

# Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials (for North Carolina Only)

**Policy Number:** CSNC.MP.006.03

**Effective Date:** December 1, 2023

[Instructions for Use](#)

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| Related Policies |
|------------------|
| None             |

## Application

This Medical Policy only applies to the state of North Carolina.

## Coverage Rationale

Coverage for clinical trials and routine patient costs incurred by members participating in clinical trials is considered a coverage expense under certain circumstances. For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy, Physician: 1A-39, Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials](#).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

**Coding Clarification:** Clinical Trials claims are not limited to these modifiers. However, if a claim has one of these modifiers it is considered to be a Clinical Trials claim.

| Modifier Code | Description   |
|---------------|---|
| Q0            | Investigational clinical service provided in a clinical research study that is in an approved clinical research study |
| Q1            | Routine clinical service provided in a clinical research study that is in an approved clinical research study         |

| HCPCS Code                           | Description  |
|--------------------------------------|--|
| <b>Covered When Criteria Are Met</b> |  |
| G0276                                | Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial  |
| G0293                                | Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day  |
| G0294                                | Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day  |
| G2000                                | Blinded administration of convulsive therapy procedure, either electroconvulsive therapy (ECT, current covered gold standard) or magnetic seizure therapy (MST, noncovered experimental therapy), performed in an approved IDE-based clinical trial, per treatment session |
| S9988                                | Services provided as part of a Phase I clinical trial  |
| S9990                                | Services provided as part of a Phase II clinical trial   |
| S9991                                | Services provided as part of a Phase III clinical trial  |
| <b>Not Covered</b>                   |  |
| S9992                                | Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion   |
| S9994                                | Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion   |
| S9996                                | Meals for clinical trial participant and one caregiver/companion   |

**Coding Clarification:** Clinical Trials claims are not limited to this diagnosis code; However, if a claim has this code it is considered to be a Clinical Trials claim.

| Diagnosis Code | Description  |
|----------------|--|
| Z00.6          | Encounter for examination for normal comparison and control in clinical research program |

## References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials. <https://medicaid.ncdhhs.gov/1a-39-routine-patient-costs-furnished-connection-participation-qualifying-clinical-trials/download?attachment>. Accessed June 7, 2023.

## Policy History/Revision Information

| Date       | Summary of Changes   |
|------------|--|
| 12/01/2023 | <p><b>Title Change</b></p> <ul style="list-style-type: none"> <li>Previously titled <i>Clinical Trials (for North Carolina Only)</i></li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Replaced reference to the “North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy for Physician, 1A-39, Routine Costs in Clinical Trial <i>Services for Life Threatening Conditions</i>” with “North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Physician: 1A-39, Routine <i>Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials</i>”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> <li>Archived previous policy version CSNC.MP.006.02</li> </ul> |

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual<sup>®</sup> criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.