Regence Oregon and Utah | Regence Idaho and select counties of Washington

Independent licensees of the Blue Cross and Blue Shield Association

Medication Policy Manual

Policy No: dru515

Topic: Extended-release (ER) Opioid Medication Products for Pain

Date of Origin: January 1, 2018

Committee Approval Date: December 7, 2023

Next Review Date: 2024

Effective Date: March 1, 2024

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

Opioids are medications used in the management of moderate to severe pain. Opioids are controlled substances regulated by the Drug Enforcement Administration (DEA). Opioids include, but are not limited to, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, tapentadol, and tramadol, alone or in combination products (such as with acetaminophen).

Tramadol-containing medications are not subject to this policy. This policy applies to all other extended-release (ER) opioids prescribed for any quantity.

Policy/Criteria

Most contracts require pre-authorization approval of extended-release (ER) opioids prior to coverage.

I. Continuation of therapy (COT): Extended-release (ER) opioids may be considered medically necessary for COT when full policy criteria below are met, including quantity limit.

Please note: *Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New starts (treatment-naïve patients): Extended-release (ER) opioid therapy may be considered medically necessary when ALL of the following criteria are met:

1. ONE of the following criterion (a through d) below are met:

a. The patient has an active diagnosis of **chronic cancer pain** due to an active malignancy.

OR

b. The patient is eligible for hospice care (see *Appendix 1).*

OR

c. The patient has a diagnosis of **sickle cell disease** (SCD).

OR

d. The patient is undergoing treatment of **chronic non-cancer pain** and ALL of the following criteria (i through v) below are met:

i. A comprehensive evaluation of what is causing the pain has been performed.

AND

ii. Step therapy with other pain management treatments is maximized and documented as insufficient for control of pain, unless use of step therapy is documented as medically contraindicated, including both criteria 1 and 2 below:

1. Non-opioid therapy (such as acetaminophen, NSAIDs, antiepileptics, and antidepressants).

AND

2. Non-pharmacological therapy, such as: exercise (e.g., regular walks, swimming, stretching, yoga, physical therapy, physical rehabilitation), relaxation techniques (e.g. meditation, yoga, Tai chi, deep breathing, visualization, listening to soothing music, progressive muscle relaxation), or other options (e.g. heat/cold therapy, massage, psychological therapy, cognitive behavioral

therapy, weight loss, biofeedback). Please note that this is not an all-inclusive list.

AND

iii. The requested agent is not prescribed as an as-needed (prn) analgesic.

AND

iv. ONE of the following:

1. The patient's medication history includes at least a 7-day trial of an immediate-release (IR) ("short acting") opioid.

OR

2. The patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to immediate-release (IR) ("short acting") opioid.

AND

v. Clinical documentation including but not limited to chart notes of the treatment plan that addresses the patient specific goals of opioid therapy.

NOTE: The expectation is this comprehensive plan will be addressed at patient evaluations, at least every six months.

AND

2. ONE of the following criterion (a or b) below are met:

a. The requested dose is within the policy quantity limit.

OR

b. The requested dose is above the policy quantity limit AND BOTH of the following:

i. The requested dose cannot be achieved using a lesser quantity of a higher strength.

AND

ii. The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist.

III. Administration and Authorization Period

A. Regence Pharmacy Services considers extended-release (ER) opioids (oral, nasal, and topical) coverable only under the pharmacy benefit (as self-administered medications).

B. When pre-authorization is approved, long-term extended-release (ER) opioids may be authorized as follows:

1. **Quantity Limits:** Extended-release (ER) opioids may be authorized in quantities as follows:
    a. Up to the quantity limits listed in the Quantity Limits Medication List (see *Appendix 2*).
    b. Quantities above the quantity limits listed in the Quantity Limits Medication List (see *Appendix 2*) may be approved when BOTH of the following criteria (i and ii) below are met:
        i. The requested dose cannot be achieved using a lesser quantity of a higher strength.

        AND

        ii. ONE of the following:
            1. The request is for continuation of therapy at the member's current dose (quantity).

