Policy Number	ADM1001.027
Policy Effective Date	12/15/2025

Clinical Trial Treatment or Therapy

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

EXCEPTION: For members residing in the state of Louisiana, R.S. 22:1044 requires coverage for patient costs incurred because of a treatment provided in accordance with a clinical trial for cancer. Coverage shall include costs incurred for health-related services.

EXCEPTION: For members residing in the state of Maine, 24-A s 4310 requires that an enrollee is eligible for coverage for participation in an approved clinical trial if the enrollee meets the following conditions: (1) The enrollee has a life-threatening illness for which no standard treatment is effective; (2) The enrollee is eligible to participate according to the clinical trial protocol with respect to treatment of such illness; (3) The enrollee's participation in the trial offers meaningful potential for significant clinical benefit to the enrollee; and (4) The enrollee's referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of the conditions in (1), (2) and (3). A carrier may not deny a qualified enrollee participation in an approved clinical trial or deny,

limit or impose additional conditions on the coverage of routine patient costs for items and services furnished in connection with participation in the clinical trial. For the purposes of this section, "routine patient costs" does not include the costs of the tests or measurements conducted primarily for the purpose of the clinical trial involved. A carrier shall provide payment for routine patient costs but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial. In the case of covered items and services, the carrier shall pay participating providers at the agreed upon rate and pay nonparticipating providers at the same rate the carrier would pay for comparable services performed by participating providers. "Approved clinical trial" means a clinical research study or clinical investigation approved and funded by the federal Department of Health and Human Services, National Institutes of Health or a cooperative group or center of the National Institutes of Health. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

EXCEPTION: For members residing in the state of Maine, 24-A s 2837-F and 24-A s 4234-D (for HMOs) requires that coverage for prescription drugs must provide coverage for off-label use in accordance with the following: A) Group insurance policies that provide coverage for prescription drugs may not exclude coverage of any such drug used for the treatment of cancer for a medically accepted indication on the grounds that the drug has not been approved by the federal Food and Drug Administration for that indication, as long as that use of that drug is a medically accepted indication for the treatment of cancer. B) Coverage of a drug required by this subsection also includes medically necessary services associated with the administration of the drug. C) This subsection may not be construed to require coverage for a drug when the federal Food and Drug Administration has determined its use to be contraindicated for treatment of the current indication. D) A drug use that is covered pursuant to paragraph A may not be denied coverage based on a "medical necessity" requirement except for a reason that is unrelated to the legal status of the drug use. E) A contract that provides coverage of a drug as required by this subsection may contain provisions for maximum benefits and coinsurance and reasonable limitations, deductibles and exclusions to the same extent that these provisions are applicable to coverage of all prescription drugs and are not inconsistent with the requirements of this subsection. For this requirement: "Medically accepted indication" includes any use of a drug that has been approved by the federal Food and Drug Administration and includes another use of the drug if that use is supported by one or more citations in the standard reference compendia or if the insurer involved, based upon guidance provided by the federal Department of Health and Human Services Medicare program pursuant to 42 United States Code, Section 1395x(t), determines that that use is medically accepted based on supportive clinical evidence in peer-reviewed medical literature. "Off-label use" means the prescription and use of drugs for medically accepted indications other than those stated in the labeling approved by the federal Food and Drug Administration. "Peer-reviewed medical literature" means scientific studies published in at least 2 articles from major peer-reviewed medical journals that present data that supports the proposed off-label use as generally safe and effective. "Standard reference compendia" means: a). The United States Pharmacopeia Drug Information or information published by its successor organization; or b). The American Hospital Formulary Service Drug Information or information published by its successor organization. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

Coverage

For members who are enrolled or participating in a clinical trial, the provision of services and/or items (devices, tests, procedures, medications, technology, etc.) that customarily would be

provided outside of the clinical trial in the treatment of a condition is considered routine patient care.

