

Medical Policy: Clinical Trials (Medicare)



POLICY NUMBER	LAST REVIEW DATE	APPROVED BY
M20190013	05/9/2025	MPC (Medical Policy Committee)

IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies(LMRP). All coding and web site links are accurate at time of publication.

Criteria

MUST MEET ALL OF THE FOLLOWING:

1. The request is for coverage of routine costs (see Definitions).
2. The request clearly defines the experimental supply, device, procedure, medication or other medical service.
3. The clinical trial meets the following requirements:
 - a. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery).
 - b. The trial must not be designed exclusively to test toxicity or disease pathophysiology; it must have therapeutic intent.
 - c. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers.
 - d. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
 - e. The principal purpose of the trial is to test whether the intervention potentially improves the beneficiary's health outcomes.

- f. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - g. The trial does not unjustifiably duplicate existing studies.
 - h. The trial design is appropriate to answer the research question being asked in the trial.
 - i. The trial is sponsored by a credible organization or member capable of executing the proposed trial successfully.
 - j. The trial is in compliance with Federal regulations relating to the protection of human subjects.
 - k. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
 - l. Investigational Device Exemption (IDE) Studies are approved by CMS. Category A for coverage of routine services and Category B for coverage of device, related services and routine services.
4. The clinical trial is qualified to receive Medicare coverage of routine costs because:
- a. The trial's lead principal investigator has certified that the trial meets the criteria and the investigator has enrolled the trial in a Medicare clinical trials registry;
- OR**
5. The trial is automatically qualified because:
- a. The trial is funded by NIH, CDC, AHRQ, CMS, DOD or the VA;
 - b. The trial is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or the VA;
 - c. The trial is conducted under an investigational new drug application (IND) reviewed by the FDA; and/or
 - d. The drug trial is exempt from having an IND under 21 CFR 312.2(b)(1) will be automatically qualified until the qualifying criteria are developed and the certification process is in place.

Definitions

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.

- Items or services that are typically provided absent a clinical trial (e.g. conventional care)
- Items or services required solely for the provision of the investigational team or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service (in particular, for the diagnosis or treatment of complications).

Not Covered

- The investigational item or service itself, unless integral to a CMS-approved Category B IDE trial or is otherwise covered outside of the clinical trial.

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- Items and services for the purpose of determining eligibility for the study not related to medically necessary clinical care
- 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.
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

References:

CMS National Coverage Determination for Routine Costs in Clinical Trials May 24, 2025:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&KeyWord=CLINICAL+TRIAL&KeyWordLookupUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAABAAAAA AAA%3d%3d&>. Accessed May 9, 2025.

Approved Investigational Device Exemption (IDE) Studies.

<http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>. Accessed May 9, 2025

Revision history

DATE	REVISION
5/9/2025	Added language clarifying that Category B devices integral to CMS-approved Category B Investigational Device Exemption (IDE) trials are covered
8/9/2024	Annual Review-no changes to policy
08/11/2023	Annual Review-no changes to policy
09/09/2022	Annual Review-no changes to policy
09/10/2021	Annual Review-no changes to policy
08/21/2020	Annual Review-no changes to policy
05/01/2019	Reformatted and reorganized policy, transferred content to new template with new Medical Policy Number
10/29/08, 11/10/10, 05/16/12, 05/01/13, 05/07/14, 05/06/15, 07/06/16	