

## **Table of Contents**

**State/Territory Name: Montana**

**State Plan Amendment (SPA) #: 22-0001**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary 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**

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June 24, 2022

Michael Randol  
Montana Medicaid and Health Services Executive Director/State Medicaid Director  
Montana Department of Public Health & Human Services  
P.O. Box 4210  
Helena, MT 59604

Dear Mr. Randol:

We have completed our review of the enclosed State Plan Amendment (SPA) Transmittal Number MT-22-0001. This amendment establishes compliance with the mandatory coverage and reimbursement of routine patient costs furnished in connection with participation in qualifying clinical trials under Section 1905(gg) of the Social Security Act.

Please be informed that this State Plan Amendment was approved on June 24, 2022, with an effective date of January 1, 2022. Enclosed is a copy of the CMS 179 summary page and the amended plan page(s).

If you have any questions or need further assistance, please contact Barbara Prehmus at (303) 844-7472 or [barbara.prehmus@cms.hhs.gov](mailto:barbara.prehmus@cms.hhs.gov).

Sincerely,

James G. Scott, Director  
Division of Program Operations

Enclosures

cc: Adam Meier, Department Director  
Marie Matthews  
Mary Eve Kulawik

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>		1. TRANSMITTAL NUMBER: 22-0001	2. STATE Montana
<b>FOR: HEALTH CARE FINANCING ADMINISTRATION</b>		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE 01/01/2022	
5. TYPE OF PLAN MATERIAL (Check One):  <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION:  42 U.S. Code § 1396d (a)(30) 42 U.S. Code § 1396d (gg) Section 1905(a)(30) of the Social Security Act		7. FEDERAL BUDGET IMPACT:  a. FFY 2022 : \$0 b. FFY 2023 : \$0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  Section 30. Coverage of Routine Patient Cost in Qualifying Clinical Trials: Attachment 3.1A, Page 1 of 1 Attachment 3.1B, Page 1 of 1 Attachment 4.19B, Page 1 of 1		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable):  New	
10. New Medicaid Coverage Requirement related to Clinical Trials:  The Montana Department of Public Health and Human Services (DPHHS) is amending coverage related to clinical trials to meet new requirements to cover routine patient costs related to Medicaid members' participation in qualifying clinical trials.			
11. GOVERNOR'S REVIEW (Check One): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED      Single Agency Director Review <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL:		16. RETURN TO: Montana Department of Public Health and Human Services Marie Matthews Attn: Mary Eve Kulawik PO Box 4210 Helena MT 59620	
13. TYPED NAME: Marie Matthews			
14. TITLE: State Medicaid Director			
15. DATE SUBMITTED: 3-31-22			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED: March 31, 2022		18. DATE APPROVED: June 24, 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 Operations	
23. REMARKS: Pen & Ink change to Box 5 to check that this SPA is an amendment authorized via email 5/27/22.			

State/Territory: Montana**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.

TN: 22-0001Approval Date: 06/24/2022Effective Date: 01/01/2022Supersedes TN: New

State/Territory: Montana**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

## 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).

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Attachment 4.19B  
Methods & Standards for  
Establishing Payment Rates  
Patient Cost-Qualifying Clinical Trials  
Service 30

Page 1 of 1

**State/Territory: Montana**

The state assures it will use the payment methodology for each service provided as required by Section 1905(gg) in accordance with the corresponding methodology described in its approved state plan at Attachments 4.19B, as appropriate.

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.

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