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 opioid analgesics therapy (both preferred and non-preferred agents) that does not abide with this criteria will require prior authorization.

The following are preferred extended-release opioids requiring prior authorization:

**Preferred:** buprenorphine patch (Butrans), Morphine/naltrexone (Embeda®), fentanyl patch (Duragesic®), morphine sulfate ER (MS Contin®), oxycodone ER (Xtampza ER™), tramadol ER (Ultra ER®)

**FDA Approved Indication(s)**
Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

**Policy/Criteria**
Provider must submit documentation (including 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 health plans affiliated with Centene Corporation® that opioid analgesics are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

A. **Cancer, Sickle Cell Disease, or Palliative Care** (must meet all):
   1. Prescribed for pain associated with cancer, sickle cell disease, or palliative care;
   2. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to preferred drugs
      a) For sickle cell disease or palliative care, member must have previously failed all preferred products
      b) OR for cancer diagnosis: member has previously failed Xtampza ER and morphine sulfate ER
   3. For request for > two (2) agents concurrently, prescriber must submit a documented clinical rationale supporting that the addition of an extended release agent and the upward titration of existing opioid analgesics is inappropriate or contraindicated;
   4. Request does not exceed AHCCCS quantity limit.

   **Approval duration:** up to 12 months
B. All other diagnoses: (Must meet all criteria below)

1. Chronic pain for which there is documentation of an objective diagnosis and/or contributing conditions
2. Documented failure of an immediate release opioid. Member has used short acting opioids for at least 3 months
3. Member meets one of the following:
   a) Failure of at least two of the following non-opioid treatments: ibuprofen, meloxicam, naproxen, nabumetone, diclofenac, etodolac, fenoprofen, ketoprofen, mefenamate, piroxicam, sulindac, tolmetin, carbamazepine, gabapentin, 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; (see 2 above)
4. Copy of signed pain contract
5. For doses greater than 90 MME/day and/or concurrent benzodiazepine use, all of the following are met:
   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
   *Provider will be advised that doses higher than the current dose will not be approved in the future
6. Documentation that the provider has reviewed the Controlled Substance Prescription Monitoring Program (CSPMP) to identify concurrently prescribed controlled substances;
7. Provider agrees to continuously assess the member’s pain management regimen for possible discontinuation of opioid therapy;
8. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to all preferred drugs;
9. For authorization of non-preferred opioids (trial and failure/intolerance or contraindication to ALL preferred controlled release products is required.
10. Member will be on no more than 2 different opioid analgesics concurrently: If member requires therapy with two opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic.

Approval duration: 3 months

C. Other diagnoses/indications
Clinical Policy: Extended Release Opioid Analgesics

1. Refer to 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, Sickle Cell Disease, or Palliative Care (must meet all):
   1. Currently receiving therapy for pain associated with cancer, sickle cell disease, or palliative care;
   2. If member is receiving more than 2 opioid analgesics concurrently, at least one of the following requirements has been met (a or b):
      a) Prescriber previously provided a documented clinical rationale for the use of > 2 opioid analgesics concurrently;
      b) Prescriber provides a documented clinical rationale supporting that addition of an extended release agent or upward titration of existing opioid analgesics is inappropriate or contraindicated;
   3. Request does not exceed health plan quantity limit.

   Approval duration: 12 months

B. All other diagnoses (must meet all):
   1. Currently receiving long term (defined as a history of chronic opioid use in the 3 months preceding the request) opioid therapy via Centene benefit or documentation supports that member is currently receiving opioids;
   2. Prescriber provides documentation supporting inability to discontinue opioid therapy;
   3. Member will not be maintained on > 2 unique opioid analgesics concurrently;
      a) If member requires therapy with two opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic
   4. If total opioid dose greater than 90 MME/day, all of the following are met:
      a) Prescribed by or in consultation with a Board Certified Pain Management Specialist;
      b) Dose reduction has occurred since previous approval, if applicable
      c) A dose taper has been attempted within the past 6 months and was not successful;
   5. Reason(s) for taper failure must be provided or medical justification why a taper should not be attempted is provided or medical justification for any dose increase that has occurred since previous approval, if applicable;
      a) Member has continued access to naloxone through a concurrent prescription for naloxone and medical record documentation of prescriber counseling to member and/or caregiver(s) regarding risk of overdose and rescue treatment with naloxone.
6. Documentation that the provider has reviewed the CSPMP to identify concurrently prescribed controlled substances
7. Documentation that random urine drug screen (UDS) is utilized and results of the most recent UDS provided.

**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 evidence of coverage documents;
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 Key*
MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
PDL: Preferred drug list
CSPMP: Controlled Substance Prescription Monitoring Program

**V. Dosage and Administration**

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for information on appropriate dosage and administration.

**VI. Product Availability**

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for product availability information.

**VII. References**

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.

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**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.

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