

OHCA Guideline

Medical Procedure Class:	Routine Care Coverage in Approved Clinical Trials
Initial Implementation Date:	September 1, 2021
Last Review Date:	March 24, 2025
Effective Date:	March 26, 2025
Next Review/Revision Date:	March 2028
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p>Clinical Trial: A study that is done to help prevent, detect, or treat cancer or a life-threatening illness, injury, or disease, is federally funded, conducted under an Investigational New Drug (IND) application or is exempt from having an IND application.</p> <p>Investigational Device Exemption (IDE): An unphased trial in which an investigational device is used in a clinical study to collect safety and effectiveness data required to support submission for approval to the FDA.</p> <p>Investigational New Drug (IND): An authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics Product License Application.</p> <p>ClinicalTrials.gov Identifier (NCT number): The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).</p> <p>Medically Necessary: Per OHCA policy (317:30-3-1), medical necessity is established through consideration of the following standards: (1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability; (2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service; (3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes; (4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider; (5) Services must be delivered in the most cost-effective manner and most appropriate setting; and, (6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.</p> <p>Phase I Clinical Trial: A study which assesses the safety of a drug or device and determines a safe dosage range.</p>	

Phase II Clinical Trial: A study which tests the efficacy of a drug or device, and to identify side effects.

Phase III Clinical Trial: A study which involves large-scale testing that provides a more thorough understanding of the effectiveness of the drug or device, the benefits and the range of possible adverse reactions. Phase III clinical trials are used to confirm effectiveness, monitor adverse reactions, compare studied treatment with commonly used treatments, and collect information that will allow the treatment to be used safely.

Phase IV Clinical Trial: A study, often called Post Marketing Surveillance Trials, conducted after a drug or device has been approved for consumer sale.

Billing Information

Modifier Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study

Note: For research and reporting purposes; providers are asked to use Modifier Q1 for routine clinical services provided during a clinical trial that is in an OHCA approved clinical research study.

Approval Criteria

- I. Sooner Care will cover routine care costs for a member enrolled in an OHCA Approved Clinical Trial for the treatment of cancer or a life-threatening or debilitating illness, injury, or disease as described in this guideline when:
 - A. The same routine care costs would be typically covered for a member who is not enrolled in the clinical trial (i.e., items that are covered outside of the trial are covered inside the trial), AND
 - B. The same routine services are medically necessary, AND
 - C. The same routine services are a covered benefit.

- II. An *OHCA Approved Clinical Trial* must include ALL the following:
 - A. The clinical trial does ONE of the following for the treatment of cancer or a life-threatening illness, injury, or disease;
 1. Tests how to administer a health care service;
 2. Tests responses to a health care service;
 3. Compares the effectiveness of a health care service;
 4. Studies new uses of a health care service.
 - B. The clinical trial is approved and funded by one of the following;
 1. A cooperative group of research facilities that has an established peer review program that is approved by the National Institutes of Health center and assures an unbiased review of standards of care with qualified individuals who do not have an interest in the review outcome.
 2. National Institutes of Health (NIH).
 3. The Centers for Disease Control and Prevention (CDC).
 4. The Agency for Health Care Research and Quality (AHRQ).
 5. The Centers for Medicare and Medicaid services (CMS).
 6. The United States Department of Veterans Affairs (VA).
 7. The United States Department of Defense (DOD).
 8. The Food and Drug Administration.
 9. The United States Department of Energy.
 10. A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.
 11. A qualified non-governmental research entity in guidelines issued by the NIH for center support grants.
 - C. The clinical trial is conducted in a facility where the personnel have training, and expertise required to provide the type of care required in the study.

- D. The clinical trial is in compliance with Federal regulations relating to the protection of human subjects.
- E. There is a written protocol for the clinical trial.
- F. The clinical trial is designed to have a therapeutic intent.

III. Included as Routine Care Costs in Approved Clinical Trials:

- A. Costs required for the administration of the investigational item or service and are not a covered benefit of the clinical trial (e.g., administration of a non-covered chemotherapeutic agent; staffing and equipment need to implant a non-covered device).
- B. Costs for the clinically appropriate monitoring of the effects of the item or service.
- C. Costs for the prevention, diagnosis or treatment of medical complications from a non-covered item or service provided in the clinical trial.

IV. Excluded from Routine Care Costs:

- A. The investigational item or service itself.
- B. Items or services the study gives for free. Items or services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.
- C. Items or services only utilized to determine if an individual is eligible to participate in the clinical trial.
- D. The research costs for the clinical trial.
- E. Items or services used only for data collection or analysis and not used in direct health care.
- F. Evaluations designed to only test toxicity or disease pathology (i.e. vaccine toxicity or collecting DNA or tissue data to study genetic changes).
- G. Experimental, investigational, and unproven treatments or procedures and all related services provided outside of an OHCA Approved Clinical Trial.
- H. After the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during an OHCA Approved Clinical Trial.
- I. Clinical trials of therapeutic interventions must enroll patients for the treatment of cancer or a life-threatening or debilitating illness, injury, or disease rather than healthy volunteers.

V. All applicable plan limitations for coverage for out-of-network and out-of-state providers will apply to routine care costs in an Approved Clinical Trial.

VI. All applicable utilization management guidelines (including prior authorizations) will apply to routine care costs in an Approved Clinical Trial.

VII. Experimental and investigational:

Sooner Care does not cover procedures, technologies, or therapies which are considered experimental or investigational.

- A. Per OHCA policy, Sooner Care does not reimburse for medical, surgical, other health care procedures or treatments, including the use of drugs, biological products, other products or devices which are considered experimental or investigational, **except**

Sooner Care will reimburse routine care costs during a member's participation in an OHCA Approved Clinical Trial which are medically necessary and would be covered if the Sooner Care eligible member were receiving standard care.

B. Experimental, investigational or unproven is any procedure, treatment, service, supply, or product showing one or more of the following:

- Current, authoritative medical and scientific evidence shows that further studies or clinical trials are necessary to determine benefits, safety, efficacy and risks.
- Final approval from the FDA or any other governmental body having authority to regulate the technology is absent or lacking.
- A procedure, treatment, service, supply, or product which is subject to Institutional Review Board review or approval.
- The effectiveness on health outcomes is unproven based on clinical evidence in peer-reviewed medical literature.
- A procedure, treatment, service, supply, or product which cannot be legally marketed in the United States without final approval from appropriate government regulatory or licensing body.

References

1. National Library of Medicine, ClinicalTrials.gov, [How to Search for Clinical Studies | ClinicalTrials.gov](#)
2. Centers for Medicare and Medicaid Services, CMS.gov, Approved IDE Studies; [Approved IDE Studies | CMS](#)
3. FDA regulations: Good clinical practice and Clinical Trials. Retrieved from <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials>
4. National Coverage Determination for Routine Costs in Clinical Trials (310.1). Retrieved from <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1>; updated 5/27/24
5. OHCA policy and rules. OAC 317:30-3-1 and 30-3-57.1