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State/Territory Name: MI

State Plan Amendment (SPA) #: 19-0013

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Page



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 Tannisse Joyce
 Keri Toback
 Leslie Campbell
 Justyna Redlinski
 Erin Black
 Division of Program Operations
 Division of HCBS Operations and Oversight East Branch
 Michigan Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTHCARE FINANCING ADMINISTRATION		FORM APPROVED OMB NO. 0938-0193
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER:	2. STATE:
	F 19 - 0013	Michigan
	3. PROGRAM IDENTIFICATION: TITLE XIX	
	SECURITY ACT (MEDICAID) TITLE XIX OF THE SOCIAL SECURITY	
TO: REGIONAL ADMINISTRATOR	4. PROPOSED EFFECTIVE DATE	
HEALTH FINANCING ADMINISTRATION DEPARTMENT OF HUMAN SERVICES	October 1, 2019	
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:	7. FEDERAL BUDGET IMPACT:	
CMS-2345-FC, 81 Fed. Reg. 5169	a. FFY 2020 \$0 b. FFY 2021 \$0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED OR ATTACHMENT (<i>If Applicable</i>):	PLAN SECTION
Supplement to Attachment 3.1-A Page 24.1	Supplement to Attachment 3.1-A Page 24.1	
	Supplement to Attachment 5.1-A Fage 2-	r. I
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):		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Kate Massey, Director		
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL Medical Services Administration		
12. SIGNATUE OF STATE AGENCY OFFICIAL:	16. RETURN TO:	
13. TYPED NAME:	Medical Services Administration	
Kate Massey	ctuarial Division - Federal Liaison	
14. TITLE:	apitol Commons Center - 7º Floor 0 South Pine	
Director, Medical Services Administration	Lansing, Michigan 48933	
15. DATE SUBMITTED:		
December 19, 2019	Attn: Erin Black	
FOR REGIONAL OFFICE USE ONLY		
17. DATE RECEIVED: 12/19/2019	18 DATE APPROVED: 03/06/2020	
PLAN APPROVED – ONE COPY ATTACHED		
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:	
10/01/2019		
21. TYPE NAME:	22. TITLE:	
James G. Scott	Director, Division of Program Operations	
23. REMARKS:		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT State of <u>MICHIGAN</u>

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

- 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 multistate 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.