Clinical Trials

I. Policy

University Health Alliance (UHA) will reimburse for treatment of Routine Patient Care Costs for members enrolled in clinical trials when determined to be medically necessary and within the medical criteria guidelines (subject to limitations and exclusions) indicated below.

This policy applies to clinical trials designed to study new methods to prevent, detect, or treat cancer or other life-threatening illnesses.

II. Criteria/Guidelines

A. Consistent with Centers for Medicare & Medicaid Services (CMS) policy, UHA covers medically necessary routine patient care costs for members who meet eligibility to participate in approved clinical trials (in the same way that it reimburses routine care for members not in clinical trials) according to the limitations outlined below. All of the following limitations apply to such coverage:

1. Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care) are covered.
    a. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications are covered; and
    b. Items or services needed for reasonable medical care arising from the provision of investigational item or service are covered.
        i. In particular, eligible members are covered for the diagnosis or treatment of complications.
2. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; and
3. All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; and
4. Members must meet all applicable plan requirements for prior authorization, registration, and referrals.
5. An approved clinical trial:
    a. Is defined as 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; and
    b. Must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to UHA, but UHA can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s). Recognized institutional review boards include the following:
        i. The National Institutes of Health (NIH)
        ii. The Centers for Disease Control and Prevention (CDC)

iii. The Agency for Healthcare Research and Quality (AHRQ)

iv. The Centers for Medicare and Medicaid (CMS)

v. A cooperative group or center of any of the entities described above (1-4)

vi. A cooperative group or center of the Department of Defense (DOD) or the Department of Veterans Affairs (DVA) or the Department of Energy (DOE)

vii. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

viii. The DOD, DVA, or Department of Energy but only if that study/investigation has been reviewed and approved through a system of peer review approved by the Department of Health and Human Services (HHS); or

ix. Clinical trial is conducted under an investigational new drug (IND) application reviewed by the Food and Drug Administration; or the study or investigation is a drug trial that is exempt from having such an investigational new drug application.

6. A qualified individual is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either:

    a. The referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or

    b. The participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member's individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

III. Limitations/Exclusions

A. UHA does not cover the following clinical trial costs:

1. Costs of data collection and record keeping that would not be required but for the clinical trial; and

2. Items and services provided by the trial sponsor without charge; and

3. The experimental intervention itself to include the item, device, or service being tested unless otherwise covered outside of the clinical trial (e.g. an established drug treatment that is being tested with a new dosing regimen)

a. Medically necessary Category B investigational devices and promising experimental and investigational interventions in certain clinical trials according to UHA's Emerging Technologies policy (see policy for details) may be covered

4. Other services to clinical trial participants necessary solely to satisfy data collection needs of the clinical trial (i.e., "protocol-induced costs").

B. UHA will accommodate reasonable laboratory and imaging requests where evidence supports their relative utility in the evaluation of the pertinent disease state. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis will not be covered.

IV. Administrative Guidelines

A. Prior authorization is required.
B. To request prior authorization, please submit via UHA's online portal.
C. This policy may apply to the following codes. Inclusion of a code in the table below does not guarantee that it will be reimbursed.

ICD-10 Code and Modifiers	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program
Modifier Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Modifier Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

V. Policy History

Policy Number: MPP-0087-120918

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References:

Centers for Medicare & Medicaid Services. NCD for Routine Costs in Clinical Trials. 310.1 Effective date July 7, 2007.