

BULLETIN

BEHAVIORAL AND PHYSICAL HEALTH AND AGING SERVICES ADMINISTRATION



Bulletin Number: MMP 25-12

Correction made 4/14/2025 for clarification in the first paragraph.

Distribution: All Providers

Issued: April 1, 2025

Subject: Physician Administered Drugs Administered for Off-Label Indications

Effective: May 1, 2025

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

This policy applies to Medicaid Fee-for-Service (FFS). Medicaid Health Plans (MHPs) and Integrated Care Organizations (ICOs) [or Highly Integrated Dual Special Needs Plan (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. **This policy does not apply to claims for physician administered drugs billed under the outpatient pharmacy benefit.**

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.

Manual Maintenance

Retain this bulletin until the information is incorporated into the MDHHS Medicaid Provider Manual.

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 800-292-2550. Atypical Providers may phone toll-free 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 "Meghan E. Groen". The signature is written in a cursive, flowing style.

Meghan E. Groen, Chief Deputy Director
Health Services