Medication Policy Manual **Policy No:** dru364

Topic: Branded Long-acting (LA) Opioids

- Arymo™ ER, morphine extended-release (ER) abuse-deterrent tablet
- Avinza®, morphine ER capsule
- Butrans®, buprenorphine transdermal
- Embeda®, morphine-naltrexone ER
- Exalgo®, hydromorphone ER tablet
- Kadian®, morphine ER capsule
- Hysingla™ ER, hydrocodone ER capsule
- MS Contin®, morphine ER tablet
- Nucynta® ER, tapentadol ER
- Opana® ER, oxymorphone ER abuse-deterrent
- OxyContin®, oxycodone ER crush resistant
- Targiniq® ER, oxycodone-naloxone ER
- Troxyca® ER, oxycodone-naltrexone ER
- Xartemis , oxycodone-acetaminophen ER
- Xtampza ER™, oxycodone ER abuse-deterrent
- Zohydro™ ER, hydrocodone ER capsule

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Committee Approval Date: October 21, 2016 **Next Review Date:** August 2017

Effective Date: March 24, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Long-acting (LA) opioids are potent narcotic pain relievers delivered as extended-release (ER) formulations. LA opioids are intended for use in patients with moderate to severe pain who require continuous pain control for an extended duration. Low-cost generic morphine ER tablets are a best-value treatment option for most chronic pain patients.

Policy/Criteria

I. Most contracts require prior authorization approval of branded long-acting opioids prior to coverage. Branded long-acting opioids may be considered medically necessary when one of criteria A, B, or C below is met.

A. The member has a current diagnosis of cancer-related pain.

OR

B. The member is enrolled in a hospice program, or meets Medicare hospice criteria (see Appendix 1).

OR

C. The member is undergoing treatment of chronic pain, not due to cancer **AND** all of criteria 1 through 5 below are met.

1. The patient does **not** have pain due to cancer.

AND

2. The prescribing provider, prior to the initiation of chronic opioid therapy, has performed a formal consultative evaluation to determine if opioids are clinically indicated, with documentation of a through c below:

   a. Nature of pain: A diagnosis related to the chronic pain.

   AND

   b. Intensity of pain: A relevant physical examination with findings that correlate with the pain diagnosis and severity of symptoms including specific details of how the pain interferes with daily functioning.

   AND

   c. Complete assessment: A complete medical history with prior therapies, including documentation that both criteria i and ii below have been inadequate to meet the goals of pain management.

      i. Non-pharmacological therapies (e.g. exercise, physical therapy, yoga, stretching, meditation, visualization, heat/cold therapy, massage therapy, psychological therapy).

      ii. Non-opioid medications (e.g. acetaminophen, NSAIDs, muscle relaxants, antidepressants, antiepileptics).

AND

3. A written treatment plan, documented prior to the initiation of chronic opioid therapy, is provided and includes both a and b below.

   a. Baseline functional status and levels of pain using objective measures (e.g. SF-36; see Appendix 2).

AND

b. Objective treatment goals in addition to relief of pain to determine treatment success (e.g. improved function, ability to work, or ability to perform activities of daily living, or reduced sleep disturbance or as needed medication use; see Appendix 3).

AND

4. A current opioid treatment agreement ("pain contract") signed by the prescribing provider and the patient is in effect (see Appendix 4 and 5).

AND

5. Low-cost generic morphine extended-release (ER) tablets have been ineffective, not tolerated, or are contraindicated.

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx considers branded long-acting opioids to be self-administered medications.

B. Authorization shall be reviewed at least every six months to confirm that current medical necessity criteria are met and that the medication is effective for chronic non-cancer pain. Authorization shall be renewed if all of criteria 1 through 4 below are met.

1. The patient demonstrates measurable, objective progress toward treatment goal following initiation of chronic opioid therapy based on regular assessment for clinical response including pain relief and pain-associated symptoms (e.g. improved function, ability to work, or ability to perform activities of daily living, or reduced sleep disturbance or as needed medication use; see Appendix 3).

AND

2. The medical rationale for continuing or modifying chronic opioid therapy (e.g. dose escalation), and the dose and quantity prescribed are clearly documented by the prescribing provider.

AND

3. There is ongoing use of non-pharmacological therapies e.g. exercise, physical therapy, yoga, stretching, meditation, visualization, heat/cold therapy, massage therapy, psychological therapy) as indicated in combination with chronic opioid therapy.

AND

4. There is documentation that a random urinalysis drug screening ("utox") has been performed within the past 12 months.

III. Branded long-acting opioids are considered not medically necessary when used for the treatment of ACUTE non-cancer pain (e.g. post-surgical pain).

