Policy:	MA.6104
Title:	**Opioid Medication Utilization Management**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 10/31/2024*
Effective Date:	01/01/2006
Revised Date:	10/01/2024
Applicable to:	☐ Medi-Cal ☒ OneCare ☒ PACE ☐ Administrative

I. PURPOSE

This policy outlines the process by which CalOptima Health identifies and minimizes potential Opioid Medication Overutilization among OneCare and PACE Members.

II. POLICY

A. CalOptima Health shall maintain reasonable and appropriate drug Utilization Management programs that assist in preventing prescribed Medication Overutilization, and to reduce Fraud, Waste, and Abuse in the Part D Drug program.

B. CalOptima Health's Opioid Medication Overutilization programs shall comply with existing Coverage Determination, Appeal, and Grievance rules, as set forth at Title 42, Code of Federal Regulations (CFR), Part 423 Subpart M, and Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

C. CalOptima Health shall ensure its Drug Management Program complies with applicable statutory and regulatory requirements, including 42 CFR § 423.153(f), and applicable guidance issued by the Centers for Medicare & Medicaid Services (CMS).

D. CalOptima Health shall utilize claim reporting methodology and drug utilization review (DUR) to identify potential Opioid Medication Overutilizers based on drug claims data through clinical thresholds and prescription patterns approved by the Pharmacy & Therapeutics (P&T) Committee. This methodology excludes, as early as possible, those Members who have legitimate clinical diagnoses that may warrant high Opioid use such as cancer patients, or others who need Palliative Care.

E. An edit pursuant to CalOptima Health's Opioid Medication Overutilization programs may override a Member's previously approved Coverage Determination Exception request, if the review conducted resulted in a determination that the previously approved dose is not Medically Necessary, appropriate, or safe for the Member.

F. If a Member, prescriber, and/or Pharmacy is involved in suspected fraudulent activity, CalOptima Health shall make referrals to the appropriate agencies, in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual and CalOptima Health Policy HH.1105: Fraud, Waste, and Abuse Detection.

G. CalOptima Health shall train customer service representatives (CSRs), staff handling Coverage Determinations, and Opioid case management staff, as appropriate, to ensure they are aware of each other's role in CalOptima Health's Opioid Medication Overutilization program.

H. CalOptima Health shall enter information into the Medicare Advantage and Prescription Drug System (MARx) in accordance with guidelines specified by CMS.

I. CalOptima Health shall ensure that all drug Utilization Management techniques are medically appropriate, and that Members are given appropriate access to Medically Necessary drugs in a timely manner, as set forth in CalOptima Health Policies MA.6101: Medicare Part D Coverage Determinations, and MA.6114: Medicare Part D Redeterminations.

J. CalOptima Health shall provide Member education regarding the risks of prolonged opioid use and alternatives for pain control in accordance with CMS requirements.

III. PROCEDURE

A. Point-of-Sale (POS) Pharmacy DUR Edits

1. CalOptima Health shall implement Opioid morphine milligram equivalent (MME) cumulative dosing POS Pharmacy edits such that:

   a. Pharmacy claims for Opioid class medications which exceed a cumulative MME threshold of ninety (90) milligrams (mg) with a prescriber count of at least two (2) prescribers will trigger a soft rejection for Opioid care coordination that may be overridden at the Pharmacy level when the pharmacist submits appropriate NCPDP codes indicating that the prescriber of the prescription triggering the edit and any other prescriber(s) the pharmacist deems clinically appropriate have been consulted.

      i. The pharmacist may only use the appropriate override code after completing the consultation with the prescriber(s) that includes the prescribers' confirmed intent and documenting the discussion.

      ii. CalOptima Health's Pharmacy Benefits Manager may audit the pharmacies' documentation of the care coordination activities described in Section III.A.1.a.i of this policy.

   b. Pharmacy claims for Opioid class medications which exceed a cumulative MME threshold of two hundred (200) mg will trigger a hard rejection for OneCare only. Hard rejections may only be overridden by a favorable Coverage Determination decision made by CalOptima Health, as set forth in CalOptima Health Policy MA.6101: Medicare Part D Coverage Determinations.

   c. Members residing in a long-term care facility, in hospice care, receiving palliative or end-of-life care, with sickle cell disease, or being treated for cancer-related pain are exempt from these POS edits.

