

Last Review Date: 04/22

Coverage for Approved Clinical Trials for Health Plan Members Policy

PURPOSE

The purpose of this policy is to outline the requirements a Member must meet to qualify for coverage of routine costs associated with an Approved Clinical Trial.

POLICY

It is policy to comply with applicable state and federal regulations provided that the regulations meet qualifying requirements for Approved Clinical Trials.

SCOPE

This policy applies to Sutter Health and any legal entity for which Sutter Health or its affiliate is the sole member or directly or indirectly controls greater than 50% of the voting power or equity interest, to the extent that entity performs delegated Utilization Management (UM) for specific benefit or service (herein after referred to as "Sutter").

Sutter is not responsible for reviewing and/or making a final determination on a request that has been identified as Health Plan responsibility to review.

DEFINITIONS

Approved Clinical Trial is defined as a phase I, II, III, or IV trial conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is one of the following:

- A trial approved or funded by a designated agency or governmental department.
- A Clinical Trial conducted under a United States Food and Drug Administration (FDA) investigational new drug application.
- A drug trial that is exempt from requiring an FDA investigational new drug application.

Clinical Trial means a research study in which one (1) or more human subjects are prospectively assigned to one (1) or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

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Health Plan means health care service plans, health maintenance organizations, and other purchasers of covered services that arrange for the provision of health care services for their Members.

Medical Director is a physician who provides guidance and leadership on the use of medicine in a health care organization.

Medical Necessity or Medically Necessary means health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.

Member is a person covered under a Health Plan, either the enrollee or eligible dependent.

Provider means any professional person, organization, health facility, or other person or institution licensed by the state of California to deliver or furnish health care services.

Utilization Management (UM) means the evaluation of the Medical Necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable Health Plan, sometimes called 'utilization review.'

PROCEDURE

- A. The Member must meet the following requirements to qualify for coverage of routine costs associated with an Approved Clinical Trial:
 1. The Member is diagnosed with cancer or another life-threatening disease or condition.
 2. The Member is accepted into 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.
 3. The Member's primary care physician (PCP) or a participating Provider refers the Member to an Approved Clinical Trial after determining that the Member is appropriate for participation according to the Clinical Trial protocol; or, the Member provides medical and scientific information establishing that their participation in the Clinical Trial is appropriate because they have cancer or another life threatening disease or condition.
 4. The study or investigation is approved or funded by one (1) or more of the following:
 - a. The National Institute of Health (NIH).
 - b. The Federal Centers for Disease Control and Prevention.
 - c. The Agency for Health Care Research and Quality.
 - d. The Centers for Medicare & Medicaid Services.

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- e. A cooperative group or center of any of the above entities or of the United States Department of Defense or the United States Department of Veterans Affairs.
 - f. One (1) of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the United States Secretary of Health and Human Services determines is comparable to the system of peer review used by the NIH and confirms unbiased review of the highest scientific standards by qualified people who have no interest in the outcome of the review:
 - i. The United States Department of Veterans Affairs; or
 - ii. The United States Department of Defense; or
 - iii. The United States Department of Energy.
5. The study or investigation is conducted under an investigational new drug application reviewed by the FDA.
6. The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the FDA.
- B. Sutter can require a qualified Member to participate in the Approved Clinical Trial through a participating Provider if the Provider accepts the Member as a Clinical Trial participant.
1. If the protocol is not available through a participating Provider, the Member might still be asked to obtain portions of the protocol involving routine Member care services from a participating Provider, as deemed appropriate after discussions with the trial coordinator, a Sutter Medical Director, and as needed, the Health Plan Medical Director.
- C. Sutter may restrict coverage to an Approved Clinical Trial in California, unless the trial is not offered or available through a participating Provider in California.
- D. Sutter covers Member routine care costs for Members participating in an Approved Clinical Trial. Routine care costs are associated with the provision of health care services and include drugs, items, devices, and services that would otherwise be covered under the Health Plan if they were not provided in connection with a Clinical Trial.
1. Routine Member care costs include the following:
 - 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 drug, item, device, or service.

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- d. Health care services provided for the prevention of complications arising from the provision of the investigational drug, device, item or service.
 - e. Health care services needed for reasonable and necessary care arising from the provision of the investigational drug, device, item or service, including the diagnosis or treatment of complications.
2. Routine Member care costs do not include the following:
- a. The provision of non-FDA approved drugs or devices that are the subject of the Clinical Trial. The government agency or pharmaceutical company that is sponsoring the trial supplies, the drug, or device at no cost.
 - b. Services other than health care that can include travel, housing, and other non-clinical expenses that a Member may incur due to participation in 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 Member's Health Plan.
 - e. Health care services that are customarily provided by the research sponsors free of charge for any Member in the Clinical Trial.
- E. This policy does not limit the Member's right to an independent medical review (IMR).
- F. The provision of services required by the act does not, in itself, give rise to liability on the part of Sutter or the Health Plan.
- G. Co-payments and deductibles applied to services delivered in a Clinical Trial shall be the same as those applied to the same services when provided outside of a Clinical Trial. In-network cost sharing and out-of-pocket maximums shall apply if the Clinical Trial is not offered or available through a participating Provider.
- H. Sutter and the Health Plan may not deny the following:
- 1. The participation of qualified Members in Approved Clinical Trials.
 - 2. Deny, limit or impose additional conditions on the coverage of covered routine Member costs for items and services furnished in connection with Clinical Trial participation.
 - 3. Discriminate against a Member on the basis of participation in such a trial.
- I. Sutter and the Health Plan may direct that items and services furnished in connection with the trial be rendered in-network when feasible, and not at the facility conducting the Clinical Trial.

- J. If the decision is made to deny a Clinical Trial, Sutter will issue a denial letter that specifically states the medical, and if applicable, scientific reasons for the denial and any alternative treatment covered by the Health Plan. Sutter will also include an application and instructions for the Member to utilize the Department of Managed Health Care (DMHC) IMR program.
- K. A Member can ask their Provider for assistance in finding Clinical Trials. Other sources of information may include the following:
1. [Sutter Clinical Trials](#): to search for active Clinical Trials within Sutter.
 2. [Clinical Trials.gov](#): is an NIH website used to conduct advanced searches.
 3. [National Cancer Institute \(NCI\)](#): to search for trials sponsored by the NCI.
 4. [Center Watch](#): to search a list of both industry sponsored and government funded Clinical Trials for cancer and other diseases.
 5. **Private companies**, such as pharmaceutical or biotechnology firms, may list the studies they're sponsoring on their websites or offer toll-free numbers so Members can call and ask about them.

REFERENCES

California Health & Safety Code §1370.6

Patient Protection and Affordable Care Act (PPACA)

ATTACHMENT

None