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State/Territory Name: Michigan

State Plan Amendment (SPA)#:MI-25-0001

This file contains the following documents in the order listed:

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

Medical Benefits Health Programs Group

April 08, 2025

Meghan Groen
Behavioral and Physical Health and Aging Services Administration
Office of Strategic Partnerships & Medicaid Administrative Services – Federal Liaison
Capitol Commons Center – 7th Floor
400 South Pine
Lansing, Michigan 48933

Dear Meghan Groen,

The CMS Division of Pharmacy team has reviewed Michigan's State Plan Amendment (SPA) 25-0001 received in the CMS Medicaid Services OneMAC application on January 22, 2025. This SPA proposes to allow coverage of medically necessary prescribed drugs that are not covered outpatient drugs, including drugs authorized for import by the U.S. Food and Drug Administration (FDA), during drug shortages. In addition, this SPA proposes to reimburse prescribed drugs that are not considered covered outpatient drugs utilizing the same methodologies as covered outpatient drugs.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 25-0001 is approved with an effective date of January 1, 2025. 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 CMS-179 form, as well as the page approved for incorporation into Michigan's state plan. If you have any questions regarding this amendment, please contact Charlotte Hammond at (410) 786-1092 or charlotte.hammond@cms.hhs.gov.

Sincerely,

[redacted]

Mickey Morgan
Deputy Director
Division of Pharmacy

cc: Erin Black, State Plan Amendment Coordinator, Michigan Department of Health
Christine Davidson, CMS, Medicaid and CHIP Operations Group

DEPARTMENT OF HEALTH ANDHUMAN 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: 25 — 0001

2. STATE: MI

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT

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

3. PROPOSED EFFECTIVE DATE
January 1, 2025

5. FEDERAL STATUTE/REGULATION CITATION
Section 1905(a)(12) of the Social Security Act, CFR 440.120(a), and 42 CFR 441.25

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2025 $0
b. FFY 2026 $0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Supplement to Attachment 3.1-A Pages 24.1 and 24.2
Attachment 4.19-B Page 1c

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTIONOR ATTACHMENT *(If Applicable)*
Supplement to Attachment 3.1-A Pages 24.1 and 24.2 (TN# 20-0007)
Attachment 4.19-B Page 1c (TN# 17-0005)

9. SUBJECT OF AMENDMENT
This SPA provides authority for coverage of authorized drug imports where prescribed drugs are medically necessary and are not covered outpatient drugs during drug shortages identified by the FDA.

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:

[redacted]

12. TITLE
Senior Deputy Director

13. DATE SUBMITTED
January 22, 2025

15. RETURN TO

Behavioral and Physical Health and Aging Services Administration
Office of Strategic Partnerships & Medicaid Administrative Services – Federal Liaison
Capitol Commons Center – 7th Floor
400 South Pine
Lansing, Michigan 48933

Attn: Erin Black

FOR CMS USE ONLY

16. DATE RECEIVED
January 22, 2025

17. DATE APPROVED
April 08, 2025

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2025

19. S [redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Mickey Morgan

21. TITLE OF APPROVING OFFICIAL
Deputy Director

22. REMARKS

FORM CMS-179 (09/24)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State of **MICHIGAN**

Amount, Duration and Scope of Medical and Remedial Care Services Provided to the Categorically and Medically Needy

12. Drug Products, Dentures, Prosthetic and Orthotic Devices, Eyeglasses (continued)

a. Drug Products (continued)

7. A drug use review program, including prospective and retrospective drug utilization review, has been implemented in compliance with federal law.

8. Claims management is electronic, in compliance with federal law.

9. The State is in compliance with 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 for the Medicaid population:

(A)

(I) CMS has authorized the State of Michigan to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on February 1, 2008, have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on September 25, 2013, has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.

(II) CMS has authorized the State of Michigan to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled “Outcomes-Based Supplemental Rebate Agreement” submitted to CMS and authorized for use beginning July 31, 2020.

(B) New contracts will be submitted to CMS for prior approval.

(C) 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 drug rebate agreement.

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

10. Coverage of selected active pharmaceutical ingredients (APIs) and excipients that are essential to the health of the beneficiary when billed as part of a compounded drug claim.

11. DRUG SHORTAGES: PRESCRIBED DRUGS THAT ARE NOT COVERED OUTPATIENT DRUGS (INCLUDING DRUGS AUTHORIZED FOR IMPORT BY THE FOOD AND DRUG ADMINISTRATION) ARE COVERED WHEN MEDICALLY NECESSARY DURING DRUG SHORTAGES IDENTIFIED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (US FDA).

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State of **MICHIGAN**

Amount, Duration and Scope of Medical and Remedial Care Services Provided to the Categorically and Medically Needy

b. Dentures

Dentures are a covered benefit for recipients under the EPSDT program if determined necessary by a licensed dentist (Item 10 of this attachment) to correct masticatory deficiencies likely to impair general health. Prior authorization is required. If the client has an existing denture, replacement is permissible only if the existing denture cannot be relined or rebased, whether or not the existing denture was obtained through the Michigan Medical Assistance Program.

Reimbursement for complete or partial dentures includes the costs of any necessary adjustments within six months of insertion. Dentures will be replaced when medically necessary. Prior authorization is required.

c. Prosthetic and Orthotic Devices
Such devices are provided under the following conditions only:

1. when provided to a hospital inpatient, upon a physician's order indicating that the device is essential to the client's medical treatment plan; or,
2. when prior authorized as medically necessary and provided on an outpatient basis or for a recipient in a long-term care facility.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of MICHIGAN

Policy and Methods for Establishing Payment Rates
(Other than Inpatient Hospital and Long Term Care Facilities)

2. Drug Product Reimbursement

a) Outpatient drug ingredient Reimbursement shall be based upon the lower of: Actual Acquisition Cost (AAC) as defined in (A) I and II below plus the professional dispensing fee, Wholesale Acquisition Cost (WAC) plus the professional dispensing fee, Maximum Allowable Cost (MAC) plus the professional dispensing fee, or the provider's charge.

I. For drugs that are not purchased through the 340B program, Federal Supply Schedule, or at the Nominal Price, AAC is based on the National Average Drug Acquisition Cost (NADAC).
II. For drugs that are purchased through the 340B program, AAC is based on the actual invoice cost for a drug product to the pharmacy or company, organization, corporation, or affiliate with which it is associated. The provider must indicate the AAC as their ingredient cost charge included in their usual and customary charge.

b) Outpatient drug ingredient reimbursement described in (2)(a) shall apply to the following:

I. Brand Drugs
II. Generic drugs
III. Clotting factor dispensed by specialty and non-specialty pharmacies
IV. Specialty drugs
V. Drugs not distributed by a retail community pharmacy (such as a long-term care facility)
VI. Drugs purchased through the federal supply schedule (FSS) shall be reimbursed at no more than the FSS price.
VII. Drugs purchased through the 340b program shall be reimbursed at no more than the 340b ceiling price.
VIII. Drugs purchased through the 340b program, and dispensed by 340b contract pharmacies will not be reimbursed by the state, unless the 340b covered entity, contract pharmacy and the department have established an arrangement to prevent duplicate discounts.
IX. Drugs purchased at nominal prices shall be reimbursed at no more than the nominal price.

c) Payment for prescribed drugs that are not considered covered outpatient drugs will follow the same reimbursement methodologies as covered outpatient drugs.