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State/Territory Name: Colorado

State Plan Amendment (SPA) #: CO-11-044

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

January 20, 2012

Suzanne Brennan
Medicaid Program Director
Colorado Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

Attn Barbara Prehmus

Dear Ms Brennan

We have reviewed Colorado State Plan Amendment (SPA) 11-044, Prescribed Drugs, received in the Regional Office on October 28, 2011. This amendment proposes to add conditional coverage of specific investigational drugs under EPSDT as long as established criteria are met. Specifically, the State is adding coverage of Stiripentol for clients up through age 20, if the coverage has been ordered by the child's physician, has been determined medically necessary by the Colorado Medical Assistance Program Medical Director (or clinical appointee of the Executive Director), and has been authorized for the specific child's use by the U.S. Food & Drug Administration. We are pleased to inform you that the amendment is approved, effective October 1, 2011.

Per your response to informal questions, we made the requested changes to block seven on the CMS-179 form. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Colorado state plan will be forwarded by the Denver Regional Office.

If you have any questions regarding this amendment, please contact Wendy Tuttle at (410) 786-8690.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc Richard Allen, ARA, Denver Regional Office
Diane Dunstan-Murphy, Denver Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR. CENTERS FOR MEDICARE & MEDICAID SERVICES		1 TRANSMITTAL NUMBER <u>1 1 - 0 4 4</u>	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 October 1, 2011	
5 TYPE OF PLAN MATERIAL (Check One)			
NEW STATE PLAN		AMENDMENT TO BE CONSIDERED AS A 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 42 CFR 441.58 and 42 CFR 440.120		7 FEDERAL BUDGET IMPACT a. FFY 2011 2012 (\$ 6521) _____ b. FFY 2012 2013 (\$ 6521) _____	
8 PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement to Attachment 3.1-A, 12 a Prescribed Drugs		9 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Supplement to Attachment 3 1-A, 12 a Prescribed Drugs, TN 07-002	
10. SUBJECT OF AMENDMENT Addition of Conditional Coverage for Stripentol and Clobazam			
11 GOVERNOR'S REVIEW (Check One)			
GOVERNOR'S OFFICE REPORTED NO COMMENT		<input checked="" type="checkbox"/> OTHER, AS SPECIFIED	
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL		Governor's letter dated 01 September 2011	
12 [REDACTED] OFFICIAL	18 RETURN TO		
13 TYPED NAME Susan E. Birch, MBA, BSN, RN,	Colorado Department of Health Care Policy and Financing 1570 Grant Street Denver, CO 80203-1818		
14. TITLE Executive Director	Attn: Barbara Prehmus		
15 DATE SUBMITTED 10/28/11			
FOR REGIONAL OFFICE USE ONLY			
17 DATE RECEIVED	18 DATE APPROVED 1/20/12		
PLAN APPROVED - ONE COPY ATTACHED			
19 EFFECTIVE DATE OF APPROVED MATERIAL 10/1/11	[REDACTED] OFFICIAL		
21 TYPED NAME RICHARD C. ALLEN	22. TITLE ARA, DMCHO		
23 REMARKS			

approved
P+I change
12/21/11 WST

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

STATE OF COLORADO

Supplement to Attachment 3 1-A
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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 an "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 11-043 11-044
Supersedes TN No 06-005 *ep*

Approval Date 1/20/2012
Effective Date 10/1/11

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

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- 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.
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 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. Stripentol and clobazam (prior to availability of Onfi in the US) may qualify for coverage (generic coverage, if available, brand coverage if no generic is available) for clients up through age 20, if the coverage has been ordered by the child's physician, has been determined medically necessary by the Colorado Medical Assistance Program Medical Director (or clinical appointee of the Executive Director), and has been authorized for the specific child's use by the U.S. Food & Drug Administration
 - f. Less-than-effective drugs (LTE) identified by the Drug Efficacy Study Implementation (DESI) program.
6. 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

TN No 11-043 11-044
Supersedes TN No 06-005 *tjl*

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