
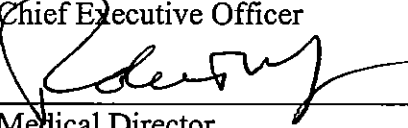



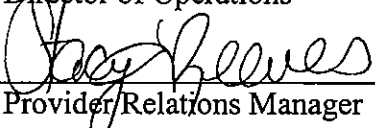



**KERN HEALTH SYSTEMS  
POLICIES AND PROCEDURES**

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SECTION: Utilization Management		ISSUE DATE: January 1, 2000					
Review Date	05/02						
Effective Date	12/01/02						
Revision No.	2002-08						

Approved		Date	<u>8/9/02</u>
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**POLICY<sup>1</sup>:**

In addition to the provision of cancer screening as a part of Kern Health Systems (KHS) preventative services, KHS also provides services for the diagnosis and treatment of cancer consistent with generally accepted medical and scientific evidence upon referral by a participating physician, nurse practitioner, or certified nurse midwife providing care to the member.

Cancer treatment will be provided in accordance with the commonly accepted guidelines.

Cancer treatment will be provided in accordance with statutory, regulatory, and contractual requirements outlined in the following sources:

- California Health and Safety Code §1367.6
- California Health and Safety Code §1370.6

## **PURPOSE:**

To clarify KHS' policy for coverage of cancer treatment services .

## **PROCEDURE:**

### **1.0 ACCESS**

All cancer treatment services must be pre-authorized and performed by KHS participating practitioners/providers. When necessary and appropriate, exceptions for treatment by non-contracting practitioners/providers may be made by the Medical Director.

### **2.0 COVERED SERVICES**

Cancer treatment should be provided in accordance with commonly accepted practices.

#### **2.1 Breast Cancer Treatment<sup>2</sup>**

If a diagnosis of breast cancer is made, all related care for the member is covered. This may include, but is not limited to:

- A. Surgical removal
- B. Radiation
- C. Chemotherapy
- D. Prosthetic devices
- E. Reconstructive surgery to restore and achieve symmetry

#### **2.2 Clinical Trials<sup>3</sup>**

With the exception of those services covered by California Children's Services (CCS), KHS covers routine patient care costs resulting from participation in a cancer clinical trial that meets specified requirements upon referral to the trial by the member's treating physician. Services related to a qualified clinical trial can not be denied on the basis that they are experimental and investigational. Participation in a cancer clinical trial is a CCS eligible service.

##### **2.2.1 Eligibility for Coverage**

To be eligible for coverage, the member must meet the following requirements:

- A. Diagnosed with cancer
- B. Accepted into a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer
- C. Received a recommendation to participate in the trial from a participating treating physician. The recommendation must be based on a determination that participation has a meaningful potential to benefit the member.

To be eligible for coverage, the trial must meet the following requirements<sup>4</sup>:

- A. Endpoints have a therapeutic intent and are not defined exclusively to test toxicity<sup>5</sup>
- B. Treatment provided is either:
  - 1. Approved by the National Institutes of Health, Federal Food and Drug Administration, US Department of Defense, or the US Veterans' Administration
  - 2. Involves a drug that is exempt under federal regulations from a new drug application

### 2.2.2 Eligible Services<sup>6</sup>

Routine patient care costs are those associated with the provision of health care services including drugs, items, devices, and services that would otherwise be covered if they were not provided in connection with a clinical trial. Covered services include the following:

- A. Services typically provided absent a clinical trial
- B. Services required solely for the provision of the investigational drug, item, device, or service
- C. Services required for the clinically appropriate monitoring of the investigational drug, device, item, or service
- D. Services provided for the prevention of complications arising from the provision of the investigational drug, device, item, or service
- E. Reasonable and necessary care arising from the provision of the investigational drug, device, item, or service, including the diagnosis or treatment of complications

The following are not eligible for coverage:

- A. The provision of non-FDA approved drugs or devices that are the subject of the trial
- B. Services other than health care services, such as for travel, housing, and other non-clinical expenses that an enrollee may incur due to participation in the trial
- 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 services that are otherwise excluded from coverage (other than those excluded on the basis that they are investigational or experimental)
- E. Health care services that are customarily provided by the research sponsors free of charge for any participant in the trial

## 3.0 DOCUMENTATION

Services should be documented in the same manner as other services.

## 4.0 COORDINATION OF CARE

Care should be coordinated in the same manner as other services.

## 5.0 REIMBURSEMENT

Payment to contracting providers shall be at the agreed-upon rate.

### 5.1 Reimbursement for Clinical Trials<sup>7</sup>

Payment to non-contracting practitioners/providers shall be at the negotiated rate that would otherwise be paid to a contracting practitioner/provider for the same services. In each case that is referred to a non-contracting provider, the Provider Relations Manager is notified and attempts to obtain a written agreement including a hold harmless clause for the member.

## 6.0 PROVIDER REQUIREMENTS

Cancer treatment provided as a KHS benefit must be provided by qualified practitioners as outlined in the Provider Relations section of the *KHS Administrative Manual*. There are no additional practitioner requirements related to Cancer treatment.

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<sup>1</sup> **Revision 2002-08:** Revised to ensure compliance with SB37 (Speier) 2001; effective 01/01/02. **Revision 2000-04:** Created to ensure compliance with SB5 1999; effective 01/01/00. **Formerly:** Breast Cancer Services.

<sup>2</sup> HSC 1367.6 (d)

<sup>3</sup> HSC §1370.6

<sup>4</sup> HSC §1370.6 (c)

<sup>5</sup> HSC §1370.6 (a)

<sup>6</sup> HSC §1370.6 (b)

<sup>7</sup> HSC §1370.6 (d)