Clinical Policy: Long-Acting Opioid Analgesics

Reference Number: AZ.CP.PMN.97b
Effective Date: 02.11
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Line of Business: Arizona Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Opioid analgesics exert their analgesic effect through opiate receptors distributed in tissues throughout the body. All long-acting opioid analgesics (both preferred and non-preferred agents) that do not abide by this criteria will require prior authorization.

AHCCCS preferred Long-Acting Opioids: Butrans® (buprenorphine patch; brand only), Embeda (morphine/naltrexone; brand only), fentanyl patch (12 mcg, 25 mcg, 50 mcg, 75 mcg & 100 mcg), morphine sulfate ER (MS Contin®), oxycodone ER (Xtampza ER™), and tramadol ER (Ultram ER®)

Non-Preferred: other long-acting opioids not listed on the PDL guide are non-preferred.
For example: hydromorphone ER (Exalgo), hydrocodone ER (Hysingla ER®), morphine sulfate ER (Kadian®), methadone, tapentadol ER (Nucynta ER®), oxymorphone ER (Opana ER®), oxycodone ER (OxyContin®), and hydrocodone ER (Zohydro ER®).
All non-preferred long-acting opioids would require preferred alternatives be used in addition to the clinical requirements below.

FDA approved indication(s)
Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health that long-acting opioid analgesics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cancer, Hospice, or End-of-life Care (must meet all)**:**

1. Diagnosis is one of the following:
   a. Active oncology diagnosis with neoplasm related pain;
   b. Hospice care;
   c. End-of-life care (other than hospice);
2. Member will not be maintained on more than 2 different opioid analgesics concurrently; If member requires therapy with two opioid analgesics, regimen must consist of one short-acting and one long-acting opioid analgesic, or the following:

   a. Prescriber must submit a documented clinical rationale supporting that the upward titration of existing opioid analgesics, and the addition of a short-acting opioid analgesic and non-opioid analgesics are clinically inappropriate or contraindicated;
3. Prescribed long-acting opioid analgesic is a preferred drug, or one of the following (a, b, or c):
   a. Member has active oncology diagnosis with neoplasm related pain: member has previously failed Xtampza ER and morphine sulfate ER, unless contraindicated or clinically significant adverse effects are experienced;
   b. Member has previously failed, is intolerant to, or has contraindications to ALL preferred long-acting opioid analgesics;
   c. Member is being treated by hospice and has a life expectancy of less than 6 months;
4. Prescribed quantity does not exceed the Health Plan limit.

Approval duration: up to 12 months

B. All other diagnoses (must meet all)**:**

1. Treatment of chronic pain for which there is documentation of an objective diagnosis and/or contributing conditions;
2. Documented failure of at least 3-month trial of a short-acting opioid analgesic;
3. Member meets one of the following (a or b):
   a. Failure of at least TWO of the following non-opioid treatments: NSAIDs (e.g., ibuprofen, meloxicam, naproxen, nabumetone, diclofenac, etodolac, fenoprofen, ketoprofen, mefenamate, piroxicam, sulindac, tolmetin), acetaminophen, carbamazepine, gabapentin, TCAs, or duloxetine, unless contraindicated or clinically significant adverse effects are experienced;
   b. Member has had a total of 90 cumulative days of opioid therapy in the last 120 days;
4. Copy of signed pain contract;
5. For doses greater than 90 MME per day and/or concurrent benzodiazepine use, all of the following (must meet all):
   a. Prescribed by or in consultation with a Board Certified Pain Management Specialist;
   b. Member has a concurrent prescription for naloxone with evidence of a paid claim or documentation that member has received naloxone through other means;
   c. Provider's attestation that a dose taper would be attempted or documentation that a dose taper has been attempted within the past 6 months, with the reasons for taper failure;
6. Documentation that the provider has reviewed the Controlled Substance Prescription Monitoring Program (CSPMP) to identify concurrently prescribed controlled substances;
7. Prescribed long-acting opioid analgesic is a **preferred** drug, or the following:
   a. Member has previously failed, is intolerant to, or has contraindications to ALL preferred long-acting opioid analgesics;
8. Member will not be maintained on more than 2 different opioid analgesics concurrently; If member requires therapy with two opioid analgesics, regimen must consist of one short-acting and one long-acting opioid analgesic, or the following:
   a. Prescriber must submit a documented clinical rationale supporting that the upward titration of existing opioid analgesics, and the addition of a short-acting opioid analgesic and non-opioid analgesics are clinically inappropriate or contraindicated;
9. Prescribed quantity does not exceed the Health Plan limit.

Approval duration: 3 months

C. Other diagnoses/indications

1. Refer to AZ.CP.PMN.53 (Off Label Use Policy) if diagnosis is NOT specifically addressed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Cancer, Hospice, or End-of-life Care (must meet all)**:**

1. Currently receiving (defined as a history of chronic opioid use in the 3 months preceding the request) long-acting opioid therapy for one of the diagnoses:
   a. Active oncology diagnosis with neoplasm related pain;
   b. Hospice care;
   c. End-of-life care (other than hospice);
2. Member will not be maintained on more than 2 different opioid analgesics concurrently; If member requires therapy with two opioid analgesics, regimen must consist of one short-acting and one long-acting opioid analgesic, or one of the following:
   a. Prescriber previously provided a documented clinical rationale for the use of two or more long-acting opioid analgesics concurrently;
   b. Prescriber must submit a documented clinical rationale supporting that the upward titration of existing opioid analgesics, and the addition of a short-acting opioid analgesic and non-opioid analgesics are clinically inappropriate or contraindicated;
3. Prescribed long-acting opioid analgesic is a preferred drug, or one of the following (a, b, or c):
   a. Member has active oncology diagnosis with neoplasm related pain: member has previously failed Xtampza ER and morphine sulfate ER, unless contraindicated or clinically significant adverse effects are experienced;
   b. Member has previously failed, is intolerant to, or has contraindications to ALL preferred long-acting opioid analgesics;
   c. Member is being treated by hospice and has a life expectancy of less than 6 months;
4. Prescribed quantity does not exceed the Health Plan limit.