2. CalOptima Health shall implement POS Pharmacy edits for OneCare such that Pharmacy claims for Opioid class medications which are attempted to be filled when there is a fill for buprenorphine-containing products within the previous thirty (30) calendar days will trigger a soft rejection that may be overridden at the Pharmacy level when the pharmacist submits appropriate NCPDP codes upon review of drug therapy.

3. CalOptima Health shall implement a hard safety edit to limit initial Opioid prescription fills to no more than a seven (7)-day supply.

    a. New starts shall be determined with a one hundred twenty (120) day lookback to determine ongoing drug therapy.

    b. Buprenorphine products are excluded from this edit.

    c. Members residing in a long-term care facility, in hospice care, or receiving palliative or end-of-life care, with sickle cell disease, or being treated for cancer-related pain are exempt from this POS edit.

4. CalOptima Health shall implement a concurrent Opioid and Benzodiazepine soft POS safety edit that may be overridden at the Pharmacy level when the pharmacist submits appropriate NCPDP codes upon review of drug therapy.

5. CalOptima Health shall implement a soft POS edit for duplicative long-acting Opioid therapy (excluding buprenorphine) with a prescriber count of at least two (2) prescribers that may be overridden at the Pharmacy level when the pharmacist submits appropriate NCPDP codes upon review of drug therapy.

B. Retrospective Identification of Opioid Medication Overutilization and Drug Management Program

1. On a monthly basis, CalOptima Health's Pharmacy Management Department shall review medication profiles to identify Opioid Medication Overutilization.

    a. Clinical case management will be performed by CalOptima Health clinical pharmacists. Staff must have a current and unrestricted pharmacist license.

2. Member risk definitions

    a. Clinical guidelines and CMS Overutilization Monitoring System (OMS) Criteria will be used to identify Potential At-Risk Beneficiaries (PARBs) based on opioid use.

    b. At-Risk Beneficiaries (ARBs) are identified from the PARB based on information obtained during case management and are subject to coverage limitations for Frequently Abused Drugs.

3. CalOptima Health's Pharmacy Management Department shall identify Potential At-Risk Members through the following OMS criteria:

    a. Level of opioid use from multiple prescribers/pharmacies:

        i. A look back period of the previous six (6) months; and

        ii. Member prescription(s) exceeded or equal to an average daily morphine milligram equivalent (MME) of ninety (90) milligrams (mg) for any duration; and

a) Filled prescriptions written by three (3) or more Opioid prescribers and filled at three (3) or more Opioid dispensing pharmacies; or

b) Filled prescriptions written by five (5) or more Opioid prescribers, regardless of the number of Opioid dispensing pharmacies.

b. History of opioid-related overdose

i. A medical claim with a primary diagnosis of opioid-related overdose within the most recent twelve (12) months; and

ii. A Part D opioid prescription (not including medication-assisted treatment) within the most recent six (6) months.

4. Members excluded from Opioid Medication Overutilization reports used to identify PARBs shall include:

a. Members being treated for cancer-related pain;

b. Members receiving hospice, palliative, or end-of-life care;

c. Members residing in a long-term care facility, a facility described in section 1905(d) of the Act, or another facility for which Frequently Abused Drugs are dispensed for residents through a contract with a single Pharmacy.

d. Members with sickle cell disease.

5. For PARBs, the Pharmacy Management Department shall also identify concurrent use of non-opioid Frequently Abused Drugs.

