Pharmacy Policy

Pharmacy Drug Management Program for Pain

Line of Business: Medicare
P & T Approval Date: November 3, 2023 **Effective Date:** December 1, 2023

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and was approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Objectives:

- To carry out an effective drug management program (DMP) that addresses overutilization of frequently abused drugs while maintaining access to such drugs, as medically necessary.

Definitions:

- **Frequently Abused Drugs (FADs)** – A controlled substance that the Secretary determines, based on several factors, is frequently abused or diverted. For the purposes of this policy, opioids (except buprenorphine for medication-assisted treatment [MAT] and injectables) and benzodiazepines are FADs.
- **Potential At-Risk Beneficiary (PARB)** – A Part D beneficiary who Centers for Medicare and Medicaid Services (CMS) believes is potentially at the highest risk of opioid-related adverse events or overdose. PARBs are not exempted from DMPs, meet the clinical guidelines described at 42 CFR § 423.153(f)(16), or who were identified as a PARB by the sponsor of the beneficiary's immediately prior Part D plan under its DMP and such identification was not terminated before disenrollment.
- **At-Risk Beneficiary (ARB)** – A beneficiary who meets the clinical guidelines described at 42 CFR § 423.153(f)(16), is not exempted from DMPs, and is identified to be at-risk by their Part D plan sponsor under its DMP, or who was identified as an ARB by the sponsor of the beneficiary's immediately prior Part D plan under its DMP and such identification had not been terminated before disenrollment.
- **Overutilization Monitoring System (OMS) Criteria** – Standards used by CMS to identify PARBs and ARBs. These standards are based on a beneficiary's level of opioid use or history of an opioid-related overdose.

Policy and Procedures:

Medicare Drug Management Program (DMP)

1. **Identify Potential At-Risk Beneficiaries (PARBs) and At-Risk Beneficiaries (ARBs)**

a. Apply the minimum OMS criteria to internally identified member cases
b. Reported suspicious fraudulent activities of controlled substance
c. CMS Opioid Monitoring System (OMS): Quarterly report of PARBs identified by CMS for potential opioid overutilization
d. Internal review of Members against OMS' PARB and ARB criteria
e. The following Members are exempted from this review:
    i. Receiving treatment for active cancer-related pain
    ii. Receiving hospice care or receiving non-hospice palliative or end-of life care
    iii. Residing in a long-term care facility
    iv. Has sickle cell disease
f. Drugs considered as Frequently Abused Drugs (FADs):
    i. Opioids [except buprenorphine for medication-assisted treatment (MAT) and injectables]
    ii. Benzodiazepines: Although the OMS criteria only consider opioid use, DMP evaluates the presence of concurrent benzodiazepine use

2. **Conduct Clinical Review:**
    a. Credentials of Clinical Staff for Drug Management Program (DMP)
        i. Licensed pharmacy technicians
        ii. Licensed registered pharmacist
    b. Information gathering process:
        i. Clinical Pharmacy Program Specialists (PPS) and/or Pharmacy Coordinator (PC) conduct initial review by obtaining drug claim records
        ii. Clinical Pharmacists provide CURES reports
        iii. PPS/PC complete pain evaluation template and provide preliminary recommendation:
            • Presence of suspected drug seeking behavior (DSB), overutilization issues, and/or inadequately managed pain
            • Assess the need to discuss with Provider about implementing a beneficiary-specific point of sale edit, or restricted authorization (RA)
            • Assess the need to make referrals to Compliance (if suspected fraudulent activity identified), and/or Case Management nursing team (for additional care coordination)
        iv. PPS/PC to consult clinical pharmacist for possible exemption from case management if all of the following are met:
            • A Member was identified as potentially at-risk (PARB) or at-risk (ARB) by his or her most recent prior plan
            • Case management information from the previous sponsor is still clinically adequate and up to date
        v. Clinical Pharmacist's secondary review:
            • Review PPS/PC recommendation and summary of research
            • Make decision to contact Providers for overutilization issues, option of RA, referrals to Compliance, and/or Care Management nursing team

