MEDICAL POLICY STATEMENT
Indiana Medicaid

Policy Name & Number	Date Effective
Clinical Trial Coverage-IN MCD-MM-0797	02/01/2024

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.

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 VetertMSr erCt((C)25t a(M)-5.9 (Sr)-s4751t)-6.6 (egr)-6 (o

- **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.

7. National Coverage Determination for Routine Costs in Clinical Trials (310.1). Accessed August 7, 2023. www.cms.gov.
8. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2021). Accessed August 7, 2023. www.govinfo.gov.

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