            OR

            2. For increased doses (quantities), clinical documentation has objective medical justification for use of higher doses (quantity) for the intended diagnosis.
2. **Short Term Authorization:** If a member is both new to the Plan **AND** established on the requested medication, a one-time, one-month authorization shall be granted only if above coverage criteria is not met. This short-term authorization may be approved over stated quantity limits, if requested, however all quantity limit criteria must be met along with coverage criteria for further authorization. Member and prescriber are to be notified of this short-term authorization, as well as criteria that must be met for continuing authorization. No further short-term authorizations shall be granted. Short-term authorizations are not to be included in timeframes allowed on authorizations if members eventually meet all coverage criteria.
3. **Cancer-related pain:** Authorization shall be reviewed at 12 months. Continued authorization requires documentation of ongoing pain due to an active malignancy or eligibility for hospice care (as defined in section I criterion 1b). For patients without clear documentation of pain due to an active malignancy, "non-cancer pain" criteria for Initial Authorization must be met (as defined in section I criterion 1c).
4. **Sickle Cell Disease related pain:** Authorization may be reviewed at 12 months.
5. **Non-cancer pain:**
    a. **Initial Authorization:** Authorization shall be reviewed at 6 months.
    b. **Continued authorization:** Long-term opioid authorization shall be reviewed at least every six months. Clinical documentation

(including, but not limited to chart notes) must be provided to confirm that current medical necessity criteria are met, including:

1. The comprehensive pain management treatment plan has been assessed and updated.

2. The patient is making progress toward the stated goals of opioid therapy.

IV. Extended-release (ER) opioids are considered not medically necessary when used for the treatment of ACUTE non-cancer pain (including, but not limited to post-surgical pain).

Position Summary

Summary

- The intent of this policy is to facilitate the best possible medical care for patients with non-cancer pain. The long-term opioid therapy criteria do not apply to restrict opioid therapy in patients with an active diagnosis of cancer-related pain or those who are in hospice care, or those with pain related to sickle cell disease (SCD) or buprenorphine therapy as medication assisted therapy (MAT) for treatment of opioid addiction.
- The intent of the Extended-Release (ER) Opioids Pre-Authorization (PA) and Quantity Limit (QL) policy is to ensure appropriate selection of patients for treatment of pain severe enough to require daily, around-the-clock, long-term opioid treatment (for which alternative treatment options are inadequate) based on product labeling and/or clinical practice guidelines and/or clinical studies.
- The policy will also allow for approval in chronic non-cancer pain when the prescriber has provided documentation for a formal consultative evaluation which includes diagnosis and complete medical history; and the requested agent is not prescribed as an as-needed (prn) analgesic; and the patient's medication history includes the use of an immediate-release (IR) ("short acting") opioid or the patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to IR ("short acting") opioid; the prescriber has confirmed that a patient-specific pain management plan is on file; and the prescriber has confirmed that the patient is not diverting.
- All patients must be assessed for overuse of opioid and other controlled substances, such as sedatives, via state prescription monitoring program database (PDMP) programs. As of the date of this publication, all states have an active PDMP (see *Appendix 6*).
- The policy will check for concurrent use of target agents and buprenorphine or buprenorphine/naloxone products used for treatment of opioid dependence, also known as medication assisted therapy (MAT). If concurrent use is found, the policy will approve concurrent use only when the prescriber provides documentation in support of the concurrent use.

- Use of extended-release (ER) opioids for management of acute pain, such as post-operative ("post-op") pain, is considered not medically necessary and is not coverable. Guidelines support the use of short-acting, immediate-release (IR) opioids for acute, severe post-operative pain in opioid naïve patients. For opioid tolerant patients undergoing surgery, "baseline" pre-operative opioids may be continued per the outpatient regimens for treatment of the underlying, chronic pain, with short-term IR opioids used for the additional acute pain.
- Quantity limits within this policy encourage appropriate dosing. Requests for opioid extended-release agents, including quantities above the allowed limit, will be reviewed when patient-specific documentation has been provided.
- All requests for coverage of ongoing ER opioid therapy ("re-authorization") will be reviewed for ongoing benefit, as well as documentation of the ongoing source of pain (pain due to an active malignancy or ongoing chronic non-cancer pain). Pain associated with non-active malignancy will be covered only if Chronic Non-Cancer Pain criteria are met.
- This medication policy has been developed to be consistent with the current guidance for the use of opioids and treatment of chronic pain, including from the Center for Disease Control (CDC) noting care should be individualized.