6. The Pharmacy Management Department shall evaluate data and determine an appropriate intervention strategy based on criteria developed by CMS, the P&T Committee, and the unique characteristics of the specific Opioid Medication Overutilization issue. Intervention strategies may include, but are not limited to:

a. Written notification to a PARB's relevant Opioid prescriber(s) regarding Overutilization of Frequently Abused Drugs by the PARB with recommendations to optimize the medication regimen;

b. Case-specific direct prescriber contact by the Pharmacy Management Department; or

c. Referral of the prescriber to CalOptima Health's Quality Improvement Department due to non-responsiveness.

7. For PARBs, CalOptima Health shall maintain case files, and shall furnish these case files to CMS when a complaint is made. The case files, at minimum, shall consist of the following contents:

a. The clinical threshold and/or prescription pattern triggering the review;

b. The PARB's medication history;

c. Documentation of written communication with the prescriber(s), PARB, and, if applicable, Pharmacy(ies);

d. Documentation of verbal communication with the prescriber(s), PARB, and if applicable, Pharmacy(ies);

e. Documentation and description of the results of communication with the prescriber(s), PARB, and, if applicable, Pharmacy(ies); and

f. Documentation and description of actions taken by CalOptima Health, such as beneficiary-level Opioid POS claim edits or Quality Improvement (QI) referrals for prescribers.

8. CalOptima Health shall determine that a PARB is an ARB and implement a one-year coverage limitation on that Member's access to Frequently Abused Drugs when the following conditions are met:

   a. Reasonable efforts have been made to contact the prescriber(s), such that:

      i. At least one (1) written inquiry to the prescriber(s) has been made;

      ii. At least three (3) attempts to reach the prescriber(s) have been made by telephone; and

      iii. At least ten (10) business days has been allotted for the prescriber(s) to reply.

   b. Clinician-to-clinician communication includes information about the existence of multiple prescribers and the PARB's total Opioid utilization and elicits information about any factors in the PARB's treatment that are relevant to an At-Risk determination, including whether the prescribed medication is appropriate for the Member's medical conditions, or the Member is an exempted beneficiary, as defined in 42 CFR § 423.100.

   c. A consensus is reached by the prescriber(s) that there is an Opioid Medication Overutilization concern and to implement a coverage limitation, or the prescriber(s) is unresponsive or unwilling to manage the PARB's Opioid Medication Overutilization. Agreement is obtained from at least one (1) prescriber of the PARB's Frequently Abused Drugs (FADs) that a coverage limitation is appropriate, except:

      i. A prescriber agreement is not required for a Pharmacy Lock-in.

      ii. If a prescriber does not respond after three (3) attempts by the sponsor to contact them within ten (10) business days, then CalOptima Health has demonstrated that the prescriber is not responsive and may proceed with a Member-specific POS edit.

      iii. A Prescriber Lock-in may not be implemented if no prescriber was responsive.

   d. Written notices have been provided to the Member:

      i. Initial Notice. Written notice of Potential At-Risk identification and the proposed coverage limitation is issued to the prescriber(s) and PARB at least thirty (30) calendar days in advance of implementing a coverage limitation. The notice shall comply with the applicable requirements of 42 CFR § 153(f)(5), and must include, if applicable, limitation on the availability of the special enrollment period described in 42 CFR § 423.38. CalOptima Health shall use the Initial Notice Letter, set forth in Attachment A, to provide such notice.

ii. Second Notice. Written notice of At-Risk determination and implementation of coverage limitation is issued to the Member, prescriber(s), and Pharmacy(ies), if applicable, for Pharmacy Lock-in, with effective and end dates, upon implementation, and no later than sixty (60) calendar days after the date of Initial Notice of the proposed coverage limitation. The notice shall comply with the applicable requirements of 42 CFR § 423.153(f)(6), and must include, if applicable, any limitation on the availability of the special enrollment period described in 42 CFR § 423.38. CalOptima Health shall use the Second Notice Letter, set forth in Attachment B, to provide such notice.

