
Table of Contents

State/Territory Name: Colorado

State Plan Amendment (SPA) #: 18-0016

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
Denver Regional Office
1961 Stout Street, Room 08-148
Denver, CO 80294



REGION VIII - DENVER

September 20, 2018

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

Dear Ms. Bimestefer:

We have reviewed the proposed State Plan Amendment (SPA) submitted under transmittal number (TN) 18-0016. This amendment removes language that pertains to pharmaceutical coverage for hair-growth, erectile dysfunction and sexual dysfunction medications, pursuant to the 21st Century Cures Act and the Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005.

Please be informed that this State Plan Amendment was approved September 18, 2018, with an effective date of July 1, 2018. We are enclosing the CMS-179 and the amended plan page(s).

In order to track expenditures associated with this amendment, Colorado should follow the CMS-64 reporting instructions outlined in Section 2500 of the State Medicaid Manual (SMM).

For those individuals whose expenditures qualify for the newly eligible federal medical assistance percentage, expenditures should be reported on the Form CMS-64.9 VIII and Form CMS-64.9 VIII Waiver; for the not newly eligible federal medical assistance percentage, expenditures should be reported on the Form CMS-64.9 VIII not newly and Form CMS-64.9 VIII Waiver; for those not enrolled in the new adult group, claims thereon should be reported on the Form CMS-64.9 Base and Form CMS-64.9 Waiver.

This amendment would affect expenditures reported on Line 7 - Prescribed Drugs.

For M-CHIP clients, expenditures should be reported on the Form CMS-64.21U.

This amendment would affect expenditures reported on Line 8 - Prescribed Drugs.



If you have any questions concerning this amendment, please contact Curtis Volesky at (303) 844-7033.

Sincerely,



Barbara B. Prehmus
Acting Associate Regional Administrator
Division for Medicaid & Children's Health Operations

cc: Gretchen Hammer
John Bartholomew
David DeNovellis
Russell Ziegler
Whitney McOwen

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: <p style="text-align: center;">18-0016</p>	2. STATE: <p style="text-align: center;">COLORADO</p>
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		3. PROGRAM IDENTIFICATION: <p style="text-align: center;">TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)</p>	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE: <p style="text-align: center;">July 1, 2018</p>	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>): <p style="text-align: center;"> NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS A NEW PLAN X AMENDMENT </p>			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (<i>Separate transmittal for each amendment</i>)			
6. FEDERAL STATUTE/REGULATION CITATION: Title XIX of the Social Security Act, Sections 1903(i)(21), 1927(d)(2) and 1935(d)(1) and (2); 42 CFR § 441.25		7. FEDERAL BUDGET IMPACT: a. FFY 2017-18: \$0 b. FFY 2018-19: -\$83,158	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Supplement to Attachment 3.1-A: Limitations to Care and Services – 12a Prescribed Drugs (Pages 1-5)		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Supplement to Attachment 3.1-A: Limitations to Care and Services – 12a Prescribed Drugs (11-044, 18-0003, 06-005, 07-002, 14-008)	
10. SUBJECT OF AMENDMENT: The proposed amendment would remove language that pertains to pharmaceutical coverage for hair-growth, erectile dysfunction and sexual dysfunction medications, pursuant to the 21st Century Cures Act and the Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005.			
11. GOVERNOR'S REVIEW (<i>Check One</i>): GOVERNOR'S OFFICE REPORTED NO COMMENT X OTHER, AS SPECIFIED COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Governor's letter dated 29 March, 2018 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO: Colorado Department of Health Care Policy and Financing 1570 Grant Street Denver, CO 80203-1818 Attn: David DeNovellis	
13. TYPED NAME: Gretchen Hammer			
14. TITLE: Medicaid Director			
15. DATE SUBMITTED: June 21, 2018			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED <p style="text-align: center;">June 21, 2018</p>		18. DATE APPROVED <p style="text-align: center;">September 18, 2018</p>	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL <p style="text-align: center;">July 1, 2018</p>		20. SIGNATURE 	
21. TYPED NAME <p style="text-align: center;">Barbara B. Prehmus</p>		22. TITLE <p style="text-align: center;">Acting ARA, DMCHO</p>	
23. REMARKS			

