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June 20, 2022

MEMORANDUM

MEMO NO.
QI-2208 [Replaces QI-2150]

TO: QUEST Integration Health Plans

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

SUBJECT: MED-QUEST GUIDANCE ON MEDICAID COVERAGE OF ROUTINE PATIENT COSTS FURNISHED IN CONNECTION WITH PARTICIPATION IN QUALIFYING CLINICAL TRIALS

The Med-QUEST Division (MQD) is providing updated guidance regarding the coverage of routine patient costs associated with participation in a qualifying clinical trial (QCT). This guidance replaces the previous guidance from QI-2150 issued December 29, 2021.

The routine patient costs that must be covered for a Medicaid beneficiary participating in a QCT are any item or service provided to the individual under the QCT, including any item or service provided to prevent, diagnose, or treat complications resulting from participation in QCT, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside of the course of participation in the QCT. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the QCT, including the administration of the investigational item or service. Some examples of routine costs in a clinical trial could include otherwise covered physician services or laboratory or medical imaging services that assist with the prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

Routine patient costs do not include any investigational item or service that is the subject of the QCT and is not otherwise covered outside of the clinical trial. Similarly, routine patient costs do not include any item or service that is provided to the Medicaid beneficiary solely to satisfy data collection and analysis for the QCT that is not used in the direct clinical management of the beneficiary. For example, if a beneficiary has a condition that typically requires monitoring through an annual medical imaging scan and the beneficiary is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the beneficiary's routine patient costs.

Routine Costs

Medicaid covers the routine costs of QCTs, 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. "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.

"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; and
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.

Qualifying Clinical Trial (QCT)

A QCT is a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and the QCT meets any one of the four categories below.

1. The QCT is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
    a. The National Institutes of Health (NIH);
    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. A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs; and
    f. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants.

2. The QCT is approved or funded by any one of the following entities, that has been reviewed and approved through a system of peer review comparable to the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
    a. The Department of Energy;
    b. The Department of Veterans Affairs; and
    c. The Department of Defense.

3. The QCT is conducted pursuant to an investigational new drug (IND) application reviewed by the Food and Drug Administration (FDA) or an exemption for a biological product undergoing investigation under section 351 (a)(3) of the Public Health Service (PHS) Act or the drug trial is exempt from being required to have one of the IND or PHS exemptions previously.

Coverage Determination Requirements

Determination with respect to coverage for a beneficiary participating in a QCT must be expedited and completed within 72 hours and must be made without regard to the geographic

location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the QCT.

For most QCTs, it is best practice to have a formal coverage analysis that provides guidance regarding the designation of items or services as routine care versus 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 non-Medicaid beneficiaries.

For any questions, please contact our Med-QUEST Medical Director, Dr. Curtis Toma at ctoma@dhs.hawaii.gov.