

MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Timothy McGinnis

Phone Number:

Initial

Public Comment

Final

Brief description of policy:

This bulletin clarifies that claims submitted for off-label uses of physician administered protected drug classes require sufficient documentation that supports medical necessity to process appropriately. Claims for off-label uses for non-protected drug classes continue to require a prior authorization.

Reason for policy (problem being addressed):

State law MCL 400.109h prohibits Medicaid from requiring prior authorization for certain drug classes. Current Medicaid policy requires prior authorization for drug uses considered off-label. Policy does not currently provide guidance as to the process for submitting claims for physician administered drugs within the protected drug classes when utilized for off-label purposes. This policy promotes consistency in billing practices and supports efficiency in the claims review process. This policy ensures that claims submitted for off-label indications of protected drug classes are reimbursable when sufficient documentation is submitted to support medical necessity.

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?

No.

Does policy have operational implications on other parts of MDHHS?

No.

Does policy have operational implications on other departments?

No.

Summary of input:

controversial (Explain)

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: <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Denied	If yes, Submission Date:
Date: Approval	Date:

DRAFT FOR PUBLIC COMMENT Michigan Department of Health and Human Services		
	Project Number: 2458-Injectables	Date: January 29, 2025

Comments Due: March 5, 2025
Proposed Effective Date: May 1, 2025
Direct Comments To: Timothy McGinnis
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E-Mail Address: McGinnisT1@michigan.gov
Phone: **Fax:**

<p>Policy Subject: Physician Administered Drugs Administered for Off-Label Indications</p> <p>Affected Programs: Medicaid, Healthy Michigan Plan, MICHild, Maternity Outpatient Medical Services (MOMS)</p> <p>Distribution: All Providers</p> <p>Summary: This bulletin clarifies that claims submitted for off-label uses of physician administered protected drug classes require sufficient documentation that supports medical necessity to process appropriately.</p> <p>Claims for off-label uses for non-protected drug classes continue to require a prior authorization.</p> <p>Purpose: Current policy language does not adequately reflect how claims for protected drug classes used off-label are processed. Clarifying this process will increase transparency for providers and improve claims processing efficiency.</p> <p>Cost Implications: Budget neutral</p> <p>Potential Hearings & Appeal Issues: None anticipated</p>

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 <i>(please print)</i>	Date
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Proposed Policy Draft

Michigan Department of Health and Human Services
Behavioral & Physical Health and Aging Services Administration

Distribution: All Providers

Issued: April 1, 2025 (Proposed)

Subject: Physician Administered Drugs Administered for Off-Label Indications

Effective: May 1, 2025 (Proposed)

Programs Affected: Medicaid, Healthy Michigan Plan, MICHild, Maternal Outpatient Medical Services

This policy applies to Medicaid Fee-for-Service (FFS). MHPs and ICOs [or HIDE-SNPs] may develop prior authorization (PA) requirements and utilization review criteria, within the confines of state law, that differ from Medicaid requirements. Providers are encouraged to check with the beneficiary's MHP or ICO for applicable PA requirements and utilization review criteria.

The purpose of this bulletin is to provide clarification regarding requirements for program coverage of physician administered drugs administered for U.S. Food and Drug Administration (FDA) off-label indications.

Coverage of Off-Label Use of Protected Drug Classes

Claims submitted for FDA off-label use of physician administered drugs within the protected drug classes, as identified in MCL 400.109h, must include documentation to support the indication is evidence-based and that it is being administered within generally accepted standards of practice. This may include but is not limited to documents from medical compendia, peer reviewed studies, progress notes, or provider letters that demonstrate other failed lines of treatment.

Coverage of Off-Label Use of Non-Protected Drug Classes

Prior authorization continues to be required for claims for off-label uses of drugs not included in the protected drug classes. Refer to the [Michigan Department of Health and Human Services \(MDHHS\) Medicaid Provider Manual](#), General Information for Providers chapter, for additional information for prior authorization of services.