

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

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[Instructions for Use](#)

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Related Policies
None

Application

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

Coverage Rationale

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.

Note: 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
Covered When Criteria Are Met	
*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
Not Covered	
*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

Codes labeled with an asterisk (*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

Note: 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

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA does not conduct clinical trials; however, it does provide oversight for some human drug, biological product, and device trials. Additional information is available at: <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials>. (Accessed April 10, 2024)

The FDA requires certain clinical trials to be registered in the ClinicalTrials.gov database. Additional information is available at: <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information>. (Accessed April 10, 2024)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials. Available at: <https://medicaid.ncdhhs.gov/1a-39-routine-patient-costs-furnished-connection-participation-qualifying-clinical-trials/download?attachment>. Accessed June 13, 2024.

Policy History/Revision Information

Date	Summary of Changes
10/01/2024	Coverage Rationale <ul style="list-style-type: none"> Removed coverage statement

Date	Summary of Changes
	<p>Supporting Information</p> <ul style="list-style-type: none"> • Added <i>FDA</i> section • Updated <i>References</i> section to reflect the most current information • Archived previous policy version CSNC.MP.006.03

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® 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.