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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
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,

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Baily Dvorak, DHS
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)

4. PROPOSED EFFECTIVE DATE
   01/01/2022

5. TYPE OF PLAN MATERIAL (Check One)
   □ NEW STATE PLAN
   X 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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)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
    □ COMMENTS OF GOVERNOR’S OFFICE ENCLOSED
    □ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
    □ OTHER, AS SPECIFIED

12. SIGNATURE OF STATE AGENCY OFFICIAL
    Lisa Olson

13. TYPED NAME
    State Medicaid Director

14. TITLE
    Lisa Olson, Department of Health Services

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

17. DATE RECEIVED
    03/31/22

18. DATE APPROVED
    April 25, 2022

19. EFFECTIVE DATE OF APPROVED MATERIAL
    January 1, 2022

20. SIGNATURE OF REGIONAL OFFICIAL
    James G. Scott
    Director, Division of Program Operation

21. TYPED NAME
    James G. Scott

22. TITLE
    Division of Program Operation

FOR REGIONAL OFFICE USE ONLY

PLAN APPROVED - ONE COPY ATTACHED
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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.
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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.