

Table of Contents

State/Territory Name: **Ohio**

State Plan Amendment (SPA) #: **22-0004**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

April 28, 2022

Maureen M. Corcoran, Director
Ohio Department of Medicaid
P.O. Box 182709
50 West Town Street, Suite 400
Columbus, Ohio 43218

Re: Ohio State Plan Amendment (SPA) Transmittal Number 22-0004

Dear Ms. Corcoran:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number 22-0004. This amendment updates the state plan language to comply with amended section 1905(a)(30) of the Social Security Act, assuring coverage for routine patient costs of items and services for Medicaid beneficiaries enrolled in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act. This letter is to inform you that Ohio Medicaid SPA 22-0004 was approved on April 28, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Christine Davidson at (312) 886-3642 or via email at christine.davidson@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of Ruth A. Hughes.

Ruth A. Hughes, Acting Director
Division of Program Operations

Enclosure

cc: Rebecca Jackson, ODM
Gregory Niehoff, ODM
Myla Adams, CMCS

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER <u>2 2</u> — <u>0 0 4</u>	2. STATE <u>OH</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
January 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
42 U.S.C. 1396d (gg)

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2022 \$ 0
b. FFY 2023 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A Item 30 Page 1 of 1 **new**

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

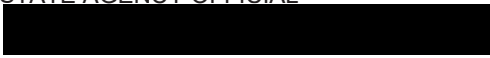
9. SUBJECT OF AMENDMENT

Coverage and Limitations: Routine Patient Costs Associated with Clinical Trials

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED:
The State Medicaid Director is the Governor's designee

11. SIGNATURE OF STATE AGENCY OFFICIAL


12. TYPED NAME **MAUREEN M. CORCORAN**

13. TITLE **STATE MEDICAID DIRECTOR**

14. DATE SUBMITTED
March 4, 2022


15. RETURN TO

**Greg Niehoff
Ohio Department of Medicaid
P.O. BOX 182709
Columbus, Ohio 43218**

FOR CMS USE ONLY

16. DATE RECEIVED March 4, 2022	17. DATE APPROVED 04/28/2022
---	--

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	19. SIGNATURE 
20. TYPED NAME OF APPROVING OFFICIAL Ruth A. Hughes	21. TITLE OF APPROVING OFFICIAL Acting Director, Division of Program Operations

22. REMARKS

State/Territory: Ohio**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:

1. General Assurances:

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

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)

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

Coverage Determination – Section 1905(gg)(3)

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: 22-004

Supersedes

TN: NewApproval Date: 04/28/2022Effective Date: 01/01/2022