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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
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,

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

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

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)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

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

The Governor’s designee:
Greg Niehoff
Acting Director, Division of Program Operations
Ohio Department of Medicaid
P.O. BOX 182709
Columbus, Ohio 43218

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

16. DATE RECEIVED
March 4, 2022

17. DATE APPROVED
04/28/2022

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

Instructions on Back
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                        Approval Date: **04/28/2022**
Supersedes
TN: New                          Effective Date: **01/01/2022**