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State/Territory Name: Indiana

State Plan Amendment (SPA) #: 23-0008

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

September 11, 2023

Cora Steinmetz
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 West Washington Street, Room W374
Indianapolis, IN 46204

Re: Indiana State Plan Amendment (SPA) 23-0008

Dear Director Steinmetz:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 23-0008. This amendment proposes to require managed care entities (MCEs) contracted with the State of Indiana follow a statewide uniform preferred drug list.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations 42 USC 1396r-8 and 42 CFR 440.120. This letter is to inform you that Indiana Medicaid SPA 23-0008 was approved on September 8, 2023, with an effective date of July 1, 2023.

If you have any questions, please contact Mai Le-Yuen at 312.353.2853 or via email at Mai.Le-Yuen@cms.hhs.gov.

Sincerely,

[redacted]

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Madison May Gruthusen, FSSA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 23-0008

2. STATE: IN

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT: (●) XIX ( ) XXI

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
July 1, 2023

5. FEDERAL STATUTE/REGULATION CITATION
42 USC 1396r-8 and 42 CFR 440.120

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2023 $ 0
b. FFY 2024 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A Addendum 7
Attachment 3.1-A Addendum 7a
~~Attachment 3.1-A Addendum Page 7a.1~~

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 3.1-A Addendum 7
Attachment 3.1-A Addendum pg 7a
~~Attachment 3.1-A Addendum pg 7a.1~~

9. SUBJECT OF AMENDMENT
The state plan amendment (SPA) proposes to implement a Statewide Uniform Preferred drug list for Indiana Medicaid. Additionally, the SPA revises the supplemental drug rebate contract to allow the State to collect rebates on all managed care and fee-for-service (FFS) outpatient drug utilization. The state may also negotiate value-based purchasing contracts with manufacturers. This SPA outlined medical necessity language for eyeglasses.

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:

11. SIGNATURE OF [redacted]

12. TYPED NAME
Allison Taylor

13. TITLE
Medicaid Director

14. DATE SUBMITTED
June 28, 2023

15. RETURN TO
Allison Taylor
Medicaid Director
Indiana Office of Medicaid Policy and Planning
402 West Washington Street, Room W374
Indianapolis, IN 46204
ATTN: Madison May-Gruthusen, Federal Relations Lead

FOR CMS USE ONLY

16. DATE RECEIVED
June 28, 2023

17. DATE APPROVED
September 8, 2023

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
July 1, 2023

19. SIGN [redacted]

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

21. TITLE OF APPROVING OFFICIAL
Director, Division of Program Operations

22. REMARKS
Box 7 and Box 8: IN gave permission for a pen & ink change to remove page 7a.1 on 8/28/23.

Instructions on Back

12.a. Prescribed Drugs Provided with limitations.

Reimbursement is available for prescribed drugs subject to the limitations set out in 405 IAC 5. The following are not covered: anorectics or any agent used to promote weight loss; topical minoxidil preparations; fertility enhancement drugs; drugs used to treat sexual or erectile dysfunction, as set forth in section 1927(d)(2)(K) of the Act, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and such uses have been approved by the Food and Drug Administration; drugs prescribed solely or primarily for cosmetic purposes. All over-the-counter and non-legend items are subject to the limitations set out in 405 IAC 5-24.

Effective July 1st, 2023, the Medicaid Managed Care Plans contracted with the State of Indiana, will follow the statewide uniform preferred drug list (SUPDL) for covered outpatient drugs listed in the classes on the fee-for-service (FFS) preferred drug list (PDL). In accordance with Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990), Indiana Medicaid will fully participate in the manufacturer rebate program. In doing so, all applicable provisions and restrictions of the legislation, as well as that of any subsequent rules and/or regulations, will be strictly adhered to. Specifically, Indiana Medicaid will reimburse for all rebating manufacturers' (as identified to the agency by CMS) products fully in accordance with the specifications of the legislation. The program will also adhere to all reporting requirements of the legislation.

Supplemental Rebates--The State is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates 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. A rebate agreement between the State and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on June 28th, 2023 and entitled, State of Indiana Supplemental Rebate agreement, has been authorized by CMS, superseding the State of Indiana Supplemental Rebate agreement approved under IN SPA TN 20-018.

Effective July 1st, 2023, all supplemental rebates received for covered outpatient drug claims, pursuant to these agreements, are collected from manufacturers based on drug utilization for fee-for-service Medicaid beneficiaries and managed care Medicaid beneficiaries.

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. All drugs covered by the program, irrespective of prior authorization requirement, will comply with the provisions of the national rebate agreement.

Effective July 1st, 2023, the State may enter into value/outcomes-based contracts with manufacturers on a voluntary basis. The Value-Based Supplemental Rebate Agreement will

apply to the Medicaid drug benefit for both the fee-for-service and managed care entity (MCE) drugs in accordance with the Statewide Uniform Preferred Drug List for all covered outpatient drugs.

12.b. Dentures	Provided with limitations. Prior review and authorization by the agency is required for all dentures, partials and repairs.
12.c. Prosthetic devices	Prior authorization by the Office of Medicaid Policy and Planning is required for all prosthetic devices, except for all customizing features once the basic prosthesis is approved. Coverage is not available for prosthetic devices dispensed for purely cosmetic reasons.
12.d. Eyeglasses	Covered for medically reasonable and necessary eyeglasses, with the following limitations: (1) Eyeglasses provided to a recipient under 21 years of age will be limited to a maximum of 1 pair per year. Limits can be exceeded based on medical necessity. (2) Eyeglasses provided to a recipient 21 years of age or over will be limited to a maximum of 1 pair every 5 years. Medically necessary and reasonable is defined as a covered service required for the care or wellbeing of the patient and is provided in accordance with generally accepted standards of medical or professional practice. Coverage is not available for: (I) Lenses with decorative designs. (2) Fashion tints, gradient tints, sunglasses and photochromatic lenses. (3) Oversized lenses larger than 61 mm, except when medically necessary.
13. Other diagnostic, screening preventive and rehabilitative services	Covered for medically necessary diagnostic preventative, therapeutic, and rehabilitative services Medically necessary is defined as a covered service required for the care or wellbeing of the patient and is provided in accordance with generally accepted standards of medical or professional practice
13.a. Diagnostic services	Covered for medically necessary diagnostic preventative, therapeutic, and rehabilitative services. Coverage for environmental lead investigations is available for a one-time, on-site environmental lead investigation of a child's home or primary residence for a child with an elevated blood lead level. This environmental lead investigation will be provided by a licensed risk assessor or licensed lead inspector. Medically necessary is defined as a covered service required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice.