Pharmacy Policy

Pharmacy Drug Management Program for Pain

Line of Business: Medicare
P & T Approval Date: December 21, 2021 **Effective Date:** January 1, 2022

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:

- Proactively manage members on multiple narcotic medications to prevent overutilization, identify unsafe and inappropriate opioid use, and address potential fraud/waste/abuse
- Comply with the Centers for Medicare and Medicaid Services (CMS) drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of frequently abused drugs

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Background:

- The Centers for Medicare and Medicaid Services (CMS), with the administration of the controlled substance overutilization monitoring system (OMS) for the Medicare Part D program, requires plan sponsors to implement a reasonable and appropriate drug utilization review (DUR) program to assist in the prevention of controlled substances overutilization.
- Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management program (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). The memorandum published by CMS on November 20, 2018, "Part D Drug Management Program Policy Guidance," provides comprehensive policy guidance for the framework and implementation of DMPs.
- By adapting and endorsing CMS guidance, this policy describes IEHP's implementation of DMP, including methodology of clinical case management, documentation, data sharing between plans and written notifications to prescribers and members as part of clinical case management.

Definitions:

PARB1	Potential at-risk beneficiary who meets the OMS criteria and is identified by CMS or health plan
PARB2	Potential at-risk beneficiary whom a new plan sponsor receives notice upon the beneficiary's enrollment through the MARx system that the beneficiary was identified as potentially at-risk by the immediately prior plan sponsor under its DMP, but a coverage limitation on FADs had not yet been complemented by the prior plan before the beneficiary disenrolled

ARB1	At-risk beneficiary who meets the OMS criteria, is not exempted from DMP, an dis identified to be at-risk by Part D plan sponsor under DMP, or who was identified as an ARB by the beneficiary's prior Part D plan under its DMP and such identification had not been terminated before disenrollment
ARB2	At-risk beneficiary whom a new plan sponsor receives notice upon the beneficiary's enrollment through MARx that the beneficiary was identified as at-risk by the immediately prior plan sponsor under its DMP and a coverage limitation on FADs had been implemented by the prior plan before the beneficiary disenrolled

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Policy and Procedures:

I. **<u>Medicare Drug Management Program (DMP)</u>**

1. **Identify Potential At-Risk Beneficiaries (PARBs) and At-Risk Beneficiaries (ARBs)**
   a. Apply the minimum OMS criteria to internally identified member cases (see below OMS criteria):
      - Morphine Milligram Equivalent (MME) > 90mg for any duration during the most recent 6 months and utilizing either of the following for narcotic medications:
        - More than 3 prescribers and more than 3 pharmacies; OR
        - More than 5 prescribers

   b. Report of suspicious fraudulent activities of controlled substance
   c. CMS Opioid Monitoring System (OMS): Quarterly report of PARBs identified by CMS for potential opioid overutilization
   d. Prior Sponsor Health Plan Identified PARB2 or ARB2: Transaction Reply Code of TRC 376 (New Enrollee CARA Status Notification) from the Daily Transaction Reply Report (DTRR) when PARB2/ARB2 is enrolled to IEHP
   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
   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 – Clinical Pharmacy Program Specialist (PPS), Pharmacy Coordinator (PC)
      ii. Licensed registered pharmacist– Clinical Pharmacist (RPH)
   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 (PARB2) or at-risk (ARB2) 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. Provider education when deemed necessary for prescriber and/or dispensing pharmacy provider:
      i. Epidemic of opioid overutilization crisis
      ii. CDC Guideline for Prescribing Opioids for Chronic Pain
      iii. Physician role in DMPs in reducing overutilization of FADs
      iv. Encouragement of prescribers to perform, or refer their patient for, a comprehensive substance abuse disorder screening and/or assessment, and if indicated, refer their patient for follow-up treatment with a pain specialist or addiction treatment provider
      v. Importance of routine CUREs review
   c. 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. 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. 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. 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*.
    e. PPS/PC may forgo providing the *Initial Notice* and may immediately provide a *Second Notice* to an ARB2 identified by previous sponsor, if the case management decision is to implement an RA that is the same as the one that was implemented by the previous sponsor.
    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 (i.e., RA) 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. In order 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. State Guidance for Implementation of Medicaid Drug Utilization Review (DUR) Provisions included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271). August 5, 2019. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf

Change Control		
Date	**Change**	**Author**
12/13/2021	• Updated P&T Approval Date and Effective Date	JM
10/30/2021	• Updated to Medicare-specific policy only • Removed policy specific to Medicaid for Medi-cal Rx Transition	TM
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	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	IK
07/02/2018	• Changed Format	IK