



STATE OF NORTH CAROLINA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER  
GOVERNOR

KODY H. KINSLEY  
SECRETARY

March 18, 2022

James Scott, Director  
Division of Program Operations  
Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
601 East 12th Street Room 355  
Kansas City, Missouri 64106

SUBJECT: State Plan Amendment  
Title XIX, Social Security Act  
Transmittal #2022-0010

Dear Mr. Scott:

Please find attached an amendment for North Carolina's State Plan under Title XIX of the Social Security Act for the Medical Assistance Program. The affected pages are Attachment 3.1-A, Page 12 and Attachment 3.1-B, Page 10.

This state plan amendment will allow Medicaid to cover routine patient costs while a beneficiary is in a qualifying clinical trial. The requirement was part of Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) which amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). NC Medicaid covers routine patient cost, but it is not reflected in the SPA.

Your approval of this state plan amendment is requested. If you have any questions or concerns, please contact me or Betty J. Staton at 919-538-3215.

Sincerely,

DocuSigned by:

A handwritten signature in blue ink, appearing to read "Kody H. Kinsley".

D7816E4CBA6F4A8...

Kody H. Kinsley  
Secretary

Enclosures

**State/Territory:** North Carolina

**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED**

**CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

\*The state needs to check each assurance below.

Provided: \_\_\_\_\_

I. General Assurances:

**Routine Patient Cost – Section 1905(gg)(1)**

X Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

**Qualifying Clinical Trial – Section 1905(gg)(2)**

X A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

**Coverage Determination – Section 1905(gg)(3)**

X A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: 22-0010  
Supersedes TN: NEW

Approval Date:  
Effective Date: 01/01/2022