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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: 18-0018

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

May 23, 2019

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

Dear Ms. Anderson:

We have reviewed North Dakota State Plan Amendment (SPA) 18-0018 received in the Centers for Medicare and Medicaid Services (CMS) Denver Regional Operations Group on December 21, 2018. This SPA proposes to revise coverage of investigational and over-the-counter drugs.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 18-0018 is approved with an effective date of November 1, 2018. A copy of the signed, revised CMS-179 form, as well as the pages approved for incorporation into North Dakota's state plan will be forwarded by the Denver Regional Operations Group.



If you have any questions regarding this request, please contact Whitney Swears at (410) 786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,

A solid black rectangular box used to redact the signature of John M. Coster.

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy

cc: Trinia Hunt, Acting Deputy Director, Denver Regional Operations Group
Kirstin Michels, Denver Regional Operations Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES		1. TRANSMITTAL NUMBER: 18-0018	2. STATE North Dakota
		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 November 1, 2018	
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: 1927 of the Act		7. FEDERAL BUDGET IMPACT: a. FFY <u>2019</u> <u>\$35,000</u> b. FFY <u>2020</u> <u>\$35,000</u>	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment to Page 5 to Attachment 3.1-A Attachment to Page 4 to Attachment 3.1-B Attachment to 4.19-B, Page 6a		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment to Page 5 to Attachment 3.1-A Attachment to Page 4 to Attachment 3.1-B Attachment to 4.19-B, Page 6a	
10. SUBJECT OF AMENDMENT: Amends the State Plan regarding coverage of investigational and over the counter drugs.			
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 <u>Maggie D. Anderson, Director</u> <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL <u>Medical Services Division</u>			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		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: Maggie D. Anderson			
14. TITLE: Director, Medical Services Division			
15. DATE SUBMITTED: <i>original submission 12/21/2018 updated pages 4, 12A, J 3/25/2019</i>			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: December 21, 2018		18. DATE APPROVED: May 23, 2019	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: November 1, 2018		20. SIGNATURE OF REGIONAL OFFICIAL: 	
21. TYPED NAME: Mary Marchioni		22. TITLE: Acting Deputy Director, DROG	
23. REMARKS:			

ON AMOUNT, DURATION AND SCOPEServices

12a. Drugs

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.
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 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.

12.a. Drugs (continued)

The state will remit the federal portion of any supplemental rebates collected. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to the Centers for Medicare & Medicaid Services (CMS) on September 30, 2015 and entitled, "SSDC North Dakota Medicaid Supplemental Rebate Agreement" has been authorized by CMS.

This Agreement may not be amended or modified without the mutual written consent of the parties. Any modification or amendment must be authorized by CMS.

The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927 (b)(3)(D) of the Social Security Act.

The Medical Services Division may require prior authorization for covered outpatient drugs. Non-preferred drugs are available with prior authorization.

The prior authorization process for covered outpatient drugs will conform to the provisions of Section 1927 (d)(5) of the Social Security Act.

5. Erectile dysfunction drugs will not be allowed for payment.
6. The early refill threshold for non-controlled substance prescriptions is 80%. This can be over-ridden by the pharmacist if:
 - a. They determine it is medically necessary to over-ride the early refill edit; and
 - b. The previous prescription is 60% utilized or more; and
 - c. The pharmacist submits the necessary over-ride codes.

The early refill threshold for controlled substance prescriptions is 87%. Pharmacists must contact Medical Services to discuss medical necessity for controlled substance prescription early refills as well as any non-controlled substance prescriptions that don't meet all three of the above conditions.

Accumulation edits allow a maximum of 10 days of supply accumulation in a rolling six month period for controlled substances and a maximum of 15 days of supply accumulation in a rolling six month period for non-controlled substances. Pharmacists must contact Medical Services to discuss medical necessity for over-rides for accumulation edits.

7. To increase the cost-effectiveness of dispensing habits, quantities of medication may be restricted if the Medical Services Division or the Drug Utilization Review (DUR) Board determines (a) an alternate method of dispensing would be medically appropriate and more cost-effective, or (b) the dose is not a medically accepted dose supported by citations in the compendia described in Section 1927(g)(1)(B)(i) of OBRA '93.
8. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

12.a Drugs (continued)

The Medicaid agency provides coverage (as specified below) for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

- a. Agents when used for anorexia, weight loss, weight gain are not covered.
 - b. Agents when used to promote fertility are not covered.
 - c. Agents when used for the symptomatic relief of cough and colds are covered.
 - d. Prescription vitamins and mineral products are only covered for vitamin B-12, folic acid, renal failure multi-vitamins, multi-vitamins typically used in cystic fibrosis, and iron.
 - e. Certain Over-The-Counter drugs are covered as outlined in the pharmacy provider manual. The drugs are covered for full benefit dual eligible beneficiaries through prior authorization if a therapeutically equivalent Part D prescription drug is determined not effective by the physician (e.g. ibuprofen prescription versus non-prescription ibuprofen).
 - f. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee are not covered.
9. Active Pharmaceutical Ingredients (APIs) will not be allowed for payment except select APIs used in extemporaneously compounded prescriptions when dispensed by a participating pharmacy provider pursuant to a prescription issued by a licensed prescriber following all state and federal laws. The select APIs will only include those that are determined by the State to be cost effective compared to other covered alternatives. APIs that have been identified as being cost effective are identified at <http://www.nd.gov/dhs/services/medicalserv/medicaid/docs/covered-APIs.pdf>

ON AMOUNT, DURATION AND SCOPEServices

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