



## Clinical Trials, Routine Patient Care Costs Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Clinical Trials, Routine Patient Care Costs		
MNG #: 104	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MA Medicare Preferred <input checked="" type="checkbox"/> MA Medicare Value <input checked="" type="checkbox"/> MA Medicare Premier <input checked="" type="checkbox"/> RI Medicare Preferred <input checked="" type="checkbox"/> RI Medicare Value <input checked="" type="checkbox"/> RI Medicare Maximum	Prior Authorization Needed? <input type="checkbox"/> Yes (always required) <input type="checkbox"/> Yes (only in certain situations. See this MNG for details) <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Benefit Type: <input checked="" type="checkbox"/> Medicare <input type="checkbox"/> Medicaid	Approval Date: 03/03/2022	Effective Date: 8/23/2022
Last Revised Date: 05/11/2023;	Next Annual Review Date: 03/03/2023; 05/11/2024;	Retire Date:

### OVERVIEW:

*Clinical trials* are prospective and interventional research studies that involve participants or volunteers to contribute to medical knowledge related to the prevention, diagnosis, or treatment of a disease or condition. The participants who meet the *eligibility criteria* receive specific *interventions* according to a research *protocol* developed by the lead investigators. The clinical studies examine, measure, or evaluate (1) one or more interventions for treating or diagnosing a disease, syndrome, or condition, (2) ways to prevent the initial development or recurrence of a disease or condition, (3) methods for identifying a condition or the risk factors for that condition, and (4) ways to improve the comfort and quality of life through supportive care for people with a chronic condition.

Historically, clinical trials and their associated routine costs were not covered because of concerns related to liabilities for additional costs associated with research services, items, tests, and potential complications. Instead, study participants, employers, third-party payers, healthcare institutions, and sponsors would share the overall clinical trial costs. At the time there was recognition that patients who were struggling with chronic, debilitating, and life-threatening diseases did not have access to all possible avenues of benefit, which included clinical trials. Moreover, there were studies to show that direct patient care costs in clinical trials were not substantially higher than in the absence of a clinical trial. Effective January 1, 2014, The Patient Protection and Affordable Care Act (ACA) added Section 2709 to the Public Health Service Act, which require private insurers to cover *routine patient costs* for *qualified individuals* who participate in *qualifying clinical trials* for the prevention, detection, and treatment of cancer or other life-threatening diseases or conditions. This federal law ensures that qualified individuals are not denied participation in clinical trials, are not denied, or imposed additional conditions on the coverage of routine patient costs, and/or are not discriminated against on the basis of participation in a trial.

### DEFINITIONS:

**Clinical Trials:** Interventional research study of human subjects that are designed to answer specific health questions. There are four phases of clinical trials.

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Phase of Trial	Description
Phase I	The purpose of this phase is to test and evaluate the experimental drug or treatment's safety and dosage in a small group of participants who are healthy or with the disease/condition of interest.
Phase II	The purpose of this phase is to study an experimental drug or treatment's efficacy, to determine its effectiveness, and further evaluate its side effects in a larger group of participants with the disease/condition of interest.
Phase III	The purpose of this phase is to confirm the drug or treatment's efficacy and effectiveness by monitoring for adverse reactions, comparing it to commonly used treatments, and collecting information that will allow the drug and treatment to be used safely in a larger group of people.
Phase IV	The purpose of this phase is to gather information on the drug's effect in various populations. This is completed after the drug or treatment has been marketed. Researchers track its safety in the general population, monitor the side effects associated with long-term use, and seek more information about the medicine or treatment's benefits.

**Eligibility Criteria:** Standards listed in the protocol that outline who can participate in the clinical study. The criteria may be based on different factors to help reduce the variation within the study and ensure that the investigators will be able to answer the research questions that they plan to study. These factors may include age, sex, type and stage of disease, previous treatment history, and other medical conditions.

**Experimental and Investigational Service(s) (EIS):** Experimental, investigational, or unproven services may refer to but not limited to a drug, test, procedure, treatment, device, or equipment that remains under study as its absolute risk is unestablished. Further study is required to determine the safety, effectiveness, toxicity, maximum tolerated dose, and efficacy of the EIS. It is generally not the standard therapy, therefore, not accepted by the professional medical community.

**Interventions** (in the context of a clinical trial): Interventions that participants may receive during a clinical trial may be medical devices, drugs, procedures, or changes to a participant's behavior (such as diet).

