

MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Vicki Goethals

Phone Number: 517-335-6611

Initial

Public Comment

Final

Brief description of policy:

This policy is being issued to comply with Section V(i) of the Public Readiness and Emergency Preparedness (PREP) Act, which expands the scope of authority for licensed pharmacists to order U.S. Food & Drug Administration (FDA) authorized, approved, or licensed COVID-19 oral therapeutics.

Reason for policy (problem being addressed):

To increase timely access to care in providing available treatments for COVID-19.

Budget implication:

- budget neutral
- will cost MDHHS \$ _____, and (select one) budgeted in current appropriation
- will save MDHHS \$ _____

Is this policy change mandated per federal requirements?

Yes

Does policy have operational implications on other parts of MDHHS?

No

Does policy have operational implications on other departments?

No

Summary of input:

- controversial
- acceptable to most/all groups
- limited public interest/comment

Supporting Documentation:

State Plan Amendment Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Public Notice Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If Yes, please provide status:	If yes, Submission Date:
<input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Denied	
Date: Approval Date:	

DRAFT FOR PUBLIC COMMENT		
Michigan Department of Health and Human Services	Project Number: 2233-Pharmacy	Date: September 19, 2022

Comments Due: October 24, 2022
Proposed Effective Date: As Indicated
Direct Comments To: Vicki Goethals
Address:
E-Mail Address: goethalsv@michigan.gov
Phone: 517-335-6611 **Fax:**

<p>Policy Subject: COVID-19 Response: Authorization of U.S. Food & Drug Administration (FDA) Emergency Use Authorization (EUA) of Pharmacists to Prescribe COVID-19 Oral Therapeutics</p> <p>Affected Programs: Medicaid, Healthy Michigan Plan, MICHild, Maternity Outpatient Medical Services (MOMS)</p> <p>Distribution: All Providers</p> <p>Summary: To comply with the 9th Amendment of the Public Readiness and Emergency Preparedness (PREP) Act, the Michigan Department of Health and Human Services (MDHHS) will provide reimbursement to licensed pharmacists enrolled in Medicaid who order and administer COVID-19 oral therapeutics in accordance with the FDA EUA and for beneficiary populations authorized by the FDA. This policy is effective according to the provisions as specified in the EUA.</p> <p>Purpose: To increase timely access to care in providing available treatments for COVID-19.</p> <p>Cost Implications: Budget neutral.</p> <p>Potential Hearings & Appeal Issues: None</p>
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State Plan Amendment Required: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If yes, date submitted:	Public Notice Required: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Submitted date:
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Tribal Notification: Yes No - Date:

THIS SECTION COMPLETED BY RECEIVER

<input type="checkbox"/> Approved	<input type="checkbox"/> No Comments
<input type="checkbox"/> Disapproved	<input type="checkbox"/> See Comments Below
	<input type="checkbox"/> See Comments in Text

Signature:	Phone Number
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Signature Printed:

Bureau/Administration (please print)	Date
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Bulletin Number: MMP 22-29

Distribution: All Providers

Issued: September 19, 2022

Subject: COVID-19 Response: Authorization of U.S. Food & Drug Administration (FDA) Emergency Use Authorization (EUA) of Pharmacists to Prescribe COVID-19 Oral Therapeutics

Effective: As Indicated

Programs Affected: Medicaid, Healthy Michigan Plan, MIChild, Maternity Outpatient Medical Services (MOMS)

To comply with the 9th Amendment of the Public Readiness and Emergency Preparedness (PREP) Act, the Michigan Department of Health and Human Services (MDHHS) will provide reimbursement to licensed pharmacists enrolled in Medicaid who order and administer COVID-19 oral therapeutics in accordance with the FDA EUA and for beneficiary populations authorized by the FDA. This policy is effective July 6, 2022, according to the provisions specified in the EUA.

The purpose of this policy is to increase timely access to care in providing available treatments for the treatment of COVID-19. Allowing pharmacists to order authorized COVID-19 oral therapeutics for treatment will broaden access to early treatment and reduce inequities given the ease of administration.

Provider Qualifications

Pharmacy providers ordering prescriptions of approved EUA products to treat COVID-19 must:

- Hold a current, active Medicaid enrollment.
- Adhere to all requirements of the FDA EUA for oral drug products approved for ordering by pharmacists to treat COVID-19.
- Adhere to all requirements of the MDHHS FDA EUA policy, established in Bulletin [MSA 20-81](#) and the [MDHHS Medicaid Provider Manual](#) unless otherwise indicated by the Centers for Medicare & Medicaid Services (CMS).

Additional Resources for Providers:

- U.S. Department of Health and Human Services (HHS) Announcement Authorizing Pharmacists to Prescribe Paxlovid with Certain Limitations:
<https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-06July2022.aspx>
- FDA EUA for Paxlovid: <https://www.fda.gov/media/155049/download>
- D.0 Pharmacy Claims Processing Manual:
https://michigan.magellanrx.com/provider/external/medicaid/mi/doc/en-us/MIRx_D0_claims_processing_manual.pdf

Public Comment

The public comment portion of the policy promulgation process is being conducted concurrently with the implementation of the change noted in this bulletin. Any interested party wishing to comment on the change may do so by submitting comments to Vicki Goethals via e-mail at GoethalsV@michigan.gov.

Please include “Authorization of FDA EUA of Pharmacists to Prescribe COVID-19 Oral Therapeutics” in the subject line.

Comments received will be considered for revisions to the change implemented by this bulletin.

Manual Maintenance

Providers should retain this bulletin until further notice of its possible continuation following the announcement of the end of the Federal Public Health Emergency, or until the discontinuation of the EUA.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 1-800-292-2550. Atypical Providers may phone toll-free 1-800-979-4662.

An electronic copy of this document is available at www.michigan.gov/medicaidproviders >>
Policy, Letters & Forms.

Approved

A handwritten signature in black ink that reads "Farah A. Hanley". The signature is written in a cursive style with a large, looping initial "F".

Farah Hanley
Chief Deputy for Health