Policy:	GG.1125
Title:	**Clinical Trials**
Department:	Medical Management
Section:	Utilization Management
CEO Approval:	*/s/ Michael Hunn 12/20/2024*
Effective Date:	11/01/2002
Revised Date:	12/01/2024
Applicable to:	☒ Medi-Cal ☒ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy establishes coverage guidelines for routine health care services provided in connection with a Member's participation in a Clinical Trial.

II. POLICY

A. CalOptima Health and its Health Networks shall cover routine patient care costs, as defined in Section II.B. of this policy, associated with a Member's participation in an approved Clinical Trial, Phase I, Phase II, Phase III, or Phase IV conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition. The Member and the Clinical Trial must also meet the requirements set forth herein.

B. Routine patient care costs:

1. Routine patient care costs include health care services that would be:

   a. Provided in the absence of a Clinical Trial;

   b. Required for the provision of the investigational drug, item, device, or service;

   c. Required for clinically appropriate monitoring of the treatment;

   d. Provided for the prevention of complications arising from the Clinical Trial treatment; or

   e. Needed for reasonable and necessary care arising from complications of the Clinical Trial.

2. Routine patient care costs do not include the costs associated with the provision of any of the following:

   a. Drugs or devices that have not been approved by the Federal Drug Administration (FDA) and are associated with the Clinical Trial;

   b. Services other than health care services, such as travel, housing, companion expenses, and other non-clinical expenses that a Member may require as a result of treatment being provided for the purposes of the Clinical Trial;

c. Any item or service that is provided solely to satisfy data collection and analysis needs and is not used in the clinical management of the Member;

d. Health care services that, except for the fact that they are being provided in a Clinical Trial, are otherwise specifically excluded from coverage under the CalOptima Health program;

e. Health care services customarily provided by the research sponsors free of charge for any Member in the Clinical Trial; and

f. Experimental treatment outside of an eligible Clinical Trial.

C. To be eligible for coverage of routine patient care costs associated with participation in a Clinical Trial, a Member must meet the following requirements:

1. The Member must be diagnosed with cancer or another life-threatening disease or condition;

2. The Member must be accepted into a Phase I, II, III, or IV Clinical Trial; and

3. The Member's treating physician, who is contracted by the Health Network to provide health care services, or who participates with CalOptima Health for a CalOptima Health Direct or CalOptima Health Community Network (CHCN) Member, must recommend the Member's participation in the Clinical Trial.

D. To be eligible for coverage of routine patient care costs associated with participation in a Clinical Trial, the Clinical Trial must meet the following requirements:

1. The Clinical Trial endpoints must not be defined exclusively to test toxicity, or disease pathophysiology, but must have a therapeutic intent;

2. The principal purpose of the Clinical Trial is to test whether the intervention potentially improves the Member's health outcomes;

3. The Clinical Trial is well-supported by available scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use;

4. The Clinical Trial does not unjustifiably duplicate existing studies;

5. The Clinical Trial design is appropriate to answer the research question being asked in the Clinical Trial;

6. The Clinical Trial is sponsored by a credible organization or individual capable of executing the proposed Clinical Trial successfully;

7. The Clinical Trial is in compliance with Federal regulations relating to the protections of human subjects; and

8. All aspects of the Clinical Trial are conducted according to the appropriate standards of scientific integrity.

9. The treatment provided in the Clinical Trial must either be:

a. Approved by one (1) of the following: National Institutes of Health, the FDA, the U.S. Department of Defense, or the U.S. Department of Veterans Affairs; or

b. Involve a drug that is exempt under federal regulations from a new drug application.

E. CalOptima Health and its Health Networks shall not be prohibited from restricting coverage for routine patient care costs associated with a Clinical Trial in California, unless the protocol for the Clinical Trial is not provided for at a California hospital or by a California physician.

F. The provision of services as defined under this policy shall not in itself give rise to liability on the part of CalOptima Health, or the Health Network.

G. CalOptima Health, or a Health Network, shall provide care management services to a Member who is participating in a Clinical Trial to assure that the Member is afforded continuity of care, referred to all available resources for his or her illness, and to continue to verify that all eligibility requirements as set forth herein continue to be met.

III. PROCEDURE

A. A Provider or Practitioner shall obtain Prior Authorization for reimbursement of routine patient care costs related to a CalOptima Health Direct or CHCN Member's participation in a Clinical Trial, in accordance with CalOptima Health Policies GG.1500: Authorization Instructions for CalOptima Health Direct and CalOptima Health Community Network Providers.

B. A Provider, or Practitioner, shall obtain Prior Authorization for reimbursement of routine patient care costs related to a Health Network Member's participation in a Clinical Trial, in accordance with the policies established by the Member's Health Network.

