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State/Territory Name: Oregon

State Plan Amendment (SPA) #: 22-0006

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

April 5, 2022

Patrick Allen, Director
Oregon Health Authority
500 Summer Street Northeast, E-15
Salem, OR 97301-1079

RE: Oregon State Plan Amendment (SPA) Transmittal Number OR-22-0006

Dear Mr. Allen:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) OR-22-0006. This amendment was submitted to comply the Consolidated Appropriations Act for 2021, which amended the Medicaid statute to add as a mandatory benefit, in both state plan and benchmark and benchmark equivalent coverage, for “routine patient costs for items and services furnished in connection with a qualifying clinical trial.”

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations at 1905(a)(30), 1905(gg), 1902(a)(10)(A) and 1937(b)(5) of the Act. This letter is to inform you that OR-22-0006 was approved on April 5, 2022, with an effective date of January 1, 2022.

If there are any questions concerning this approval, please contact me or you may contact Nikki Lemmon at nicole.lemmon@cms.hhs.gov or at 303-844-2641.

Sincerely,

A black rectangular box redacts the signature of James G. Scott. A small blue and yellow arc is visible below the box, matching the CMS logo.

Digitally signed by James
G. Scott -S
Date: 2022.04.05 15:49:18
-05'00'

James G. Scott, Director
Division of Program Operations

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

1. TRANSMITTAL NUMBER

2 2 — 0 0 0 6

2. STATE

OR

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

1/1/22

5. FEDERAL STATUTE/REGULATION CITATION

1905(a)(30), 1905(gg), 1902(a)(10)(A) and 1937(b)(5) of the Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

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

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A, Page 12

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

9. SUBJECT OF AMENDMENT

This transmittal is being submitted to describe coverage for clinical trials under Section 210 of the Consolidated Appropriations Act, 2021. Although Oregon had previously adopted coverage based upon Medicare criteria several years ago this required preprint includes the expedited review language which is a new requirement.

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 Signature]

12. TYPED NAME

Dana Hittle

13. TITLE

Interim Medicaid Director

14. DATE SUBMITTED

3/16/22

15. RETURN TO

Oregon Health Authority
Medical Assistance Programs
500 Summer Street NE E-65
Salem, OR 97301

ATTN: Jesse Anderson, State Plan Manager

FOR CMS USE ONLY

16. DATE RECEIVED

3/17/22

17. DATE APPROVED

April 5, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

1/1/22

19. SIGNATURE OF APPROVING OFFICIAL

[Redacted Signature]

Digitally signed by James G. Scott -S
Date: 2022.04.05 15:50:02 -05'00'

20. TYPED NAME OF APPROVING OFFICIAL

James G. Scott

21. TITLE OF APPROVING OFFICIAL

Director, Division of Program Operations

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: OREGON

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL
CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

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.