9. If, after providing the Initial Notice, case management findings determine that PARB is an exempted beneficiary, the Member and prescriber(s) will be notified within three (3) calendar days of determining the Member is exempt. The notice shall comply with the applicable requirements of 42 CFR § 423.153(f)(8), and must include, if applicable, that the limitation on the special enrollment period no longer applies. CalOptima Health shall use the Alternate Second Notice Letter, set forth in Attachment C, to provide such notice.

10. If, after providing the Initial Notice, case management findings determine that PARB is not an ARB and no coverage limitation is warranted, the Member and prescriber(s) will be notified after thirty (30) calendar days from the date of the Initial Notice but no later than sixty (60) calendar days from the date of the Initial Notice. The notice shall comply with the applicable requirements of 42 CFR § 423.153(f)(7), and must include, if applicable, that the limitation on the special enrollment period no longer applies. CalOptima Health shall use the Alternate Second Notice Letter, set forth in Attachment C, to provide such notice.

11. If CalOptima Health implements a POS claim edit per Section 423.153(f)(3)(i), CalOptima Health shall not cover FADs for the Member in excess of the edit, unless the edit is terminated or revised based on a subsequent determination (including a successful Appeal).

12. If CalOptima Health implements a Prescriber Lock-in or a Pharmacy Lock-in for a Member, CalOptima Health shall cover FADs for the Member only when they are obtained from the selected Pharmacy(ies) or prescriber(s) or both, as applicable:

    a. In accordance with all other coverage requirements of the prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination (including a successful Appeal); and

    b. Except as necessary to provide reasonable access in accordance with Section 423.153(f)(12).

    c. The ARB's Pharmacy/prescriber preferences (as long as in-network) shall be accepted unless CalOptima Health determines that the selection would contribute to drug abuse or diversion.

        i. If a Member submits preferences for prescribers and/or pharmacies, CalOptima Health will inform the Member of the selection or change in selection in:

            a) The Second Notice; or

            b) If the Second Notice is not feasible due to the timing of the Member's submission, in a subsequent written notice, issued no later than fourteen (14) days after receipt of the submission.

ii. In the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.

iii. In the case of a Pharmacy that has multiple locations that share real-time electronic data, all such locations of the Pharmacy shall collectively be treated as one Pharmacy.

iv. CalOptima Health shall notify the prescriber or Pharmacy, as applicable, that the Member has been identified for inclusion in the DMP and that the prescriber or Pharmacy or both is (are) being selected as the Member's designated prescriber or Pharmacy or both for FADs. For prescribers, this notification occurs during case management or when the prescriber provides agreement that the specific limitation is appropriate for the Member. CalOptima Health shall then receive and retain in case files confirmation from the prescriber(s) or Pharmacy(ies) or both, as applicable, that the selection is accepted before conveying this information to the Member.

v. If CalOptima Health determines that the Member's selection would contribute to drug abuse or diversion, written notice of change of selected Pharmacy or prescriber for lock-in with rationale shall be issued to the ARB at least thirty (30) calendar days before changing the selections.

13. If an ARB appeals an At-Risk determination within sixty (60) days of the date of the Second Notice, CalOptima Health shall review the appeal subject to the existing Part D appeals process and timelines, in accordance with CalOptima Health Policy MA.6114: Medicare Part D Redeterminations and 42 CFR § 423.562.

    a. If CalOptima Health upholds its At-Risk determination on appeal, CalOptima Health shall automatically forward the case to the Independent Review Entity (IRE) for review, pursuant to 42 CFR § 423.590(i).