Examples of services and/or items (devices, tests, procedures, medications, technology, etc.) provided within the context of a clinical trial that are NOT considered routine care and therefore subject to applicable contract limitations/exclusions, include but are not limited to:

- The investigational item or service itself;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Policy Guidelines

Definitions and information regarding approved clinical trials, including federally funded trials, are described in the Description below.

Coverage should be consistent with requirements of the Patient Protection and Affordable Care Act and all applicable State legislative mandates.

Description

Clinical Trial

A clinical trial (commonly referred to as a clinical study, research study, or research urgent treatment study) is one of the final steps in the extensive research process for confirming the effectiveness of new medical advances. These trials are crucial not only for finding ways to better treat conditions or diseases, but also finding improved ways to detect problems early as well as prevention in the first place. Trials allow doctors and researchers to gain information on the benefits, side effects, and possible applications to the new treatment modality. They may gain information on different combinations of treatments, doses of drugs, devices, and possible applications of therapies. As a result, the medical community may be able to determine new ways to detect, diagnose, avoid, and control clinical factors responsible for disease.

To determine the effectiveness of a particular strategy for fighting or preventing a disease, a clinical trial will compare its effect to that of the best existing alternative. To make the comparison as accurate as possible, researchers often randomly select which clinical trial participants receive the new agent or treatment and which participants receive the current standard. What the “standard” is depends on the type of trial. For a treatment trial, it might be the most commonly used drug, while for a prevention trial it might be no intervention at all.

Types of Clinical Trials (4)

There are several different types of clinical trials:

- Behavioral Trials – evaluate or compare ways to promote behavioral changes designed to improve health; or
- Diagnostic Trials – scrutinizes avenues to find better tests or procedures for diagnosing a particular disease or condition; or
- Epidemiological Studies – aim to identify the patterns, causes, and control of disorders in groups of people; or
- Interventional or Treatment Trials – evaluates the effectiveness of new drugs, new types or approaches of surgery or radiation/ancillary therapies, different combinations of therapies, and new methods of stopping or reversing the disease course; or
- Observational Trials – help researchers understand a situation and come up with hypotheses that can be put to the test in clinical trials. Researchers do not do experiments or test new treatments; they observe. Observational studies can find associations between things but can't prove that one thing causes another; or
- Prevention Trials – tests strategies for reducing the risk of acquiring the disease, which include strategies in taking medicines, vitamins supplements, vaccines, mineral supplements, learning new dietary or exercise strategies, or making lifestyle changes; or
- Quality of Life/Supportive Care Trials – examines ways to make the lives of people with terminal diseases as comfortable as possible and to help them maintain a high quality of living despite their condition; or
- Screening Trials – explores the best way to find or detect the disease at the earliest and most treatable stage, such as comparing the effectiveness of a blood test in detecting a disease with that of a physical examination as a screening procedure.

Phases of a Clinical Trial (2)

Clinical Trials are conducted in phases or stages. The trials at each phase have a different purpose and help scientists answer different questions:

- 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 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.

Pros and Cons of Participating in a Clinical Trial (3, 4)

In addition to receiving high-quality care, there are many benefits to enrolling in a clinical trial. A patient's participation could potentially benefit others by increasing knowledge about a disease and its potential treatments. Also consider that, as a clinical trial participant, a patient may be one of the first patients to experience positive results from a new therapy. On the other hand, it is possible that new treatments may not be better than the standard care, and unknown side effects may be worse than those experienced with standard treatments. Also, the patient may be placed in a control group that receives the standard care instead of the experimental study treatment. These are the factors a patient needs to be comfortable with before deciding to join a clinical trial. The patient, whether in the clinical trial or control group, will receive the same close monitoring and evaluations. So, no matter which group a patient is in, he or she will receive excellent care for the condition being treated by a team of researchers.

