Medica Central Coverage Policy

Policy Name:	**Clinical Trial Participation MP9447**
Effective Date:	**09/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Routine patient costs for a qualified individual participating in an approved clinical trial are COVERED when all of the following apply:

1. The items or services would be a covered benefit if not provided in connection with an approved clinical trial, including but not limited to:
    a. Professional services
    b. Hospital services
    c. Laboratory tests
    d. X-rays and other imaging
2. An approved clinical trial is a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening condition*, is not designed exclusively to test toxicity or disease pathophysiology, and one of the following applies:
    a. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration (FDA).
    b. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.
    c. The study or investigation is approved or funded by one or more of the following:
        i. National Institutes of Health (NIH)
        ii. Centers for Disease Control and Prevention
        iii. Agency for Health Care Research and Quality

iv. Centers for Medicare and Medicaid Services

v. Cooperating group or center of any of the entities mentioned above

vi. Cooperative group or center of the U.S. Department of Defense

vii. Cooperative group or the U.S. Department of Veterans Affairs

viii. Qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants

ix. U.S. Departments of Veterans Affairs, Defense or Energy if the trial has been reviewed or approved through a system of peer review determined by the secretary, and BOTH of the following criteria are met:

a) Be comparable to the system of peer review of studies and investigations used by the NIH, and

b) Provide an unbiased review of the scientific standards by qualified individuals who have no interest in the outcome of the review.

*NOTE: Life threatening condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

3. A qualified individual is defined as:
   a. Eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening condition, and
   b. One of the following applies:
      i. The individual's referring health care professional is participating in the trial and has concluded that the individual's participation in the trial would be appropriate, or
      ii. The individual provides medical or scientific information establishing that their participation would be appropriate.
4. In connection with an approved clinical trial, the following items and services are NOT COVERED:
   a. The investigational item, device, service itself, or drug.
   b. Items and services that are provided solely to satisfy data collection and analysis needs and are not used in direct clinical management of the member including, but not limited to, the costs of data collection and record keeping, research physician and/or clinician time, and result analysis costs.
   c. Items or services provided by the research sponsors free of charge for any person enrolled in the trial
   d. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
   e. Travel, room and board, and related expenses.
   f. Items and services otherwise excluded from coverage under the member's coverage document.

Description

A clinical trial is the scientific evaluation of a new or emerging intervention, such as a drug, vaccine, device, diagnostic procedure, medical or behavioral treatment or procedure, or surgical procedure. Preclinical studies are first conducted in laboratory or animal testing settings. If results indicate there are no serious safety problems in these settings, human testing may begin in order to study therapeutic intent. Therapeutic intent means that trial study design is aimed at determining

if the intervention under study is expected to provide some benefit in improving a subject's condition (e.g., extension of life, shrinkage of a tumor, or improved quality of life), even though cure or dramatic improvement cannot necessarily be affected. However, until clinical research is completed, it remains unclear whether the new treatment is the same as, better than, or worse than current standard treatment(s).

Clinical Trial Phases: The Food and Drug Administration (FDA) has established categories for describing the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants:

- Phase I: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- Phase II: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
- Phase III: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- Phase IV: Studies occurring after FDA has approved a drug for marketing. These including postmarket requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use (National Institutes of Health [NIH], 2012).

Participants are often randomly selected for placement in either the test group or the control group of the trial. The test group is the set of individuals receiving the new or emerging intervention. The control group is the set of individuals that will not receive the new or emerging intervention. If the participant is in the control group, he/she may receive a placebo (used frequently in drug studies), sham treatment (used frequently in device studies), no treatment, or current standard treatment. Blinding is the technique used in clinical trials to maintain the integrity of results. In many trials, the participant does not know (i.e., is blinded to) into which study group (test or control) he/she has been placed. In addition, the provider of services and the evaluator of results are also frequently blinded to which group the participants have been assigned.

Results obtained through a clinical trial are intended to benefit society and future patients through the advancement of medical knowledge. From the individual participant's perspective, it is important to note that the participant may or may not benefit from the experimental treatment being evaluated in the trial. Clinical trials are often conducted for interventions related to life threatening conditions, which are defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. The participant is requested to sign a consent form attesting to the fact that he/she has been informed of the ramifications of participation in the study, including potential adverse events that may occur during the treatment regimen. In addition to an explanation of the treatment under study, the study groups in the trial, and the possibility of randomization into any of the study groups, it is also stated that due to the nature of clinical trials, a guarantee that the treatment being currently investigated will prove beneficial to any one individual is not possible.

FDA Approval

Therapies and procedures are not regulated through the FDA approval process.

The FDA does not oversee clinical trial protocol. Current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state

lines. However, investigational drugs under clinical study are usually shipped to clinical investigators in many states, and therefore an exemption from this legal requirement is available under the granting of FDA Investigational New Drug (IND) or Supplemental New Drug Application (SNDA) status. The assigned IND and SNDA number is the means through which the drug's sponsor technically obtains the necessary exemption to current federal law. In addition, the FDA grants Investigative Device Exemption (IDE) status to certain investigational devices that do not yet have an approved marketing application.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS code modifiers:

- **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

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division	December 19, 2018
Revised:	Medical Policy Committee/Health Services Division	November 20, 2019
	Medical Policy Committee/Health Services Division	October 21, 2020
	Medical Policy Committee/Health Services Division	November 16, 2022
	Medical Policy Committee/Health Services Division	April 19, 2023
	Medical Policy Committee/Health Services Division	August 16, 2023
	Medical Policy Committee/Health Services Division	August 21, 2024
Reviewed:	Medical Policy Committee/Health Services Division	November 20, 2019
	Medical Policy Committee/Health Services Division	October 21, 2020
	Medical Policy Committee/Health Services Division	October 20, 2021
	Medical Policy Committee/Health Services Division	November 16, 2022
	Medical Policy Committee/Health Services Division	April 19, 2023
	Medical Policy Committee/Health Services Division	August 16, 2023
	Medical Policy Committee/Health Services Division	August 21, 2024