MANAGEMENT OF PAIN [1,3,10]

- Nonopioid therapies are at least as effective as opioids for many common types of acute pain and are preferred for acute, subacute, and chronic pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for pain and function if benefits are anticipated to outweigh risks to the patient.
- A systematic review found that for musculoskeletal injuries such as sprains, whiplash, and muscle strains, topical non-steroidal anti-inflammatory drugs (NSAIDs) provided the greatest benefit-harm ratio, followed by oral NSAIDs or acetaminophen with or without diclofenac. NSAIDs have been found to be more effective than opioids for surgical dental pain and kidney stone pain and similarly effective to opioids for low back pain. Evidence is limited on comparative effectiveness of therapies for acute neuropathic pain, neck pain, and postoperative pain. For episodic migraine, triptans, NSAIDs, antiemetics, dihydroergotamine, calcitonin gene-related peptide antagonists (gepants), and lasmiditan are associated with improved pain and function with usually mild and transient adverse events.
- Some examples of non-medication treatments include:
    * 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, gentle stretching, yoga, physical therapy, and interdisciplinary rehabilitation.
    * Relaxation techniques: meditation, yoga, Tai chi, deep breathing, visualization, listening to soothing music, and progressive muscle relaxation.

    * Other options (variable, depending on the type of pain): heat/cold therapy, massage therapy, psychological therapy, cognitive behavioral therapy, weight loss, and biofeedback.

- According to the CDC guidance, when starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids.
- ER/LA opioids should be reserved for severe, continuous pain. The FDA has noted that some ER/LA opioids should be considered only for patients who have received certain dosages of opioids of immediate-release opioids daily for at least 1 week.
- Guidelines recommend use of long-term opioids only when a comprehensive pain management plan is ineffective for controlling pain. Key elements include: [1-4]
    * Specific assessment of pain, including past medical history, and risk of addiction, abuse, and overdose
    * Documentation of baseline objective pain scores and functional status
    * Use of step therapy with non-opioid and/or non-pharmacologic therapies
    * Screening for mental health co-morbidities such as anxiety and depression, substance use disorder (SUD), and naloxone use.
- Clearly-stated, objective, realistic pain management treatment goals in addition to relief of pain to determine treatment success. Goals may include improved function, ability to work, or ability to perform activities of daily living (ADLs), or reduced sleep disturbance or as needed medication use (see Appendix 3).When patients have been taking opioids for longer durations (e.g., for ≥1 year), tapers of 10% per month or slower are likely to be better tolerated than more rapid tapers.
- Each patient should be evaluated for ongoing treatment success, based on their realistic pain management treatment goals determined during their initial long-term pain assessment. If treatment goals are not being achieved despite medication adjustments, the appropriateness of continued treatment should be re-evaluated. [1,3,5] Use of ongoing opioids without documentation of clinically meaningful improvement in pain is considered not medically necessary. [1,2,4]
- Chronic opioid therapy has not been shown to improve overall patient quality of life in non-cancer pain despite reported improvement in pain.
- Before increasing total opioid dosage to ≥50 MME/day, clinicians should pause, considering that dosage increases to >50 MME/day are unlikely to provide substantially improved pain control for most patients while overdose risk increases with dosage, and carefully reassess evidence of benefits and risks. Overdose risk is doubled across multiple studies for dosages of 50 to <100 MME/day relative to <20 MME/day.

MEDICATION ASSISTED THERAPY (MAT) FOR OPIOID ADDICTION

- Opioid treatment programs (OTPs) provide medication assisted therapy (MAT) for individuals diagnosed with an opioid use disorder.
- Buprenorphine is partial opioid agonist and can be effective as MAT for opioid addiction, as office-based opioid dependence treatment (OBOT).

- The intent of this policy is not to specifically restrict the prescribing of buprenorphine for MAT; however, there is significant use in clinical practice of buprenorphine for pain management. Therefore, any use of buprenorphine for pain management will be subject to coverage under the long-term opioid therapy criteria.
- Buprenorphine for MAT is available as sublingual (SL) tablets (generic), subdermal implant (Probuphine), and in combination with naloxone (generic SL tablets, Suboxone SL film, Bunavail buccal film, and Zubsolv SL tablets). All these dosage forms have been studied for use in MAT for opioid addiction. [7]
- Buprenorphine buccal film (Belbuca) and buprenorphine transdermal (Butrans) have not been studied in management of MAT and are coverable only under the long-term opioid therapy criteria. [7]
- Use of methadone for MAT is not covered herein this ER Opioid Medication Products for Pain Policy. Methadone for MAT is covered under major medical benefits. It is not covered under retail pharmacy benefits, per the terms of most member contracts.

