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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: 18-0002

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) 179
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

March 16, 2018

Ms. Maggie D. Anderson, Director
Medical Services Division
ND Department of Human Services
600 East Boulevard Ave, Dept 325
Bismarck, ND 58505-0250

Dear Ms. Anderson:

We have reviewed North Dakota's State Plan Amendment (SPA) 18-0002, Prescribed Drugs, received in the Denver Regional Office on January 3, 2018. The SPA amends the North Dakota State Plan regarding an effective date for coverage of stiripentol, a non-U.S. Food and Drug Administration (FDA) approved drug, classified by the state as an experimental or investigational drug. This SPA establishes that effective September 1, 2021, stiripentol will no longer be covered as an experimental or investigational drug by the state. Until then, North Dakota will continue to cover stiripentol for any child receiving Medicaid coverage for whom stiripentol has been ordered by the child's physician, determined medically necessary by the U.S. Department of Health and Human Services and has been authorized for the specific child's use by the U.S. Food & Drug Administration.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 18-0002 is approved with an effective date of January 1, 2018. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into North Dakota's state plan, will be forwarded by the Denver Regional Office.

If you have any questions regarding this request, please contact Pamela Schweitzer at (410) 786-2832 or Pamela.Schweitzer@cms.hhs.gov.

Sincerely,

A black rectangular redaction box covers the signature of Meagan T. Khau.

Meagan T. Khau
Deputy Director
Division of Pharmacy

cc: Richard Allen, Associate Regional Administrator, CMS
Kirstin Michel, CMS
Brendan Joyce, North Dakota Medicaid

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: <div style="text-align: center; font-size: 1.2em;">18-0002</div>	2. STATE <div style="text-align: center; font-size: 1.2em;">North Dakota</div>
FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE <div style="text-align: center; font-size: 1.2em;">January 1, 2018</div>	
5. TYPE OF PLAN MATERIAL <i>(Check One)</i> : <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT </div> <div style="text-align: center; font-size: 0.8em; margin-top: 5px;"> COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT <i>(Separate Transmittal for each amendment)</i> </div>			
6. FEDERAL STATUTE/REGULATION CITATION: <div style="text-align: center; font-size: 1.1em;">1927 of the Act</div>		7. FEDERAL BUDGET IMPACT: a. FFY <u>2018</u> <u>\$no federal fiscal impact expected</u> b. FFY <u>2019</u> <u>\$no federal fiscal impact expected</u>	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Page 5 to Attachment 3.1-A Page 4 to Attachment 3.1-B		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT <i>(If Applicable)</i> : Page 5 to Attachment 3.1-A Page 4 to Attachment 3.1-B	
10. SUBJECT OF AMENDMENT: Amends the State Plan regarding an effective date for coverage of Stiripentol			
11. GOVERNOR'S REVIEW <i>(Check One)</i> : <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL </div> <div style="text-align: right;"> <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <u>Maggie D. Anderson, Director</u> <u>Medical Services Division</u> </div> </div>			
12. SIGNATURE OF STATE AGENCY OFFICIAL: <div style="background-color: black; height: 20px; width: 100%;"></div>		16. RETURN TO: Maggie D. Anderson, Director Medical Services Division ND Department of Human Services 600 East Boulevard Avenue Dept 325 Bismarck ND 58505-0250	
13. TYPED NAME: <div style="text-align: center; font-weight: bold;">Maggie D. Anderson</div>		16. RETURN TO: Maggie D. Anderson, Director Medical Services Division ND Department of Human Services 600 East Boulevard Avenue Dept 325 Bismarck ND 58505-0250	
14. TITLE: <div style="text-align: center; font-weight: bold;">Director, Medical Services Division</div>			
15. DATE SUBMITTED: <div style="text-align: center; font-weight: bold;">January 3, 2018</div>			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: <div style="text-align: center;">January 3, 2018</div>		18. DATE APPROVED: <div style="text-align: center;">March 16, 2018</div>	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: <div style="text-align: center;">January 1, 2018</div>		20. SIGNATURE OF REGIONAL OFFICIAL: <div style="background-color: black; height: 20px; width: 100%;"></div>	
21. TYPED NAME: <div style="text-align: center;">Richard C. Allen</div>		22. TITLE: <div style="text-align: center;">ARA, DMCHO</div>	
23. REMARKS:			

ON AMOUNT, DURATION AND SCOPEServices

- 12a. In compliance with Section 1902(a)54 and Section 1927 of the Social Security Act the Medical Services Division of the Department of Human Services will cover drugs supplied by those manufacturers participating in the drug rebate program with the federal Centers for Medicare & Medicaid Services (CMS) with the following limitations as defined by the Medical Services Division of the Department of Human Services:
1. Drug Efficacy Study Implementation (DESI) Study drugs as determined by the Food and Drug Administration to be less-than-effective and items that are identical, related, or similar (IRS) will not be allowed for payment.
 2. Experimental or investigational drugs will not be allowed for payment, with the exception of stiripentol (generic, if available; brand if generic is not available) for children if the coverage has been ordered by the child's physician, determined medically necessary by the Department of Human Services, and has been authorized for the specific child's use by the U.S. Food & Drug Administration. Effective September 1, 2021, stiripentol will no longer be covered.
 3. Drugs dispensed in quantities of more than a 34-day supply will not be allowed for payment with the exception of:
 - a. Claims received in which a third party liability has been processed; or
 - b. Claims for unit of use products where the directions are such that the supply will last longer than 34 days.
 4. Drugs identified by the Medical Services division as requiring prior approval and listed in the Pharmacy Provider Manual will not be allowed for payment except in accordance with SSA 1927(d). The following prior authorization requirements, found in section 1927(d)(5) of the Act, are met: The prior authorization program provides a response by telephone or other telecommunication device within 24 hours of a request and the prior authorization program provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation.
 - a. Supplemental Rebate Agreements: Certain covered products in accordance with Section 1927 of the Social Security Act may not be among the baseline preferred drugs identified by the State of North Dakota's Drug Use Review Board for various therapeutic classes. The state may negotiate supplemental rebate agreements that would reclassify any drug not designated as preferred in the baseline listing for as long as the agreement is in effect.

In addition, the State has the following policies for the supplemental rebate program for the Medicaid Population:

The state of North Dakota has entered into an agreement with the "Sovereign States Drug Consortium (SSCD)" Medicaid multi-State purchasing pool. In addition to collecting supplemental rebates for fee-for-service claims, the state may, at its option, also collect supplemental rebates for Medicaid member utilization through MCO(s) under an agreement. Funds received from supplemental rebate agreements will be reported to CMS.

ON AMOUNT, DURATION AND SCOPEServices

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