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State/Territory: Wisconsin

State Plan Amendment (SPA)#: 22-0007

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 E. 12th St., Room 355
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

April 25, 2022

Lisa Olson, Medicaid Director
Division of Medicaid Services
Wisconsin Department of Health Services
1 W. Wilson St.
Madison, Wisconsin 53701

Re: Wisconsin State Plan Amendment (SPA) 22-0007


Dear Ms. Olson:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number 22-0007. This amendment provides attestation to coverage of usual and customary care for Wisconsin Medicaid beneficiaries participating in clinical trials as required by the Consolidated Appropriations Act of 2021 effective January 1, 2022.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act at section 1905(a)(30). This letter is to inform you that Wisconsin Medicaid SPA 22-0007 was approved on April 25, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Mai Le-Yuen at 312.353.2853 or via email at mai.le-yuen@cms.hhs.gov.

Sincerely,

 Digitally signed by
James G. Scott -S
Date: 2022.04.25
16:23:01 -05'00'

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Baily Dvorak, DHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICESFORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER WI 22-0007	2. STATE Wisconsin
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE 01/01/2022	

5. TYPE OF PLAN MATERIAL (Check One) NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN
 AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION 1905(a)(30)	7. FEDERAL BUDGET IMPACT i. FFY 2022 \$ 0 j. FFY 2023 \$ 0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 3.1-A, page 22 and Attachment 3.1-B, page 21	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) New New

10. SUBJECT OF AMENDMENT

Coverage of Routine Patient Costs for Items and Services Furnished in Connection with Participation in Qualifying Clinical Trials

11. GOVERNOR'S REVIEW (Check One)

- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

DocuSigned by:

Nathan Bollhorst

3/14/2022

12. SIGNATURE OF STATE AGENCY OFFICIAL

13. TYPED NAME

Lisa Olson

14. TITLE

State Medicaid Director

15. DATE SUBMITTED

03/31/2022

16. RETURN TO

Autumn Knudtson

Bureau Director, Bureau of Benefits Policy
Interim State Plan Amendment Coordinator
Department of Health Services

1 W. Wilson St.

P.O. Box 309

Madison, WI 53701-0309

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

03/31/22

18. DATE APPROVED

April 25, 2022

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

January 1, 2022

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

James G. Scott

22. TITLE

Director, Division of Program Operation

State/Territory: WI

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.

State/Territory: WI

**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED MEDICALLY NEEDY
GROUP(S)**

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.