MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
05/19/2015	05/19/2016	05/19/2015
Policy Name		**Policy Number**
Clinical Trials		**AD-0002**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Clinical Trials

The purpose of this policy is to address the requirements of health insurer to continue to pay for routine care costs while a qualified individual participates in an approved clinical trial. 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 drugs, biological products, devices, medical treatments, behavioral treatments, radiological procedures and surgical 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.

Covered clinical trial services are exempt from the medical policy criteria outlined under the CareSource Experimental or Investigational Technologies medical policy.

B. BACKGROUND

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:

- **Phase I** clinical trials - the study drug or treatment is given to a small group of people for the first time to evaluate its safety, determine a safe dosage range and to identify side effects;
- **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;

- **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;
- **Phase IV** clinical trials – 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.

C. DEFINITIONS

Kentucky Statute

Based on Kentucky General Statutes **304.17A-136 Coverage for cancer clinical trials.**

(1) As used in this section, unless the context requires otherwise:

(a) "Cancer clinical trial" means a clinical trial that:

1. Is approved by:
   a. The National Institutes of Health, or any institutional review board recognized by the National Institutes of Health;
   b. The United States Food and Drug Administration;
   c. The United States Department of Defense; **OR**
   d. The United States Veterans Administration

AND

2. Does one **(1)** of the following:
   a. Tests how to administer a health care service, item, or drug for the treatment of cancer;
   b. Tests responses to a health care service, item, or drug for the treatment of cancer;
   c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer; **OR**
   d. Studies new uses of health care services, items, or drugs for the treatment of cancer

AND

(b) "Routine patient healthcare costs" means all healthcare services, items, and drugs for the treatment of cancer, **EXCEPT** for **ALL** of the following:

1. The health care service, item, or investigational drug that is the subject of the cancer clinical trial
2. Any treatment modality outside the usual and customary standard of care required to administer or support the healthcare service, item, or investigational drug that is the subject of the cancer clinical trial
3. Any healthcare service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient
4. An investigational drug or device that has not been approved for market by the United States Food and Drug Administration
5. Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the cancer clinical trial
6. Any services, items, or drugs provided by the cancer clinical trial sponsors free of charge for any new patient
7. Any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the clinical trial

(2) A health benefit plan shall not exclude coverage for routine patient healthcare costs that are incurred in the course of a cancer clinical trial if the health benefit plan would provide coverage for the routine patient healthcare costs had they not been incurred in a cancer clinical trial
(3) The coverage that may not be excluded under this section shall be subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the policy, plan, or contract, including the treatment under the policy, plan, or contract of services performed by participating and nonparticipating providers
(4) (a) Nothing in this section requires a policy, plan, or contract to offer cancer clinical trial services by a participating provider
(b) Nothing in this section prohibits a policy, plan, or contract from offering cancer clinical trial services by a participating provider
(c) Nothing in this section requires services that are performed in a cancer clinical trial by a nonparticipating provider of a policy, plan, or contract to be reimbursed at the same rate as those performed by a participating provider of the policy, plan, or contract
(5) Nothing in this section shall be construed as imposing a new health benefit mandate

Ohio Statute
3923.80 Denial of coverage to cancer clinical trial participant.
(A) Notwithstanding section 3901.71 of the Revised Code, no health benefit plan or public employee benefit plan shall deny coverage for the costs of any routine patient care administered to an insured participating in any stage of an eligible cancer clinical trial, if that care would be covered under the plan if the insured was not participating in a clinical trial
(B) The coverage that may not be excluded under division (A) of this section is subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the plan, policy, or arrangement for services performed by participating and nonparticipating providers. Nothing in this section shall be construed as requiring reimbursement to a provider or facility providing the routine care that does not have a health care contract with the entity issuing the health benefit plan or public employee benefit plan, or as prohibiting the entity issuing a health benefit plan or public employee benefit plan that does not have a health care contract with the provider or facility providing the routine care from negotiating a single case or other agreement for coverage
(C) As used in this section:
(1) "Eligible cancer clinical trial" means a cancer clinical trial that meets **ALL** of the following criteria:
(a) A purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes
(b) The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes
(c) The trial has a therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology
(d) The trial does **ONE** of the following:
(i) Tests how to administer a health care service, item, or drug for the treatment of cancer
(ii) Tests responses to a health care service, item, or drug for the treatment of cancer
(iii) Compares the effectiveness of a health care service, item, or drug for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer
(iv) Studies new uses of a health care service, item, or drug for the treatment of cancer

(e) The trial is approved by **ONE** of the following entities:
(i) The national institutes of health or one of its cooperative groups or centers under the United States department of health and human services
(ii) The United States food and drug administration
(iii) The United States department of defense
(iv) The United States department of veterans' affairs

(2) "Subject of a cancer clinical trial" means the health care service, item, or drug that is being evaluated in the clinical trial and that is not routine patient care

(3) "Health benefit plan" has the same meaning as in section 3924.01 of the Revised Code

(4) "Routine patient care" means all health care services consistent with the coverage provided in the health benefit plan or public employee benefit plan for the treatment of cancer, including the type and frequency of any diagnostic modality, that is typically covered for a cancer patient who is not enrolled in a cancer clinical trial, and that was not necessitated solely because of the trial

