

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOTICE OF PROPOSED POLICY

Public Act 280 of 1939, as amended, and consultation guidelines for Medicaid policy provide an opportunity to review proposed changes in Medicaid policies and procedures.

Please review the policy summary and the attached materials that describe the specific changes being proposed. Let us know why you support the change or oppose the change.

Submit your comments to the analyst by the due date specified. Your comments must be received by the due date to be considered for the final policy bulletin.

Thank you for participating in the consultation process.



Director, Program Policy Division  
Bureau of Medicaid Policy, Operations, and Actuarial Services

**Project Number:** 2458-Injectables    **Comments Due:** March 5, 2025    **Proposed Effective Date:** May 1, 2025

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**Policy Subject:** Physician Administered Drugs Administered for Off-Label Indications

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

**Distribution:** All Providers

**Policy 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.

Claims for off-label uses for non-protected drug classes continue to require a prior authorization.

**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.

# 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.