

How to Complete:

The Medicaid Attestation Form on the Appropriateness of Qualified Clinical Trial

Summary of Requirements:

To comply with CMS' directive, the Medicaid Attestation Form on the Appropriateness of Qualified Clinical Trial (Attestation Form) must be complete for each Medicaid member enrolled in a Qualifying Clinical Trial (QCT) for whom Medicaid reimbursement is requested, prior to providing treatment in the trial.

The **Principal Investigator** and referring **Health Care Provider** (if applicable) must complete and upload the Attestation Form to Epic:

- For each **Medicaid member enrolled in a Qualifying Clinical Trial (QCT)**
- **Prior to enrollment**

Note: Completion of the Attestation Form is a requirement for Medicaid reimbursement

Background:

- The regulation found in [H.R. 133—The Consolidated Appropriations Act, 2021](#) (The Act), makes coverage of routine patient costs associated with a member participating in a QCT a mandatory benefit under each state Medicaid plan.
- Per [NC Medicaid Clinical Coverage Policy, No: 1A-39](#) (The CCP), routine patient costs must be covered for a beneficiary participating in a QCT.
- The CCP requires that the Principal Investigator (and the healthcare provider if applicable) sign the Attestation Form, for each participant who is enrolled in a QCT and receives Medicaid benefits.
- The CCP states that NC Medicaid will recoup all associated costs if the Attestation Form is not completed and, in the beneficiary's medical record, prior to participation in the study.

What is a Qualifying Clinical Trial:

As defined by The Act and CCP, 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 additionally must be **authorized by a specified governing agency or meet described drug requirements** as outlined in the Act and CCP.

Note: Consult your study's Billing Coverage Analysis (BCA) for the QCT determination.

When does the attestation need to be completed?

Initially: **Prior** to participation in the study.

Ongoing: Provider(s) shall verify each Medicaid beneficiary's eligibility **each time a service is rendered**.

Who is responsible for completing this attestation?

Per The CCP, the **health care provider** and **principal investigator (PI)** complete the Medicaid Attestation Form.

The PI may delegate the processes surrounding the completion of the Attestation Form to their team, but the PI and healthcare provider are ultimately **responsible for signing and attesting to this documentation**.

Principal Investigator: The person who is responsible for the scientific and technical direction of the entire clinical study.

Health Care Provider: Provider who has referred beneficiary to qualifying clinical trial.

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How to determine when the Attestation Form is required?

1. Is the participant enrolling in a Qualifying Clinical Trial:
If yes, continue onward. If no, then no further action is required.
2. Will items/services be billed to the participant or their insurance?
If yes, continue onward. If no, then no further action is required.
3. Does the patient have Medicaid or a different insurer?
If yes, continue onward. If no, then no further action is required.

Questions:

UNC Contacts:

- **Research Billing:** resbilling@unc.edu

UNC Health Contact Information: (Network Entities):

- **ORSC Finance:** ORSCFinance@unchealth.unc.edu

Resources:

- [Clinical Coverage Policy, No: 1A-39 NC Medicaid: Routine Patient Costs/ Clinical Trials, 1A-39.](#)
- [Consolidated Appropriations Act](#)
- [The Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial](#)