Position Statement

- Long-acting opioids are used to relieve moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended duration.
- Long-acting opioids are effective in reducing chronic non-cancer pain, but do not completely eliminate pain. Additionally, their use is associated with clinically significant safety concerns. [1,2]
- Chronic opioid therapy should be used only after a complete initial patient assessment, to determine if opioids are clinically indicated and to evaluate the associated risks. [3-5]
- Stepwise therapy is recommended for management of chronic non-cancer pain. [3-5]
    * Non-medication therapies such as exercise, relaxation techniques, and healthy sleep habits, provide pain relief for many patients, and may augment pain relief in combination with chronic opioid therapy.
    * Use of non-opioid medications such as acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) should be maximized prior to initiation of opioids. Non-cancer pain is variable, but commonly includes neuropathic pain, and can be managed with a variety of non-opioid medications, such as muscle relaxants, antidepressants, and antiepileptics. The analgesic efficacy of opioids for chronic neuropathic pain is uncertain. [6]
- A comprehensive treatment plan with objective treatment goals must be used to evaluate whether opioid therapy is effective for improving a patient's physical and psychological function. [3-5]
- Use of a treatment agreement ("pain contract") is a standard of care and required by many state regulatory agencies to ensure appropriate monitoring, to deter aberrant behaviors, and to document patient consent, education, and responsibilities of the treatment plan. [3,4]
- Re-assessment of pain and documentation of pain intensity, level of function, and progress towards treatment goals should be performed regularly and as needed (e.g. with dose escalation) to ensure adequate benefits relative to potential harms. [3-5]
- Periodic random urinalysis drug testing (urine toxicology) is useful to monitor chronic opioid therapy and assess for compliance as well as potential diversion. [3-5]
- There is no reliable evidence that any one opioid is more effective or safer than another, including abuse-deterrent formulations, long-acting opioids compared to short-acting opioids, Schedule 3 Controlled Substances, such as buprenorphine (Butrans) compared to Schedule 2 Controlled substances (all other high-cost and branded opioids), or partial- versus pure opioid agonists. [2]

    * An FDA Advisory Committee recently issued a recommendation to restrict the use of oxymorphone ER (Opana ER), given the increased risks of intravenous (IV) abuse. [13] Although oxymorphone ER (Opana ER) is an abuse deterrent formulation that deters snorting (intranasal ingestion), it has an increased risk for IV abuse and associated sequelae. Careful consideration is recommended before using any opioid, as all have a boxed warning for risk of abuse, including abuse via oral ingestion.
    * Use of partial opioid agonists or mixed mechanism opioid agonists, such as buprenorphine (generic tablets or transdermal Butrans) and tapentadol (IR or ER Nucynta) are considered third-line treatment options among available opioid options. Pure opioid agonist options, such as morphine, oxycodone, hydromorphone, or hydrocodone, are recommended opioid options to be used prior to consideration of partial agonists or mixed mechanism opioid agonist use. [4]
    * As a partial opioid agonist, buprenorphine transdermal (Butrans) has a ceiling analgesic effect; therefore the utility of use in management of chronic pain is uncertain.
- Because branded long-acting opioids have not been proven to be superior to the many available lower-cost short- or long-acting opioids, the use of branded long-acting opioids in the treatment of acute, non-cancer pain is considered not medically necessary.

Clinical Efficacy

- All branded long-acting opioids have similar analgesic effects to morphine, when adjusted for dose.
- Clinical trials have demonstrated the clinical effectiveness of branded long-acting opioids, but there is low certainty that any one is more effective than other available short- or long-acting opioid in the treatment of pain.
- There is moderate certainty in the evidence that all opioids are similarly effective for providing pain relief given decades of clinical experience, systematic reviews, and clinical practice guidelines. [2-5,7-9]
    * There is insufficient evidence to determine that any one long-acting opioid is superior to any other in the treatment of chronic non-cancer pain.
    * There is no high quality evidence to suggest long-acting opioids are superior to short-acting opioids.
    * There is no clear difference in efficacy between scheduled dosing of sustained-release opioids versus as needed dosing of immediate-release products.
    * There is no clear difference in efficacy overall between different opioid products.
    * Opioid medications, despite differences in potency, pharmacokinetics (e.g. time to onset, duration of effect) and route of administration can be dosed equivalently using well-established equianalgesic charts, which have been validated by numerous years of use in clinical practice. [10]

<u>Non-medication therapies</u>:

- Patients may have pain relief, or find that medications are even more effective, when non-medication therapies are used. Some examples include: [5]
    * Regular exercise: When advised by a physician, exercise can gradually increase general fitness, strength, coordination, range of flexibility and motion, and postural and muscle balance. Exercise may include regular walks, swimming, or gentle stretching.
    * Healthy sleep habits: Good sleep habits include maintaining a structured sleep schedule (e.g. avoid napping, going to sleep at the same time each night), creating a comfortable sleep environment (e.g. reduce noise, lighting, temperature), and preparing well for sleep (e.g. avoid caffeine and large meals close to bedtime, take a warm bath).
    * Relaxation techniques: Some examples of relaxation techniques include listening to soothing music, meditation, Yoga, Tai chi, deep breathing, visualization, and progressive muscle relaxation.