14. CalOptima Health may extend a coverage limitation regarding an ARB for one (1) additional year after the first year limitation subject to the following requirements:

    a. CalOptima Health determines at the end of the first year of limitation that there is a clinical basis to extend the limitation;

    b. CalOptima Health obtains the agreement of a prescriber of FADs for the ARB that the limitation should be extended, except that:

        i. A prescriber agreement is not required to extend a Pharmacy Lock-in.

        ii. If no prescriber was responsive after three (3) attempts by CalOptima Health to contact the prescribers within the (10) business days, a prescriber's agreement is not necessary to extend a beneficiary-specific POS edit.

        iii. A Prescriber Lock-in may not be extended if no prescriber was responsive.

    c. CalOptima Health provides another written Second Notice to the ARB in compliance with 42 CFR § 423.153(f)(6).

15. If CalOptima Health subsequently intends to make a change to the terms of an ongoing limitation(s), including the intention to impose an additional limitation on the ARB, CalOptima Health must comply with Section 423.153(f)(3) and the applicable requirements for Member notices in Section 423.153(f)(5) to (8).

16. The identification of an ARB shall terminate as of the earlier of the following:

    a. The date the Member demonstrates through subsequent determination (including but not limited to a successful Appeal) that the Member is no longer likely to be At-Risk in the absence of the limitation; or

    b. The date that is the end of:

        i. The one (1) year period calculated from the effective date of the limitation (as specified in the Second Notice), unless the limitation was extended; or

        ii. The two (2) year period calculated from the effective date of the limitation (as specified in the Second Notice) if the limitation was extended.

17. CalOptima Health shall address Members who meet the definition of ARB or PARB and enroll or disenroll from the plan.

    a. CalOptima Health shall monitor reports and notifications of incoming enrollees who meet the definition of an ARB or a PARB.

        i. CalOptima Health Pharmacy Management will be notified of such new enrollees by Customer Service.

    b. CalOptima Health shall respond to requests from other sponsors for information about ARBs and PARBs who recently disenrolled from CalOptima Health's prescription drug benefit plan.

    c. If a Member is identified as a PARB or an ARB by his or her most recent prior Part D plan and such identification has not been terminated, CalOptima Health is not required to engage in case management, so long as CalOptima Health obtains case management information from the previous sponsor and such information is still clinically adequate and up to date.

    d. CalOptima Health may forego providing the Initial Notice and may immediately provide a Second Notice to an ARB if CalOptima Health is the gaining plan sponsor and is implementing either:

        i. A beneficiary-specific POS claim edit, if the edit is the same one that was implemented in the immediately prior plan.

        ii. A limitation on access to coverage, if the limitation would require the Member to obtain FADs from the same location of Pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan.

18. CalOptima Health shall enter information about all Member-level Opioid POS claims edits or coverage limitations into the Medicare Advantage and Prescription Drug System (MARx) for affected ARBs:

    a. Within seven (7) calendar days of the date on the Initial Notice of Potential At-Risk status;

    b. Within seven (7) calendar days of the date on the ARB's Second Notice when a decision is made to implement a Member-level Opioid POS claim edit or limitation on access to coverage for FADs; and

c. Within seven (7) calendar days of the event of implementation, termination, and modification of Member-level Opioid POS claim edits or limitation on access to coverage for FADs.

19. CalOptima Health shall include ARBs in its Medication Therapy Management program for OneCare and OneCare Connect.

20. CalOptima Health's Drug Management Program communication materials may include, but are not limited to:

    a. Initial Notice Letter (Attachment A): Initial Notice to the Member that the Member has been identified as a PARB, the Member's high Opioid use is being reviewed as a health care safety issue, and coverage limitation has been proposed.

    b. Initial Prescriber Inquiry Letter: Written inquiry to a prescriber of the Opioid medication(s) about the appropriateness, Medical Necessity, and safety of the identified high dosage.

    c. Second Notice Letter (Attachment B): A notice that would be issued to the ARB and the prescriber(s) informing about Appeal rights that:

        i. The Member is considered an ARB and a coverage limitation shall be implemented on Opioid and/or Benzodiazepine medications, which may include:

            a) Member-level FAD POS claim edit, which allows coverage of none, or only a certain amount of FAD prescriptions; and/or

            b) Pharmacy Lock-in; and/or

            c) Prescriber Lock-in; or

        ii. An ongoing coverage limitation has had a change in terms in response to an ARB's appeal request.

    d. Alternate Second Notice Letter (Attachment C): A notice that would be issued to the PARB and the prescriber(s) informing them that the Member is not considered an ARB and no coverage limitation will be implemented.

