



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 another life-threatening illness.

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 the following limitations apply to such coverage:
 1. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; and
 2. 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
 3. Members must meet all applicable plan requirements for prior authorization, registration, and referrals.
 4. 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).
 5. 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.
- B. UHA covers costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials.

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 (except 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)); and
 - 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. To request prior authorization, please submit via UHA's online portal. If login has not been established, you may contact UHA at 808-532-4000 to establish one. The following documentation must be submitted:
 - 1. Clinical notes from the requesting/ordering physician
 - 2. Detailed breakdown of the clinical trial, including information on coverage by the study sponsor

When submitting claims, all items/services must be identified with the appropriate "Q0" or "Q1" procedure code modifier. The modifiers are line item specific and must be used to identify items/services that constitute medically necessary routine patient care or treatment of complications arising from a beneficiary's participation in a covered clinical trial.

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

Current Effective Date: 08/01/2022

Original Document Effective Date: 09/18/2012

Previous Revision Dates: 09/01/2016, 06/12/2018

PAP Approved Date: 09/18/2012

References:

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