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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,

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James G. Scott, Director Division of Program Operations

Enclosures

cc: Erin Black, MDHHS

CENTERS FOR MEDICARE & MEDICAID SERVICES		OMB No. 0938-0193			
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	220001 3. PROGRAM IDENTIFICATION: TITLE XI	2. STATE <u>MI</u> XOF 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 (Amou a. FFY 2022 \$0 b. FFY 2023 \$0	nts in WHOLE dollars)			
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 3.1-A.1 Page 13	8. PAGE NUMBER OF THE SUPERSEI SECTIONOR ATTACHMENT (If App.				
9. SUBJECT OF AMENDMENT					
This SPA provides authority for the new mandatory clin	ical trials benefit.				
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	15. RETURN TO				
 11. TYPED NAME Kate Massey 12. TITLE Director, Health and Aging Services Administration 13. DATE SUBMITTED 	Health and Aging Services Administrati Office of Strategic Partnerships & Medi Services – Federal Liaison Capitol Commons Center – 7 th Floor 400 South Pine Lansing, Michigan 48933 Attn: Erin Black	on caid Administrative			
February 18, 2022					
16. DATE RECEIVED FOR CMS	USE ONLY 17. DATE APPROVED				
02/18/2022	03/23/2022				
PLAN APPROVED - C	NE COPY ATTACHED				
18. EFFECTIVE DATE OF APPROVED MATERIAL 01/01/2022	19. SIGNATURE OF APPROVING OFFICI	AL			
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL	. TITLE OF APPROVING OFFICIAL			
James G. Scott	Director, Division of Program Ope	rector, Division of Program Operations			
22. REMARKS FORM CMS-179 (09/24)					

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: <u>X</u>

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 unlessit 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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN NO.: 22-0001

Supersedes TN No.: <u>NEW</u>

Approval Date: 03/23/2022

Effective Date: 01-01-2022