

Clinical Trials

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Developed By: Medical Necessity Criteria Committee

I. Description

Clinical trials are research studies designed to evaluate the safety and effectiveness of new medical treatments, drugs, diagnostic tests, and screenings. They are scientific investigations that compare new, untested, or non-standard treatment to standard treatments that are currently accepted and utilized in the medical community. All clinical trials are based on a set of rules called a protocol. The protocol describes all study details including characteristics of people who may or may not participate, the length of the study, schedule of tests, procedures, medications, etc. Clinical trials generally consist of the following four phases.

Phase I: Researcher tests a new drug or treatment in a small group of people for the first time to evaluate safety, determine a safe dosage range, and identify side effects.

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

Phase III: The drug or treatment is given to a larger group of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV: Studies are performed after the drug or treatment has been marketed to gather information about its effect in various populations and any side effects associated with long term use.

There are two types of costs associated with a clinical trial: patient care costs and research costs.

Patient care costs fall into two categories:

Usual care costs, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, etc, that occur whether the patient is participating in a trial or receiving standard treatment. These costs are usually covered by a third-party health plan.

Extra care costs associated with clinical trial participation, such as the additional tests that may or may not be fully covered by the clinical trial sponsor and/or research institution.

Research costs are those associated with conducting the clinical trial, such as data collection and management, research physician and nurse time, analysis of results, and tests purely performed for research

purposes. Such costs are usually covered by the organization sponsoring the clinical trial. Costs for the drugs or devices being studied may also be covered by the organization sponsoring the clinical trial.

II. Criteria: CWQI HCS-0017

- A. Moda Health considers Clinical Trials qualified when **1 or more** of the following are met:
- a. Qualified clinical trials for **Oregon members** are limited to trials meeting **All** of the following:
 - i. Funded, or supported by **1 or more** of the following:
 1. National Institutes of Health (NIH) includes National Cancer Institute (NCI)
 2. Centers for Disease Control and Prevention (CDC)
 3. Agency for Healthcare Research and Quality (AHRQ)
 4. Centers for Medicare and Medicaid Services (CMS)
 5. United States Department of Defense (DOD)
 6. United States Department of Veterans Affairs (VA)
 - ii. The clinical trial meets **1 or more** of the following:
 1. Conducted as **1 or more** of the following:
 - a. An investigational new drug application
 - b. An investigational device exemption
 - c. A biologics license application to the United States Food and Drug Administration
 2. Exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration
 - b. Qualified clinical trials for **Alaska members** are limited to trials that meet **All** of the following:
 - i. An approved clinical trial includes **1 or more** of the following:
 1. A scientific study using human subjects designed to test and improve prevention, diagnosis, treatment, or palliative care of cancer; **or**
 2. The safety and effectiveness of a drug, device, or procedure used in the prevention, diagnosis, treatment, or palliative care of a subject
 - ii. The study must be approved by **All** of the following:
 1. An institutional review board that complies with 45 CFR Part 46 and **1 or more** of the following:
 - a. United States Department of Health and Human Services, National Institute of Health, or its institutes or centers
 - b. United States Department of Health and Human Services, United States Food and Drug Administration
 - c. United States Department of Defense
 - d. United States Department of Veterans Affairs; **or**
 - e. A non-governmental research entity abiding by current National Institutes of Health guidelines.
 - c. Qualified clinical trials for **Texas members** are limited to trials that meet **ALL** of the following:
 - i. The clinical trial is approved by;
 - (1) the Centers for Disease Control and Prevention of the United States Department of Health and Human Services;

- (2) the National Institutes of Health;
- (3) the United States Food and Drug Administration;
- (4) the United States Department of Defense;
- (5) the United States Department of Veterans Affairs; or
- (6) an institutional review board of an institution in this state that has an agreement with the Office for Human Research Protections of the United States Department of Health and Human Services.