C. Reporting

1. CalOptima Health shall disclose any data and information to CMS and other Part D sponsors that CMS deems necessary to oversee the Part D DMP at a time, and in a form and manner specified by CMS, including:

    a. Provide information to CMS within thirty (30) days of receiving OMS report about a PARB.

    b. Provide information to CMS about any PARB that CalOptima Health identifies within 30 days from the date of the most recent CMS report identifying PARBs.

    c. Transfer case management information using the DMP Sponsor Information Transfer Memorandum (Attachment E) upon request of a gaining sponsor as soon as possible but not later than two (2) weeks from the gaining sponsor's request when:

i. An At-Risk or PARB disenrolls from CalOptima Health's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and

ii. The edit or limitation that CalOptima Health implemented for the beneficiary had not terminated before disenrollment.

2. CalOptima Health Pharmacy Management Department shall report information concerning the Opioid Medication Overutilization management program internally to the P&T Committee.

3. CalOptima Health is responsible for reporting certain data elements relating to Members with either a soft and/or hard formulary-level cumulative MME POS edit, as described in the annual Medicare Part D Reporting Requirements document.

IV. ATTACHMENT(S)

A. Initial Notice Letter – Notice of Intent to Limit Access to Certain Part D Drugs
B. Second Notice Letter – Your Access to Certain Part D Drugs is Limited
C. Alternate Second Notice Letter
D. CMS Form Instructions for Drug Management Program Notices
E. Drug Management Program Sponsor Information Transfer Memorandum

V. REFERENCE(S)

A. Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits, CMS Letter: October 23, 2018.
B. Applications from Medicare Advantage Prescription Drug Plans (MA-PD) Sponsors
C. CalOptima Health Policy MA.6101: Medicare Part D Coverage Determination
D. CalOptima Health Policy MA.6114: Medicare Part D Redeterminations
E. CalOptima Health Policy HH.1105: Fraud, Waste, and Abuse Detection
F. Contract Year 2019 Part D Drug Management Program Guidance, CMS Letter: November 20, 2018
G. Contract Year 2021 Part D Drug Management Program Guidance, CMS Letter: December 23, 2020
H. Contract Year 2023 Part D Drug Management Program Guidance, CMS Letter: (Correction Update - April 20, 2023).
I. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance: Effective July 19, 2024
J. Improving Drug Utilization Review Controls in Part D, CY 2019 Final Call Letter: April 2, 2018
K. Improving Drug Utilization Review Controls in Part D, CY 2020 Final Call Letter: April 1, 2019
L. Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Final Rule. January 19, 2021.
M. Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs), CMS Letter: December 19, 2022
N. Medicare Prescription Drug Benefit Manual, Chapter 9: Revised January 11, 2013
O. Title 42, Code of Federal Regulations (CFR), Part 423, Subpart M
P. Title 42, Code of Federal Regulations (CFR), §423.100, 423.128, 423.153, 423.562
Q. CMS-10141 – Supporting Statement Part A: Part D Drug Management Program. CMS-10874, OMB 0938-1465
R. Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits, July 5, 2024
S. Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy

and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Final Rule. April 23, 2024

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD APPROVAL(S)

