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CLINICAL TRIALS: COVERAGE OF

POLICY STATEMENT:

Provided that the member's treating physician has determined that participation in the trial has a meaningful potential to benefit the member, and the clinical or principal investigator managing the clinical trial has provided detailed information about the trial to the Plan, including the therapeutic intent and end point, the following applies:

Consistent with Centers for Medicare & Medicaid Services (CMS) policy, VCHCP covers medically necessary routine patient care costs in clinical trials (in the same way that it reimburses routine care for members not in clinical trials) according to the limitations outlined below. Copayments and deductibles for services provided will also be the same as for services provided for patients that are not in a clinical trial. All the following limitations apply to such coverage:

If, upon the recommendation of their VCHCP physician, a member participates in a clinical trial for treatment of cancer, VCHCP may cover the costs of health care services that a member would normally receive had the member not enrolled in the clinical trial. This includes services required for the provision of the investigational drug, item, device, or service and services required for the clinically appropriate monitoring of and prevention, diagnosis or treatment of complications arising from the investigational item, device or service. Costs of the investigational drug or device, however, are not covered (see below for a list of non-covered items). The trial must have a therapeutic intent and end points and the trial must have a meaningful potential to benefit the member. Evidence of such should be provided by the clinical trial investigators (see below).

Payment Responsibilities:

If the trial is provided by a contracted hospital or physician, VCHCP shall pay the contracted rate and the member shall only be responsible for the applicable co-payment for services covered by the plan. If the trial is provided by a non-contracted provider, VCHCP shall obtain a case agreement for services covered by the plan. The member shall be responsible for the applicable copayment in addition to any non-covered costs.

Specified Requirements for Plan Coverage of a Clinical Trial:

The enrollee is eligible to participate in the clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening condition (a condition from which the likelihood of death is probable unless the course of the condition is interrupted), as determined in one of the following ways:

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- i. A plan provider makes this determination, or
- ii. The enrollee, provider, or clinical trial investigators provides the plan with medical and scientific information establishing this determination.

If any plan providers participate in the clinical trial and will accept the enrollee as a participant, the enrollee must participate in the trial through the plan provider unless the trial is outside the state where the enrollee lives, or the clinical trial is an approved clinical trial, meaning it is a phase I, II, III, or IV clinical trial related to the prevention, detection, or treatment of cancer or other life-threatening condition and it meets one of the following requirements:

- i. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration, or
- ii. The study or investigation is a drug trial that is exempt under federal regulations from a new drug application, or
- iii. The study or investigation is approved or funded by at least one of the following:
 - a. The National Institutes of Health,
 - b. The Centers for Disease Control and Prevention,
 - c. The agency for Health Care Research and Quality,
 - d. The Centers for Medicare & Medicaid Services,
 - e. A cooperative group or center of any of the above entities or of the Department of Defense or the Department of Veterans Affairs,
 - f. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants,
 - g. The Department of Veterans Affairs of the Department of Defense or the Department of Energy, but only if the study or investigation has been reviewed and approved through a system of peer review that the U.S. Secretary of Health and Human Services determines meets all the following requirements:
 1. It is comparable to the National Institutes of Health system of peer review of studies and investigations.
 2. It assures unbiased review of the highest scientific standards by qualified people who have no interest in the outcome of the review.

Procedure:

The clinical or principal investigator who is managing the clinical trial and seeking coverage on behalf of a member shall provide all the following information to the plan:

- (1) The name of the trial
- (2) The phase of the trial
- (3) The condition being treated by the trial
- (4) The method by which further information about the trial may be obtained

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VCHCP's Medical Director shall review the above information and may authorize coverage of the routine patient care costs that would otherwise be covered. If a Treatment Plan is provided, VCHCP may authorize services for periods of up to 90 days, which may then be renewed, in accordance with the procedures described in the Standing Referral to a Specialist policy. *

*This can be found under 'Utilization Management' / 'Standing Referrals to Specialists' on the following website address: <https://www.vchealthcareplan.org/providers/medicalPolicies.aspx>

Non-covered services:

VCHCP does not cover any of the following when a member is enrolled in a clinical trial:

- (1) The cost of an investigational drug, device or experimental intervention which would otherwise not be provided by the Plan.
- (2) Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.
- (3) The costs associated with managing the research related to the clinical trial, for example, data collection, analysis and other protocol-induced costs.
- (4) The costs that would not be covered under the member's coverage with respect to a medical procedure not involving a clinical trial.
- (5) Trials to determine safety or dosing levels of a drug.
- (6) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses.
- (7) Items and services generally made available by the trial sponsor without charge.

A. **Attachments:** None

B. **History:**

Reviewer/Author: Richard O. Ashby MD, QA Committee; October 2000

Reviewer/Author: David Chernof, MD; October 04, 2003

Reviewer/Author: David Chernof, MD; July 01, 2004

Committee Review: QAC: November 16, 2004

Reviewed/Revised by: Sheldon Haas, MD; June 30, 2008

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C. Reference:

SB 1839 (June 19, 2000)
 California Insurance Code § 10145.4

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
2/9/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
11/9/17	Yes	Catherine Sanders, MD; Robert Sterling, MD	Updated the clinical trial process to match the updates in the Explanation of Coverage (EOC)

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2/20/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated policy statement and added Standing referral policy link. Modified Specified Requirements for Plan Coverage of a Clinical Trial