

**AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE SERVICES PROVIDED  
TO THE CATEGORICALLY NEEDY**

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**30. Coverage of Routine Patient Cost in Qualifying Clinical Trials**Provided:  X **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.

NEW 1-01-2022

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Supersedes TN# NEW

**METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES**  
**ROUTINE PATIENT COST IN QUALIFYING CLINICAL TRIALS**

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**30. Coverage of Routine Patient Cost in Qualifying Clinical Trials**

Reimbursement for routine patient costs associated with qualified clinical trials follows the existing rate methodology approved within the Oklahoma State Plan for the individual service/item provided.

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