(5) For purposes of this section, a health benefit plan or public employee benefit plan may **EXCLUDE COVERAGE FOR ANY** of the following:
(a) A health care service, item, or drug that is the subject of the cancer clinical trial
(b) A health care service, item, or drug provided solely to satisfy data collection and analysis needs for the cancer clinical trial that is not used in the direct clinical management of the patient
(c) An investigational or experimental drug or device that has not been approved for market by the United States food and drug administration
(d) Transportation, lodging, food, or other expenses for the patient, or a family member or companion of the patient, that are associated with the travel to or from a facility providing the cancer clinical trial
(e) An item or drug provided by the cancer clinical trial sponsors free of charge for any patient
(f) A service, item, or drug that is eligible for reimbursement by a person other than the insurer, including the sponsor of the cancer clinical trial

Federal Statute

Section 10103(c) of PPACA (Patient Protection and Affordable Care Act of 2010) added a new provision to the federal Public Health Service Act which requires group health plans and health insurance issuers offering individual or group health insurance products to provide for coverage of routine patient costs associated with approved clinical trials. The term “approved clinical trial” under PPACA is defined in the statute as 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 disease or condition and is **ONE** of the following:

1. A federally funded or approved trial. The study or investigation is approved or funded (which may include funding through in-kind contributions) by **ONE OR MORE** of the following:
(i) The National Institutes of Health
(ii) The Centers for Disease Control and Prevention
(iii) The Agency for Health Care Research
(iv) The Centers for Medicare & Medicaid Services
(v) Cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.
(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants

(vii) **ANY** of the following, if the conditions described for studies conducted by a Department are met:

(I) The Department of Veterans Affairs
(II) The Department of Defense
(III) The Department of Energy

Studies or investigations conducted by a Department must be approved through a system of federal peer review to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and that assure unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:
1. A clinical trial conducted under an FDA investigational new drug application
2. A drug trial that is exempt from the requirement of an FDA investigational drug application

Life-Threatening Condition The term 'life-threatening condition' means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Informed Consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate.

Medical and Scientific Evidence is defined by CareSource as **ONE** of the following:
a. Drug Facts and Comparisons
b. Publication Pharmacist Letter or Prescriber Letter
c. National panels and consortiums such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), AHRQ (Agency for Healthcare Research and Quality), or NCCN (National Comprehensive Cancer Network)
d. Commercial External Review Organizations such as MCG, ECRI and Hayes, Inc.
e. Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which supports the proposed use for the specific medical condition as safe and effective
   i. Examples of accepted journals include, but are not limited to: Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet
   ii. Accepted study designs include, but are not limited to: randomized, double-blind, placebo controlled clinical trials
f. Additional resources may include:
   i. Clinical practice guidelines published by consortiums of medical organizations and generally accepted as industry standard
   ii. Specialty and sub-specialty society guidelines, when appropriate, including, but not limited to the following:

D. POLICY

CareSource will provide coverage for Clinical Trial Services when benefits are available and criteria shown below are met.

CareSource may provide coverage for clinical trial services when **ALL** of the following criteria are met:
A) The member, who is a potential clinical trial enrollee, has a "life-threatening condition" (see DEFINITIONS):

- even if treated with currently accepted treatment options; **and/or**
- standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate;

NOTE: Benefit plans covered under Section 10103(c) of PPACA (Patient Protection and Affordable Care Act of 2010) also include coverage of clinical trials related to the prevention, detection, or treatment of cancer, whether life threatening or not.)

B) **Federal Statue:** The clinical trial is a Phase II, III, or IV research study. (**NOTE:** Benefit plans covered under Section 10103(c) of PPACA (Patient Protection and Affordable Care Act of 2010) also include coverage of Phase I clinical trials.
Kentucky Statue: The clinical trial is a Phase III, or IV research study. (**NOTE:** KRS **304.17A-136**).
Ohio Statue: The clinical trial is a Phase III, or IV research study. (**NOTE:** ORC **3923.80**)
C) The member is to be treated as part of a clinical trial satisfying **ALL** of the following criteria:

- The clinical trial has passed independent scientific review in a manner that is unbiased and comparable to the system of peer review of studies and investigation by the National Institutes of Health (NIH)
- The clinical trial must be conducted in a setting and by personnel who maintain a high level of expertise because of their training, experience, and volume of patients
- The clinical trial been approved by an Institutional Review Board (IRB) that will oversee the investigation
- The research study has been approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, or the Department of Veterans Affairs.

NOTE: Benefit plans covered under Section 10103(c) of PPACA (Patient Protection and Affordable Care Act of 2010) also include coverage of clinical trials funded or approved by Centers for Medicare and Medicare and Medicaid Services; the Department of Energy; drug trials conducted under an FDA investigational new drug application, or that are exempt from the requirement of an FDA investigational drug application; or a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health (NIH) for center support grants. For further information regarding NIH grant eligibility, please see: http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch2.htm#determining_applicant_org_eligibility
D) The member must meet **ALL** of the following clinical trial criteria:

- Meet all protocol requirements
- Be enrolled in the trial
- Provide informed consent
- Be treated according to protocol

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

E. REVIEW/REVISION HISTORY

Date Issued:	05/19/2015
Date Reviewed:	05/19/2015
Date Revised:	

F. REFERENCES

1. National Institutes of Health (NIH). http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch2.htm#determining_applicant_org_eligibility.
2. General Assembly of N. C., Session 2001; Session Law 2001-446; Senate Bill 199; Part III. Mandated Benefits; Subpart A. Clinical Trials; Section 3.1; Article 3 of Chapter 58 of the General Statutes **§** 58-3-255. *Coverage of clinical trials*.
3. KRS **304.17A-136**
4. ORC **3923.80**

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.