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State/Territory Name: Colorado

State Plan Amendment (SPA) #: 23-0011

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS Form 179
- 3) Approved SPA Page

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



March 8, 2023

Kim Bimestefer, Executive Director
Department of Health Care Policy & Financing
1570 Grant Street
Denver, CO 80203

Re: Colorado State Plan Amendment (SPA) CO-23-0011

Dear Ms. Bimestefer:

The Centers for Medicare & Medicaid Services (CMS) reviewed the proposed Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 23-0011. This amendment proposes to cover routine patient costs in qualifying clinical trials.

Pursuant to section 1135(b)(5) of the Social Security Act (Act), for the period of the public health emergency, CMS is modifying the requirement at 42 C.F.R. §430.20 that the state submit SPAs related to the COVID-19 public health emergency by the final day of the quarter, to obtain a SPA effective date during the quarter, enabling SPAs submitted after the last day of the quarter to have an effective date in a previous quarter, but no earlier than the effective date of the public health emergency.

The State of Colorado also requested a waiver to modify the tribal consultation timeline applicable to this SPA submission process. Pursuant to section 1135(b)(5) of the Act, CMS is also allowing states to modify the timeframes associated with tribal consultation required under section 1902(a)(73) of the Act, including shortening the number of days before submission or conducting consultation after submission of the SPA.

CMS conducted our review of your submittal according to statutory requirements in Title XIX of the Act and implementing regulations. This letter is to inform you that Colorado's Medicaid SPA Transmittal Number 23-0011 is approved effective January 1, 2022.

If you have any questions, please contact Curtis Volesky at 303-844-7033 or via email at Curtis.Volesky@cms.hhs.gov.

Sincerely,
Alissa M.
Deboy -S

Digitally signed by Alissa
M. Deboy -S
Date: 2023.03.08
08:10:48 -05'00'

Alissa Mooney DeBoy
On Behalf of Anne Marie Costello, Deputy Director
Center for Medicaid and CHIP Services

Enclosures

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

1. TRANSMITTAL NUMBER <u>2 3</u> — <u>0 0 1 1</u>	2. STATE <u>CO</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
4. PROPOSED EFFECTIVE DATE <u>January 1, 2022</u>	
6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2022</u> \$ <u>0</u> b. FFY <u>2023</u> \$ <u>0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <u>Attachment 3.1-A -- Coverage of Routine Patient Costs in Qualifying Clinical Trials at section 1905(a)(30) of the Social Security Act – Page 1 of 1 (NEW)</u>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

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

5. FEDERAL STATUTE/REGULATION CITATION
Social Security Act, Sections 1905(a)(30) and 1905(gg)

9. SUBJECT OF AMENDMENT
This SPA will cover routine patient costs in qualifying clinical trials.

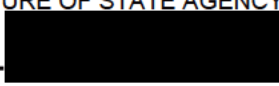
10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED:
Governor's letter dated 24 September 2022

11. SIGNATURE OF STATE AGENCY OFFICIAL


12. TYPED
Adela Flores-Brennan

13. TITLE
Medicaid Director

14. DATE SUBMITTED
2/14/2023

15. RETURN TO
Colorado Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203-1818

Attn: Alex Lyons

FOR CMS USE ONLY

16. DATE RECEIVED <u>February 14, 2023</u>	17. DATE APPROVED <u>March 8, 2023</u>
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL <u>January 1, 2022</u>	19. SIGNATURE OF APPROVING OFFICIAL <u>Alissa M. Deboy -S</u> <small>Digitally signed by Alissa M. Deboy -S Date: 2023.03.08 08:11:04 -05'00'</small>
20. TYPED NAME OF APPROVING OFFICIAL <u>Alissa Mooney DeBoy</u>	21. TITLE OF APPROVING OFFICIAL <u>On Behalf of Anne Marie Costello, Deputy Director, CMCS</u>

22. REMARKS

State/Territory: Colorado**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

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: 23-0011
Supersedes TN: NEW

Approval Date: 3/8/2023
Effective Date 1/1/2022