3. **Perform Case Management:**
    a. Provider notification:
        i. At least 3 attempts to speak to and provide written inquiries to Provider with CMS pre-approved letter template
        ii. Include in the written information the Member's actual total utilization of opioids and/or benzodiazepines
        iii. Present findings to Provider and elicit information and opinions from the Provider including:
            • Whether the Member is an exempted Member

- Whether the prescribed medications are appropriate, medically necessary, and safe for the Member's medical conditions
- Any other relevant treatment factors
- Agreement, if necessary, as to whether a limitation on the Member's access to coverage of FADs (e.g., restricted authorization) is warranted for the safety of the Member
- Discuss with Provider option of pain management referral, and/or schedule a follow-up appointment with Member

b. Providers who do not respond to Case Management:
   i. Conduct at least 3 outreach attempts to contact Provider over 10 business days

4. **Member Notification:**
   a. After completion of case management, if a Provider verifies that the Member is at- risk and agrees that the Member's access to coverage for FADs should be limited, the Member needs to be notified prior to the placement of a restricted authorization (RA).
   b. **Initial Notice:** After Provider's verification that the Member is at-risk, provide Member a written *Initial Notice* with CMS pre-approved letter template and allow a 30-day time period for the Member's response.
   c. **Second Notice:** If the Member was determined at-risk for abuse or misuse of FADs and coverage limitation was deemed necessary, PPS/PC to send a *Second Notice* (CMS pre-approved letter template) to the Member as soon as possible after the end of the Member's 30-day response period but no later than 60 days from the date of the *Initial Notice*.
   d. **Retraction Notice:** If IEHP determines the Member to be exempt from the Plan's DMP and less than 30 days has passed since the initial Notice, the Member will receive a Retraction Notice informing them of such.
   e . **Alternative Second Notice:** After providing an *Initial Notice* to a Member, if it was determined that the Member was not an at-risk Member, PPS/PC must provide an *Alternate Second Notice* (CMS pre-approved letter template) to the Member as soon as possible after the end of the Member's 30-day response period but no later than 60 days after the date of the *Initial Notice*.
   f. PPS/PC must provide a copy of the *Initial Notice* and *Second Notice* or *Alternative Second Notice* to Member's prescribers of FADs for patient treatment purpose.

5. **Implement Limitation on An ARB's Access to Coverage for FADs:**
   a. Beneficiary-specific POS Claim Edit, also known as Restricted Authorization (RA), at the highest dosage a prescriber asserts is medically necessary
   b. PPS/PC must submit coverage limitation information to MARx (see Section 7.c for details)

6. **Effective and Termination Dates and Extensions of Identification as an ARB**
   a. Effective date of a coverage limitation implemented is the date of the *Second Notice*
   b. Termination date is the earliest date of the following:
      i. The date the Member demonstrates that he or she is no longer likely to be at risk for abuse or misuse of FADs without the limitation through a subsequent determination, including but not limited to, a successful appeal; or
      ii. The date that is the end of:
         - The 1-year period calculated from the effective date of the limitation, unless the limitation is extended, or
         - The date that is the end of a 2-year period calculated from the effective date of limitation, if the limitation was extended
   c. To extend a coverage limitation, PPS/PC/RPH must do the following:
      i. Determine at the end of the 1-year limitation period that there is a clinical basis to

extend the limitation

ii. Assessment includes a review of claims records, CURES and any relevant information provided by pharmacy and/or Provider

iii. Obtain the agreement of a Provider of FADs for the ARB that the limitation should be extended, except the following:

- If no Provider was responsive after 3 attempts within 10 business days, provide another Second Notice to ARB

