



Emerging Technology

I. Policy

University Health Alliance (UHA) will reimburse for procedures related to emerging technology when determined to be medically necessary and within the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Background

UHA recognizes the increasing availability of novel devices, advanced technology, and evolving procedures which employ these new instruments, techniques, and implantable materials. UHA endorses processes which lead to safe, appropriate, and cost-effective adoption of the techniques and materials. Examples of this include the application of robotics and certain minimal access approaches to a variety of operative procedures, emerging endovascular techniques, and refinements in imaging. In many cases, the relative advantages or weaknesses of new methods and/or materials can take years to be adequately defined. Despite this fact, direct marketing to the lay public, the acquisition of equipment by providers (institutional and individual), and a competitive marketplace can all drive a process of introduction, evaluation, and clinical application, which may prove to be too rapid or insufficiently scholarly to achieve the goals of safety, appropriateness, and cost effectiveness.

To achieve these goals of safety, appropriateness, and cost effectiveness, and to serve UHA's commitment to evidence-based medicine, UHA operates under the following guidelines for emerging medical techniques, technology, and experimental procedures.

III. Criteria/Guidelines

- A. UHA does not reimburse for medical treatments, drugs, devices, or care which cannot be designated as being reasonably necessary for a patient's care relative to other well established available services or equipment.
- B. UHA does not reimburse for incrementally improved drugs, devices, or care when the potential therapeutic benefits of these improvements are judged to be of a degree insufficient to offset the risk to patient safety and the economic cost, both direct and opportunistic, to UHA and its members.
- C. UHA covers experimental or investigational technologies (i.e., drugs, procedures, and devices), subject to the limitations below, when all the following criteria are met:
 1. The member has a current diagnosis that will result in a markedly reduced life expectancy despite therapy with currently accepted treatment; and
 2. Standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and
 3. The proposed treatment is likely to be beneficial to the member based on at least two documents of medical and scientific evidence (as defined below); and
 4. The member is to be treated as part of a clinical trial satisfying ALL of the following criteria:
 - a. The investigational drug, device, therapy, or procedure is under current review by the FDA and has an Investigational New Drug (IND) number; and the clinical trial has passed independent scientific scrutiny and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation; and

- b. The clinical trial is sponsored by the National Cancer Institute (NCI) or similar national cooperative body (e.g., Department of Defense, VA Affairs) and conforms to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials; and
 - c. The clinical trial is not a single institution or investigator study (NCI-designated Comprehensive Cancer Center trials are exempt from this requirement); and
 - d. The member must not be treated “off protocol” and must actually be enrolled in the trial.
5. Medical and scientific evidence means the following sources:
- a. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
 - b. Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health’s National Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline or MEDLARS database, or Health Services Technology Assessment Research (STAR).
 - c. Medical journals recognized by the Secretary of Health and Human Services under Section 1861 (t)(2) of the Social Security Act (42 U.S.C. 1395x).
 - d. The following standard reference compendia: The American Hospital Formulary Service-Drug Information, The American Medical Association Drug Evaluations, The American Dental Association Accepted Dental Therapeutics, and The United States Pharmacopoeia Drug Information.
 - e. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - i. Federal Agency for Healthcare Research and Quality
 - ii. National Institutes of Health
 - iii. National Cancer Institute
 - iv. National Academy of Sciences
 - v. Centers for Medicare and Medicaid Services (CMS)
 - vi. Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services

D. UHA covers the “**off label**” **use of drugs** when the following criteria are met:

- 1. There exists published evidence and expert opinion regarding the benefits of particular drugs that an accepted drug compendium considers of proven value, whether or not the FDA has formally approved the drug for a given use.
- 2. Group C cancer drugs which are sponsored by the National Cancer Institute (NCI).

E. UHA covers the use of **Investigational Medical Devices** when the following criteria are met:

- 1. The device has been granted an FDA Investigational Device Exemption (IDE) and has shown an incremental improvement over approved devices that have been demonstrated to be safe and effective, and there exists no evidence to believe that such incrementally improved device is not safe and effective.

2. It has been classified by CMS as an IDE Category B Device, it is considered reasonable and necessary, and all other applicable UHA coverage requirements are met.
 - a. The FDA assigns a special identifier number that corresponds to each device granted an investigational device exemption (IDE). Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes. Class I devices are the least regulated. These are devices that the FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations. Class II devices are those which, in addition to general controls, require special controls such as performance standards or post-market surveillance, to assure safety and effectiveness. Class III devices are those which cannot be classified into class I or class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require pre-market approval.
 - b. An IDE Category B device is a non-experimental/investigational device believed to be in Class I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval or clearance for that device type.
- F. UHA may provide coverage for an **investigational procedure** if the following criteria are met.
1. The procedure is considered by a nationally recognized professional organization to be promising in the treatment of a serious condition.
 2. Comparable, non investigational procedures have not been effective or are not feasible.
 3. The member has a current diagnosis that results in serious morbidity or a significantly reduced life expectancy.

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 members' 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.

IV. Limitations/Exclusions

- A. If the criteria listed above are not satisfied, and the member desires reconsideration, the member may submit an appeal in accordance with the relevant appeal process. Any such appeal may be expedited when required by the member's medical condition.
- B. Coverage is limited to conditions being treated as life-threatening, the experimental therapy is potentially curative and not palliative, and the experimental technology is therapeutic and not diagnostic. Coverage for experimental technologies is limited to circumstances in which all nonexperimental options have been exhausted.

- C. Technology being considered must be in an advanced stage of development. Examples of circumstances in which this construct would apply are new drugs and devices that are being evaluated in FDA- or institutional review board (IRB)-approved Phase III clinical trials and new procedures being evaluated in IRB-approved studies after there has been experience with at least ten patients that suggests that the procedure is safe and effective.
- D. When the investigational technology meets the above criteria, coverage may be limited to the costs associated with the use of experimental technologies and exclude coverage for the technology itself.

V. Administrative Guidelines

- A. Prior authorization is required.
- B. UHA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria and to ensure proper reimbursement is made.
- C. 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.

VI. Policy History

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