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State/Territory Name: Iowa

State Plan Amendment (SPA) #: 22-0005

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 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

May 5, 2022

Elizabeth Matney Medicaid Director Iowa Medicaid Enterprise 1305 East Walnut Street Des Moines, IA 50319

Re: Iowa State Plan Amendment (SPA) 22-0005

Dear Ms. Matney:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0005. This amendment assures that Iowa will cover the mandatory benefit for costs of routine services related to participation in clinical trials in the state plan.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and the Consolidated Appropriations Act, 2021. This letter is to inform you that Iowa Medicaid SPA 22-0005 was approved on May 5, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Michala Walker at 816-426-6503 or via email at Michala.Walker@cms.hhs.gov.

Sincerely,

James G. Scott, Director Division of Program Operations

Enclosures

cc: Jennifer Steenblock

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 5. FEDERAL STATUTE/REGULATION CITATION Section 210 of the Federal Consolidated Appropriations Act (CAA) 7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT ATTACHMENT 3.1-A, Page 19 and ATTACHMENT 3.1-B, Page 25	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT XIX XXI 4. PROPOSED EFFECTIVE DATE January 1, 2022 6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
9. SUBJECT OF AMENDMENT Ensures that Iowa Medicaid appropriately covers and pays for the 10. GOVERNOR'S REVIEW (Check One)	costs of items and services for beneficiaries enrolled in qualifyin
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	OTHER, AS SPECIFIED:
12. TYPED NAME Flizabeth Matney	15. RETURN TO Elizabeth Matney, Medicaid Director owa Department of Human Services 1305 East Walnut Street Des Moines, IA 50319
FOR CMS U	SE ONLY
16. DATE RECEIVED March 29, 2022	17. DATE APPROVED May 5, 2022
PLAN APPROVED - ON	
18. EFFECTIVE DATE OF APPROVED MATERIAL	19. SIGN'ATURE OF APPROVING OFFICIAL Digitally signed by James G. Scott -S
January 1, 2022	Date: 2022.05.05 14:00:53 -05'00'
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL
James G. Scott	Division of Program Operations
22. REMARKS	

State/Territory: <u>Iowa</u>

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED CATECORICALLY NEEDY CROUP(S)

	CATEGORICALLY NEEDY GROUP(S)	
30.	Coverage of Routine Patient Cost in Qualifying Clinical Trials	

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*The state needs to check each assurance below.
Provided: X
I. General Assurances:
Routine Patient Cost – Section 1905(gg)(1)
\underline{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)

 \underline{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: IA-22-005
Supersedes TN: NEW
Approval Date: May 5, 2022
Effective Date: January 1, 2022

State/Territory: <u>Iowa</u>

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED MEDICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

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