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April 9, 2025

MEMORANDUM

MEMO NO.
QI-2503 (Replaces QI-2208)
FFS 25-02

TO: QUEST Integration Health Plans and Koan Risk Solutions, Inc.

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

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

This memorandum is an addendum to QI-2208 (MED-QUEST GUIDANCE ON MEDICAID COVERAGE OF ROUTINE PATIENT COSTS FURNISHED IN CONNECTION WITH PARTICIPATION IN QUALIFYING CLINICAL TRIALS Addendum), initially released June 20, 2022. The text of memo QI-2208 is incorporated into this revision. Updated guidance is inserted as shaded text. Unless specified in this memo, the implementation guidelines as stated in QI-2208 are unchanged. This memo is also being issued to Fee-For-Service Providers.

Changes to this document:

- This memorandum adds a new requirement of an Attestation Form, as required by the Consolidation Appropriation Act of 2022.
- The Attestation Form must be completed by the Principal Investigator of the Qualified Clinical Trial (QCT) as well as the Medicaid Member's Healthcare Professional (if

different) in order for routine patient costs to be authorized and paid by the Medicaid Health Plan or FFS Provider.

- The Health Plan or FFS Provider must maintain a copy of the completed Attestation Form, and additionally forward a copy to Med-QUEST Division's Clinical Standards Office for its records.

The Med-QUEST Division (MQD) is providing additional updated guidance regarding the coverage of routine patient costs associated with participation in a QCT. This guidance replaces the previous guidance from QI-2208 issued June 20, 2022.

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.

<u>Routine Costs</u>

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.

<u>Qualifying Clinical Trial (QCT)</u>

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.

Attestation Form

CMS has issued an attestation form (Attachment A) that must be completed by the Medicaid member's healthcare provider, as well as the QCT's principal investigator (if different from the healthcare provider) in order to attest to the QCT's appropriateness in coverage determinations for the routine patient costs associated with the QCT benefit. Per section 1905(gg)(3) of the Social Security Act, this attestation form must be completed as part of the process to determine coverage for the routine patient costs for items and services furnished in connection with participation in a QCT. The requested routine patient costs related to the QCT may not be authorized by Health Plans or FFS Providers without a signed attestation form.

The attestation form requirement is effective immediately.

- Health Plans or FFS Providers must require that a completed form be submitted as part of the prior authorization request for the routine patient costs related to the QCT; and/or mandate the submission of this form along with any claim(s) for these services.

The Health Plan or FFS Providers must maintain copies of the completed attestation forms; and additionally, forward a copy of each complete attestation form to Med-QUEST Division's Clinical Standards Office (CSO) at mqdcso@dhs.hawaii.gov. Submitters must use their organization's secure mail protocols to appropriately encrypt Protected Health Information (PHI).

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.

Attachment

ATTACHMENT A: MEDICAID ATTESTATION FORM ON THE APPROPRIATENESS OF THE QUALIFIED CLINICAL TRIAL

Participant

Participant Name: _____

Medicaid I.D.: _____

Qualified Clinical Trial

National Clinical Trial Number (from clinicaltrials.gov): _____

Principal Investigator Attestation

Principal Investigator Name: _____

☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

☐ The Principal Investigator is also the Health Care Provider and hereby attests to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of principal investigator*) (*month, day, year*)

Health Care Provider Attestation

Health Care Provider Name: _____

☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of health care provider*) (*month, day, year*)

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-0193. Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.