- d. Qualified clinical trials for Idaho members are limited to trials that meet **ALL** of the following;
 - i. The study or investigation is approved or funded, which may include funding through in-kind contributions, by **one** of the following;
 1. The National Institute of Health
 2. The Centers for Disease Control and Prevention
 3. The Agency for Healthcare Research and Quality
 4. The Centers for Medicare and Medicaid services
 5. A cooperative group or center of any of the entities through the Department of Defense, the Department of Veteran Affairs; or
 6. A qualified nongovernmental research entity identified in the guidelines issued by the national institutes of health for center support grants
 - ii. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration
 - iii. The study or investigation is not a new drug trial and therefore exempt from having such an investigational new drug application by the Food and Drug Administration
 - iv. The study or investigation has been reviewed and approved by an institutional review board of an institution that has an agreement with the Office for Human Research Protection of the United States Department of Health and Human Services.

B. If the above criteria are not met, the study is not considered a qualified clinical trial. Please refer to the ***Moda Health Experimental and Investigational Services and Supplies Criteria***

C. Moda Health will cover **Patient Care Costs** in Clinical Trials that meet **1 or more** of the following:

a. **Oregon Members**

- i. Moda Health will cover routine costs in clinical trials for Oregon members and **ALL** of the following:
 1. Routine cases for the care of a member who is enrolled in or participating in a qualifying clinical trial are covered as defined by **ALL** of the following:
 - a. Routine costs mean medically necessary conventional care, items or services covered by the healthcare insurance plan if typically provided, absent a clinical trial (i.e., hospital costs, labs, imaging)
 2. **Limitations as indicated by ALL of the following:**
 - a. Routine costs will be subject to the applicable cost sharing as if provided in the absence of a clinical trial.
 - b. Routine costs for treatment of adverse effects of a clinical trial are covered

- ii. **All** of the following services are **Not Covered** by Moda Health
 1. The drug, device, or service being tested in the clinical trial unless it would be covered by the Moda Health plan if provided outside of a clinical trial.
 2. Items or services required solely for the provision of the drug, device, or service being tested in the clinical trial
 3. Items or services required solely for the clinically appropriate monitoring of the drug, device, or services being tested in the clinical trial.
 4. Items or services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member
 5. Items or services customarily provided by a clinical trial sponsor free of charge to any person participating in the clinical trial; or
 6. Items or services that are not covered by Moda Health if provided outside of the clinical trial

b. Alaska Members:

- i. Moda Health will cover routine costs for the care of an Alaska member who is enrolled in an approved clinical trial as defined in federal or state laws related to cancer or other life-threatening disease or condition, including leukemia, lymphoma and bone marrow stem cell disorders and meets **ALL** of the following:
 1. Only if the member's treating physicians determines that there is no clear superior non-investigational treatment alternative; and
 2. Available clinical or preclinical data provide a reasonable expectation that the treatment provided in the clinical trial will be at least as efficacious as any non-investigational alternative
- ii. Limitations as indicated by **ALL** of the following:
 1. Covered costs will be subject to applicable cost sharing as if provided in absence of a clinical trial
 2. Routine costs for treatment of adverse effects of a clinical trial are covered
- iii. **All of the following** costs are covered in addition to the standard routine costs.
 1. Prevention, diagnosis, treatment, and palliative care of a qualified medical condition.
 2. Medical care for an approved clinical trial that would otherwise be covered under a health benefit plan if the medical care were not in connection with an approved clinical trial related to a qualified medical condition.
 3. Items or services necessary to provide an investigational item or service
 4. The diagnosis or treatment of complications
 5. A drug or device approved by the United States Food and Drug administration (FDA) without regard to whether the FDA approved the drug or device for use in treating a member's particular condition, but only to the extent that the drug or device is not paid for by the manufacturer, distributor, or provider of the drug or device
 6. Services necessary to administer a drug or device under evaluation in the clinical trial