**Life-threatening Condition:** Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

**Protocol** (in the context of a clinical trial): Research plan that is designed to answer specific research questions and safeguards the health of participants. The protocol should include the reason for conducting the study, the eligibility criteria, the number of participants needed, the schedule of tests/procedures/drugs and their dosages, the length of the study, and the information that will be gathered about the participants.

**Routine Patient Costs:** All items and services that are otherwise generally available to Medicare beneficiaries when there is a benefit category, when it is not statutorily excluded, and when there is not a national noncoverage decision.



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**Qualified Individual:** Participant or member who is eligible to participate in an approved clinical trial according to the trial's protocol and either the participant's practitioner (the referring healthcare professional) has concluded that their participation in such a trial would be appropriate, or the participant provides medical and scientific information that establishes that their participation is appropriate.

**Qualified Clinical Trial:** An approved clinical trial refers to a phase I, II, III, or IV clinical trial that is being conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition.

### DECISION GUIDELINES:

#### Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

1. Commonwealth Care Alliance will provide coverage for *routine costs* when a member is a *qualified individual* enrolled in a *qualified clinical trial* to the same extent as they would be covered and reimbursed if the member did not receive care in a qualified clinical trial.

Routine costs include:

- a. Items or services typically provided absent a clinical trial (e.g., conventional care); *or*
- b. Items or services required solely for the provision of the investigational item or service; *or*
- c. Clinically appropriate monitoring of the effects of the investigational item or service; *or*
- d. Items or services for the prevention, diagnosis, and management of complications; *or*
- e. Items or services for reasonable and necessary care that may occur from the provision of an investigational item or service.

Clinical trials that are considered qualified include:

- a. Trials that are funded by the National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare and Medicaid Services (CMS), Department of Defense (DoD), Veterans Affairs (VA); *or*
- b. Trials that are supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DoD, or VA; *or*
- c. Trials conducted under an investigational new drug application (IND) reviewed by the United States Food and Drug Administration (FDA); *or*
- d. Trials that are exempt from having an investigational new drug application. IND exempt drug trials under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the self-certification process is in place.

Other clinical trials that do not fall into the above categories but may also be considered qualified have the following characteristics:



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- a. The trial must evaluate an item or service that falls within a Medicare benefit category and not be statutorily excluded from coverage; *and*
  - b. Trials of *therapeutic* interventions must enroll patients with diagnosed disease, not healthy volunteers, or trials of *diagnostic* interventions may enroll healthy patients as a control group; *and*
  - c. The trial must not be conducted in relation to the prevention, detection, or treatment for cancer or other life-threatening disease or condition. It must have a therapeutic intent. It must not be designed exclusively to test toxicity or disease pathophysiology; *and*
  - d. The trial is well supported by available scientific literature or is intended to clarify the health outcomes of interventions already in common clinical use; *and*
  - e. The trial does not unjustifiably duplicate existing studies; *and*
  - f. The trial design is appropriate to answer the research question; *and*
  - g. The trial is sponsored by a credible and capable organization or individual; *and*
  - h. The trial is in compliance with Federal regulations on the protection of human subjects; *and*
  - i. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
2. Commonwealth Care Alliance may cover the *routine care* costs otherwise non-covered items and/or services, including items and/or services that are statutorily prohibited, if such items and/or services are required for the treatment of complications related to the qualifying clinical trial.
  3. Commonwealth Care Alliance may cover *routine care* costs in a qualifying clinical trial but will not cover any investigational items or services in such qualifying clinical trial that are not covered by virtue of an NCD.

### LIMITATIONS/EXCLUSIONS:

1. Commonwealth Care Alliance will not deny nor limit the coverage for routine care just because an individual is enrolled in a clinical trial. There shall be no changes to existing coverage.
2. Standard prior authorization (PA) requirements and coverage outlined in the CCA Provider Manual for the applicable product applies.
3. Commonwealth Care Alliance will limit the coverage of the routine items and services to the costs that are incurred within the context of the clinical trials.
4. Commonwealth Care Alliance will not cover **any** of the following:
  - a. For Massachusetts, the investigational item or service, itself when it is paid for by the manufacturer, distributor, or provider of the drug/device in accordance with *MGL 175 Section 110L(a)(1)*; or
  - b. For Rhode Island, the investigational item or service, itself is not covered regardless of manufacturer, distributor, or provider of the drug/device payment or nonpayment in accordance with *RIGL Section 27-20-60(b)(2)(B)(i)*; or
  - c. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member; *or*
  - d. Items and services that are customarily provided by the research sponsors free-of-charge for any enrollee in the trial; *or*
  - e. Items and services for the purpose of determining eligibility for the study not related to medically necessary clinical care; *or*



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- f. Items and services that are deemed investigational in a qualifying clinical trial by virtue of an NCD; *or*
- g. Tests and services in excess of what is required for conventional clinical care.

