
Table of Contents

State/Territory Name: Colorado

State Plan Amendment (SPA) #: 18-0003

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

March 9, 2018

Kim Bimestefer, Executive Director
Department of Health Care Policy & Financing
303 East 17th Avenue, 7th Floor
Denver, CO 80203

Dear Ms. Bimestefer:

We have reviewed the proposed State Plan Amendment (SPA) submitted under transmittal number (TN) 18-0003. This Amendment expands payment for investigational drug Stiripentol from children only to all Medicaid members.

Please be informed that this State Plan Amendment was approved today with an effective date of January 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.



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

Sincerely,



Richard C. Allen
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 FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER: 18-0003	2. STATE: COLORADO
		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE: January 1, 2018	
5. TYPE OF PLAN MATERIAL (Check One): NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS A NEW PLAN X AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: Social Security Act Title XIX, Sections 1902(a)(54), 1903(a), 1905(a)(12), and 1927, and 42 CFR 447		7. FEDERAL BUDGET IMPACT: a. FFY 2017-18: \$4,198 b. FFY 2018-19: \$9,158	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Supplement to Attachment 3.1-A – Limitations to Care and Services – 12.a. – Prescribed Drugs – Page 2 of 2 Attachment 4.19-B – Methods and Standards for Establishing Payment Rates – 12.a. – Pharmaceutical Services – Page 2 of 3		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Supplement to Attachment 3.1-A – Limitations to Care and Services – 12.a. – Prescribed Drugs – Page 2 of 2 (TN 11-044) Attachment 4.19-B – Methods and Standards for Establishing Payment Rates – 12.a. – Pharmaceutical Services – Page 2 of 3 (TN 17-0004)	
10. SUBJECT OF AMENDMENT: Expanding payment for investigational drug Stiripentol from children only to all Medicaid members.			
11. GOVERNOR'S REVIEW (Check One): GOVERNOR'S OFFICE REPORTED NO COMMENT X OTHER, AS SPECIFIED COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Governor's letter dated 15 January, 2015 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: <u>Initial: January 24, 2018</u> <u>Update #1: February 28, 2018</u>			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED January 24, 2018		18. DATE APPROVED March 9, 2018	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2018		20. SIGNATURE OF REGIONAL OFFICIAL 	
21. TYPED NAME Richard C. Allen		22. TITLE ARA, DMCHO	
23. REMARKS			

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

STATE OF COLORADO

Attachment 4.19-B
Page 2 of 3

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –
OTHER TYPES OF CARE

- H. Drugs dispensed by Covered Entities (as defined in the Social Security Act, Section 1927(a)(5)(B)) not purchased through the 340B Pricing Program shall be reimbursed as defined in A.
- I. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.
- J. Physician-administered drugs are reimbursed at the published Medicare Average Sales Price (ASP) Drug Pricing File minus 3.3 percent for drugs included in that file. Physician administered drugs that are not included in the Medicare ASP Drug Pricing File will be reimbursed at Wholesale Acquisition Cost (WAC). Covered entities using drugs purchased at the prices authorized under Section 340B of the Public Health Services Act for Medicaid members must bill Medicaid the 340B purchase price. No professional dispensing fee is applied.
- K. Clotting factor dispensed by specialty pharmacies or Hemophilia Treatment Centers shall be reimbursed the lesser of the provider's usual and customary charge to the general-public, or the submitted ingredient cost plus the professional dispensing fee, or the wholesale acquisition cost plus the professional dispensing fee.
- L. Experimental or investigational drugs will not be allowed for reimbursement, except for Stiripentol. Stiripentol may be covered if the coverage has been ordered by the member's physician, has been deemed medically necessary by the Department, and has been authorized for the specific member's use by the U.S. Food & Drug Administration. Investigational drugs are reimbursed at invoice pricing which includes the cost of the drug, and the international regulatory, shipping and handling fees.
- M. Any pharmacy, except a mail order pharmacy, that is the only pharmacy enrolled with the Medical Assistance Program within a twenty-mile radius, may submit a written request to the Department requesting the designation of a rural pharmacy.
- N. In the aggregate, the Medical Assistance Program expenditures for outpatient drugs shall be in compliance with the federal upper limits as set forth in 42 CFR §§447.512 and 447.514.

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

STATE OF COLORADO

Supplement to Attachment 3.1-A
Page 2 of 2

- f. The client has taken a generic drug but is unable to continue treatment on the generic drug.
 - g. A client requests a brand name drug for a prescription and none of the above-listed exceptions apply. In that case, the client may pay the allowed ingredient cost difference between the generic drug and the brand name drug.
 - h. Any exceptions to the generic drug requirement shall be granted in accordance with procedures established by the Department.
1. 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 Department guidelines;
 - c. Personal care items such as mouthwash, deodorants, talcum powder, bath powder, soap of any kind, dentifrices, etc.;
 - d. Medical supplies;
 - e. Drugs classified by the FDA as "investigational" or "experimental," except for the following:
 - 1. Stiripentol may be covered if the coverage has been ordered by the member's physician, has been deemed medically necessary by the Department, and has been authorized for the specific member's use by the U.S. Food & Drug Administration.
 - f. Less-than-effective drugs (LTE) identified by the Drug Efficacy Study Implementation (DESI) program.
2. Injectable drugs, allergen extracts, infusion drugs and immunizations administered in a physician's office are considered part of the physician's services and not a pharmacy benefit. However, a licensed physician who prepares, dispenses and instructs patients to self-administer medications and whose offices are located more than twenty-five miles from the nearest participating pharmacy may be reimbursed for drugs that are dispensed from the offices for self-administration by the patient.