HEALTH CARE AUTHORITY

Michelle Lujan Grisham, Governor
Kari Armijo, Secretary
Dana Flannery, Medicaid Director

Letter of Direction #46

Date: **January 6, 2025**

To: **Turquoise Care Managed Care Organizations**

From: **Dana Flannery, Director, Medical Assistance Division**

Subject: **Qualified Clinical Trials**

Title: **Qualified Clinical Trials (QCT) Information**

The purpose of this letter of direction is to provide the Turquoise Care Organizations (TC) with clarification and information related to the Centers for Medicare & Medicaid Services (CMS) letter, #SMD-21-005, related Qualifying Clinical Trial (QCT). The CMS letter can be at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

The Health Care Authority (HCA) Medical Assistance Division (MAD) will expand coverage for routine patient care costs incurred as a result of the Medicaid eligible recipient's participation in an approved QCT. HCA/MAD does not cover experimental or investigational medical, surgical or health care procedures or treatments, including the use of drugs, biological products, other products or devices included in the QTC. Similarly, HCA/MAD does not cover any routine patient cost item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the QTC that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

1. **Provider Requirements:** Providers must ensure that billed services adhere to one or more criteria as described in CMS letter, #SMD-21-005, at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

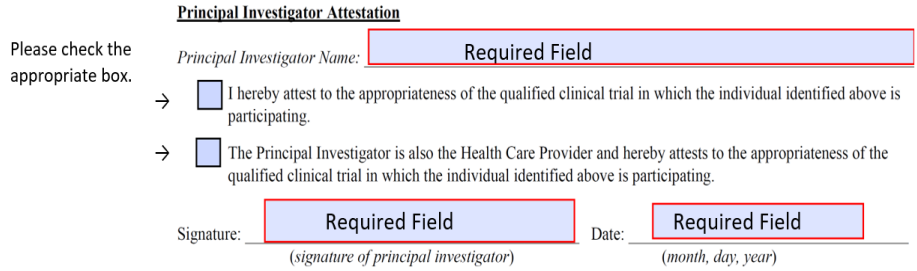
2. **Member eligibility requirements:** Any Medicaid eligible participant that agrees and is participating in a qualifying clinical trial without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying clinical trial.

   Coverage must also be based on an attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator and be made using a streamlined uniform form developed for the state.

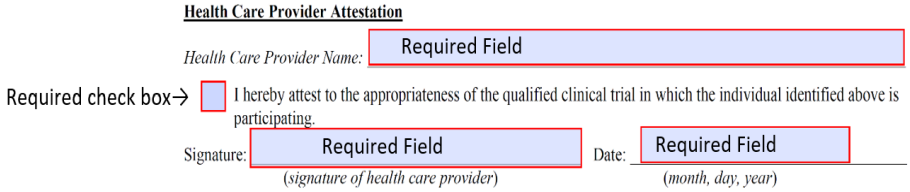
3. **Prior Authorization:** A Prior Authorization is not required. The requested routine patient care services or products must be automatically approved and covered when requested with a completed "Qualified Clinical Trial Medicaid Attestation Form" and is required with each claim submission.

4. **Qualified Clinical Trial Medicaid Attestation Form:**
    a. Providers must complete a Qualified Clinical Trial Medicaid Attestation Form, MAD form number 901 found at New Mexico Medicaid Portal (conduent.com)
        i. Each field of the form must be completed.
        ii. It must include QCT existing identification number, medical, surgical or health care procedures or treatments, including the name of drugs/biological product, treatment or devices included as part of the QTC.
        iii. For a list of approved QCT see https://www.clinicaltrials.gov/
        iv. A new QCT attestation form must be submitted for each trial.

5. **Billing and Reimbursement:**
    a. **Qualified Clinical Trial Medicaid Attestation Form:** A Claim **must** include a complete Qualified Clinical Trial Medicaid Attestation Form with a QCT identification number, specific details included in the QCT.
        i. Routine patient care service and other medical services that are not included as part of the QCT are reimbursed at the current fee schedule published at https://www.hsd.state.nm.us/providers/fee-schedules/.
        ii. Claims that are submitted may be denied if:
            1) QCT form is incomplete,
            2) Does not include QCT identification number,
            3) Does not include medical, surgical or health care procedures or treatments, including the name of drugs/biological product, treatment or devices included as part of the QTC, or
            4) Does not meet the definition of QTC as described in page 2-3 in CMS letter at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf
            5) Does not include "Principal Investigator Attestation" (note: In this section you must check one of the following):
                a. Check either the first box, "I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating" **OR** the second box, "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."



iii. Does not include "Health Care Provider Attestation" (note: all fields in this section are required)



b. **Institutional claims billed on UB-04 for QCT must include the following with the claim submission:**
   i. National Clinical Trial NCT identifier number must be reported.
      1) Paper claim submission: 8-digit NCT identifier number in the value amount value code 'D4' of FORM CMS UB-04 (Form Locators 39-41)
      2) Electronic claim submission: 8–digit NCT identifier number on equivalent 837I in Loop 2300 REF02 (REF01=P4)
   ii. Condition code: 30
   iii. ICD-10 diagnosis code Z00.6 in the primary or secondary positions
   iv. Modifier: Q0 and/or Q1, as appropriate (outpatient claims only)

c. **Professional claims billed on CMS-1500 for QCT must include the following with the claim submission:**
   i. NCT identifier number must be reported.
      a. Paper claim submission: 8-digit NCT identifier number preceded by alpha characters 'CT' in Field 19 of Form CMS-1500 (for example: CT12345678)
      b. Electronic claim submission: 8-digit NCT identifier number on equivalent 837P in Loop 2300 REF02(REF01=P4) no 'CT' (for example: 12345678)
   ii. ICD-10: diagnosis code Z00.6 (in either the primary or secondary positions)
   iii. Modifier: Q0 and/or Q1 as appropriate (outpatient claims only)

MCOs are directed to implement changes associated with these instructions, including system changes and provider contract negotiations as needed no later than 60 days from the date of issuance of this directive.

This LOD will sunset in the New Mexico Administrative Code (NMAC) 8.308.9 Managed Care Program.