

Table of Contents

State/Territory: Colorado

State Plan Amendment (SPA) #: 24-0015

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 S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

July 17, 2024

Kim Bimestefer
Executive Director
Colorado Department of Health Care Policy & Financing
1570 Grant Street
Denver, CO 80203

Dear Kim Bimestefer,

The CMS Division of Pharmacy team has reviewed Colorado's State Plan Amendment (SPA) 24-0015 received in the CMS Medicaid Services OneMAC application on May 9, 2024. This SPA proposes to add coverage of select prescribed drugs that are not covered outpatient drugs, and also add coverage of prescribed drugs that are not covered outpatient drugs in cases of a drug shortage.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 24-0015 is approved with an effective date of April 11, 2024. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed, revised CMS-179 form, as well as the pages approved for incorporation into Colorado's state plan. If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.
Director
Division of Pharmacy

cc: Adela Flores-Brennan, Medicaid Director, CO Dept. of Health Care Policy & Financing
Russell Ziegler, CO Dept. of Health Care Policy & Financing
Mandy Strom, CMS, CO Medicaid State Lead

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

1. TRANSMITTAL NUMBER <u>2 4 — 0 0 1 5</u>	2. STATE <u>CO</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
April 11, 2024

5. FEDERAL STATUTE/REGULATION CITATION
Social Security Act, Section 1927(k)(4) / 42 CFR 447.502

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2024 \$ 27,755
b. FFY 2025 \$ 29,004

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Supplement to Attachment 3.1-A: Limitations to Care and Services -- Item 12.a Prescribed Drugs -- Page 5 of 5
Pages 2-3a of 5

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Supplement to Attachment 3.1-A: Limitations to Care and Services -- Item 12.a Prescribed Drugs -- Page 5 of 5 (TN CO-23-0014)
Pages 2-3a of 5 (TNs 18-0016, 18-0044)

9. SUBJECT OF AMENDMENT
Cover select outpatient drugs that are not covered when medically necessary and prescribed by an enrolled provider, including: over-the-counter nutritional supplements, US FDA-approved emergency use authorization drugs, non-traditional prescribed products like insect repellent, and certain drugs during drug shortages (including drugs authorized for import by the US FDA)

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:
Governor's letter dated 5 April 2023

[Redacted]
Adela Flores-Brennan

15. RETURN TO
Colorado Department of Health Care Policy and Financing
303 E. 17th Avenue, Suite 1100
Denver, CO 80203

13. TITLE
Medicaid Director

Attn: Alex Lyons

14. DATE SUBMITTED
May 9, 2024

FOR CMS USE ONLY

16. DATE RECEIVED
May 9, 2024

17. DATE APPROVED
July 17, 2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
April 11, 2024

19. SIGNATURE OF APPROVING OFFICIAL
[Redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denemark, R.Ph.

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS
Update July 12, 2024: The state updated boxes 7 and 8 to reflect the updated state plan pages affected by this State Plan Amendment. The amendments have been moved from page 5 to pages 2-3a of the Item 12.a Prescribed Drugs in Supplement to Attachment 3.1-A.

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM**

STATE OF COLORADO

Supplement to Attachment 3.1-A

Page 2

- f. The client has taken a generic drug but is unable to continue treatment on the generic drug.
 - g. Any exceptions to the generic drug requirement shall be granted in accordance with procedures established by the Department.
5. Select prescribed drugs that do not meet the definition of covered outpatient drugs are covered as listed on the Pharmacy Resources webpage on the Department’s website.
6. Prescribed drugs that are not covered outpatient drugs (including drugs authorized for import by the Food and Drug Administration) are covered when medically necessary during drug shortages identified by the Food and Drug Administration, as listed on the Pharmacy Resources webpage on the Department’s website.
7. The following are not pharmacy benefits of the Medical Assistance Program
- a. Spirituous liquors of any kind;
 - b. Dietary needs or food supplements unless prior authorized within the Department guidelines;
 - c. Personal care items such as mouthwash, deodorants, talcum powder, bath powder, soap of any kind, dentifrices, etc.;
 - d. Medical supplies; and
 - e. Drugs classified by the FDA as “investigational” or “experimental.”

TN No. 24-0015

Approval Date July 17, 2024

Supersedes TN No. 18-0016

Effective Date April 11, 2024

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM**

State of Colorado

Services**Limitations**

12.a Prescribed Drugs

8. Pursuant to 42 U.S.C. Section 1396r-8, the Department is establishing a Preferred Drug List which indicates the Preferred and Non-preferred Drugs in selected therapeutic drug classes. Those products within a selected therapeutic drug class that are designated Non-preferred will require prior authorization. All drugs covered by the National Drug Rebate Agreements remain available to Medical Assistance Program clients, though some drugs may require 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. The Department will appoint a Pharmacy and Therapeutics Committee and utilize the Drug Utilization Review Board in accordance with Federal Law.

9. CMS has authorized the state of Colorado to enter into the Colorado Medicaid Supplemental Drug Rebate Agreement for drugs provided to the Medical Assistance Program. This supplemental drug rebate agreement was submitted to CMS on November 2, 2007 and has been authorized by CMS. Any additional versions of the rebate agreements negotiated between the state and manufacturer(s) after November 2, 2007 will be submitted to CMS for authorization. The Department may collect supplemental rebates from drug manufacturers for Preferred Drugs. Supplemental rebates received by the Department in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement. All drugs covered by the Medical Assistance Program, irrespective of a supplemental rebate agreement, will comply with the provisions of the National Drug Rebate Agreement. The unit rebate amount is confidential and cannot be disclosed except in accordance with Section 1927(b)(3)(D) of the Social Security Act.

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM**

State of Colorado

Services

Limitations

12.a Prescribed Drugs

10. CMS has authorized the State of Colorado to also enter into Medicaid Value-Based Supplemental Drug Agreements with Manufacturers on a voluntary basis. These contracts will be executed on a model agreement entitled “Value-Based Supplemental Agreement” submitted to CMS on December 4, 2018 with an effective date of October 1, 2018.

TN No. 24-0015

Approval Date July 17, 2024

Supersedes TN No. 18-0044

Effective Date April 11, 2024