Date	Meeting
05/07/2020	Regular Meeting of the CalOptima Board of Directors
12/20/2021	Special Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	01/01/2006	MA.6104	Medication Utilization Management	OneCare
Revised	03/01/2007	MA.6104	Medication Utilization Management	OneCare
Revised	10/01/2012	MA.6104	Controlled Substance Medication Utilization Management	OneCare
Revised	06/01/2015	MA.6104	Controlled Substance Medication Utilization Management	OneCare OneCare Connect
Revised	11/01/2016	MA.6104	Opioid Medication Utilization Management	OneCare OneCare Connect
Revised	11/01/2017	MA.6104	Opioid Medication Utilization Management	OneCare OneCare Connect
Revised	05/07/2020	MA.6104	Opioid Medication Utilization Management	OneCare OneCare Connect PACE
Revised	12/20/2021	MA.6104	Opioid Medication Utilization Management	OneCare OneCare Connect PACE
Revised	12/31/2022	MA.6104	Opioid Medication Utilization Management	OneCare PACE
Revised	07/01/2023	MA.6104	Opioid Medication Utilization Management	OneCare PACE
Revised	10/01/2024	MA.6104	Opioid Medication Utilization Management	OneCare PACE

IX. GLOSSARY

Term	Definition
Abuse	A Provider practice that is inconsistent with sound fiscal, business, or medical practice, and results in an unnecessary cost to CalOptima Health and the OneCare program, or in reimbursement for services that are not Medically Necessary or that fail to meet professionally recognized standards for health care. It also includes Member practices that result in unnecessary cost to CalOptima Health and the OneCare program.
Alternate Second Notice	Written communication to a Member if CalOptima Health determines that a Member is not at-risk and states that CalOptima Health will not limit their access to FADs under the DMP and that the limitation on the special enrollment period (SEP) no longer applies.
Appeal	OneCare: As defined at 42 CFR §422.561 and §423.560, the procedures that deal with the review of adverse initial determinations made by the plan on health care services or benefits under Part C or D the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for, or approving the health care services or drug coverage (when a delay would adversely affect the health of the enrollee) or on any amounts the enrollee must pay for a service or drug as defined in 42 CFR §422.566(b) and §423.566(b). These appeal procedures include a plan reconsideration or redetermination (also referred to as a level 1 appeal), a reconsideration by an independent review entity (IRE), adjudication by an Administrative Law Judge (ALJ) or attorney adjudicator, review by the Medicare Appeals Council (Council), and judicial review. PACE: A Member's action taken with respect to the PACE organization's noncoverage of, modification of, or nonpayment for, a service including denials, reductions or termination of services, as defined by federal PACE regulation 42 CFR Section 460.122.
At-Risk Beneficiary (ARB)	A Part D eligible individual: (1) who is identified using clinical guidelines, who is not an exempted beneficiary, and is determined to be at-risk for misuse or abuse of frequently abused drugs such as Opioid medications under CalOptima Health's drug management program; or (2) with respect to whom CalOptima Health receives a notice upon the Member's enrollment that the Member was identified as an at-risk beneficiary under the Part D plan in which the Member was most recently enrolled and such identification had not been terminated upon disenrollment.
Coverage Determination	Any decision made by CalOptima Health regarding: 1. Receipt of, or payment for, a prescription drug that a Member believes may be covered; 2. A tiering or Formulary Exception request; 3. The amount that the plan sponsor requires a Member to pay for a Part D prescription drug and the Member disagrees with the plan sponsor; 4. A limit on the quantity (or dose) of a requested drug and the Member disagrees with the requirement or dosage limitation; 5. A requirement that a Member try another drug before the plan sponsor will pay for the requested drug and the Member disagrees with the requirement; and 6. A decision whether a Member has, or has not, satisfied a Prior Authorization or other Utilization Management requirement.

