

Contra Costa Health Plan

Utilization Management

Title: Cancer Clinical Trial

Policy #: UM15.037

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Applies to:

Medi-Cal Medicare Commercial
 BAC State Sponsored All N/A

Regulatory / Accreditation:

Department of Managed Care HCFA: DHCS:
 Other Reg. References: SB 37 NCQA H&S 1370.6

Units:

Administration Advice Nurses All Staff
 Business Services Care Management Health Ed/Cultural Living
 Marketing Member Services Planning, Survey, Reg. Affairs
 Provider Affairs Quality Management Auth/Utilization Management

OPS Council Approval Date & Sign Off

POLICY

A member referred by their Contra Costa Health Plan (CCHP) contracted treating provider to a cancer clinical trial, shall be covered for “routine patient care costs” if the member meets specific requirements and is accepted into a Phase I to Phase 4 cancer clinical trial.

PURPOSE

To allow an enrollee with the diagnosis of cancer to participate in approved clinical trials for the treatment of their disease when the outcome would be a “meaningful potential benefit to the enrollee” without the consequences of non-coverage for routine patient care costs related to the clinical trial.

PROCEDURE

To qualify for a cancer clinical trial, the requirements specified below must apply:

1. The enrollee must be diagnosed with cancer, accepted into a Phase I to Phase IV clinical trial for cancer, and the treating physician must recommend participation in the clinical trial after determining that participation will have a **“meaningful potential benefit to the enrollee.”**
2. The clinical trial’s endpoints must not be defined exclusively to test toxicity but must have a **therapeutic intent**. The trial must also be approved by one of the following: National Institutes of Health, the FDA, U.S. Department of Defense, or U.S. Department of Veteran’s Affairs, or involve a drug that is exempt under federal regulations from a new drug application.

Prior authorization (PA) is required for clinical trials. PA is not required for cancer biomarker testing for stage III or stage IV cancer that is associated with an FDA-approved therapy for that cancer (see UM 15.003 Policy for Prior Authorization) A Prior Authorization Form (PAR) must be completed and submitted to the Authorization Unit for processing. Supporting information such as, but not limited to, confirmation of cancer, specialist consultation notes, labs, diagnostic and radiological procedures, clinical study excerpts, trial protocols (inclusions and exclusions), etc., should be submitted to expedite clinical review turnaround time. Timeframe for the decision-making process adheres to established criteria in policy #UM15.018 Timeliness of the Utilization Review Decision and Communication.

Definitions:

I. Routine patient care costs:

Costs associated with the provision of health care services, including drugs, devices, and services that would otherwise be covered under the Plan if they were not provided in connection with a clinical trial, including the following:

- Services typically provided absent a clinical trial,
- Services required solely for the provision of the investigational drug, device or service,
- Services required for the clinically appropriate monitoring of the investigational drug,
- Services provided for the prevention of complications arising from the provision of the investigational drug, device, or service,
- Reasonably necessary care arising from the provision of the investigational drug, device, or service, including the diagnosis or treatment of the complications.

Does NOT include:

- Non-FDA approved drugs or devices that are associated with the clinical trial.
- Services other than health care services, such as, housing, companion expenses, comfort and convenience items, and other non-medical expenses, that an enrollee may require as a result of the treatment being provided for the purposes of the clinical trial.
- 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 member.
- Health care services that are otherwise excluded from an enrollee's contract with the Plan (other than those excluded on the basis that it is investigational or experimental).
- Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.

II. Meaningful potential benefit:

A drug, item or service that has the potential to sustain an individual's mental and/or physical health and well-being or increase their longevity.

The reimbursement rate for coverable health care services associated with the trial conducted by the Plan's participating provider shall be based on existing contractual agreement for similar services. If a clinical trial is conducted by a non-participating provider, the reimbursement shall be at the negotiated rate the Plan would otherwise pay to a participating provider for the same services, less any applicable copayments and deductibles. Copayments and deductibles are still applicable, as long as it is the same as those applied to the same services not connected to a clinical trial.

CCHP reserves the right to restrict coverage for clinical trials to participating hospitals and physicians in California, unless the protocol for the trial is not provided in California. This policy does not limit the enrollee's right to independent medical review (IMR) as indicated in policy

#UM15.033- Request for Experimental or Investigational Services and Independent Medical Review Option.

Services provided under this policy do not, in itself, give rise to liability on the part of the Plan. Prior authorization is required for non-emergent medically necessary care not related to the clinical trial and could be covered when the enrollee is outside the Plan's service area while participating in a clinical trial.