Clinical Trials

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➲ Instructions for Use

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Community Plan Policy

- Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials

Medicare Advantage Policy

- Experimental Procedures and Items, Investigational Devices, and Clinical Trials

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Indications for Coverage

Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act ("PPACA") requires non-grandfathered health plans to cover "Routine Patient Costs" incurred by a "Qualifying Individual" who is participating in an "Approved Clinical Trial." Benefits include the reasonable and necessary items and services used to prevent, diagnose, and treat complications arising from participation in a qualifying Clinical Trial. Benefits are available only when the covered person is clinically eligible for participation in the qualifying Clinical Trial as defined by the researcher.

Approved Clinical Trial (Cancer or Life-Threatening Disease)

An "Approved Clinical Trial" is defined as:

- Phase I, Phase II, Phase III, or Phase IV Clinical Trial
- Being conducted in relation to the prevention, detection, or treatment for cancer or other life-threatening disease or condition; **and**
- Meets the requirements under Criteria for Approved Clinical Trials

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.

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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)

Coverage of Routine Patient Costs incurred by members participating in Clinical Trials for the treatment of non-life threatening diseases or conditions is not currently mandated by PPACA. However, some UnitedHealthcare plans contain a benefit that includes such coverage. Refer to the member specific benefit plan document for coverage details.

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 for Qualifying Clinical Trials

Included are 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.

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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, except for the following:
  - Certain Category B Devices. Only certain FDA-designated Category B Devices are covered. In order to be covered, all 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 UnitedHealthcare's determination, meet specified criteria in accordance with UnitedHealthcare's 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; 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 section above

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Category B Devices: As determined by the FDA, non-experimental and/or investigational devices where the incremental risk is the primary risk in question (that is, initial 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 or clearance for that device type (CFR, 1995).

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

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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 postmarket 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, 2024)

Covered Health Care Service(s): Health care services, including supplies or pharmaceutical products, which we determine to be all 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 the member is not a participant in a qualifying Clinical Trial, as described under Clinical Trials in *Section 1: Covered Health Care Services* and has a sickness or condition that is likely to cause death within one year of the request for treatment UnitedHealthcare 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, UnitedHealthcare 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 (Certificate of Coverage).

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 UnitedHealthcare makes 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 as appropriate for proposed use in any of the following:
  - AHFS Drug Information (AHFS DI) under therapeutic uses section
  - Elsevier Gold Standard's Clinical Pharmacology under the indications section
  - DRUGDEX System by Micromedex under the therapeutic uses section and has a strength recommendation rating of class I, class IIa, or class IIb; **or**
  - National Comprehensive Cancer Network (NCCN) drugs and biologics compendium category of evidence 1, 2A, or 2B.
- 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.
- Only obtainable, with regard to outcomes for the given indication, within research settings.

Exceptions:
- Clinical Trials for which benefits are available as described under Clinical Trials in *Section 1: Covered Health Care Services*.
- UnitedHealthcare may, as we determine, consider an otherwise Experimental or Investigational Service to be a Covered Health Care Service for that sickness or condition if:
  - The member is not a participant in a qualifying Clinical Trial, as described under Clinical Trials in *Section 1: Covered Health Care Services*; **and**
  - The member has a sickness or condition that is likely to cause death within one year of the request for treatment.

Prior to such a consideration, UnitedHealthcare must first establish that there is sufficient evidence to conclude that, even though unproven, the service has significant potential as an effective treatment for that sickness or condition (Certificate of Coverage).

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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 the member specific benefit plan document 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.

Modifier Code	Description
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.	
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	Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day
G0294	Noncovered 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, noncovered 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

Diagnosis Code	Description
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.	
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 are intended to add to medical knowledge. Participants receive specific interventions according to a research plan or protocol created by the trial investigators. These interventions may be medical products, such as drugs or devices, procedures, or changes to participants' behavior. Clinical Trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. A Clinical Trial may also compare existing interventions to each other. Clinical Trials aim to determine the safety and efficacy of interventions by measuring certain outcomes (ClinicalTrials.gov, 2024).

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Benefit Considerations

Most benefit plans include coverage for Clinical Trials that meet the indications in the Coverage Rationale section. For more details, refer to the member specific benefit plan document.

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 information on good clinical practice and clinical trials. Refer to https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials for additional information. (Accessed June 4, 2026)

The FDA requires certain Clinical Trials to be registered in the ClinicalTrials.gov database. Refer to https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information for additional information. (Accessed June 4, 2026)

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Medicare Benefit Policy Manual, Chapter 14 - Medical Devices. § 20.2 Category B. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html. Accessed June 4, 2026.

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United Healthcare Insurance Company Individual Exchange Health Benefit Plan Generic Certificate of Coverage 2025.

UnitedHealthcare Insurance Company Generic Certificate of Coverage 2018.

Policy History/Revision Information

Date	Summary of Changes
09/01/2026	**Coverage Rationale** ***Additional Clinical Trials (Other [Than Cancer or Life-Threatening Disease] Indications)*** • Revised language to indicate coverage of routine patient costs incurred by members participating in Clinical Trials for the treatment of non-life threatening diseases or conditions is not currently mandated by the Patient Protection and Affordable Care Act (PPACA), however, some UnitedHealthcare plans contain a benefit that includes such coverage; refer to the member specific benefit plan document for coverage details **Supporting Information** • Archived previous policy version MP.006.26

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Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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