



MEDICAL POLICY STATEMENT

Indiana Medicaid

Policy Name & Number	Date Effective
Clinical Trial Coverage-IN MCD-MM-0797	02/01/2025
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Clinical Trial Coverage

B. Background

Clinical trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose or treat a disease. Clinical trials evaluate new or emerging devices, treatments, and procedures. They may also compare a new treatment to a treatment that is already available. Every clinical trial has a protocol or action plan for conducting the trial. The protocol or action plan describes what will be done in the study, how it will be conducted and why each part of the study is necessary.

Clinical trials are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients.

Clinical trials generally proceed through four phases:

- a. **Phase I** - the study treatment is given to a small group of people who are healthy or have the disease/condition for the first time to evaluate its safety and determine a safe dosage range;
- b. **Phase II** - the study treatment is given to a large group of people who have the disease/condition to see if it is effective and to identify side effects;
- c. **Phase III** - the study treatment is given usually to large groups of people who have the disease/condition to confirm its effectiveness, monitor adverse reactions, compare it to commonly used treatments and collect information that will allow the treatment to be used safely;
- d. **Phase IV** - studies performed after the treatment has been marketed to collect information about its effects in various populations of people who have the disease/condition and to identify side effects associated with long-term use.

NOTE: Experimental, investigational, and unproven treatment, procedures and all related services are not a covered service by Medicaid.

C. Definitions

- **Clinical Trial** is a Phase I, II, III, or IV research study that does **ONE** of the following for the treatment of cancer or a life-threatening disease:
 - tests how to administer a health care service
 - tests responses to a health care service
 - compares effectiveness of a health care service
 - studies new uses of a health care service **AND**Is approved and funded by **ONE** of the following:
 - A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health Institute or center

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and assures an unbiased review of standards of care with qualified individuals who do not have an interest in the review outcome

- National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)
- The Agency for Health Care Research and Quality (AHRQ)
- The Centers for Medicare and Medicaid services (CMS)
- A cooperative group or center of NIH, CDC, AHRQ, DOD, VA, or CMS
- The United States Department of Veterans Affairs (VA)
- The United States Department of Defense (DOD)
- The Food and Drug Administration
- The United States Department of Energy
- The institutional review board of an institution located in Ohio that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103
- A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center
- A qualified non-governmental research entity in guidelines issued by the NIH for center support grants **AND**
- Is conducted in a facility where the personnel have training, and expertise required to provide type of care required in the study **AND**
- Has a written protocol for the clinical trial **AND**
- Designed to have a therapeutic intent
- **Routine care cost** – The cost of medically necessary items and services related to the care method which is under evaluation in the clinical trial.
- **Life-threatening disease or condition** – Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.
- **Category A (Experimental) device** – Per Centers for Medicare and Medicaid Services “a device for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective”.
- **Category B (Non-experimental/investigational) device** – Per Centers for Medicare and Medicaid Services “a device for which 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”.
- **Experimental/Investigational/Unproven** – Any procedure, treatment, service, supply, or product that meets one or more of the following:
 - Is subject to Institutional Review Board review or approval
 - Effectiveness on health outcomes is unproven based on clinical evidence in peer-reviewed medical literature
 - Cannot be legally marketed in the United States without final approval from appropriate government regulatory or licensing body.

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- **ICD-10-CM Code Z00.6** – A billable ICD code used to specify a diagnosis of encounter for examination for normal comparison and control in clinical research program. The Z00.6 diagnosis code reports that the service involved "examination of participant in clinical trial". The Z00.6 diagnosis code must be used for all services provided as part of a Qualified Clinical Trial or approved study, even if it would otherwise be conventional care for the patient absent the trial.

D. Policy

- I. Prior Authorization is required for ICD-10-CM Code Z00.6.
- II. Informed consent approved by an IRB accredited Association for the Accreditation of Human Research Protection Programs (AAHRPP) must be obtained from the member before enrolling in a clinical trial.
- III. CareSource will cover routine care costs for a member enrolled in a clinical trial as described in this policy when
 - A. The same routine care costs would be typically covered for a member who is **NOT** enrolled in the clinical trial **AND**
 - B. All items and services are medically necessary **AND**
 - C. All items and services are a covered benefit.
- IV. CareSource will cover routine care costs for member in a clinical trial where the item or service is
 - A. Required for the administration and provision of the item or service such as the staffing and equipment need to implant the device **OR**
 - B. For the clinically appropriate monitoring of the effects of the item or service **OR**
 - C. For the prevention, diagnosis or treatment of complications from item or service provided in the clinical trial.
- V. CareSource will **NOT** cover the following items as they are not considered routine care costs typically covered by a member who is not enrolled in the clinical trial
 - A. Item or service being evaluated.
 - B. Item or service that is only utilized for data collection and analysis and not related to the direct clinical management of member.
 - C. Item or service reimbursed or provided for free from another source including the research sponsor.
 - D. Item or service only utilized to determine if individual is eligible to participate in clinical trial.
 - E. Clinical trials designed to only test toxicity or disease pathology.
 - F. Treatment that is not standard of care to support or administer the item or service in the clinical trial.
 - G. Transportation, housing, food or expenses for the member or family members/companions associated with travel to or from facility providing the clinical trial.
 - H. Experimental/investigational/unproven procedure, treatment, service, supply, device, or product.

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VI. All applicable plan limitations for coverage for out-of-network providers will apply to routine care costs in a clinical trial.

VII. All applicable utilization management guidelines (including prior authorizations) will apply to routine care for members in a clinical trial.

E. Conditions of Coverage
N/A

F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	05/19/2015	
Date Revised	05/19/2015	
	05/17/2016	Changed title from Clinical Trials. Changed from AD-0002.
	07/10/2019	Removed all other state requirements. Added specific criteria. Added PA requirement.
	11/01/2019	
	10/28/2020	Updated references. Per SIU expanded definition Z00.6, Encounter for examination for normal comparison and control in clinical research program
	10/27/2021	No changes; updated references
	08/31/2022	Changed title to Clinical Trial Coverage. Updated references. No other changes.
	08/30/2023	Updated references. Approved at Committee.
	09/11/2024	Updated references. Approved at Committee.
Date Effective	02/01/2025	
Date Archived		

H. References

1. Association for the Accreditation of Human Research Protection Programs (AAHRPP). Accessed August 27, 2024. www.aahrpp.org.
2. eCFR - Code of Federal Regulations. (n.d.). Accessed August 7, 2023. www.ecfr.gov.
3. Indiana Administrative Code Rule 29 Services Not Covered by Medicaid 405 IAC 5-29-1. Accessed August 27, 2024. www.in.gov.
4. Indiana Family & Social Services Administration. Medical Policy Manual (2020). Accessed August 27, 2024. www.in.gov
5. Local Coverage Article. Clinical Trials - Medical Policy Article (A52430). Accessed August 27, 2024. www.cms.gov.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

6. Medicare and Medicaid Services Medicare Learning Network (2015). MLN Matters. Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies. Accessed August 27, 2024. www.cms.gov.
7. National Coverage Determination for Routine Costs in Clinical Trials (310.1). Accessed August 27, 2024. www.cms.gov.
8. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2021).

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