blue california
Promise Health Plan

Policy Title: Clinical Trials		POLICY #: 10.2.13 Line of business: Medi-Cal	
Department Name: Utilization Management	**Original Date:** 1/02	**Effective Date:** 5/19	**Revision Date:** 6/24
Governing Committee: Medical Services Committee			
Governing Committee Approval: Jennifer Nuovo, MD, Blue Shield Promise Chief Medical Officer		**Date:** 06/11/2024	
Vice President (VP) Approval: Tracy Alvarez, VP, Medical Care Solutions		**Date:** 06/11/2024	

A. PURPOSE

To define the policy and procedure and provide guidance on how Blue Shield Promise Health Plan (Blue Shield Promise) will cover routine patient care services that are related to a qualifying clinical trial conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition pursuant to state and federal law.

B. DEFINITIONS

1. "Approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:
    a. The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:
        i. The National Institutes of Health.
        ii. The federal Centers for Disease Control and Prevention.
        iii. The Agency for Healthcare Research and Quality.
        iv. The federal Centers for Medicare and Medicaid Services.
        v. A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

vi. A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

vii. One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

1. The United States Department of Veterans Affairs.
2. The United States Department of Defense.
3. The United States Department of Energy.

b. The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.

c. The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

2. "Qualifying clinical trial" is defined as a clinical trial, in any clinical phase of development, that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition.

3. "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the Medi-Cal program if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including:

a. Health care services typically provided absent a clinical trial.
b. Health care services required solely for the provision of the investigational drug, item, device, or service.
c. Health care services required for the clinically appropriate monitoring of the investigational item or service.
d. Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.
e. Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.

"Routine patient care costs" does not include the following:

a. Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.
b. Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that a beneficiary may require as a result of the treatment being provided for purposes of the clinical trial, except as required under the Medicaid Program (42

USC section 1396a et seq.).

c. Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.
d. Health care items or services that, except for the fact that they are being provided in a clinical trial, are not otherwise covered by the Medi-Cal program.
e. Health care services customarily provided by the research sponsors free of charge for any beneficiary in the trial.

C. POLICY

I. Pursuant to Title 42 of the United States Code (USC) section 1396d(gg), Blue Shield Promise covers routine patient care costs for patients accepted into qualifying clinical trials, including clinical trials for cancer, listed for the United States at https://clinicaltrials.gov

II. Coverage determination will be regardless of the geographic location or network affiliation of the treating provider or principal investigator of the qualifying clinical trial.

III. Blue Shield Promise will provide coverage for routine patient care costs related to the clinical trial program if the member's treating physician or principal investigator, who is providing covered health care services to the member under the plan, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the member.

IV. Requirements for cancer clinical trials:

a. Member must be diagnosed with cancer and be accepted into an approved Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer.
b. The treating physician who is providing covered health care services to the member under the plan must recommend participation in the clinical trial.
c. The clinical trial program's endpoint must be defined to test toxicity as well as to have a therapeutic intent.
d. Blue Shield Promise will only approve coverage for clinical trials to participating hospitals and physicians in the Blue Shield Promise provider network unless the protocol for the clinical trial is not provided by a Blue Shield Promise participating provider.

D. PROCEDURE

I. The Member's treating physician will submit a Treatment Authorization Request (TAR) to the Blue Shield Promise Utilization Management (UM) department for a member participating in a clinical trial for coverage of routine health care services associated with the member's participation in the clinical trial.

a. The Medicaid Attestation Form on the Appropriateness of the Qualifying Clinical Trial must be submitted for approval of the clinical trial. The attestation form must include the following information:
    i. The member's name and client identification number;
    ii. The national clinical trial number;
    iii. A statement signed by the principal investigator attesting to the appropriateness of the qualified clinical trial; and
    iv. A statement signed by the provider attesting to the appropriateness of the qualified clinical trial.

II. The Medical Director or physician designee reviews the TAR and determines whether the request meets all the applicable requirements as listed above.
    a. The coverage determination will be expedited and completed within 72 hours.
    b. If it meets all requirements, the request is approved.
    c. If not approved, both the requesting provider and the member will be notified in writing according to the required timeframes for the determination and notification. (Refer to UM Policy 10.2.8, Authorization Denial, Pending/Deferral, and/or Modification Notification)

III. The Blue Shield Promise decision to deny or modify experimental or investigational therapies will be subject to the Independent Medical Review (IMR) process under California Health and Safety Code (HSC) section 1370.4. (Refer to UM P&P 10.2.47 Experimental and Investigational Services).

IV. Upon the Blue Shield Promise decision to deny or modify the service, the member and the requesting provider will be notified in writing of the following:
    a. A statement setting forth the specific medical and scientific reasons for denying the coverage.
    b. A description of alternative treatment, services, or supplies covered by the Plan, if applicable.
    c. Member's right to request an external independent review through the DMHC within five (5) business days of the decision.

V. Blue Shield Promise only approves coverage for clinical trial programs to participating hospitals and physicians in the Blue Shield Promise provider network unless the protocol for the clinical trial is not provided by a Blue Shield Promise participating provider.

VI. After participation in the clinical trial is authorized, the Blue Shield Promise UM clinician will submit a referral to case management to assist in assuring the member receives continuity of care and has been referred to all available resources for his/her illness.

E. MONITORING

N/A

F. REPORTING

N/A

G. ATTACHMENTS

N/A

H. REFERENCES

1. HSC section 1370.6
2. HSC section 1370.4
3. 42 USC section 1396d(gg)
4. BSCPHP Medi-Cal Provider Manual 7.9.21: Cancer Clinical Trials
5. 2024 DHCS Contract Exhibit A, Section III, Subsection 5.3.8
6. Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial
7. UM P&P 10.2.8, Authorization Denial, Pending/Deferral, and/or Modification Notification
8. UM P&P 10.2.47 Experimental and Investigational Services
9. W&I section 14132.98

I. REVISION HISTORY

Date	Modification (Reviewed and/or revised)	E-Filing Number
6/2024	Annual Review • Added definitions, updated references • Formatting/grammatical updates • Removed content related to biomarker testing	
6/2023	Annual Review	