Clinical Trials, Routine Patient Care Costs
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Clinical Trials, Routine Patient Care Costs		
MNG #: 104	**☒ CCA Senior Care Options (HMO D-SNP) (MA)** **☒ CCA One Care (Medicare-Medicaid) (MA)**	**Prior Authorization Needed?** **☐ Yes (always required)** **☐ Yes (only in certain situations. See this MNG for details)** **☐ No**
Benefit Type: **☒ Medicare** **☐ Medicaid**	**Approval Date:** 03/03/2022	**Effective Date:** 8/23/2022; 6/13/2024; 1/1/2025
Last Revised Date: 05/11/2023; 6/13/2024; 1/22/2025	**Next Annual Review Date:** 03/03/2023; 05/11/2024; 6/13/2025;	**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.

There are four phases of clinical trials:

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.

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Clinical trials are key to understanding the appropriate use of medical interventions of all types. A very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States. 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:

Approved Clinical Trial: 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.

Clinical Trials: Interventional research studies of human subjects that are designed to answer specific health questions.

Coverage with Evidence Development (CED): Medicare coverage of a treatment or technology conditioned on data-gathering through a clinical trial or registry to determine its effectiveness, allowing Medicare beneficiaries to access promising therapies and services while additional data are collected.

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).

Investigational Device Exemption (IDE): An FDA determination that allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data, and permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE exemption may apply to either of the following:

- Category A (Experimental) device - initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective. For an IDE-approved device assigned to Category A, CMS may cover only routine care items and services, but not the cost of the device itself.
- Category B (Nonexperimental/Investigational) device: it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type (by virtue of a "predicate device"). For an IDE-approved device assigned to Category B, CMS may cover routine care items and services as well as the cost of the investigational device if specific criteria are met.

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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.

Predicate Device: A device that is already on the market that is determined to be substantially equivalent, regarding safety and effectiveness, to a (newer generation) device that is being reviewed by the FDA for 510(k) clearance.

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.

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: A trial that meets the requirements set forth in the Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Service (CMS).

DECISION GUIDELINES:

Clinical Coverage Criteria:

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

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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:

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 or IDE CED.

4. An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device.

5. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

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. 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
    b. Items and services that are customarily provided by the research sponsors free-of-charge for any enrollee in the trial; or

c. Items and services for the purpose of determining eligibility for the study not related to medically necessary clinical care; or
d. Items and services that are deemed investigational in a qualifying clinical trial by virtue of an NCD; or
e. Tests and services in excess of what is required for conventional clinical care.

Documentation Requirements:

All of the following are required:

1. Notification of qualified individual status, including age, and clinical and treatment history
2. National Institutes of Health National Library of Medicine's https://clinicaltrials.gov/ NCT number (e.g., NCT00000123)
3. Institutional Review Board (IRB) approval letter (interested parties need only submit one IRB approval letter with their request.)
4. Clinical Trial protocol;
5. Informed, signed consent to participate in the study.
6. Clinical trials that are also an Investigational Device Exemptions (IDE) must document the associated IDE number
7. Approval letter from the sponsor or institution (where the trial will be conducted) re device coverage, e.g., for IDE CED.

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Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, 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. 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.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

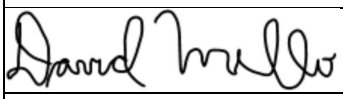
This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these

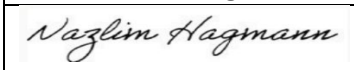
criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. 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.

REVISION LOG:

REVISION DATE	DESCRIPTION
1/22/2025	Template update
1/21/2025	UMC Approval
1/13/2025	MPC Approval by email vote – to remove MAPD products from product grid
6/25/2024	Utilization Management Committee Approval.
6/13/2024	Medical Policy Committee Approval
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:

David Mello	Senior Medical Director Utilization Review and Medical Policy
CCA Clinical Lead	**Title**
	1/13/2025
Signature	**Date**

Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee	**Title**
	1/13/2025
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