Efficacy [1, 5]

- Pharmacologic therapy is most effective when it is combined with non-pharmacologic strategies to optimize pain management. All patients with a diminished quality of life as a result of chronic pain are candidates for non-pharmacologic pain management strategies.
- Continuation or modification of therapy should depend on progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function (e.g. ability to work, need for health care resources, activities of daily living, quality of life.)
- No long-acting opioid analgesic has demonstrated consistently superior efficacy or safety over other opioids in the treatment of chronic non-cancer pain.
- Clinical evidence reviews found that effects of opioids on short-term pain and function were generally consistent across duration of action (short- or long-acting) and opioid type (opioid agonist, partial agonist, or mixed mechanism [with mixed opioid and nonopioid mechanisms of action] agent).
- Immediate release products may be administered on an as needed basis whereas extended-release agents are used in the treatment of chronic pain. Morphine remains the prototype opioid; as newer agents are introduced; their efficacy and safety are compared to morphine as the gold standard. Morphine is considered the drug of choice for severe pain.[9] Tramadol has been found to be efficacious in several randomized trials for the treatment of neuropathic pain, chronic non-cancer pain, and osteoarthritis pain.[7]
- Some extended-release/long-acting opioids are only indicated for opioid-tolerant patients. Patients who are opioid tolerant/experienced are those receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, or an equianalgesic dose of another opioid.

Abuse-Deterrent Formulations

- No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse.
- Although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.
- The "abuse-deterrent" label does not indicate that there is no risk for abuse.
- Abuse-deterrent technologies do not prevent unintentional overdose through oral intake.

Guidelines

- The CDC guideline for pain provides 12 treatment recommendations across four categories and can be found here: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#recommendations.
- The CDC defines acute therapy as a duration of <1 month, subacute therapy as a duration of 1–3 months, and chronic therapy as a duration of >3 months. *[1]*
- The National Comprehensive Cancer Network (NCCN) Guidelines: Adult Cancer Pain reserves immediate-release opioids for moderate/severe pain in opioid naïve patients. Use of non-opioids and adjuvant therapies are generally recommended for mild pain. [11]
- The World Health Organization (WHO) analgesic ladder for cancer pain relief is meant to be bi-directional. For chronic pain, a step-wise approach may be employed in the following order: nonopioids (aspirin and acetaminophen); then, as necessary, mild opioids (codeine); then strong opioids such as morphine; then invasive or minimally invasive treatments (such as nerve blocks and epidural analgesia). For acute pain, the strongest analgesic for that intensity of pain should be used as initial therapy and later de-escalated. [14]

Safety [1,5,7]

- Inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use.
- Adverse effects resulting from long-term use include immunologic effects, hormonal changes, and hyperalgesia. Hyperalgesia can occur at any dosage but occurs more often with higher doses and long-term use.
- Abuse-deterrent formulations are intended to deter abuse, such as by crushing and injecting and snorting. However, none have been evaluated in clinical trials to be safer for any outcomes related to overdose, addiction, abuse, or misuse, including prevention of oral abuse. [1]
- In an effort to combat the rising rate of opioid-related deaths, the FDA requires safety information in the FDA labeling of all extended release and long-acting opioid analgesics (extended-release and long-acting opioids include hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol).[16]
    * The safety information emphasizes that the drugs are only to be used for patients requiring continuous treatment when other treatment options, including non-

opioid analgesics or immediate-release opioids, are ineffective or intolerable. The labels also indicate that the drugs should not be used on an "as-needed" pain relief basis.

* Boxed warnings on ER/LA opioid analgesics include risk of addiction/abuse/misuse, Risk Evaluation and Mitigation Strategy (REMS), life threatening respiratory depression, accidental ingestion, neonatal opioid withdrawal syndrome (NOWS), and risks from concomitant use with benzodiazepines or other CNS depressants. Some medications such as oxycodone may also have significant drug interactions.
* The FDA will also require drug companies to conduct longer studies and trials of extended-release and long-acting opioid painkillers that are already on the market. The studies will assess known risks associated with the drugs, including increased sensitivity to pain, misuse, abuse, addiction, overdose, and death.

- State prescription drug monitoring programs (PDMPs) are available for monitoring for safe use of opioids and other controlled substances (see *Appendix 6* for more information).

