

Clinical Trials (for North Carolina Only)

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Related Policies
None

Application

This Coverage Determination Guideline 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 clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy for Physician, 1A-39, Routine Costs in Clinical Trial Services for Life Threatening Conditions](#).

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
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

HCPCS Code	Description
Covered When Criteria Are Met	
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

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 Costs in Clinical Trial Services for Life Threatening Conditions, No: 1A-39. [NC DMA: Routine Costs in Clinical Trial Services for Life Threatening Conditions, 1A-39](#). Accessed March 26, 2021.

Guideline History/Revision Information

Date	Summary of Changes
07/01/2021	<ul style="list-style-type: none"> New Coverage Determination Guideline

Instructions for Use

This Coverage Determination Guideline 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 guideline, 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 Coverage Determination Guideline 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 Coverage Determination Guidelines 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.