Rights and Measures that Protect Clinical Trial Participants (2, 3)

Clinical trials are regulated by a number of governing groups and processes to help protect patient safety and the ethicality of scientific research. The rights of clinical trial patients are notably protected by:

- Institutional Review Board (IRB) – Institutional review boards (IRBs) review and monitor most clinical trials in the United States. An IRB works to protect the rights, welfare, and privacy of human subjects. An IRB usually includes a team of independent doctors, scientists, and community members. The IRB's job is to review potential studies, weigh the risks and benefits of studies, and ensure that studies are safe and ethical.
- Peer Review (PR) – Clinical trials are often reviewed by experts such as the National Cancer Institute, or a pharmaceutical company chosen by the study sponsor. Prior to IRB submission, these groups review the trials for scientific merit, patient safety, and ethical considerations. Many research organizations have peer review groups in addition to their IRBs.
- Informed Consent (IC) – A document with detailed information about the study, including details about the length of the trial, required visits, medications, and medical procedures. It explains the expected outcomes, potential benefits, possible risks, and other trial details.
- Data Monitoring Committee (DMC) – A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The DMC can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also called a data safety and monitoring board, or DSMB.

Where do the ideas for trials come from and who sponsors them? (4)

Ideas for clinical trials usually come from researchers. After the researchers test new therapies and procedures in the laboratory and in animal studies, the treatment with the most promising laboratory results are moved into clinical trials. The clinical trials are then sponsored or funded by a variety of organizations or individuals, such as physicians, medical institutions, voluntary groups, and pharmaceutical companies. The studies will then be conducted in a variety of places, such as hospitals, universities, physician offices, or community clinics.

Approved Clinical Trials

The term approved clinical trials 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, as determined by the treating physician. Clinical trials should be sponsored, approved or funded (which may include funding through in-kind contributions) by one or more of the following:

- The National Institutes of Health (NIH);
- The Centers for Disease Control (CDC) and Prevention;
- The Agency for Health Care Research and Quality (AHCRQ);
- The Centers for Medicare & Medicaid Services (CMS);
- The Department of Veterans Affairs (VA);
- The Department of Defense (DOD);
- The Department of Energy (DOE);
- Cooperative group or center of the entities listed above; or
- A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants.

Glossary of Terms (2)

- Active comparator arm: An arm type in which a group of participants receives an intervention/treatment considered to be effective (or active) by health care providers.
- Adverse event: An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.
- All-cause mortality: A measure of all deaths, due to any cause, that occur during a clinical study.
- Allocation: A method used to assign participants to an arm of a clinical study. The types of allocation are randomized allocation and nonrandomized.
- Arm: A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment, or no intervention, according to the trial's protocol.
- Arm type: A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm, active comparator arm, placebo comparator arm, sham comparator arm, and no intervention arm.
- Baseline characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age,

sex/gender, race and ethnicity, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

- Clinical study: A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.
- Clinical trial: Another name for an interventional study.
- ClinicalTrials.gov identifier (NCT number): The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).
- Collaborator: An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.
- Cross-over assignment: A type of intervention model describing a clinical trial in which groups of participants receive two or more interventions in a specific order. For example, two-by-two cross-over assignment involves two groups of participants. One group receives drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. So during the trial, participants "cross over" to the other drug. All participants receive drug A and drug B at some point during the trial but in a different order, depending on the group to which they are assigned.
- Eligibility criteria: The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by sex.
- Enrollment: The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.
- Exclusion criteria: A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study.
- Expanded access: A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. There are different expanded access types.
- Experimental arm: An arm type in which a group of participants receives the intervention/ treatment that is the focus of the clinical trial.
- Extension request: In certain circumstances, a sponsor or investigator may request an extension to delay the standard results submission deadline (generally one year after the primary completion date). The request for an extension must demonstrate good cause (for example, the need to preserve the scientific integrity of an ongoing masked trial). All requests must be reviewed and granted by the National Institutes of Health. This process for review and granting of extension requests is being developed.

