MEDICAL MUTUAL®

Drug Policy

Policy:	**Long-Acting Opioids (Oral)**	**Annual Review Date:** **06/15/2023**
Impacted Drugs:	**Arymo ER** **Hysingla ER** **Kadian** **MS Contin** **Nucynta ER** **Oxycodone extended-release (branded products)** **OxyContin** **Xtampza ER** **Zohydro ER**	**Last Revised Date:** **06/15/2023**

OVERVIEW

Opioid analgesics have a central role in the management of moderate to severe pain. These medications produce most of their effects by binding to μ, κ, and δ receptors in the central nervous system (CNS). However, Nucynta ER has a unique dual mechanism of action. It demonstrates μ-opioid agonist activity and inhibition of norephinephrine reuptake. Sustained-release opioid dosage forms offer a long duration of effect, reduce severity of end-of-dose pain, and allow many patients to sleep through the night. Long-acting products should be prescribed with an immediate-release dosage form, to be used as needed for breakthrough pain. Oxycontin may be given for in pediatric patients 11 years and older already receiving and tolerating opioids for at least 5 consecutive days with a minimum of 20 mg per day of oxycodone or its equivalent for at least two days immediately preceding dosing with Oxycontin.

Morphine sulfate, oxycodone, oxymorphone, hydromorphone, tapentadol, and hydrocodone are the currently available oral long-acting opioids. All of the long-acting oral opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin is the only product specifically indicated in pediatric patients 11 years to 18 years of age. Discontinue all other around-the-clock opioid drugs when Oxycontin therapy is initiated. Concomitant use with serotonergic drugs may result in serotonin syndrome. Discontinue Oxycontin if serotonin syndrome is suspected. Nucynta ER is the only product also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults. Morphine sulfate is available in long-acting forms as sustained-release capsules (Kadian [generics]) and controlled-release tablets (MS Contin, generics) and extended-release tablets (Arymo ER). MS Contin and Kadian are available generically. Tapentadol is available as an extended-release tablet (Nucynta ER).

Hysingla ER should only be taken once daily. Kadian (generics) can be dosed once or twice daily. MS Contin (generics) and Arymo ER are dosed every 8 to 12 hours. OxyContin, Nucynta ER, Xtampza ER, and Zohydro ER are dosed every 12 hours

All products should be swallowed whole and not broken, crushed, dissolved, or chewed. Alternatively, Kadian (generics) capsules can be opened and sprinkled on applesauce immediately before ingestion. In addition, Kadian capsules may be opened and the contents sprinkled in water and flushed through a gastrostomy tube (G-tube). Xtampza ER capsules can be taken by sprinkling the capsule contents on soft foods or sprinkling the contents into a cup and then administering directly into the mouth or through a gastrostomy or nasogastric feeding tube.

The patient's history of controlled substance prescriptions should be periodically reviewed using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations putting them at high risk for overdose.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. Approval for a patient requesting therapy for pain which is associated with a progressive terminal disease or illness may be authorized indefinitely, when clinically appropriate. Other details of the program are as follows:

- **Continuation of Therapy:** Approval for a patient requesting continuation therapy with a **Non-Preferred** medication for chronic pain must meet the *Medical Mutual of Ohio Extended Use Opioid Prior Authorization criteria*, in addition to the preferred step therapy criteria, when clinically appropriate, and is approved for 1 year, unless otherwise noted.

Preferred Medications

- Generic hydrocodone bitartrate extended-release
- Generic hydromorphone extended-release
- Generic morphine sulfate controlled-release
- Generic morphine sulfate extended-release
- Generic oxymorphone extended-release

Non-Preferred Medications

- Arymo ER (morphine sulfate extended-release)
- Hysingla ER (hydrocodone bitartrate extended-release)
- Kadian (morphine sulfate extended-release)
- MS Contin (morphine sulfate controlled-release)
- Nucynta ER (tapentadol extended-release)
- Oxycodone extended-release (branded products)
- OxyContin (oxycodone controlled-release)
- Xtampza ER (oxycodone extended-release)
- Zohydro ER (hydrocodone bitartrate extended-release)

PREFERRED STEP THERAPY CRITERIA

1. The provider must verify no current substance abuse treatments are being prescribed (examples including but are not limited to: Suboxone [buprenorphine/naloxone], Vivitrol [naloxone], oral naloxone, buprenorphine).

AND

2. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given

3. Authorization may be given for Hysingla ER, OxyContin, oxycodone extended-release (branded products), Nucynta ER, Xtampza ER, or Zohydro ER if the patient has renal insufficiency

4. Authorization may be given for OxyContin in opioid-tolerant pediatric patients 11 to 18 years of age

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product);

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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