproportionally higher in patients with lower income and those who travel farther, and unexpected medical costs were more common among non-White or Hispanic patients. The study was limited by a single center setting and lack of assessment of patients who may have been deterred from clinical trial enrollment due to concerns about financial toxicity.

Nipp et al. (2019) note financial burdens may be a barrier to clinical trial enrollment. The authors note that patient populations with historically lower financial resources are often underrepresented in cancer clinical trials. Disparities in clinical trial enrollment can contribute to a lack of data about the impact of therapies and disparities in care. The authors note few practical solutions have emerged to prevent and alleviate the financial burden to clinical trial participation. They further note that evidence to support efforts to address financial concerns associated with clinical trial participation is lacking as a way to enhance clinical trial enrollment and retention.

In a case series with historical controls, Nipp et al. (2016) implemented a cancer care equity program (CCEP) to address financial burden associated with trial participation. Linear regression models compared trial enrollment before and after the CCEP. Patient characteristics were compared before and after the CCEP and between CCEP and non-CCEP participants. CCEP and non-CCEP participants were surveyed to compare pre-enrollment financial barriers. After accounting for increased trial availability and the trends in accrual for prior years, the authors found that enrollment increased after CCEP implementation (18.97 participants per month greater than expected; p < .001). A greater proportion of CCEP participants were younger, female, in phase I trials, lived farther away, had lower incomes, and had metastatic disease. Of 87 participants who completed the financial barriers survey, 49 CCEP and 38 matched, non-CCEP participants responded (63% response rate). CCEP participants were more likely to report concerns regarding finances (56% vs. 11%), medical costs (47% vs. 14%), travel (69% vs. 11%), lodging (60% vs. 9%), and insurance coverage (43% vs. 14%) related to trial participation (all p < .01). The authors concluded these findings highlight the need to address the financial burden associated with clinical trial participation. There were several limitations to the study. The authors could not definitively conclude that the intervention was responsible for the increase in clinical trial enrollment. Changes in the patient population enrolling in trials (e.g., younger patients, those with metastatic disease, those seeking phase I studies) may have contributed to, rather than resulted from, the increase associated with CCEP. Other factors, including increased awareness about the importance of clinical trials, the emergence of novel drug targets, and improved infrastructure for pursuing clinical trials in the cancer center, likely also contributed to the increase. The authors could not explain the exact mechanism by which the CCEP might have produced an increase in clinical trial enrollment. The authors also noted that although the CCEP participants experienced considerable financial concerns and barriers to trial enrollment, it was not determined if the program reduced their financial distress. The study was also limited to a single academic institution with a distinct patient population and may not apply to a more general cancer clinical trial population.

Clinical Practice Guidelines

American Society of Clinical Oncology (ASOC)

In a ASCO (2018) policy statement, the ASCO Health Disparities Committee prioritized the development of a set of recommendations to address the financial barriers to clinical trials participation in the cancer setting. These recommendations broadly address the following key areas: (1) improving the policy environment for coverage of clinical trials; (2) facilitating transparency among providers, patients, and payers for trial-related out-of-pocket costs; (3) refuting the specter of inducement to enable targeted financial support for patients; and (4) improving the available data on costs of cancer clinical trials.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA does not conduct clinical trials; however, it does provide oversight for some human drug, biological product, and device trials. See https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials for additional information. (Accessed April 15, 2022)

The FDA requires certain clinical trials to be registered in the ClinicalTrials.gov database. See https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information for additional information. (Accessed April 15, 2022)

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~~Medicare Transmittal 126, September 19, 2000, new section 30-1: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R126CIM.pdf. Accessed February 4, 2020.~~

~~NCD for Routine Costs in Clinical Trials, Section 310.1, Publication 100-3 @ http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=AgAAAAAAAAAAAA%3d%3d&. Accessed February 4, 2020.~~

~~US Department of Health and Human Services, Healthcare.gov Health Care Law information page: http://www.healthcare.gov/law/index.html. https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies. Accessed February 4, 2020.~~

Policy History/Revision Information

Date	Summary of Changes
TBD	**Template Update** • Changed policy type classification from "Coverage Determination Guideline" to "Medical Policy" **Coverage Rationale** ***Indications for Coverage*** • Added language to indicate routine patient costs associated with approved Clinical Trials are covered when the [listed] criteria are met **Additional Clinical Trials (Other Indications)** • Removed language pertaining to the Patient Protection and Affordable Care Act (PPACA) ***Coverage Limitations and Exclusions*** • Added language pertaining to Experimental or Investigational Services/Items to indicate only certain FDA-designated Category B Devices are covered; in order to be covered, all of the following criteria must be met: ○ The device must be used within the context of an FDA-approved clinical trial ○ The device must be used according to the clinical trial's approved protocols ○ Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines ○ The device is medically necessary for the member and the amount, duration, and frequency of use or application of the service is medically appropriate ○ The device is furnished in a setting appropriate to the member's medical needs and condition • Removed list of examples of Clinical Trials that do not meet the requirements listed in the *Indications for Coverage* section of the policy **Definitions** • Added definition of "Covered Health Care Service(s)"

	• **Updated definition of:**
	  ○ **Category B Devices**
	  ○ **Clinical Trials/Studies Involving Investigational New Drugs**
	Applicable Codes
	• **Added language to indicate HCPCS codes G0276, G0293, G0294, G2000, S9988, S9990, S9991, S9992, S9994, and S9996 are not on the State of Louisiana Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program**
	Supporting Information
	• **Added *Description of Services*, *Clinical Evidence*, and *FDA* sections**
	• **Updated *References* section to reflect the most current information**
	• **Archived previous policy version CS018LA.N**

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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