Approval duration: up to 12 months

B. All other diagnoses (must meet all):

1. Currently receiving (defined as a history of chronic opioid use in the 3 months preceding the request) long-acting opioid therapy via Centene benefit or member has previously met initial approval criteria;
2. Prescriber provides documentation supporting inability to discontinue opioid therapy;
3. Member will not be maintained on more than 2 different opioid analgesics concurrently; If member requires therapy with two opioid analgesics, regimen must consist of one short-acting and one long-acting opioid analgesic, or one of the following:
   a. Prescriber previously provided a documented clinical rationale for the use of two or more long-acting opioid analgesics concurrently;
   b. Prescriber must submit a documented clinical rationale supporting that the upward titration of existing opioid analgesics, and the addition of a short-acting opioid analgesic and non-opioid analgesics are clinically inappropriate or contraindicated;

4. For doses greater than 90 MME per day, all of the following (a, b, and c):
   a. Prescribed by or in consultation with a Board Certified Pain Management Specialist;
   b. Dose reduction has occurred since previous approval, or one of the following (i or ii):
      i. A dose taper has been attempted within the past 6 months and was not successful (Reason(s) for *taper failure* **or** medical justification why a taper should not be attempted must be provided);
      ii. If request is for dose increase, documented medical justification supports why the member must increase the dose, and the addition of non-opioid analgesics are clinically inappropriate or contraindicated;
   c. Member has continued access to naloxone through a concurrent prescription for naloxone filled within the last 12 months and medical record documentation of prescriber counseling to member and/or caregiver(s) regarding risk of overdose and rescue treatment with naloxone must be provided;
5. Documentation that the provider has reviewed the Controlled Substance Prescription Monitoring Program (CSPMP) to identify concurrently prescribed controlled substances;
6. Documentation that random urine drug screen (UDS) is utilized and results of the most recent UDS provided;
7. Prescribed quantity does not exceed the Health Plan limit.

Approval duration: up to 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – AZ.CP.PMN.53 for Arizona Medicaid;
B. Prescriptions written from non-contracted AHCCCS providers;
C. Members also currently on Suboxone or other drug as part of substance abuse treatment. (Current use implies a fill within the last 30 days);
D. Immediate post-surgical pain;
E. Use in members who require opioid analgesia for a short period of time.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AHCCCS: Arizona Health Care Cost Containment System
FDA: Food and Drug Administration
MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
PDL: Preferred drug list
TCA: tricyclic antidepressants

Appendix B: General Information

PA is required for all long-acting opioid prescription medications unless the member's diagnosis is one the following:
a. Active oncology diagnosis with neoplasm related pain,
b. Hospice care, or
c. End of life care (other than hospice).

I. Active oncology diagnosis
   a. Prescriber communicates to the pharmacy that the short-acting opioid prescription is for G89.3 Neoplasm related pain.
   b. The pharmacy staff must enter the diagnostic code in the prescription claim's NCPDP fields as notated below:
      NCPDP Field 492-WE, Enter 02 to notate an ICD-10 CM code.
      NCPDP Field 424-DO, Enter G89.3.

II. Hospice Care
   a. Hospice pharmacies are excluded from the 5-day supply limit of prescription opioid medications.
   b. Prescriber communicates to the non-hospice pharmacy that the short-acting opioid prescription is for hospice care.
   c. For non-hospice pharmacies, the pharmacy shall obtain an override for the short-acting opioid prescription through the Pharmacy Benefit Manager's (PBM) helpdesk when the prescriber notifies the pharmacy that the short-acting opioid prescription is for "hospice care".

III. End-of-Life Care (other than Hospice)
   a. Prescriber communicates to the pharmacy that the short-acting opioid prescription is for "end-of-life care".
   b. For non-hospice pharmacies, the pharmacy shall obtain an override for the short-acting opioid prescription through the PBM's helpdesk when the prescriber notifies the pharmacy that the short-acting opioid prescription is for "end-of-life care".

V. Dosage and Administration

Varies by drug product.

VI. Product Availability

Varies by drug product.

VII. References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.
2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015 Sep-Oct;9(5):358-67

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.19.18	04.18
Added Non Preferred drugs to Description section.	07.31.18	10.18
1Q 2020 Annual Review; No significant changes.	01.29.20	
Changed "extended release" to "long-acting" to streamline with	02.20.20	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
AHCCCS verbiage per 310-V; Updated format of the preferred LA opioids; Removed palliative care from the approval criteria I.A. and II.A as palliative care falls under "all other diagnoses" criteria; Criteria I.B.3.a: added acetaminophen and TCAs; Combined criteria I.B.8 &9 requirements for non-preferred long-acting opioids; Criteria II.A.1: added definition of currently receiving; Criteria II.A.3 added: requirements for non-preferred long-acting opioids; Criteria II.B.1: member must have met initial approval criteria if member has not had an authorization by the Plan; II.B.4: updated format for better readability, and requirements for dose increase: documented medical justification supports why the member must increase the dose, and the addition of non-opioid analgesics are clinically inappropriate or contraindicated; Added situations when only an override may be needed, although Prior Authorization is not required in the General Information section per 310-V Attachment B.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.