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

STATE OF COLORADO

Supplement to Attachment 3.1-A

Page 1

LIMITATIONS TO CARE AND SERVICES

12.a. Prescribed Drugs

1. Only those drugs designated by companies participating in the federally approved Medicaid drug rebate program and not otherwise excluded according to the Department's rules are regular drug benefits, with the following exceptions:
 - a. Brand name drugs not covered by rebate agreements are a covered benefit if the Department has made a determination that the availability of the drug is essential, such drug has been given a "1-A" rating by the Food and Drug Administration (FDA), and a prior authorization has been approved. Reimbursement of any drugs that are a regular drug benefit may be restricted as set forth in the Department's rules.
 - b. Only those investigational drugs that are specifically named in the state plan are a covered benefit.
2. Restrictions, including prior authorizations, may be placed on drugs for which it has been deemed necessary to address instances of fraud or abuse, potential for, and history of, drug diversion and other illegal utilization, over-utilization, other inappropriate utilization or the availability of more cost-effective alternatives. The prior authorization process provides for a turn-around response by telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medication.
3. Erectile dysfunction drugs will only be covered for FDA approved indications other than erectile or sexual dysfunction.
4. Generic drugs shall be prescribed to clients in the fee-for-service program unless
 - a. Only a brand name drug is manufactured.
 - b. A generic drug is not therapeutically equivalent to the brand name drug.
 - c. The final cost of the brand name drug is less expensive to the Department.
 - d. The drug is used for the treatment of
 - 1) Biologically based mental illness as defined in C.R.S. 10-16-104 (5.5);
 - 2) Treatment of cancer;
 - 3) Treatment of epilepsy; or
 - 4) Treatment of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome
 - e. The client has been stabilized on a brand name medication and the treating physician, or a pharmacist with the concurrence of the treating physician, is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive.

TN No. 18-0016

Approval Date September 18, 2018

Supersedes TN No. 11-044

Effective Date July 1, 2018

**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. 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. 18-0016
Supersedes TN No. 18-0003

Approval Date September 18, 2018
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**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM**

State of Colorado

Services**Limitations**

12.a Prescribed Drugs

6. 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.

7. 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

Supplement to Attachment 3.1-A

Page 4

LIMITATIONS TO CARE AND SERVICES

Citation	Provision
1935(d)(1)	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.
1927(d)(2) and 1935(d)(2)	The Medicaid agency provides coverage 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.

The following excluded drugs are covered

("All" drugs categories covered under the drug class)

("Some" drugs categories covered under the drug class
-List the covered common drug categories not individual drug products directly under the drug class

("None" of the drugs under this class are covered)

(a) agents when used for anorexia or weight loss

(b) agents when used for weight gain

(c) agents when used to promote fertility

(d) agents when used for the symptomatic relief of cough and colds.

TN No. 18-0016
Supersedes TN No. 14-008

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

STATE OF COLORADO

Supplement to Attachment 3.1-A

Page 5

- (e) prescription vitamin and mineral products, except prenatal vitamins and fluoride, for documented deficiency.

- (f) nonprescription drugs.
Nonprescription drugs prescribed for a medically accepted indication in the following classes: aspirin; cough and cold or allergy preparations consisting of antihistamines, analgesics/antipyretics, cough suppressants, decongestants, and expectorants or combinations thereof; doxylamine; emergency contraceptives; fluoride preparations; intranasal corticosteroids; iron supplements; laxatives; l-methylfolate; pain relievers; proton pump inhibitors; pyridoxine; smoking cessation preparations.

- (g) 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

TN No. 18-0016
Supersedes TN No. 14-008

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