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State/Territory Name: Michigan

State Plan Amendment (SPA)#: 22-0001

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179
- 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

March 24, 2022

Ms. Kate Massey
Medicaid Director
Medical Services Administration
400 S Pine St 7th Fl
Lansing, MI 48933-2250

RE: State Plan Amendment (SPA) Transmittal Number 22-0001

Dear Ms. Massey:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) MI 22-0001. This amendment proposes to provide authority for the new mandatory clinical trials benefit.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations Section 1905(a)(30) of the Social Security Act. This letter is to inform you that Michigan Medicaid SPA MI 22-0001 was approved on March 23, 2022, with an effective date of January 1, 2022.

If you have any questions please contact Keri Toback at 312 353 1754 or via email at keri.toback@cms.hhs.gov.

Sincerely,

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Erin Black, MDHHS

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

1. TRANSMITTAL NUMBER <u>22</u> — <u>0001</u>	2. STATE <u>MI</u>
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3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT

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

3. PROPOSED EFFECTIVE DATE
January 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
Section 1905(a)(30) 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.1 Page 13

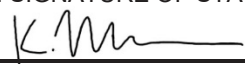
8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

9. SUBJECT OF AMENDMENT

This SPA provides authority for the new mandatory clinical trials benefit.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL


11. TYPED NAME
Kate Massey

12. TITLE
Director, Health and Aging Services Administration

13. DATE SUBMITTED
February 18, 2022

15. RETURN TO
Health and Aging Services Administration
Office of Strategic Partnerships & Medicaid Administrative Services – Federal Liaison
Capitol Commons Center – 7th Floor
400 South Pine
Lansing, Michigan 48933

Attn: Erin Black

FOR CMS USE ONLY

16. DATE RECEIVED
02/18/2022

17. DATE APPROVED
03/23/2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2022

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

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

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of MICHIGAN

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

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 NO.: 22-0001

Approval Date: 03/23/2022

Supersedes TN No.: NEW

Effective Date: 01-01-2022