Clinical Policy: Clinical Trial Coverage

Reference Number: MO.IFP.MP.01
Date of Last Revision: 09/25

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The purpose of this policy is to outline medical necessity guidelines for certain clinical trials related to prevention, early detection, and treatment of cancer or other life threatening diseases or conditions. Clinical Trial Coverage includes routine patient care costs incurred as the result of an approved phase I,II, III or phase IV clinical trial when the clinical trial is undertaken for the purposes of prevention, early detection, or treatment of cancer or other life threatening disease or condition.

Policy/Criteria

I. It is the policy of Ambetter from Home State that routine patient care costs of a qualifying clinical trial and services used to diagnose and treat complications arising from participating in a qualifying clinical trial are **medically necessary** based upon the following guidelines and limitations:

A. Routine costs in a clinical trial include all items and services generally considered **medically necessary** and a covered benefit to Plan members/enrollees that are provided in either the experimental or control arms and include:
   1. Drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the enrollee's particular condition. This includes coverage for reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial;
   2. Reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial;
   3. All items and services that are otherwise generally available and provided to a qualified individual in the clinical trial.

B. Excluded costs/services:
   1. The investigational item or service itself;
   2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the enrollee;
   3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

   Note: Health benefit plans may limit coverage for the routine patient care costs of enrollees in phase II of a clinical trial to those treating facilities within the health benefit plan's provider network; except that, this provision shall not be construed as relieving a health benefit plan of the sufficiency of network requirements under state statute.

C. Clinical trials must meet the following requirements:

1. Documentation that there is equal to or superior noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives;
2. Phase I and II of a clinical trial shall apply to Phase III or IV of clinical trials that are approved or funded by one of the following groups:
   a. One of the National Institutes of Health (NIH);
   b. The Centers for Disease Control and Prevention;
   c. The Agency for Health Care Research and Quality;
   d. The Centers for Medicare & Medicaid Services;
   e. A cooperative group or center of any of the entities listed above or the Department of Defense or the Department of Veteran Affairs;
   f. An NIH Cooperative Group or Center;
   g. The FDA in the form of an investigational new drug application;
   h. The federal Department of Veterans' Affairs, Defense, or Energy;
   i. An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human services assuring compliance with and implementation of regulations for the protection of human subjects;
   j. The study or investigation is a drug trial that is exempt from having such an investigational new drug application;
   k. A qualified non-governmental research entity that meets the criteria for NIH Center support grant eligibility;

D. Individual is enrolled in the clinical trial. (This section shall not apply to an enrollee who is only following the protocol of phase I or II of a clinical trial, but not actually enrolled);
E. Phase III or IV of clinical trials that are approved or funded by one of the following entities:
   1. One of the National Institutes of Health (NIH);
   2. An NIH cooperative group or center;
   3. The FDA in the form of an investigational new drug application;
   4. The federal Departments of Veterans' Affairs or Defense;
   5. An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects (45 CFR 46);
   6. A qualified research entity that meets the criteria for NIH Center support grant eligibility.
F. An entity seeking coverage for treatment, prevention, or early detection in a clinical trial approved by an institutional review board shall maintain and post electronically a list of the clinical trials meeting the requirements above that includes all of the following:
   1. The phase for which the clinical trial is approved;
   2. The entity approving the trial;
   3. The particular disease;
   4. The number of participants in the trial;
   5. An electronic or written list of trials providing the information required.
G. A qualified individual must be eligible to participate in the clinical trial and meet one of the following:

1. Have a referral from a doctor stating that the clinical trial would be appropriate based upon the individual having cancer or a life-threatening disease or condition;
2. The individual must provide medical and scientific information establishing that their participation in the clinical trial would be appropriate based on the individual having cancer or a life-threatening disease or condition.

   Note: Providers participating in clinical trials shall obtain an enrollee's informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards. Such documents shall be made available to the health plan upon request.

II. It is the policy of Ambetter from Home State that provisions in this policy related to clinical trials and services used to diagnose and treat complications arising from participating in a qualifying clinical trial are **not medically necessary** for the following indications:

A. A policy, plan or contract paid under Title XVIII or Title XIX of the Social Security Act;
B. Accident-only policy, specified disease policy, hospital indemnity policy, Medicare supplement policy, long term care policy, short-term major medical policy of six months or less duration, or other limited benefit health insurance policies.

Background

Treating Facility and Personnel

In the case of treatment under a clinical trial, the treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients.

DEFINITIONS:

Cooperative Group: A formal network of facilities that collaborate on research projects and have an established NIH-approved Peer Review Program operating within the group, including the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program.

Multiple Project Assurance Contract: A contract between an institution and the federal Department of Health and Human Services (DHHS) that defines the relationship of the institution to the DHHS and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

Routine Patient Care Costs: Includes coverage for reasonable and medically necessary services needed to administer the drug, or device under evaluation in the clinical trial. Routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:

- 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.
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date	05/19	
Annual review; no changes	04/20	
Annual review; no changes	03/21	
Annual review; no changes	12/21	
Annual review; no changes	10/22	
Changed "HIM" in policy ID to "IFP"; updated reference section.	10/23	
Annual review. Transitioned policy to state specific clinical policy template and sent to market for approval; policy number changed from MO.IFP.UM.13 to MO.IFP.MP.01. References reviewed and updated.	09/24	
Annual review. Minor edits with no impact to criteria meaning. References reviewed and updated.	08/25	

References
1. Revisor of Missouri. Title XXIV Business and Financial Institutions: Chapter 376-Section 376.429; Coverage for certain clinical trials for prevention, early detection and treatment of cancer, restrictions — definitions — exclusions. Missouri Revisor of Statutes - Revised Statutes of Missouri, RSMo Section 376.429. Effective August 28 , 2006. Accessed July 14, 2025.
2. National Institutes of Health U.S. National Library of Medicine. ClinicalTrials.gov. https://clinicaltrials.gov/. Accessed July 14, 2025.
3. National Cancer Institute. U.S. Department of Health and Human Services; National Institutes of Health. https://www.cancer.gov/research/participate/clinical-trials-search. Accessed July 14, 2025.
4. U.S. Food and Drug Administration. Clinical Trials and Human Subject Protection. https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection. Updated June 5, 2024. Accessed July 14, 2025.

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.