DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106

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

Medicaid and CHIP Operations Group

May 10, 2022

Susan Birch, Director
Dr. Charissa Fotinos, Acting Medicaid Director
Health Care Authority
PO Box 45502
Olympia, WA 98504-5010

Re: Washington State Plan Amendment (SPA) Transmittal Number WA-22-0008

Dear Dr. Fotinos and Susan Birch:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) WA-22-0008. This amendment was submitted to comply with coverage of routine patient costs for services and items provided to Medicaid beneficiaries in connection with participation in qualifying clinic trials, in accordance with the federal 2021 Consolidated Appropriations Act (CAA).

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations 1905(a), 1905(gg) of the Act. This letter is to inform you that Washington Medicaid SPA 22-0008 was approved on May 10, 2022 with an effective date of January 1, 2022.

If you have any questions, please contact Edwin Walaszek at 212-616-2512 or via email at Edwin.Walaszek1@cms.hhs.gov.

Sincerely,

Digitally signed by James G. Scott -S
Date: 2022.05.10 17:12:11 -05'00'

James G. Scott, Director
Division of Program Operations

cc: Ann Myers-ann.myers@hca.wa.gov

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: 22-0008

2. STATE: WA

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, 2022

5. FEDERAL STATUTE/REGULATION CITATION
1905(a) of the Social Security 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 69 (new)
Attachment 3.1-B page 64 (new)
Attachment 4.19-B page 53 (new)

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*

9. SUBJECT OF AMENDMENT
Coverage of Routine Patient Costs Associated with 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: Exempt

11. SIGNATURE OF STATE AGENCY OFFICIAL
Charissa Fotinos MD, MSc

12. TYPED NAME
Charissa Fotinos, MD, MSc

13. TITLE
Acting Medicaid Director

14. DATE SUBMITTED
March 8, 2022

15. RETURN TO
State Plan Coordinator
Office of Rules & Publications
Health Care Authority
POB 42716
Olympia, WA 98504

FOR CMS USE ONLY

16. DATE RECEIVED
March 8, 2022

17. DATE APPROVED
May 10, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
1/1/22

19. SIGNATURE OF APPROVING OFFICIAL
James G. Scott
Digitally signed by James G. Scott -S
Date: 2022.05.10 17:12:41 -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 WASHINGTON

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 notconduct 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 PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State WASHINGTON

AMOUNT, DURATION, AND SCOPE OF SERVICES PROVIDED TO THE MEDICALLY NEEDY GROUP(S): ALL

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30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: ___X__

II. 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.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State WASHINGTON

POLICY AND METHODS USED IN ESTABLISHING PAYMENT RATES FOR EACH OF THE OTHER TYPES OF CARE OR SERVICE LISTED IN SECTION 1905(A) OF THE ACT THAT IS INCLUDED IN THE PROGRAM UNDER THE PLAN.

XXIV. Payment for items and services furnished in connection with client participation in qualifying clinical trials

A. Maximum allowable fees are established and updated using the Resource Based Relative Value Scale (RBRVS) methodology as adopted in the Medicare Fee Schedule Data Base (MFSDB). In this methodology, under WAC 182-531-1850, the agency uses CMS-established relative value units (RVU) multiplied by both the Geographic Practice Cost Indices (GPCI) for Washington State (supplied by the Federal Register) and the conversion factors specific to Washington. The agency's conversion factor that is annually adjusted based on utilization and budget neutrality from year-to-year. For the current conversion factor, and further description, see Supplement 3 to Attachment 4.19-B.

B. When no MFSDB RVU exists, some of the codes are reimbursed using flat fee (based upon market value, other state's fees, budget impacts, etc.), acquisition cost (the cost of the actual item being billed), Medicare Laboratory Fee Schedule, ASP (106% of ASP), and/or Point of Sale (POS) actual acquisition cost (AAC).

Except as otherwise noted in the plan, fee schedule rates are the same for both governmental and private providers of items and services furnished in connection with participation in a qualified clinical trial. See 4.19-B I, General, #G for the agency's website where the fee schedules are published.