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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: 22-0003

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
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



April 22, 2022

Caprice Knapp, Medicaid Director
Division of Medical Services
North Dakota Department of Human Services
600 East Boulevard Avenue, Dept. 325
Bismarck, ND 58505-0250

RE: North Dakota State Plan Amendment (SPA) 22-0003

Dear Ms. Knapp:

The Centers for Medicare & Medicaid Services (CMS) reviewed the proposed Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0003. This amendment proposes to amend the State Plan to assure coverage of items and services furnished in connection with a qualified clinical trial. This letter is to inform you that North Dakota's Medicaid SPA Transmittal Number 22-0003 is approved effective April 22, 2022.

The State of North Dakota requested a waiver to modify the tribal consultation timeline applicable to this SPA submission process. Pursuant to section 1135(b)(5) of the Act, CMS is also allowing states to modify the timeframes associated with tribal consultation required under section 1902(a)(73) of the Act, including shortening the number of days before submission or conducting consultation after submission of the SPA.

CMS conducted our review of your submittal according to statutory requirements in Title XIX of the Act and implementing regulations.

If you have any questions, please contact Curtis Volesky at (303) 844-7033 or via email at curtis.volesky@cms.hhs.gov.

Sincerely,

Alissa M.
Deboy -S

Digitally signed by Alissa
M. Deboy -S
Date: 2022.04.22
08:00:45 -04'00'

Alissa Mooney DeBoy
On Behalf of Anne Marie Costello, Deputy Director
Center for Medicaid and CHIP Services

Enclosures

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

1. TRANSMITTAL NUMBER 2 2 — 0 0 0 3	2. STATE ND
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
1905(gg)(1) of the Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY **2022** \$ **8,039**
b. FFY **2023** \$ **7,733**

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A, page 12
Attachment 3.1-B, page 12
Attachment 4.19-B, page 7b

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 4.19-B, page 7b (TN 21-0018)

9. SUBJECT OF AMENDMENT

Amends the State Plan to assure coverage of items and services furnished in connection with a qualified clinical trial.

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:
Caprice Knapp, Director
Medical Services Division

11. AGENCY OFFICIAL

[Redacted]

12. TYPED NAME
Caprice Knapp

13. TITLE
Medical Services Director

14. DATE SUBMITTED
March 25, 2022

15. RETURN TO
Caprice Knapp, Director
Medical Services Division
ND Department of Human Services
600 East Boulevard Avenue Dept 325
Bismarck ND 58505-0250

FOR CMS USE ONLY

16. DATE RECEIVED
March 25, 2022

17. DATE APPROVED
April 22, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

19. SIGNATURE OF APPROVING OFFICIAL
Alissa M. Deboy -S
Digitally signed by Alissa M. Deboy -S
Date: 2022.04.22 08:01:26 -04'00'

20. TYPED NAME OF APPROVING OFFICIAL
Alissa Mooney DeBoy

21. TITLE OF APPROVING OFFICIAL
On Behalf of Anne Marie Costello, Deputy Director, CMCS

22. REMARKS

State/Territory: North Dakota

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: 22-0003
Supersedes TN: NEW

Approval Date: 04-22-2022
Effective Date: 01-01-2022

State/Territory: North Dakota

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)

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TN: 22-0003
Supersedes TN: NEW

Approval Date: 04-22-2022
Effective Date: 01-01-2022

40. Payment for vaccines outside of the Vaccines for Children program will be based on the Average Sales Price (ASP) + 6% as of August 1 each year. If ASP + 6% is not available, then vaccines will be reimbursed at the Wholesale Acquisition Cost from the ND Medicaid vendor for HCPC to NDC crosswalk available as of August 1 of each year. Payment for vaccine administration is based on the rates approved on page 66(b) of the State Plan.
41. Payment for routine patient cost for items and services that are furnished in connection with participation in a qualified clinical trial will be the lower of billed charges or fee schedule established by the state agency.