MEDICAL POLICY STATEMENT
D-SNP

Policy Name & Number	Date Effective
Clinical Trial Coverage-DSNP-MM-1554	01/01/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical

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.

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:

a. **Phase I** clinical trials - the study treatment is given to a small group of people who are healthy or have the disease/condition for the first time to evaluate its safety and determine a safe dosage range;
b. **Phase II** clinical trials - the study treatment is given to a large group of people who have the disease/condition to see if it is effective and to identify side effects;
c. **Phase III** clinical trials - the study treatment is given usually to large groups of people who have the disease/condition to confirm its effectiveness, monitor adverse reactions, compare it to commonly used treatments and collect information that will allow the treatment to be used safely;
d. **Phase IV** clinical trials - studies performed after the treatment has been marketed to collect information about its effects in various populations of people who have the disease/condition and to identify side effects associated with long-term use.

NOTE: Experimental, investigational, and unproven treatment, procedures and all related services are not a covered service by Medicaid.

C. Definitions

- **Clinical Trial** is a Phase I, II, III, or IV research study that does **ONE** of the following for the treatment of cancer or a life-threatening disease:
  - tests how to administer a health care service
  - tests responses to a health care service
  - compares effectiveness of a health care service
  - studies new uses of a health care service **Ae**

  - 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 Veterans Affairs (VA)
  - The United States Department of Defense (DOD)
  - The Food and Drug Administration
  - The United States Department of Energy
  - The institutional review board of an institution located in Ohio that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103
  - a research entity that meets eligibility criteria for a support grant from a National Institutes of Health center
  - a qualified non-governmental research entity in guidelines issued by the NIH for center support grants **AND**
  - is conducted in a facility where the personnel have training, and expertise required to provide type of care required in the study **AND**
  - has a written protocol for the clinical trial **AND**
  - designed to have a therapeutic intent.
- **Routine care cost** - The cost of medically necessary items and services related to the care method which is under evaluation in the clinical trial.
- **Life-threatening disease or condition** - Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.
- **Category A (Experimental) device** - Per the Centers for Medicare and Medicaid Services, “a device for which “absolute risk” of the device type has not been established (that is, initial clinical trials are not complete) and the device is not

E. Conditions of Coverage
N/A

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	09/27/2023	New Policy. Approved at Committee.
Date Revised		
Date Effective	01/01/2024	
Date Archived		

H. References

1. Association for the Accreditation of Human Research Protection Programs (AAHRPP). Accessed September 12, 2023. www.aahrpp.org.
2. eCFR - Code of Federal Regulations. (n.d.). Accessed September 12, 2023. www.ecfr.gov.
3. Local Coverage Article. Clinical Trials - Medical Policy Article (A52430). Accessed September 12, 2023. www.cms.gov.
4. Medicare and Medicaid Services Medicare Learning Network (2015). MLN Matters. Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies. Accessed September 12, 2023. www.cms.gov.
5. National Coverage Determination for Routine Costs in Clinical Trials (310.1). Accessed September 12, 2023. www.cms.gov.
6. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2021). Accessed September 12, 2023. www.govinfo.gov.