### **AUTHORIZATION:**

Standard prior authorization (PA) requirements outlined in the CCA Provider Manual for the applicable product applies. In that, PA for routine costs are not required when under conventional circumstances the items and services do not require PA and are consistent with the coverage provided in the member's plan. However, CCA may request documentation at any time to confirm that the clinical trial meets the standards of care.

### **REGULATORY NOTES:**

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. Centers for Medicare & Medicaid Services, Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4: Section 310.1 Routine Costs in Clinical Trials, Effective date: 09/04/2014
2. Centers for Medicare & Medicaid Services, Publication 100-04, Medicare Claims Processing Manual, Chapter 32, Sections 68.1-68.4 Investigational device exemption studies, Effective date: 01/05/2015
3. Centers for Medicare & Medicaid Services, Publication 100-04, Medicare Claims Processing Manual, Chapter 32, Section 69 Qualifying clinical trials, Effective date: 02/05/2007
4. Centers for Medicare & Medicaid Services, Local Coverage Article (National Government Services), A52840 Medical Policy Article: Clinical trials, Effective date: 10/01/2015
5. Code of Federal Regulations, Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 405 Federal Health Insurance for the Aged and Disabled, Subpart B Medical Services Coverage Decisions that Relate to Health Care Technology, Section 405.207: Services Related to a Noncovered Device, Effective date: 09/19/1995, Revised Date: 04/03/2023.
6. Code of Federal Regulations, Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 405 Federal Health Insurance for the Aged and Disabled, Subpart B Medical Services Coverage Decisions that Relate to Health Care Technology, Section 405.212: Medicare Coverage IDE Study Criteria, Effective date: 12/10/2013, Revised Date: 04/03/2023.
7. Commonwealth of Massachusetts, General Laws, Part I Administration of the Government, Title XXII Corporations, Chapter 175 Insurance, Section 110L: Clinical Trials, Definitions, Coverage, Up to Date: 01/04/2023
8. Rhode Island General Assembly, General Laws, Title 27 Insurance, Chapter 27-20 Nonprofit Medical Service Corporations, Section 27-20-60 Coverage for Individuals Participating in Approved Clinical Trials, Effective date: 01/01/2014.

### **Disclaimer**



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This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

### RELATED REFERENCES:

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4. Centers for Medicare and Medicaid Services. (2015). *Local coverage article (A52840): Clinical trials – Medical policy article*. Retrieved from <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52840&ver=2&keyword=clinical%20trials&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>
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14. National Heart, Lung, and Blood Institute. (2023). *Clinical trials: How clinical trials work*. Retrieved from <https://www.nhlbi.nih.gov/research/clinical-trials/how-studies-work>
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### ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

### REVISION LOG:

REVISION DATE	DESCRIPTION
05/05/2023	Revisions made to the overview, definitions, clinical coverage criteria, limitations/exclusions, authorization, and regulatory notes sections. Added background information on what clinical trials are, purpose, and the Patient Protection and Affordable Care Act. Added definitions for Category B Devices, Clinical Trials, Eligibility Criteria, Experimental and Investigational Services, Interventions, Investigational Device Exemption, Life-threatening Condition, Protocol, Routine Patient Costs, Qualified Individual, and Qualified Clinical Trial. Clinical coverage criteria updated to include the definitions of what is considered as routine costs and qualified clinical trials, and coverage of routine costs otherwise non-covered items and/or services if they are for the treatment of complications. Moved the prior authorization requirements statement to the Authorization section. References added in the regulatory notes and related references. Approvals updated to reflect current leadership.

### APPROVALS:

Debra Poskanzer, MD	Medical Director
CCA Senior Clinical Lead [Print]	Title [Print]
	5/11/2023
Signature	Date
<a href="#">Click here to enter text.</a>	
CCA Senior Operational Lead [Print]	Title [Print]
Signature	Date
Nazlim Hagmann, MD	Senior Vice President, Associate Chief Medical Officer
CCA CMO or Designee [Print]	Title [Print]
	5/11/2023





**Clinical Trials, Routine Patient Care Costs  
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*Nazlim Hagmann*

5/11/2023

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**Signature**

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**Date**