MEDICAL POLICY

Medical Policy Title	**Clinical Trials**
Policy Number	**11.01.10**
Current Effective Date	**September 18, 2025**
Next Review Date	**September 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Clinical trial participation coverage requests, must meet **ALL** of the following criteria:

- A. Eligible under the trial's protocol to participate;
- B. A copy of the clinical trial protocol, including the institutional review board (IRB) approval, must be provided to the Health Plan;
- C. Must be an approved clinical trial that meets **all** of the following criteria:
  1. A Phase I, II, III, or IV clinical trial;
  2. Clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition;
  3. Clinical trial is approved or funded by **any** of the following:
     - a. The National Institutes of Health (NIH);
     - b. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants;
     - c. The Centers for Disease Control and Prevention (CDC);
     - d. The Agency for Health Care Research and Quality (AHRQ);
     - e. The Centers for Medicare & Medicaid Services (CMS);
     - f. Clinical trial is being conducted under an investigational new drug (IND) application reviewed by the U.S. Food and Drug Administration (FDA);
     - g. A drug trial that is exempt from the FDA's IND application process;
     - h. A cooperative group or center of the NIH, CDC, AHRQ, CMS, Department of Defense (DOD), or the Department of Veterans Affairs (VA);
     - i. The VA, DOD, or the Department of Energy (DOE), may conduct a study or investigation if it has been approved through a peer review process that includes **both** of the following:
       - i. Determined by the agency's Secretary to be comparable to the peer review system studies and investigations used by the NIH; **and**

ii. Ensures an unbiased review of the highest scientific standards by qualified individuals with no conflicts of interest regarding the outcome.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

I. Routine costs associated with approved clinical trials that are eligible for coverage include:

A. Items and/or services that would be provided if there were no clinical trial (e.g., conventional care such as hospital services, room and board, physician services, office visits, laboratory and diagnostic tests);

B. Items and/or services required to administer the item or service being investigated (e.g., administration of a chemotherapy drug being tested);

C. Clinical monitoring of the effects of the item and/or service being investigated;

D. Items and/or services for the prevention of complications; and

E. Other reasonable and necessary items and/or services arising from the trial (e.g., the diagnosis or treatment of complications).

II. Non-routine costs that are ineligible for coverage, include, but are not limited to, the following:

A. The item and/or service being investigated;

B. Items and/or services provided only to satisfy the collection and analysis of data for the trial, which are not used in the direct clinical management of the patient (e.g., monthly CT scans when only a single scan would be medically necessary);

C. Non-health care services (e.g., transportation, lodging and meal expenses)

D. Items and/or services inconsistent with the established standard of care for the patient's diagnosis (e.g., the study of a new combination of drugs in order to determine the safety and efficacy of those drugs when used in combination);

E. Items and/or services provided by the research sponsors free of charge; and

F. Duplicative items and/or services.

III. For Medicare Advantage members, original Medicare (not Medicare Advantage) is primary for routine services rendered as part of a clinical trial. Refer to the CMS section of this policy, regarding routine costs of clinical trials and special rules regarding clinical trials for Medicare Advantage members.

DESCRIPTION

Clinical trials are research studies, conducted with patients, which are designed to answer scientific questions and to achieve multiple ends. Clinical trials evaluate the safety and efficacy of new

investigational treatments in comparison to standard or conventional treatments. They may or may not involve investigational treatments. All research studies are not of comparable quality. While many studies are well-designed, using proper scientific methodology and avoiding bias, others are not. Data from poorly designed, poor-quality studies are not meaningful and cannot be used to resolve scientific questions.

