

DAVID Y. IGE
GOVERNOR



PANKAJ BHANOT
DIRECTOR

CATHY BETTS
DEPUTY DIRECTOR

STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES


Med-QUEST Division
Clinical Standards Office
P. O. Box 700190
Kapolei, Hawai'i 96709-0190

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MEMORANDUM

MEMO NO.
QI-1934

TO: QUEST Integration Health Plans

FROM:  Judy Mohr Peterson, PhD
Med-QUEST Division Administrator

SUBJECT: MED-QUEST GUIDANCE REGARDING THE COVERAGE OF ROUTINE COSTS
ASSOCIATED WITH QUALIFYING CLINICAL TRIALS

The purpose of the memorandum is for the Med-QUEST Division (MQD) to provide guidance to the QUEST Integration (QI) health plans and Medicaid FFS program regarding the coverage of routine costs associated with qualifying clinical trials (QCT). The QI health plans shall provide coverage for all routine patient care costs related to participation in qualifying clinical trials for the prevention, diagnosis, treatment, or supportive care of cancer, as well as medically necessary items and services used to prevent, diagnose and treat complications arising from participation in clinical trials.

Clinical Trial

There are two main types of clinical studies: Clinical trials (also called interventional studies) and observational studies. A clinical trial, as defined by the National Institutes of Health (NIH), is a research study in which human subjects are prospectively assigned to interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. In a clinical trial, participants receive specific interventions according to the research plan or protocol designed by the investigators. Clinical trials may compare a new medical

approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other.

Qualifying Clinical Trial

A qualifying clinical trial (QCT) is a trial that meets the requirement set forth in Clinical Trial Policy (Refer to Attachment NCD 310.1) by the Center for Medicare and Medicaid Services (CMS). This policy delineates the requirements that a trial must meet to be designated as a QCT.

A QCT means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, diagnosis, treatment, palliative care or supportive care of cancer and is described in any of the following clauses:

1. Trials reviewed and approved by one or more of the following:
 - a. The National Institutes of Health (NIH), including National Cancer Institute (NCI)-designated Cancer Centers with an approved Scientific Review Committee
 - b. The Centers for Disease Control and Prevention (CDC)
 - c. The Agency for Healthcare Research and Quality (AHRQ)
 - d. The Centers for Medicare and Medicaid Services (CMS)
 - e. The Department of Defense (DOD)
 - f. The Department of Veterans Affairs (VA)
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA; and
3. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA).

Routine Costs

Medicaid covers the routine costs of QCT's, as such costs are defined below, as well as medically necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicaid rules apply. The QCT must use in-network providers and be located in the state of Hawaii. Out-of-state clinical trials may be considered on a case by case basis.

"Routine patient care costs" include all items and services that are a benefit under a health plan that would be covered if the covered person were not involved in a clinical trial. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

“Routine patient care costs” include:

- a. Items or services that are typically provided absent a clinical trial;
- b. Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;
- c. Items or services needed for medically necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

“Routine patient care costs” does not include:

- a. The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- b. Items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management of the patient;
- c. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial;
- d. Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee’s health plan;
- e. Items or services that are excluded from Medicaid coverage; and
- f. Items or services for a clinical trial that does not have therapeutic intent. These are trials that are designed exclusively to test toxicity or pathophysiology without therapeutic intent.

For most QCT's, it is best practice to have a formal coverage analysis that provides guidance regarding the designation of items or services as routine care vs. non-routine care. This coverage analysis may have been generated at the national level by the sponsor (i.e. National Cancer Institute or Industry sponsor) or at the local level. If desired, a copy of the coverage analysis may be requested from the local billing or trial coordinating entity.

Clinical trials allow for the advancement of medicine while improving the quality of care for patients. Our intent is to assure that our Medicaid beneficiaries have the same access to clinical trials and treatment options as would the non-Medicaid beneficiaries.

For any questions, please contact our Med-QUEST Medical Director, Dr. Curtis Toma at ctoma@dhs.hawaii.gov or (808) 692-8105.