7. **Data Disclosure and Submission**
   a. Data received from OMS and MARx
      i. OMS provides a list of identified PARB on a quarterly basis
      ii. MARx provides PARB/ARBs identified by previous sponsor plans through DTRR
   b. Data to be submitted to CMS
      i. Submit CMS case management status for each PARB identified through OMS within 30 days of receiving an OMS report
      ii. Submit CMS case management status for each PARB identified through SPI within 30 days from the date of the most recent OMS report
      iii. Submit CMS case management status for each PARB/ARB identified through the transaction reply code of TRC 376 from DTRR within 30 days from the date of the most recent OMS report
   c. Data to be submitted to Marx
      i. Must submit coverage limitation information to MARx as soon as possible but no later than 7 days from the:
         - Date of the Initial Notice to a PARB: Notification start-date
         - Date of the Second Notice to an ARB: Implementation start-date (i.e., effective date)
         - Date that the sponsor terminates a PARB status or an ARB's coverage limitation for the FADs before the original termination date: Notification end-date or implementation end-date
   d. PPS/PC report to Compliance when:
      i. Fraudulent activities are involved
      ii. RA is determined necessary
   e. Information Transfer to another Health Plan Sponsor
      i. Provide case management information to the gaining health plan sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request

8. **Case Management Documentation**
   a. Paid claims record and summary
   b. CURES report
   c. Pain evaluation summary
   d. Documentation of communications with Providers and pharmacies, number of attempts, results of communication, date of written inquiries sent to Providers, Compliance notification, date of RA implementation, date of Member letter sent, and date of Case Management (CM) referral
   e. Copy of written inquiries or notifications sent to Providers or Pharmacies
   f. Copy of letters sent to Member

9. **Care Management/Behavioral Health Nursing Team Referral**
   a. PPS/PC to submit a request to CM team when Providers agree that Member will benefit from specialist referral

References:

1. Part D Drug Management Program Policy Guidance. November 20, 2018. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf
2. HPMS Memo, "Correction - Contract Year 2023 Part D Drug Management Program Guidance," April 20, 2023. Section 11.2
3. HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022. Available at: https://www.cms.gov/files/document/2023partddmpguidance11282022g.pdf

Change Control		
Date	**Change**	**Author**
10/10/2023	• Aligned purpose with IEHP Provider Manual Policy MA 11_O and retired background • Updated the Member Communication section to align with IEHP Provider Manual policy MA_11O • Updated to reflect the latest internal OMS review process	SV
10/5/2022	• Updated background to include 2022 CMS requirement for all Part D sponsor to have a DMP • Added references from CMS • Updated P&T Approval Date and Effective Date	YA
11/22/2021	• Added new minimum OMS criteria: History of opioid-related overdose	VM
10/30/2021	• Updated to Medicare-specific policy only • Removed policy specific to Medi-caid for Medi-Cal Rx Transition	TL
04/16/2021	• Renew with no changes	JM
11/20/2019	• Added references from Centers for Medicare and Medicaid Services • Identify PARBs and ARBs: added reports of suspicious of fraudulent activities of controlled substances • Provider education applies to prescriber and/or dispensing pharmacy provider • Revised verbiage that fraud, waste and abuse are reported to IEHP compliance team • Added internal Proactive DSB report process for Medi-Cal • Removed RPH review for Medi-Cal • Added initial notice requirement for both members and providers prior to placing RA for Medi-Cal • Added expiration date of 12 months from RA placement date for Medi-Cal • Added pharmacy lock-in detail in case management documentation for Medi-Cal	HC/CN/ND
08/21/2019	• Revised member identification method according to OMS criteria for both LOBs • Removed SPI/ER reports	ND
02/20/2019	• Revised policy to adopt the "Part D Drug Management Program Policy Guidance" published by the CMS on November 20, 2018	HC/ND
07/30/2018	• Updated Goals section: June 29, 2012 HPMS Memo expects that there is documentation of the opioid overutilization program in written policies and procedures that are periodically reviewed, updated as necessary, and approved by the plan's P&T committee	IK
07/02/2018	• Changed Format	IK