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: Quantity Limits Medication List
Asuris Forms Page
Bridgespan Forms Page
Regence BlueShield of Idaho Forms Page
Regence BlueShield (Washington) Forms Page
Regence BlueCross BlueShield of Oregon Forms Page
Regence BlueCross BlueShield of Utah Forms Page

PLEASE NOTE: After you click one of the above links, you will need to choose a formulary or "drug list" – if you are unsure of which drug list to choose for your plan, please call the Customer Service number on the back of your insurance card.

Appendix 3: Example of improved physical and psychosocial function
- Ability to work. - Need for health care resources. - Ability to perform activities of daily living. - Quality of life, including the ability to undertake specific activities (patient is able to enjoy hobbies again, etc.).

Appendix 4: Buprenorphine for use as Medication Assisted Therapy (MAT) for Office-based Opioid Dependence Treatment (OBOT) [7]	
Buprenorphine	buprenorphine SL tablet (generic) buprenorphine/naloxone SL tablet (generic, Zubsolv), SL film (Suboxone film), buccal film (Bunavail) buprenorphine subdermal implant (Probuphine)

Appendix 5: Pain contracts, treatment agreements
Federation of State Medical Boards Model Pain Guidelines: [3] "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 (i.e., violation of agreement)." http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Sample%20Pain%20Management%20Contract.pdf

Appendix 6: State Prescription Drug Monitoring Programs, Guidelines, Administrative Rules, and Statues Regarding Chronic Opioid Therapy for Non-Malignant Pain.
IDAHO https://idaho.pmpaware.net/login https://bom.idaho.gov/BOMPortal/BOM/PDF%20FORMS/oa_guide.pdf Idaho's Response to the Opioid Crisis (IROC): https://healthandwelfare.idaho.gov/Medical/SubstanceUseDisorders/AccessIROCServices/IROC/tabid/1728/Default.aspx
OREGON www.oregon.gov/omb/Topics-of-Interest/Pages/Pain-Management.aspx www.orpdmp.com/health-care-provider/ www.oregonpainguidance.org/clinical-tools
UTAH https://health.utah.gov/prescription/pdf/guidelines/final04.09opioidGuidlines_summary%20WEB.pdf https://dopl.utah.gov/controlled-substance-database/
WASHINGTON https://doh.wa.gov/public-health-healthcare-providers/healthcare-professions-and-facilities/prescription-monitoring-program-pmphttps://www.wapmp.org/ www.agencymeddirectors.wa.gov www.hca.wa.gov/billers-providers/programs-and-services/opioids

Cross References
transmucosal immediate-release fentanyl- containing medications (TIRFs), Medication Policy Manual, Policy No. dru073
Compounded Medications, Medication Policy Manual, Policy No. dru135
Immediate-release (IR) Opioid Medication Products for Pain, Medication Policy Manual, Policy No. dru516