7. Transportation for the member that is primarily for and essential to the medical case

iv. **Not covered as indicated by ALL of the following:**

1. A drug or device that is associated with the clinical trial that has not been approved by the FDA
 - a. This includes indication, dose, frequency of administration and combination therapy
2. Housing, companion expenses, or other non-clinical expenses associated with the clinical trial
3. An item or service provided solely to satisfy data collection and analysis and not used in the clinical management of the member
4. An item or service excluded from coverage in the **General Exclusions** section of the member handbook
5. An item or service paid for or customarily paid for through grants or other funding

c. **Texas members**

- i. Moda Health will cover **routine patient care costs** for a member enrolled in a qualified clinical trial if **ALL** of the following are met:
 1. The request is in connection with a phase I, phase II, phase III, or phase IV clinical trial
 2. The clinical trial is conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition
- ii. Routine care costs **DO NOT** include:
 1. The cost of an investigational new drug or device that is not approved for any indication by the United States Food and Drug Administration, including a drug or device that is the subject of the clinical trial
 2. The cost of a service that is not a health care service, regardless of whether the service is required in connection with participation in a clinical trial
 3. The cost of a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
 4. A cost associated with managing a clinical trial
 5. The cost of a health care service that is specifically excluded from coverage under a health plan benefit
- iii. Moda Health will **NOT** be required to reimburse the research institution conducting the clinical trial for the cost of routine patient care unless the research institution, and each health care professional providing routine patient care through the research institution, agrees to accept reimbursement under the health benefit plan, at the rates that are established under the plan, as payment in full for the routine patient care provided in connection with the clinical trial.

- iv. Moda Health is **NOT** required to provide benefits for services that are a part of the subject matter of the clinical trial and that are customarily paid for by the research institution conducting the clinical trial.

d. Idaho members

- i. Routine patient care costs is defined as the cost of any medically necessary health care service for which benefits are provided under a health benefit plan, without regard to whether the enrollee is participating in a clinical trial.
- ii. Routine patient care costs will be covered for an enrollee in connection with **ALL** of the following;
 - 1. An approved clinical trial at either phase I, phase II, phase III, or phase IV
 - 2. The clinical trial is conducted in relation to the prevention, detection, or treatment of a disease or condition
- iii. Routine patient care costs do not include **ALL** of the following;
 - 1. An investigational new drug or device that is not approved for any indication by the United States Food and Drug Administration
 - 2. A service that is not a health care service regardless of whether the service is required in connection with participation in the clinical trial
 - 3. A service that is inconsistent with widely accepted and established standards of care for a particular diagnosis
 - 4. The costs associated with managing a clinical trial
 - 5. A health care service that is specifically excluded from coverage under the health benefit plan

D. Federal Regulations for Clinical Trials- General Regulations governing all States.

Qualified clinical trials

- a. An approved clinical trial means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease, or condition and is described in any of the following subparagraphs:
 - i. The study or investigation is approved or funded by **1 or more** of the following:
 - 1. The National Institutes of Health
 - 2. The Centers for Disease Control and Prevention
 - 3. The Agency for Health Care Research and Quality
 - 4. The Centers for Medicare & Medicaid Services
 - 5. Cooperative group or center of any of the entities described in 1-4 or the Department of Defense or the Department of Veterans Affairs.
 - 6. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
 - 7. Any of the following if the conditions described in paragraph II.D.b are met:
 - a. The Department of Veterans Affairs
 - b. The Department of Defense
 - c. The Department of Energy
 - ii. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration
 - iii. The study or investigation is a drug trial that is exempt from having such an investigational new drug application

- b. The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines;
 - i. To be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and
 - ii. Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
- c. **Criteria for Coverage of Patient Care Costs in Clinical Trials:**
 - i. The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition
 - ii. And **1 or more** of the following:
 - 1. The referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (i); or
 - 2. The participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based on the individual meeting the conditions described in paragraph (i).
- d. **Not covered:**
 - i. The investigation item, device, or service, itself
 - ii. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient, or
 - iii. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

III. Information Submitted with the Prior Authorization Request:

1. History and physical
2. Treatment history for the condition for which a clinical trial is being requested
3. A detailed clinical trial protocol
4. A copy of the informed consent document signed by the patient
5. A copy of the Institutional Review Board (IRB) approval

