

Clinical Trials (for New Jersey Only)

Policy Number: CS018NJ.P

Effective Date: September 1, 2023

[Instructions for Use](#)

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Related Policies
None

Application

This Medical Policy only applies to the state of New Jersey.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the New Jersey Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services: 4.2.8 Clinical Trials, Investigational Treatment, Experimental Treatment at https://www.nj.gov/humanservices/dmahs/info/d-snp_contract.pdf.

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.

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	Non covered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day
*G0294	Non covered 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, non-covered experimental therapy), performed in an approved IDE-based clinical trial, per treatment session

HCPCS Code	Description
Covered When Criteria Are Met	
*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

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

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

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	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

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. Refer to <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials> for additional information. (Accessed May 4, 2023)

The FDA requires certain clinical trials to be registered in the ClinicalTrials.gov database. Refer to <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrials.gov-information> for additional information. (Accessed May 4, 2023)

References

New Jersey Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services: 4.2.8 Clinical Trials, Investigational Treatment, Experimental Treatment at: https://www.nj.gov/humanservices/dmahs/info/d-snp_contract.pdf. Accessed May 4, 2023.

Policy History/Revision Information

Date	Summary of Changes
09/01/2023	<p data-bbox="337 216 597 247">Coverage Rationale</p> <ul data-bbox="337 254 1495 317" style="list-style-type: none"><li data-bbox="337 254 1495 317">• Replaced instruction to “refer to the [contract] for <i>coverage guidelines</i>” with “refer to the [contract] for <i>medical necessity clinical coverage criteria</i>” <p data-bbox="337 323 646 354">Supporting Information</p> <ul data-bbox="337 361 889 392" style="list-style-type: none"><li data-bbox="337 361 889 392">• Archived previous policy version CS018NJ.O

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.