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State/Territory Name: West Virginia

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 (with 179-like data)
- 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 23, 2022

Cynthia Beane

Bureau for Medical Services

350 Capitol Street, Room 251

Charleston, West Virginia 25301-3706

Re: West Virginia State Plan Amendment (SPA) 22-0002

Dear Commissioner Beane:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0002. This amendment provides required assurances that the state is appropriately covering and paying for routine patient costs of items and services for beneficiaries enrolled 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. This letter is to inform you that West Virginia Medicaid SPA 22-0002 was approved on March 23, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Dan Belnap at 215-861-4273 or via email at Dan.Belnap@cms.hhs.gov

Sincerely,

A large black rectangular box redacting the signature of James G. Scott.

James G. Scott, Director
Division of Program Operations

cc: Sarah Young
Riley Romeo
Britany Mullins

**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

WV3. 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

01/01/2022

5. FEDERAL STATUTE/REGULATION CITATION

Section 1905(a)(30)

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2022 \$ 0b. FFY 2023 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1 A page 12Attachemnt 3.1B page 108. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (If Applicable)

9. SUBJECT OF AMENDMENT

Coverage for 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

12. TYPED NAME
Cynthia Beane13. TITLE
Commissioner, Bureau for Medical Services14. DATE SUBMITTED
03/10/202215. RETURN TO
Bureau for Medical Services
350 Capitol Street Room 251
Charleston, West Virginia 25301**FOR CMS USE ONLY**16. DATE RECEIVED
March 10, 202217. DATE APPROVED
March 23, 2022**PLAN APPROVED - ONE COPY ATTACHED**18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott21. TITLE OF APPROVING OFFICIAL
Director, Division of Program Operations

22. REMARKS

State/Territory: West Virginia**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 No:	22-0002	Approval Date:	03/23/2022	Effective Date:	01/01/2022
Supersedes:	New				

State/Territory: West Virginia**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****MEDICALLY NEEDY GROUP(S)****30. Coverage of Routine Patient Cost in Qualifying Clinical Trials**

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