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State/Territory Name: Kentucky

State Plan Amendment (SPA)#: 22-0010

This file contains the following documents in the order listed

1) Approval Letter
2) CMS 179 Form
3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 East12th Street, Suite 0300
Kansas City, Missouri 64106-2898

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

December 8, 2022

Ms. Lisa Lee
Commissioner, Department for Medicaid Services
Commonwealth of Kentucky
Cabinet for Health and Human Services
275 East Main Street, 6 West A
Frankfort, KY 40601

RE: State Plan Amendment (SPA) Transmittal Number 22-0010

Dear Ms. Lee:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0010. This amendment proposes to allow the state to provide coverage of routine patient costs in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations in Section 1905 (a)(30) of the Social Security Act. This letter is to inform you that KY Medicaid SPA 22-0010 was approved on December 7, 2022, with an effective date of January 1, 2023.

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

Sincerely,

[redacted]

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Erin Bickers, KY DMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 22-0010

2. STATE: KY

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
January 1, 2023

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

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2023 $ _____
b. FFY 2024 $ _____

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A Page 18
Attachment 3.1-B Page 43

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 3.1-A Page 18 - New
Attachment 3.1-B Page 43 - New

9. SUBJECT OF AMENDMENT
Coverage of Routine Patient Costs 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
Lisa Lee

13. TITLE
Commissioner

14. DATE SUBMITTED
12/1/2022

15. RETURN TO
Lisa Lee
275 E. Main St.
Frankfort, KY 40601

FOR CMS USE ONLY

16. DATE RECEIVED
12/01/2022

17. DATE APPROVED
12/07/2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2023

19. SIGN
[redacted]

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

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

22. REMARKS

State/Territory: Kentucky

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 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.

State/Territory: Kentucky

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

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