

POLICY NUMBER	DATE OF LAST REVIEW	APPROVED BY
M20190013	8/11/2023	MPC (Medical Policy Committee)

### **IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.

## **CLINICAL TRIALS**

### **Criteria:**

Certain routine care for a Member who is a patient in a disabling or Life-Threatening chronic diseases clinical trial, such as for cancer, is **covered** just as routine care would be covered if the Member were not involved in a disabling or Life-Threatening chronic diseases clinical trial.

In order for the Member to be eligible for coverage, the trial must be Pre-Authorized and must take place under an independent peer-reviewed protocol approved or funded by:

- One of the National Institutes of Health,
- The Centers for Disease Control and Prevention,
- The Agency for Health Care Research and Quality,
- The Centers for Medicare & Medicaid Services,
- A National Cancer Institute affiliated cooperative group or the federal Department of Defense, Department of Energy, or Department of Veterans Affairs, or
- The federal Food and Drug Administration (FDA) as part of an investigational new medication or device application or exemption

## Medical Policy: Clinical Trials (Commercial)

We may require the following in order for a Member to be considered for coverage:

- Evidence that the Member meets all of the selection criteria for the trial;
- Evidence that the Member has given appropriate informed consent to the trial;
- Copies of any medical records, rules, test results or other clinical information used to enroll the Member in the trial;
- A summary of how the expected routine care costs would exceed the costs for standard treatment;
- Information about any items or services (including routine care) that may be paid for by another entity, including the name of the company paying for the trial; and/or
- Any other information we may reasonably need to review the request.

There is **no coverage** for the following:

- Costs of Experimental Or Investigational medicines or devices that are not exempt from new medicine or device application by the Food and Drug Administration (FDA)
- Costs for non-Health Services
- Costs that would not be covered by this Plan for a non-Experimental Or Investigational treatment
- Facility, ancillary, professional services and medicine costs paid for by grants or funding for the trial
- Routine costs that are:
  - Experimental Or Investigational,
  - Provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the Member, or
  - Services that are clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
  - Transportation, lodging, food or other travel expenses for the Member or any family member or companion of the Member

*For the purposes of this clinical trials benefit, Life-Threatening means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted*

### References:

2023 ConnectiCare Insurance Company, Inc. Membership Agreement

# Medical Policy: Clinical Trials (Commercial)

## Review history:

DATE	REVISION
08/11/2023	<ul style="list-style-type: none"><li>Annual Review. No changes made to policy</li></ul>
09/09/2022	<ul style="list-style-type: none"><li>Annual Review. No changes made to policy</li></ul>
06/11/2021	<ul style="list-style-type: none"><li>Annual Review. No changes made to policy</li></ul>
06/12/2020	<ul style="list-style-type: none"><li>Annual Review. No changes made to policy</li></ul>
4/24/2019	<ul style="list-style-type: none"><li>Reformatted and reorganized policy, transferred content to new template with new Medical Policy Number</li></ul>
11/03/2016, 4/24/2019	