



# KERN HEALTH SYSTEMS

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| <b>KERN HEALTH SYSTEMS</b>                           |  |      |  |                   |  |
| <b>POLICY AND PROCEDURES</b>                         |  |      |  |                   |  |
| SUBJECT: Cancer Treatment                            |  |      |  | POLICY #: 3.53-P  |  |
| DEPARTMENT: Health Services - Utilization Management |  |      |  |                   |  |
| Effective Date:<br><br>2002-08                       | Review/Revised Date:<br><br>11/11/2022 | DMHC |  | PAC               |  |
|  |  | DHCS |  | QI/UM COMMITTEE   |  |
|  |  | BOD  |  | FINANCE COMMITTEE |  |

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Emily Duran  
Chief Executive Officer

Date \_\_\_\_\_

\_\_\_\_\_  
Chief Medical Officer

Date \_\_\_\_\_

\_\_\_\_\_  
Chief Financial Officer

Date \_\_\_\_\_

\_\_\_\_\_  
Chief Operating Officer

Date \_\_\_\_\_

\_\_\_\_\_  
Chief Health Services Officer

Date \_\_\_\_\_

\_\_\_\_\_  
Director of Claims

Date \_\_\_\_\_

\_\_\_\_\_  
Director of Utilization Management

Date \_\_\_\_\_

**POLICY:**  
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

## **PROCEDURES:**

### **1.0 ACCESS**

All requested cancer treatment services maybe subject to preauthorization by KHS participating practitioners/providers. When necessary and appropriate, exceptions for treatment or diagnostic testing by both participating and non-contracting practitioners/providers may be made by the Chief Medical Officer or their designee.

### **2.0 COVERED SERVICES**

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

#### **2.1 Breast Cancer Treatment<sup>1</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>2</sup>**

Except for 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 cannot be denied on the basis that they are experimental and investigational. Participation in a cancer clinical trial is a CCS eligible service and subject to review by CCS.

##### **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. Acceptance includes, but is not limited to, any acceptance into such a trial that is contingent upon the member's receiving coverage of routine patient care costs.
- 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>3</sup>:

- A. Endpoints have a therapeutic intent and are not defined exclusively to test toxicity<sup>4</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 Biomarker Testing**

KHS is required to cover medically necessary biomarker testing for members with:

- Advanced or metastatic stage 3 or 4 cancer.
- Cancer progression or recurrence in the member with advanced or metastatic stage 3 or 4 cancer.

KHS is prohibited from imposing prior authorization requirements on biomarker testing that is associated with a federal Food and Drug Administration (FDA)-approved therapy for advanced or metastatic stage 3 or 4 cancer. Additionally, KHS will not limit, prohibit, or modify a member's right to cancer biomarker testing as part of an approved clinical trial under HSC 1370.6

If the biomarker test is not associated with an FDA-approved cancer therapy for advanced or metastatic stage 3 or 4 cancer, KHS may still require prior authorization for such testing.

### **2.2.3 Eligible Services<sup>5</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. Drugs, items, devices, and services that would be 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. 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
- C. Health care services that are otherwise excluded from coverage (other than those excluded on the basis that they are investigational or experimental)
- D. 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.

Updates to the list of cancer biomarker tests that are associated with a federal FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer, as the FDA makes updates to its drug therapy approvals will be conducted annually.

### **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>6</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 Senior Director of Provider Relations or their designee 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.

### **7.0 DELEGATED OVERSIGHT AND MONITORING**

KHS is responsible for ensuring that their Subcontractors and Network Providers comply with all applicable state and federal laws and regulations, contract requirements, and other Department of Health Care Services' guidance, including APLs and Policy Letters. These requirements must be communicated by KHS to all Subcontractors and Network Providers.

## REFERENCE:

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**Revision 2022-09:** Revisions by Chief Health Services Officer to align with APL-22-010. Policy revision approved by the DHCS on 9/22/2022. Policy approved by the DMHC on 10/26/2022, Filing No. 20223470 <sup>1</sup>**Revision 2017-10:** Revision added clarifying eligibility for coverage in cancer trials. **Revision 2014-08:** Routine review. **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.

HSC 1367.6 (d)

<sup>2</sup> HSC §1370.6

<sup>3</sup> HSC §1370.6 (c)

<sup>4</sup> HSC §1370.6 (a)

<sup>5</sup> HSC §1370.6 (b)

<sup>6</sup> HSC §1370.6 (d)