Phases of Clinical Trials

- Phase I- Safety and Dosage: This phase is the initial step in testing an experimental drug or treatment in a small group of people (20-100) to evaluate the safety, determining a safe dosage range, and identifying side effects.
- Phase II- Efficacy and Side Effects: This phase involves a larger group of people (100-300), to assess efficacy, and to further evaluate the safety of experimental drugs or treatments.
- Phase III- Large-Scale Testing: This phase involves a larger group of people (1,000-3,000), to confirm the efficacy, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- Phase IV- Post-Marketing Surveillance: This phase is conducted after market approval to gather data on long-term safety, efficacy, and best practices for use. These studies are essential for detecting rare or delayed side effects and ensuring ongoing safety across a wider population.

Types of Clinical Trials

- Treatment trials test experimental treatments, new combinations of drugs, new approaches to surgery or radiation therapy or compare two conventional treatments.
- Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent the disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
- Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- Screening trials test the best way to detect certain diseases or health conditions.
- Observational trials monitor participants without intervention to better understand disease progression and risk factors.
- Quality of Life Trials (or supportive dare trials): Explore ways to improve comfort and the quality of life for individuals with a chronic illness.

Coverage with Evidence Development (CED)

CED is a Medicare policy that allows coverage of a treatment or technology while evidence is being gathered through a clinical trial or registry to determine its effectiveness.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

The Affordable Care Act (ACA) requires the Health Plan to provide coverage for members covered under insured, non-grandfathered health plans, for the standard of care costs associated with participation in clinical trials, for plan years beginning on or after January 1, 2014. Under the ACA, routine costs include all items and services that the Health Plan would cover for a patient not enrolled in a clinical trial. For purposes of clinical trials, the ACA defines "life-threatening" as "any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted."

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

HCPCS Codes

Code	Description
S9988	Services provided as part of a Phase I clinical trial
S9990	Services provided as part of a Phase II clinical trial
S9991	Services provided as part of a Phase III clinical trial
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/ companion
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/ companion
S9996	Meals for clinical trial participant and one caregiver/companion

Modifiers

Code	Description
FB	Item provided without cost to provider, supplier or practitioner, or full credit received for replaced device (examples, but not limited to covered under warranty, replaced due to defect, free samples)
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

ICD10 Codes

Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program
Multiple Codes	

REFERENCES

National Institutes of Health (NIH) [Internet]. Clinicaltrials.gov. Learn About Clinical Studies. [accessed 2025 Jul 25] Available from: https://www.clinicaltrials.gov/study-basics/learn-about-studies

National Institutes of Health (NIH) [Internet]. Clinicaltrials.gov. Background. [accessed 2025 Jul 25] Available from: https://clinicaltrials.gov/about-site/about-ctg

National Institutes of Health (NIH) [Internet]. NIH Grants Policy Statement: Definition of Terms. [accessed 2025 Jul 25] Available from: https://grants.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm

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National Institutes of Health (NIH), Department of Health and Human Services (HHS). Clinical Trials Registration and Results Information Submission. Final rule. Fed Regist. 2016 Sep 21;81(183):64981-5157.

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World Health Organization (WHO) [Internet]. International Standards for Clinical Trial Registers. [accessed 2025 Jul 25] Available from: https://www.who.int/publications/i/item/international-standards-for-clinical-trial-registers

Zon R, et al. American Society of Clinical Oncology Statement on minimum standards and exemplary attributes of clinical trial sites. J Clin Oncol. 2008 May 20;26(15):2562-7.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Routine Costs in Clinical Trials (NCD 310.1) [accessed 2025 Jul 25]

Clinical Trials – Medical Policy Article (LCA A52840) [accessed 2025 Jul 25]

Medicare Managed Care Manual [accessed 2025 Jul 25]

Coverage with Evidence Development | CMS [accessed 2025 Jul 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/24/02, 03/27/03, 02/26/04, 02/24/05, 12/01/05, 10/26/06, 08/23/07, 08/28/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 12/12/13, 12/11/14, 12/10/15, 12/08/16, 12/14/17, 12/13/18, 12/12/19, 12/10/20, 11/18/21, 10/20/22, 09/21/23, 09/18/24, 09/18/25	
Date	**Summary of Changes**
09/18/25	• Annual review; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
01/24/02	• Original effective date