Random urinalysis screening:

- Random urinalysis drug screening can provide useful clinical information to prescribers of chronic high-dose opioids for non-cancer pain. It is recognized as a useful tool for the monitoring of patients on chronic high-dose opioids by The Washington State Agency Medical Directors' Group, the American Pain Society, [4] the American Society of the Interventional Pain Physicians' (ASIPP), [5] and the Federation of State medical Boards. [3]
- In clinical practice, random urinalysis drug screening, also referred to as “utox”, is used to identify the use of undisclosed substances, to uncover diversion, and to evaluate compliance with prescribed opioid medications. [11]
- Both qualitative and quantitative opioid urinalysis screening is covered by OmedaRx without prior authorization.

Safety [1]

- All long-acting opioids have a boxed warning for risk of addiction, abuse, misuse, life-threatening respiratory depression, and accidental ingestion.
- Several long-acting opioids also have a boxed warning for a risk of increased opioid levels and potential for overdose with co-ingestion of alcohol.
- The value of abuse-deterrent opioid formulations remains unclear with no evidence that they are safer (e.g. risk for abuse, misuse, or addiction) than those products which do not contain abuse-deterrent mechanisms.
- Constipation is among the most common adverse effects with long-acting opioids and does not improve over time.
- Adverse effects resulting from long-term use of opioids include immunologic effects, hormonal changes, and hyperalgesia.
- Consumption of broken, chewed, dissolved, or crushed long-acting opioid tablets or capsules may lead to rapid release and absorption of a potentially fatal dose.

Appendix 1: Medicare Coverage Criteria for Hospice

Coverage criteria for hospice per Centers for Medicare and Medicare (CMS) is available online under "Section 10. Requirements – General" at:

https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/hospice/index.html

Appendix 2: RAND 36-Item Short Form Health Survey (SF-36) [12]

This tool was developed at RAND Health as part of the Medical Outcomes Study. The SF-36 scoring tool is available online at

http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html

Appendix 3: Examples of improved physical and psychosocial function

- Improved ability to work.
- Reduced need for health care resources (such as office or ED visits for poorly controlled pain).
- Improved ability to perform activities of daily living (ADLs).
- Improvement in pain-associated symptoms, such as sleep disturbance, depression, anxiety.
- Improved quality of life (QOL), including the ability to undertake specific activities (patient is able to enjoy hobbies again, etc.).

Appendix 4: Pain contracts, treatment agreements

Federation of State Medical Boards Model Pain Guidelines – Informed Consent and Agreement for Treatment

"The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including:

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g. violation of agreement)."

A sample pain contract can be found at
http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Sample%20Pain%20Management%20Contract.pdf

Appendix 5: State Prescription Drug Monitoring Programs, guidelines, administrative rules, and statues regarding chronic opioid therapy for non-malignant pain
FEDERATION OF STATE MEDICAL BOARDS http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf
IDAHO http://www.healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/LongActingNarcoticAnalgesics.pdf https://idaho.pmpaware.net/login
OREGON http://www.oregon.gov/omb/Topics-of-Interest/Pages/Pain-Management.aspx http://www.orpdmp.com/health-care-provider/
UTAH http://health.utah.gov/prescription/pdf/guidelines/final04.09opioidGuidlines_summary%20WEB.pdf http://www.dopl.utah.gov/programs/csdb/index.html
WASHINGTON http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement.aspx http://www.wapmp.org/ http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

Cross References
Fentanyl-containing Medications, OmedaRx Medication Policy Manual, Policy No. dru073
High-cost Generic Long-acting Opioids, OmedaRx Medication Policy Manual, Policy No. dru365
Opioids for Chronic Non-cancer Pain, OmedaRx Medication Policy Manual, Policy No. dru084

Codes	**Number**	**Description**
N/A		

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Revision History

Revision Date	Revision Summary
3/24/2017	Add new warning regarding safety of oxymorphone ER (Opana ER)
3/16/2017	Add Arymo ER, a newly-approved branded LA opioid.
10/14/2016	Add Troxyca ER, a newly-approved branded LA opioid.
8/12/2016	No changes with this annual update.