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State/Territory Name: Utah

State Plan Amendment (SPA) #: 22-0002

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

April 28, 2022

Jennifer Strohecker
State Medicaid Director
Division of Health Care Financing
Utah Department of Health
P O Box 144102
Salt Lake City, UT 84114-4102

RE: TN 22-0002

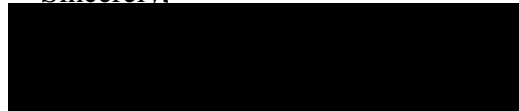
Dear Ms. Strohecker:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of Utah's State Plan Amendment (SPA) Transmittal #22-0002, submitted on March 31, 2022. The SPA provides assurances that the State complies with federal requirements regarding coverage of routine patient care associated with participation in clinical trials as required by the Consolidated Appropriations Act, 2021.

CMS approved SPA #22-0002 on April 28, 2022, with an effective date of January 1, 2022. Enclosed is a copy of the CMS-179 summary form, as well as the approved pages for incorporation into the Utah State Plan.

If you have any questions regarding this amendment, please contact Mandy Strom at mandy.strom@cms.hhs.gov or (303)844-7068.

Sincerely,



Ruth A. Hughes, Acting Director
Division of Program Operations

Enclosures

cc: Craig Devashrayee, Utah Medicaid

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

1. TRANSMITTAL NUMBER <u>2 2</u> — <u>0 0 0 2</u>	2. STATE <u>UTAH</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> 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
Section 1905gg 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 & B, Attachment #1, Page 1;
ATTACHMENT 3.1 A & B, Attachment #2;
ATTACHMENT 3.1 A & B, Attachment #4c;
ATTACHMENT 3.1 A & B, Attachment #5, Page 1;
ATTACHMENT 3.1-A, Page 11; and
ATTACHMENT 3.1-B, Page 10.**

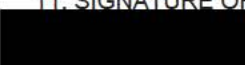
8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
**ATTACHMENT 3.1 A & B, Attachment #1, Page 1;
ATTACHMENT 3.1 A & B, Attachment #2;
ATTACHMENT 3.1 A & B, Attachment #4c; and
ATTACHMENT 3.1 A & B, Attachment #5, Page 1.**

9. SUBJECT OF AMENDMENT
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:

11. SIGNATURE OF STATE AGENCY OFFICIAL


12. TYPED NAME
Nate Checketts

13. TITLE
Executive Director, Utah Department of Health

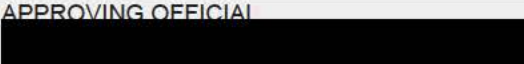
14. DATE SUBMITTED
March 31, 2022

15. RETURN TO
**Craig Devashrayee, Manager
Technical Writing Unit
Utah Department of Health
Division of Medicaid and Health Financing
cdevashrayee@utah.gov**

FOR CMS USE ONLY

16. DATE RECEIVED March 31, 2022	17. DATE APPROVED April 28, 2022
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	19. SIGNATURE OF APPROVING OFFICIAL 
20. TYPED NAME OF APPROVING OFFICIAL Ruth A. Hughes	21. TITLE OF APPROVING OFFICIAL Acting Director, Division of Program Operations

22. REMARKS
Utah authorized pen & ink changes in box 7 and box 8 on April 21, 2022.

State/Territory:

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

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Provided:

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

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)

A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

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.

T.N. # 22-0002Approval Date 4-28-22Supersedes T.N. # NewEffective Date 1-1-22

State/Territory:
UTAH

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

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