Medica Central Utilization Management Policy

Policy Name:	**Clinical Trial Utilizing Car-T Therapy, Bone Marrow or Stem Cell Transplantation MP9790 (III-MED.10)**
Effective Date:	**01/01/2025**

This policy was developed with input from specialists in family practice, internal medicine, and obstetrics and gynecology and endorsed by the Medical Policy Committee.

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.

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

I. Definitions
   A. **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:

      1. **Phase I clinical trials** - the study drug or treatment is given to a small group of people (e.g., 20-80) for the first time to evaluate its safety, determine a safe dosage range and to identify side effects.
      2. **Phase II clinical trials** - the study drug or treatment is given to a large group of people to see if it is effective and to further evaluate its safety.
      3. **Phase III clinical trials** - the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely.

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4. **Phase IV** - studies performed after the drug or treatment has been marketed to collect information about its effects in various populations and any side effects associated with long-term use.

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 is described in any of the following subparagraphs:

1. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration.
2. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.
3. The study or investigation is approved or funded by one of the following: the 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 any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA); a qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants; the United States 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 to: (a) be comparable to the system of peer review of studies and investigations used by the NIH, and (b) provide an unbiased scientific review by qualified individuals who have no interest in the outcome of the review.

B. **CAR T-cell therapy:** A type of treatment in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added to the T cells in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion. CAR T-cell therapy is used to treat certain blood cancers, and it is being studied in the treatment of other types of cancer. Also called chimeric antigen receptor T-cell therapy.

C. **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.

II. Legislation

A. Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act ("PPACA") requires non-grandfathered health plans to cover "Routine Patient Costs" incurred by a "Qualifying Individual" who is participating in an "Approved Clinical Trial." Benefits include the reasonable and necessary items and services used to prevent, diagnose, and treat complications arising from participation in a qualifying clinical trial. Benefits are available only when the covered person is clinically eligible for participation in the qualifying clinical trial as defined by the researcher.

B. Coverage for participation in approved clinical trials must also meet specific state statutes requirements.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for clinical trial participation related to CAR-T therapy and Bone Marrow or Stem Cell Transplantation.

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Note: For clinical trials related to cancer and life-threatening conditions other than CAR-T therapy, bone marrow or stem cell transplantation see coverage policy: ***Clinical Trial Participation***.

2. Coverage may vary according to the terms of the member's plan document.
3. Routine patient care costs for a qualified individual participating in an approved clinical trial are considered medically necessary and a covered benefit to Plan members, including but not limited to:
   a. Items and services that are consistent with the coverage that applies to routine care for individuals not enrolled in clinical trials, such as:
      - Professional services
      - Hospital services
      - Laboratory tests
      - X-rays and other imaging
   b. Items or services that are needed for the reasonable and necessary care used to prevent, diagnose, and treat unexpected complications arising from participation in the approved clinical trial.

   Note: Benefits are available only when the covered person is clinically eligible for participation in the qualifying clinical trial as defined by the researcher.
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.
   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.
   e. Travel, room and board, and related expenses.
   f. Items and services otherwise excluded from coverage under the member's coverage document.
5. If the Medical Necessity Criteria and Benefit Considerations are met, The Health Plan will authorize benefits within the limits in the member's plan document.
6. If it appears that the Medical Necessity Criteria and Benefit Considerations criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Provider Administrative Manual.

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MEDICAL NECESSITY CRITERIA

I. Criteria for Approved Clinical Trial Study or Investigation (CAR-T therapy, bone marrow transplantation, or stem cell transplantation).
To qualify, the Approved Clinical Trial must meet all **of the following** criteria:

A. Have a written protocol comparable to the system of peer review of studies and investigations used by the NIH, that describes a scientifically sound study, and
   1. Have been approved by all relevant institutional review boards (IRBs) that will oversee the investigation before participants are enrolled, and
   2. Provide an independent unbiased review of the scientific standards by qualified individuals who have no interest in the outcome of the review.

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B. Defined as Phase I, II, III, or IV research study 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 must be:
   1. Conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration (FDA); or
   2. Exempt from obtaining an investigational new drug application; or
   3. Approved or funded by one or more of the following:
      a. National Institutes of Health (NIH)
      b. Centers for Disease Control and Prevention
      c. Agency for Health Care Research and Quality
      d. Centers for Medicare and Medicaid Services
      e. Cooperating group or center of any of the entities mentioned above
      f. Cooperative group or center of the U.S. Department of Defense
      g. Cooperative group or the U.S. Department of Veterans Affairs
      h. Qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants
      i. 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.

II. Indications for an individual to qualify for a clinical trial (CAR-T therapy, bone marrow transplantation, or stem cell transplantation)**:**
Clinical trial participation is considered medically necessary when documentation from the medical record indicates that the member meets all of the following criteria:

A. Have a cancer or other life-threatening condition from which the likelihood of death is probable:
   1. Even if treated with currently accepted treatment options; and/or
   2. Standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate.

B. Eligible requirements to participate in an approved clinical trial according to the trial protocol when the individual:
   1. Was referred to the clinical trial by a health care professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol; **or**
   2. Provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

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DOCUMENT HISTORY	
Original Effective Date	01/01/2025
MPC Endorsement Date(s)	09/11/2024
Administrative Update(s)	

References:

09/11/2024 MPC

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