# Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials (for Idaho Only)

**Policy Number**: CS018ID.B
**Effective Date**: May 1, 2026

Instructions for Use

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| Related Policies |
| --- |
| None |

## Application

This Medical Policy only applies to the state of Idaho, including Idaho Medicaid Plus plans.

## Coverage Rationale

### Indications for Coverage

#### *Criteria for Qualified Clinical Trials*

The Qualified Clinical Trial must be described in section 1, 2, or 3 below.

1. The study or investigation is approved, conducted, or supported (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 Department of Veterans Affairs (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 (Secretary) 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 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**
3. The study or investigation is a drug trial that is exempt from being required to have an exemption as described in section 2 above

### Qualified Clinical Trial

Defined as:

- Phase I, Phase II, Phase III, or Phase IV Clinical Trial;
- Being conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition; and
- Meets the requirements under Criteria for Qualified Clinical Trials

### Additional Requirements

- Coverage determinations will be based on an attestation regarding the appropriateness of the Clinical Trial by the health care provider and principal investigator, which shall be made using a streamlined, uniform form, developed for use by the Secretary, and that includes the option to reference information regarding the qualifying Clinical Trial that is publicly available on a website maintained by the Secretary (such as clinicaltrials.gov).

### *Covered Routine Patient Costs During Qualified Clinical Trials*

Any item or service provided to the individual under the qualifying clinical, 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 would otherwise be covered outside the course of participation in the Qualifying Clinical Trial. 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. Services that assist with prevention, diagnosis, monitoring, or treatment of complications arising from Clinical Trial participation may include:

- Physician services
- Laboratory services
- Medical imaging services

### Coverage Exclusions

Routine patient costs do not include the following:

- An item or service that is the investigational item or service that is the subject of the qualifying Clinical Trial and not otherwise covered outside of the Clinical Trial
- Items and services provided solely to satisfy data collection and analysis needs for the qualifying Clinical Trial 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
- Items and services provided by the research sponsors free of charge for any person enrolled in the trial

**Note**: Refer to the federal, state, and contractual requirements and the Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials for details.

## Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, 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 services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

## Definitions

Check the definitions within the federal, state, and contractual requirements that supersede the definitions below.

**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, micro dose 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, 2024)

## 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.

| Modifier | Description |
|---|---|
| Clinical Trial claims are not limited to these modifiers. However, if a claim has one of these modifiers, it is considered to be a Clinical Trial 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 Trial claims are not limited to this diagnosis code. However, if a claim has this code, it is considered to be a Clinical Trial 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 participant's 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).

## 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 April 16, 2025)

The FDA requires certain clinical trials to be registered in the ClinicalTrials.gov database. Additional information is available at: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information. (Accessed April 16, 2025)

## References


42 USC 1396d, subsection (a)(30) and subsection (gg). Available at: https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXIX.htm. Accessed April 16, 2025.

ClinicalTrials.gov website. Learn about studies. Available at: https://clinicaltrials.gov/ct2/about-studies/learn#ClinicalTrials. Bethesda: U.S. National Library of Medicine. May 2023. Accessed April 16, 2025.

Federal Food, Drug and Cosmetic Act, Federal code; 21 USC 355: New drugs house.gov, https://uscode.house.gov/view.xhtml?req=(title:21%20section:355%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section355)&f=treesort&edition=prelim&num=0&jumpTo=true. Accessed April 15, 2025.

Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf. Accessed April 15, 2025.


## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 05/01/2026 | **Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>  ○ 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<br>  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services<br>  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures<br>  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request<br>**Supporting Information**<br>• Updated *FDA* section to reflect the most current information |

| Date | Summary of Changes |
|---|---|
| | • Archived previous policy version CS018ID.A |

# 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, 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.