Term	Definition
Drug Management Program (DMP)	Program to address Members at-risk for misuse or abuse of Frequently Abused Drugs (FADs).
Exempted Beneficiaries	A Member who: (1) has elected to receive hospice care or is receiving palliative or end-of-life care; (2) is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single Pharmacy; (3) is being treated for cancer-related pain; or (4) has a diagnosis of sickle-cell disease.
Fraud	An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law, in accordance with Title 42 Code of Federal Regulations section 455.2, Welfare and Institutions Code section 14043.1(i).
Frequently Abused Drugs (FADs)	A controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors: (1) The drug's schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused. (3) An analysis of Medicare or other drug utilization or scientific data. These drugs are determined by CMS annually.
Grievance	OneCare: An expression of dissatisfaction with any aspect of the operations, activities or behavior of a plan or its delegated entity in the provision of health care items, services, or prescription drugs, regardless of whether remedial action is requested or can be taken. A grievance does not include, and is distinct from, a dispute of the appeal of an organization determination or coverage determination or an LEP determination. PACE: A complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished, as defined by the federal PACE regulation 42 CFR Section 460.120.
Initial Notice	Written communication to a Potential At-Risk Member (PARB) that notifies them that they have been identified as potentially at-risk for misuse or abuse of FADs, and that CalOptima Health intends to limit their access to FADs under its DMP, describes the specific coverage limitation(s) and decision timeframe, explains how the Member or their prescriber can provide additional information if they do not agree with the intended action, explains Appeal rights, and informs the Member of the limitation on the availability of the special enrollment period (SEP).
Medically Necessary	OneCare: The services, supplies, or drugs that are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice. PACE: Necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness, or injury.

Term	Definition
Medication Overutilization	Any medication when used; 1. In excessive dose, including duplicate therapy; 2. For an excessive duration; 3. Without adequate monitoring; 4. Without adequate indications for its use; 5. In the presence of adverse consequences indicating a reduction in dose, or a discontinuation of the medication; or 6. Any combinations of the reasons above.
Member	A beneficiary enrolled in a CalOptima Health program.
Overutilization Monitoring System (OMS) Criteria	Criteria determined by CMS annually to identify Part D beneficiaries whom CMS believes are at the highest risk of adverse events or overdose due to their level of opioid use and/or obtaining them from multiple prescribers/pharmacies.
Opioid drug	For the purposes of this policy, means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.
Palliative Care	Patient- and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering.
Part D Program	Medicare's prescription drug benefit program.
Pharmacy	An area, place, or premise licensed by the State Board of Pharmacy in which the profession of pharmacy is practiced and where Prescriptions are compounded and dispensed.
Pharmacy & Therapeutics (P&T) Committee	A committee, the majority of whose Members shall consist of individuals who are practicing physicians or practicing pharmacists (or both), that is charged with developing and reviewing a formulary. Such committee shall include at least one practicing physician and at least one (1) practicing pharmacist, each of whom is independent and free of conflict with respect to the Sponsor and at least one practicing physician and at least one practicing pharmacist who have expertise in the care of elderly or disabled persons. (See Title 42 C.F.R. § 423.120(b)(1)).
Pharmacy Lock-in	Coverage limitation which limits access to coverage for FADs to selected pharmacies
Potential At-Risk Beneficiary (PARB)	A Part D eligible individual: (1) who is identified using clinical guidelines for potential overutilization of frequently abused drugs such as Opioid medications under CalOptima Health's Drug Management Program; or (2) with respect to whom CalOptima Health receives a notice upon the Member's enrollment that the Member was identified as a potential at-risk beneficiary under the Part D plan in which the Member was most recently enrolled and such identification had not been terminated upon disenrollment.
Prescriber Lock-in	Coverage limitation which limits access to coverage for FADs to drugs prescribed by selected prescribers.
Provider (Part D)	All contracted Providers including physicians, Non-physician Medical Practitioners, ancillary providers, and facilities or institutions who are licensed to furnish Covered Services.

Term	Definition
Second Notice	Written communication to an ARB that notifies them that CalOptima Health has identified them as at risk for misuse or abuse of FADs and is limiting their access to FADs under the DMP, describes the specific coverage limitations, explains how the Member can submit preferences for the selected Pharmacy and/or prescriber, if applicable, explains the Member's right to redetermination, and informs them that the limitation on the special enrollment period (SEP) continues.
Waste	The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to a CalOptima Health Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.