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State/Territory Name: Missouri

State Plan Amendment (SPA) #: 22-0023

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

January 12, 2023

Todd Richardson
Director
MO HealthNet Division
P.O. Box 6500
Jefferson City, MO 65102-6500

Dear Todd Richardson,

The CMS Division of Pharmacy team has reviewed Missouri's State Plan Amendment (SPA) 22-0023 received in the CMS Medicaid & CHIP Operations Group on October 17, 2022. This SPA proposes to allow the state to enter into Value Based Agreements, as well as updating the state's Pharmacy coverage pages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 22-0023 is approved with an effective date of October 1, 2022. 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 Missouri's state plan. If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or lisa.shochet@cms.hhs.gov.

Sincerely,

A black rectangular redaction box covers the signature of Cynthia R. Denemark.

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

cc: Josh Moore, PharmD, Director of Pharmacy, MO HealthNet Division
Michala Walker, CMS, Medicaid and CHIP Operations Group

<p>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES</p>		1. TRANSMITTAL NUMBER 2 2 — 0 0 2 3	2. STATE MO
		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 10/01/2022	
5. FEDERAL STATUTE/REGULATION CITATION Sections 1902 (a)(54) and 1927 of the Social Security Act		6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY _____ \$ 0 b. FFY _____ \$ 0	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Pages 15a-15ag of Attachment 3.1-A Pages 15a-15ah of Attachment 3.1-A.		8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)	
9. SUBJECT OF AMENDMENT This State Plan Amendment is to clean up duplicate and outdated information on the pharmacy pages. This State Plan Amendment also adds a template for Value Based Agreements.			
10. GOVERNOR'S REVIEW (Check One) <input checked="" type="radio"/> GOVERNOR'S OFFICE REPORTED NO COMMENT SLV <input type="radio"/> OTHER, AS SPECIFIED: <input type="radio"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="radio"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
11. AGENCY OFFICIAL [Redacted] Robert Knodell	15. RETURN TO MO HealthNet Division Post Office Box 6500 Jefferson City, MO 65102-6500		
13. TITLE Acting Director			
14. DATE SUBMITTED 10-14-22			
FOR CMS USE ONLY			
16. DATE RECEIVED October 17, 2022	17. DATE APPROVED January 12, 2023		
PLAN APPROVED - ONE COPY ATTACHED			
18. EFFECTIVE DATE OF APPROVED MATERIAL October 1, 2022	19. SIGNATURE OF APPROVING OFFICIAL [Redacted]		
20. TYPED NAME OF APPROVING OFFICIAL Cynthia R. Denemark, R.Ph.	21. TITLE OF APPROVING OFFICIAL Acting Director, Division of Pharmacy		
22. REMARKS			

Pen & Ink changes authorized by the state on 1/11/2023 for Boxes 6 and 7.

Effective January 1, 1991, the Missouri Medicaid Program covers prescribed drugs, in accordance with Sections 1902 (a)(54) and 1927 of the Social Security Act, which are covered by a national or State agreement, with the following restrictions or exceptions (as indicated by X).

- X A. Prior authorization program which complies with Section 1927(d)(5) of the Social Security Act.
- X B. The following drugs are covered, or restricted, as indicated by the X:
- X 1. Certain drugs are not covered if the prescribed use is not for medically accepted indication, as defined by Section 1927(k)(6).
 - 2. Drugs subject to restrictions pursuant to an agreement between a manufacturer and this State authorized by the Secretary under 1927(a)(1) or 1927(a)(4).
 - X 3. Certain products may be limited by online clinical or fiscal edits to monitor appropriate utilization and secure cost savings.
 - X 4. Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication. Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.
 - X 5. The state will meet the requirements of Section 1927 of the Social Security Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program and value-based supplemental rebate program for Medicaid recipients:
 - a) The state will be negotiating supplemental rebates and value-based agreements in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.
 - b) A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 30, 2004 and entitled, "State of Missouri Supplemental Rebate Agreement," has been authorized by CMS.
 - c) A value-based supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on October 17, 2022 and entitled, "State of Missouri Value-Based Supplemental Rebate Agreement," has been authorized by CMS.
 - d) Supplemental rebates and value-based supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
 - e) All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.
- X C. In accordance with 1927(d)(2) the following drugs or classes of drugs, or their medical uses, are included, subject to restriction from coverage or otherwise restricted as determined by the Missouri Medicaid Program. Coverage criteria for drugs or classes of drugs, if covered, are located within the state's Pharmacy Provider Manual.
- 1. Agents when used for anorexia, weight loss, or weight gain.
 - 2. Agents when used for the symptomatic relief of cough and colds.
 - 3. Nonprescription drugs when determined to be the least costly therapeutic alternative for a medically accepted indication.
 - 4. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

The following drugs or classes of drugs, or their medical uses, are excluded from coverage pursuant to 1927(d)(2):

1. Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are being used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.
2. Agents when used to promote fertility.
3. Prescription vitamins and mineral products, except prenatal vitamins fluoride preparations, and for adults with documented vitamin deficiency.
4. 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.

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State Plan TN# MO 22-0023
Supersedes TN# 02-30

Effective Date October 1, 2022
Approval Date January 12, 2023

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State Plan TN# MO 22-0023
Supersedes TN# 05-21

Effective Date October 1, 2022
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State Plan TN# MO 22-0023
Supersedes TN# 06-03

Effective Date October 1, 2022
Approval Date January 12, 2023

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State Agency: Missouri

MEDICAID PROGRAM: REQUIREMENTS RELATEING TO COVERED OUTPATIENT
DRUGS FOR THE CATEGORICALLY NEEDY

12.a Prescribed Drugs: Description of Service Limitation

Citation (s)	Provision (s)
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)	<p>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.</p> <p><input type="checkbox"/> The following excluded drugs are covered:</p> <p><i>("All" drugs categories covered under the drug class)</i> <input type="checkbox"/></p> <p><i>("Some" drugs categories covered under the drug class</i> <input type="checkbox"/> <i>-List the covered common drug categories not individual drug products directly under the appropriate drug class)</i></p> <p><i>("None" of the drugs under this drug class are covered)</i> <input type="checkbox"/></p> <p><input type="checkbox"/> (a) agents when used for anorexia, weight loss, weight gain</p> <p><input type="checkbox"/> (b) agents when used to promote fertility</p> <p><input checked="" type="checkbox"/> (c) agents when used for the symptomatic relief of cough and colds</p> <p><input checked="" type="checkbox"/> (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride</p> <p><input checked="" type="checkbox"/> (e) nonprescription drugs (Select list of Over-the-Counter (OTC) products covered for all Medicaid recipients)</p> <p><input type="checkbox"/> (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 (see specific drug categories below)</p>

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