IV. CPT or HCPC codes covered:

Codes	Description
G0293	Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare-qualifying clinical trial, per day
G0294	Noncovered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day
S9988	Services provided as a part of a phase I clinical trial

S9990	Services provided as a part of a phase II clinical trial
S9991	Services provided as a part of a phase III clinical trial
Modifier Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Modifier Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

V. Annual Review History

Review Date	Revisions	Effective Date
01/2009	Criteria Developed	01/2009
02/2011	Annual Review	02/2011
12/2011	Update to criteria- Added Washington regulations	12/2011
09/2012	Annual Review: - Added Alaska Regulations	09/26/2012
07/2013	Annual Review	07/2013
07/2014	Annual Review	07/2014
06/2015	Annual Review- included Medicare criteria, added California regulations	06/15
05/2016	Annual Review: Removed CA regulations. Updated wording added by Regulatory	06/16
05/2017	Annual Review: Updated to new template	05/24/2017
05/2018	Annual Review: Remove WA clinical trial regulations.	05/23/2018
07/2019	Annual Review: No changes	08/01/2019
1/2020	Update: iv.1.a: expanded indications for a non-covered drug or device	01/28/2020
07/2020	Annual Review: Reworded section II. A- "Moda Health considers Clinical Trials qualified..." Removed codes S9992, S9994, S9996 – services not covered	08/01/2020
10/2021	Annual Review: Added coverage guidelines for clinical trials that apply to Texas Members	11/1/2021
09/2022	Annual Review: No changes	10/01/2022
09/2023	Annual Review: Added clinical trials coverage guidelines for Idaho members	10/01/2023

VI. References

- Centers for Medicare & Medicaid Services. (2011). Medical clinical trials policies. Accessed on February 8, 2011, at <http://www.cms.hhs.gov>.
- Centers for Medicare & Medicaid Services, National Coverage Determination (NCD) for Routine Costs in CLINICAL TRIALS (310.1); <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2&fromdb=true> Accessed 9/12/2022
- Clinical Trials and Insurance Coverage. National Cancer Institute. Accessed on February 8, 2011 at: <http://www.cancer.gov/clinicaltrials/education/insurance-coverage/page2>
- National Cancer Institute. (2010). States that require health plans to cover patient care core costs in clinical trials. Accessed on May 24, 2017 at <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs>

5. State of Alaska Department of Commerce, Community, and Economic Development Division of Insurance, (2011. Coverage for clinical trials related to cancer). Sec. 21.42.415. Assessed February 8, 2011 at <http://www.legis.state.ak.us/basis/folioiproxy.asp?url=http://wwwjnu01.legis.state.ak.us/cgi-bin/folioisa.dll/stattx10/query>
6. State of Oregon Chapter 743A—Health Insurance: Required Reimbursements 2009 Edition. 743A.192 Clinical trials. Accessed on February 8, 2011 at <http://www.leg.state.or.us/ors/743a.html>
7. State of Washington, Title 284 WAC, Office of the Insurance Commissioner, Section 284-43-850 (Clinical trials). Assessed on July 22, 2013 at WAC 284-43-850: Clinical trials.
8. U.S. National Institutes of Health. (2008). Clinical trials. Accessed on February 7, 2011 at www.clinicaltrials.gov 42 U.S.C 300gg-8 accessed on July 23, 2013 at <http://www.law.cornell.edu/uscode/text/42/300gg-8>
9. State of Texas: TITLE 8. HEALTH INSURANCE AND OTHER HEALTH COVERAGES; <https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1379.htm>
10. 2023; State of Idaho Title 41 Insurance Chapter 65: Coverage for participants in Clinical Trials. <https://legislature.idaho.gov/statutesrules/idstat/title41/t41ch65/sect41-6502/>
11. Physician Advisors

Appendix 1 – Covered Diagnosis Codes

ICD 10 code	ICD 10 Code Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
	CMS National Coverage Determination (NCD) for Routine Costs in CLINICAL TRIALS (310.1)

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC