Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials (for Louisiana Only)
Retired April 1, 2026

Policy Number: CS018LA.R
Effective Date: January 1, 2026 – March 31, 2026

➲ Instructions for Use
Content mandated by Louisiana Department of Health

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Application

This Medical Policy only applies to the state of Louisiana. The coverage rationale contained in this policy represents Louisiana Medicaid coverage policy and is set forth below in accordance with State requirements.

Coverage Rationale

Routine Care Provided to Enrollees Participating in Clinical Trials

Louisiana Medicaid shall cover any item or service provided to an enrollee participating in a qualifying clinical trial to the extent that the item or service would otherwise be covered for the enrollee when not participating in the qualifying clinical trial. This includes any item or service provided to present, diagnose, monitor, or treat complications resulting from participation.

Qualifying Clinical Trial

A qualifying clinical trial is defined as 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 that meets any of the following criteria:

- The study or investigation is approved, conducted, or supported (which may include funding) by one or more of the following:
  - The National Institutes of Health
  - The Centers for Disease Control and Prevention
  - The Agency for Healthcare Research and Quality
  - The Centers for Medicare & Medicaid Services
  - A cooperative group or center of any of the entities described in subclauses (I) through (IV) or the Department of Defense or the Department of Veterans Affairs
  - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
  - The study or investigation is approved or funded by one or more of the following and has been reviewed and approved through a system of peer review comparable to the system of peer review of studies and investigations used by the National Institutes of Health which assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
    - The Department of Veterans Affairs

        - The Department of Defense
        - The Department of Energy
    - The clinical trial is conducted pursuant to an investigational new drug exemption under section 335(i) of Title 21 or an exemption for a biological product undergoing investigation under section 262(a)(3) of this title
    - The clinical trial is a drug trial that is exempt from having such an investigational new drug application

Coverage determinations shall be:

- Expedited and completed within 72 hours
- Made without limitation on the geographic location or network affiliation of the health care provider treating such individual or the principal investigator of the qualifying clinical trial
- Based on attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator using the following form and kept on file by the provider: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx
- Completed without any requirement of submission of the protocols of the qualifying clinical trial, or any other documentation that may be proprietary or determined by the HHS Secretary to be burdensome to provide

Coverage Limitations

Louisiana Medicaid shall not cover any of the following:

- The investigational item or service that is the subject of the qualifying clinical trial
- Any service provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial and is not used in the direct clinical management of the individual
- Services not otherwise covered Louisiana Medicaid

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.

Modifier	Description
Clinical trial claims are not limited to these modifiers. However, if a claim has one of these modifiers, it is considered to be a clinical trial claim.	
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

HCPCS Code	Description
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 Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

Diagnosis Code	Description
Clinical trial claims are not limited to this diagnosis code. However, if a claim has this code, it is considered to be a clinical trial claim.	
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 information on good clinical practice and clinical trials. Refer to: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials. (Accessed April 16, 2025)

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 16, 2025)

References

Louisiana Department of Health, Louisiana Medicaid Managed Care Organization Manual. Updated April 23, 2025. Part 4: Services Professional Services. Available at: https://ldh.la.gov/assets/medicaid/Manuals/MCO_Manual.pdf. Accessed June 4, 2025.

Policy History/Revision Information

Date	Summary of Changes
04/01/2026	• Retired policy; Louisiana plan membership disenrolled on Apr. 1, 2026
01/01/2026	**Application** • Added language to indicate the *Coverage Rationale* contained in this policy represents Louisiana Medicaid coverage policy and is set forth [in the policy] in accordance with State requirements **Coverage Rationale** • Revised language to indicate: ***Routine Care Provided to Enrollees Participating in Clinical Trials*** ○ Louisiana Medicaid shall cover any item or service provided to an enrollee participating in a qualifying clinical trial to the extent that the item or service would otherwise be covered for the enrollee when not participating in the qualifying clinical trial; this includes any item or service provided to present, diagnose, monitor, or treat complications resulting from participation ***Qualifying Clinical Trial*** ○ A qualifying clinical trial is defined as 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 that meets any of the following criteria: ▪ The study or investigation is approved, conducted, or supported (which may include funding) by one or more of the following: – The National Institutes of Health

Date	Summary of Changes
	– The Centers for Disease Control and Prevention – The Agency for Healthcare Research and Quality – The Centers for Medicare & Medicaid Services – A cooperative group or center of any of the entities described in subclauses (I) through (IV) or the Department of Defense or the Department of Veterans Affairs – A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants – The study or investigation is approved or funded by one or more of the following and has been reviewed and approved through a system of peer review comparable to the system of peer review of studies and investigations used by the National Institutes of Health which assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review: • The Department of Veterans Affairs • The Department of Defense • The Department of Energy ▪ The clinical trial is conducted pursuant to an investigational new drug exemption under section 335(i) of Title 21 or an exemption for a biological product undergoing investigation under section 262(a)(3) of this title ▪ The clinical trial is a drug trial that is exempt from having such an investigational new drug application ○ Coverage determinations shall be: ▪ Expedited and completed within 72 hours ▪ Made without limitation on the geographic location or network affiliation of the health care provider treating such individual or the principal investigator of the qualifying clinical trial ▪ Based on attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator using the following form and kept on file by the provider: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx ▪ Completed without any requirement of submission of the protocols of the qualifying clinical trial, or any other documentation that may be proprietary or determined by the HHS Secretary to be burdensome to provide ***Coverage Limitations*** ○ Louisiana Medicaid shall not cover any of the following: ▪ The investigational item or service that is the subject of the qualifying clinical trial ▪ Any service provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial and is not used in the direct clinical management of the individual ▪ Services not otherwise covered Louisiana Medicaid **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information • Removed *Definitions* and *Description of Services* sections • Archived previous policy version CS018LA.Q

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.