C. CalOptima Health and its Health Networks shall not require Prior Authorization, nor limit, prohibit, or modify a Member's rights for Biomarker Testing that is associated with a federal FDA-approved therapy for cancer progression or recurrence in Members with advanced or metastatic stage 3 or 4 cancer or as part of an approved Clinical Trial, in accordance with Department of Health Care Services (DHCS) All Plan Letter (APL) 22-010: Cancer Biomarker Testing, and Health and Safety Code, §1370.6.

1. CalOptima Health's Claims Department shall ensure the list of cancer Biomarker Test codes that are associated with a federal FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer are continuously updated in CalOptima Health's processes.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
B. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
C. CalOptima Health, Health Network Service Agreement
D. CalOptima Health Policy GG.1500: Authorization Instructions for CalOptima Health Direct and CalOptima Health Community Network Providers
E. CalOptima Health Policy 1508: Authorization and Processing of Referrals

F. Department of Health Care Services (DHCS) All Plan Letter (APL) 22-010: Cancer Biomarker Testing
G. Department of Health Care Services (DHCS) California Children's Services (CCS) Numbered Letter (NL) 05-1020: Coverage of Experimental and/or Investigational Services, Supersedes CCS NL 37-1292
H. Health and Safety Code, §1370.6
I. Medicare National Coverage Determination 100-03, 310.1; Routine Costs in Clinical Trials (Effective July 9, 2007)
J. Welfare and Institutions Code, §14087.11

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
02/29/2016	Department of Health Care Services (DHCS)	Approved as Submitted
09/27/2022	Department of Health Care Services (DHCS)	Approved as Submitted - AIR

VII. BOARD ACTION(S)

Date	Meeting
04/04/2019	Regular Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	11/01/2002	GG.1125	Cancer Clinical Trials	Medi-Cal
Revised	05/01/2007	GG.1125	Cancer Clinical Trials	Medi-Cal
Revised	11/01/2015	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Non-Substantive Edit	05/10/2016	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	10/01/2016	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	08/01/2017	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	04/04/2019	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	08/01/2020	GG.1125	Cancer Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	05/01/2021	GG.1125	Clinical Trials	Medi-Cal OneCare OneCare Connect
Revised	09/01/2022	GG.1125	Clinical Trials	Medi-Cal OneCare OneCare Connect

Action	Date	Policy	Policy Title	Program(s)
Revised	12/31/2022	GG.1125	Clinical Trials	Medi-Cal OneCare
Revised	12/01/2024	GG.1125	Clinical Trials	Medi-Cal OneCare

IX. GLOSSARY

Term	Definition
Biomarker Test	A diagnostic test, single or multigene, of an individual's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide treatment. Biomarkers, also called tumor markers, are substances found in higher-than-normal levels in the cancer itself, or in blood, urine, or tissues of some individuals with cancer. Biomarkers can determine the likelihood some types of cancer will spread. They can also help doctors choose the best treatment. For some cancers, certain tumor markers may be more helpful for staging than treatment planning.
CalOptima Health Community Network (CHCN)	A managed care network operated by CalOptima Health that contracts directly with physicians and hospitals and requires a Primary Care Provider (PCP) to manage the care of the Members.
CalOptima Health Direct (COHD)	A direct health care program operated by CalOptima Health that includes both COHD- Administrative (COHD-A) and CalOptima Health Community Network (CHCN) and provides services to Members who meet certain eligibility criteria as described in Policy DD.2006: Enrollment in/Eligibility with CalOptima Health Direct.
Clinical Trial	Trials certified to meet the qualifying criteria and funded by National Institute of Health, Centers for Disease Control and Prevention, Food and Drug Administration (FDA), Department of Veterans Affairs, or other associated centers or cooperative groups funded by these agencies. Criteria for Clinical Trials include the following characteristics: 1. The principal purpose of the Clinical Trial is to test if the intervention potentially improves a participant's health outcomes; 2. The Clinical Trial is well supported by available scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use; 3. The Clinical Trial does not unjustifiably duplicate existing studies; 4. The Clinical Trial is designed appropriately to answer the research question being asked in the trial; 5. The Clinical Trial is sponsored by a credible organization or individual capable of successfully executing the proposed Clinical Trial; 6. The Clinical Trial complies with federal regulations relating to the protection of human subjects; and 7. All aspects of the Clinical Trial are conducted according to the appropriate standards of scientific integrity.
Health Network	For purposes of this policy, a Physician Hospital Consortium (PHC), physician group under a shared risk contract, or health care service plan, such as a Health Maintenance Organization (HMO) that contracts with CalOptima Health to provide Covered Services to Members assigned to that Health Network.
Member	A beneficiary enrolled in a CalOptima Health program.

Term	Definition
Prior Authorization	Medi-Cal: A formal process requiring a Provider to obtain advance approval for the amount, duration, and scope of non-emergent Covered Services. OneCare: A process through which a physician or other health care provider is required to obtain advance approval, from CalOptima Health and/or a delegated entity, that payment will be made for a service or item furnished to a Member.