



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

March 6, 2020

Ms. Kate Massey
Medicaid Director
Medical Services Administration
400 S Pine St 7th Fl
Lansing, MI 48933-2250

Dear Ms. Massey:

The CMS Division of Pharmacy team has reviewed Michigan State Plan Amendment (SPA) 19-0013 received in the Division of Program Operations East Branch on December 19, 2019. This SPA proposes to clarify coverage of certain active pharmaceutical ingredients (APIs) and excipients when billed as part of a compounded drug claim.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0013 is approved with an effective date of October 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Michigan's state plan will be forwarded by the Division of Program Operations East Branch.

If you have any questions regarding this request, please contact Justin Aplin at (410) 786-6901 or Justin.Aplin@cms.hhs.gov.

Sincerely,

/s/

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: James G. Scott, Director Division of Program Operations
Tannisse Joyce Division of Program Operations
Keri Toback Division of Program Operations East Branch
Leslie Campbell Division of Program Operations Midwest Branch
Justyna Redlinski Division of HCBS Operations and Oversight East Branch
Erin Black Michigan Department of Health and Human Services

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 19 - 0013	2. STATE: Michigan
3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
4. PROPOSED EFFECTIVE DATE October 1, 2019	

TO: REGIONAL ADMINISTRATOR
HEALTH FINANCING ADMINISTRATION
DEPARTMENT OF HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (*Check One*):

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate Transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION: CMS-2345-FC, 81 Fed. Reg. 5169	7. FEDERAL BUDGET IMPACT: a. FFY 2020 \$0 b. FFY 2021 \$0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Supplement to Attachment 3.1-A Page 24.1	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Supplement to Attachment 3.1-A Page 24.1

10. SUBJECT OF AMENDMENT:
The purpose of this SPA is to clarify coverage of certain Active Pharmaceutical Ingredients (APIs) and Excipients when billed as part of a compounded drug claim.

11. GOVERNOR'S REVIEW (*Check One*):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Kate Massey, Director
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL Medical Services Administration

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Medical Services Administration Actuarial Division - Federal Liaison Capitol Commons Center - 7 th Floor 400 South Pine Lansing, Michigan 48933 Attn: Erin Black
13. TYPED NAME: Kate Massey	
14. TITLE: Director, Medical Services Administration	
15. DATE SUBMITTED: December 19, 2019	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 12/19/2019	18. DATE APPROVED: 03/06/2020
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PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/01/2019	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPE NAME: James G. Scott	22. TITLE: Director, Division of Program Operations

23. REMARKS:

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 September 30, 2018.
 - (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.
- 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.