

Table of Contents

State/Territory Name: Indiana

State Plan Amendment (SPA) #: 22-0002

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Page

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

June 9, 2022

Allison Taylor, Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington St. Room W374, MS07
Indianapolis, IN 46204

Re: Indiana State Plan Amendment (SPA) 22-0002

Dear Ms. Taylor:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number 22-0002. This amendment modifies coverage requirements for routine patient costs associated with participation in clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act, section 1905(a)30 and 1905(gg). This letter is to inform you that Indiana Medicaid SPA 22-0002 was approved on June 9, 2022, with an effective date of June 1, 2022.

If you have any questions, please contact Mai Le-Yuen at 312.353.2853 or via email at mai.leyuen@cms.hhs.gov.

Sincerely,



James G. Scott, Director
Division of Program Operations

Enclosures

cc: Madison May Gruthusen, FSSA
Keith McConomy, FSSA

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

1. TRANSMITTAL NUMBER
2 2 — 0 0 0 2

2. STATE
I N

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT
 XIX XXI

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

4. PROPOSED EFFECTIVE DATE
June 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
Section 1905(a)30 and Section 1905(gg) of the Social Security Act

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 Page 13

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)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

9. SUBJECT OF AMENDMENT
This State Plan Amendment proposes to modify coverage requirements for coverage of routine patient costs associated with participation in qualifying 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:

11. SIGNATURE OF STATE AGENCY OFFICIAL
[Redacted]

12. TYPED NAME
Allison Taylor

13. TITLE
Medicaid Director

14. DATE SUBMITTED
05/13/2022

15. RETURN TO
Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 West Washington Street, Room W374
Indianapolis, IN 46204
Attn: Madison May-Gruthusen, Federal Relations Lead

FOR CMS USE ONLY

16. DATE RECEIVED
May 13, 2022

17. DATE APPROVED
June 9, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
June 1, 2022

19. SIGNATURE OF APPROVING OFFICIAL
[Redacted]

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

21. TITLE OF APPROVING OFFICIAL
Director, Division of Program Operations

22. REMARKS

State/Territory: Indiana**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: 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.

TN: 22-0002

Supersedes TN: New

Approval Date: June 9, 2022

Effective Date: June 1, 2022