References

1. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. Available at: http://dx.doi.org/10.15585/mmwr.rr7103a1 [cited 10/4/2023]
2. Agency Medical Director's Group. Recommendations on Prescribing Long-Term Opioid Therapy from Bree Collaborative and Washington Agency Medical Directors' Group. Olympia, WA. June 2020. [cited 10/4/2023] Available at: https://www.qualityhealth.org/bree/wp-content/uploads/sites/8/2020/05/Bree-Long-Term-Opioid-Use-Recommendations-FINAL-20-05.pdf
3. Federation of State Medical Boards (FSMB). Guidelines for the Chronic Use of Opioid Analgesics: The Federation, April 2017. [cited 10/4/2023] Available at: opioid_guidelines_as_adopted_april-2017_final.pdf (fsmb.org)
4. Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, et al; American Pain Society American Academy of Pain Medicine (APS-AAPM) Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009 Feb;10(2):113-30. PMID: 19187889.
5. Carson S, Thakurta S, Low A, et al. Drug Class Review: Long-Acting Opioid Analgesics: Final Update 6 Report [Internet]. Portland (OR): Oregon Health & Science University; 2011 Jul. [cited 3/26/2018] Available from: http://www.ncbi.nlm.nih.gov/books/NBK62335/
6. Substance Abuse and Mental Health Services Administration (SAMHSA). Verify Physician Waivers (For Pharmacists). [cited 10/4/2023] Available at: https://www.samhsa.gov/medication-assisted-treatment/pharmacist-verification
7. Facts & Comparisons 4.0 (electronic version, updated periodically). Wolters Kluwer Health, Inc.
8. Substance Abuse and Mental Health Services Administration (SAMHSA). Medication-Assisted Treatment (MAT). [cited 10/4/2023] Available at: https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone
9. Wiffen PJ, McQuay HJ. Oral morphine for cancer pain. Cochrane Database Syst Rev. 2008;17:CD003868
10. American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology 2012;116:248–73. PMID 22227789
11. National Comprehensive Cancer Network (NCCN) Guidelines: Adult Cancer Pain [updated regularly] Available at: www.nccn.org.
12. Bril V, England J, Franklin GM, et al. Evidenced-based guideline: treatment of painful diabetic neuropathy (report from the American Academy of Neurology, the American Assoc of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation). *Neurology* 2011;76:1758-1765
13. Opioids for chronic noncancerpain: a position paper of the American Academy of Neurolog. *Neurology*. September 2014.
14. Anekar AA, Hendrix JM, Cascella M. WHO Analgesic Ladder. 2023 Apr 23. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 32119322.
15. Manchikanti l, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain. *Pain Physician* 2012;15:S1-S66
16. FDA. News Release. Long Acting Oral Opioids. [cited 9/10/2013]. Available at: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm
17. Drug Enforcement Agency (DEA). DEA to Publish Final Rule Rescheduling Hydrocodone Combination Products. [cited 3/26/2018] Available at: www.dea.gov/divisions/hq/2014/hq082114.shtml

18. Rand Health. "Medical Outcomes Study: 36-Item Short Form (SF-36) Survey Instrument. [cited 3/26/2018] Available at: www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html.

19. U.S. Department of Health and Human Services.Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors table for prescription drug coverage

[cited 10/28/2022] Available at: https://www.hhs.gov/guidance/document/opioid-oral-morphine-milligram-equivalent-mme-conversion-factors-0

20. Washington State Health Care Authority. Opioid Policy Criteria, October 19, 2016. [cited 3/26/2018]. Available at: https://www.hca.wa.gov/billers-providers/programs-and-services/opioids

21. U.S. Department of Health and Human Services (2020, August). Pain Management Best Practices Inter-Agency Task Force Report Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/opioids/prevention/pain-management-options/index.html

Revision History

Revision Date	Revision Summary
12/7/2023	• No criteria changes with this annual review. • Updated and simplified backend of the policy with recent guidelines.
6/15/2023	Removed all listed targeted agents and quantity limits from Appendix 2 and updated it to "Quantity Limits Medication List." Appendix 2 now has website links to each commercial plan, and information on how to access the member's specific "Quantity Limits Medication List."
12/9/2022	No criteria changes with this annual update.
1/20/2021	No criteria changes with this annual update.
1/22/2020	• Added coverage for pain associated with sickle cell disease. • Clarified intent of coverage for extended duration (long-term) non-cancer pain, including simplification of criteria and removal of clinical documentation requirements for step therapy. • Removed tramadol-containing products from policy.
4/25/2019	Added language to allow for short-term authorization for members new to the Plan AND established on therapy (effective 7/1/2019).
1/31/2019	• Clarified wording for treatment plan requirement, including regular assessment of the plan and use for reauthorization criteria. • Removed standard of care documentation: PDMP & UTOX requirement for reauthorization.
4/20/2018	Clarified wording of coverage criteria for cancer (active malignancy will be reviewed with each authorization period), intent of step therapy with non-opioid treatments and PDMP review, and coverage of acute pain, such as post-operative surgical (Not Medically Necessary).
1/30/2018	Clarified position statement, to include statements on the use of opioids (IR and ER formulations) for management of post-operative pain.
1/19/2018	Clarified wording for quantity limit to allow continuation of therapy at current doses that are above the set limit
11/10/2017	Clarified wording for intent - 12-month authorization for cancer-related pain.
8/11/2017	New policy; a merge of the existing opioid policies (Branded Long-acting Opioids, High-cost Generic Long-acting Opioids, and Opioids for Chronic Non-Cancer Pain) and addition of all other partial and full long-acting opioid agonists with potential use for the management of pain. Intent is safety guardrails, in-line with new federal and state guidance for use and prescribing of opioids. Effective 1/1/2018.

Drug names identified in this policy are the trademarks of their respective owners.