- Group/cohort: A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes.
- Inclusion criteria: A type of eligibility criteria. These are the reasons that a person is allowed to participate in a clinical study.
- Intervention/treatment: A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.
- Interventional study (clinical trial): A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
- Investigator: A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator.
- Masking: A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions. Types of masking include: open label, single blind masking, and double-blind masking.
- NCT number: A unique identification code given to each clinical study record registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). Also called the ClinicalTrials.gov identifier.
- No intervention arm: An arm type in which a group of participants does not receive any intervention/treatment during the clinical trial.
- Observational study: A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study.
- Other adverse event: An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.
- Outcome measure: For clinical trials, a planned measurement described in the protocol that is used to determine the effect of an intervention/treatment on participants.
  For observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Types of outcome measures include primary outcome measure and secondary outcome measure.
- Patient registry: A type of observational study that collects information about patients' medical conditions and/or treatments to better understand how a condition or treatment affects patients in the real world.

- Phase: The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.
- Placebo: An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.
- Placebo comparator arm: An arm type in which a group of participants receives a placebo during a clinical trial.
- Primary outcome measure: In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.
- Protocol: The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.
- Randomized allocation: A type of allocation strategy in which participants are assigned to the arms of a clinical trial by chance.
- Secondary outcome measure: In a clinical study's protocol, a planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.
- Serious adverse event: An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above.
- Sham comparator arm: An arm type in which a group of participants receives a procedure or device that appears to be the same as the actual procedure or device being studied but does not contain active processes or components.
- Sponsor: The organization or person who initiates the study and who has authority and control over the study.
- Study design: The investigative methods and strategies used in the clinical study.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	G0276, G0293, G0294, G9057, G9537, M1396, M1404, S9988, S9990, S9991, S9992, S9994, S9996

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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1. National Coverage Determination (NCD) Routine Clinical Trials (310.1) (version 3) (May 27, 2024). Centers for Medicare and Medicaid Services. Available at <https://www.cms.gov> (accessed November 11, 2025).
2. ClinicalTrials.gov – Glossary Terms. (May 21, 2025) National Institutes of Health and National Library of Medicine. Available at <https://clinicaltrials.gov> (accessed November 11, 2025).
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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2025	Document updated. The following change was made to Coverage: Modified to provide information related to routine services provided during participation in a clinical trial with removal of statements related to medical necessity. No new references added; some updated and others removed.

03/15/2025	Document updated with literature review. Coverage unchanged. References 9 and 10 added, other references removed.
03/15/2024	Reviewed. No changes.
03/15/2023	Document updated with literature review. Coverage unchanged. Reference 18 added; some references were updated and one removed.
08/15/2022	Reviewed. No changes.
01/15/2022	Document updated with literature review. Coverage unchanged. References 20-22 were added; other references were updated.
08/15/2020	Reviewed. No changes.
07/01/2019	Document updated with literature review. Coverage unchanged. No new references added.
04/15/2018	Reviewed. No changes.
04/15/2017	Document updated with literature review. Coverage unchanged. The following was added to the Coverage section: "NOTE 1: Definitions and information regarding approved clinical trials, including federally funded trials, are described in the Description below."
08/01/2016	Reviewed. No changes.
08/15/2015	Document updated with literature review. Coverage unchanged.
12/15/2014	Document updated with literature review. A note was added regarding the Patient Protection Affordable Care Act.
05/15/2013	Document updated. The following was added: 1) Service(s) and/or item(s) not considered routine care costs are considered experimental, investigational and unproven when the a) The specific service(s) and/or item(s) are considered investigational; OR b) The specific service(s) and/or item(s) are provided solely to satisfy data collection and analysis for the clinical trial but are not required for clinical management of the patient's diagnosis or condition; OR c) The specific service(s) and/or item(s) inconsistent with generally accepted and established standards of care for a particular diagnosis or condition; and 2) When a patient is enrolled or participating in a clinical trial, the usual and routine patient care that customarily would be provided outside of the clinical trial may be considered medically necessary.
03/15/2013	Document updated with literature review. Coverage unchanged.
09/01/2009	Coverage revised to include Texas Contracts ONLY Legislative Mandate for allowance of routine patient care in clinical trials effective on 9/1/09.
06/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
05/01/2006	New medical document.