Medication Policy Manual

Policy No: dru516

Topic: Immediate-release (IR) Opioid Medication Products for Pain

Date of Origin: January 1, 2018

Committee Approval Date: December 12, 2024

Next Review Date: 2025

Effective Date: March 1, 2025

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, codeine, fentanyl, dihydrocodeine, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol, and tramadol, alone or in combination products (such as with acetaminophen).

This policy applies to all immediate-release (IR) opioids prescribed for more than fourteen (14) days of cumulative opioid use. Tramadol-containing products are not subject to this policy when prescribed up to their FDA-approved maximum dosage.

NOTE: Extended-release (ER) opioids are covered in a separate policy.

Policy/Criteria

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

I. Continuation of therapy (COT): Immediate-release (IR) 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): **Immediate-release (IR) opioid therapy** (defined as treatment with any IR opioid beyond fourteen days total in 30 days) may be considered medically necessary when ALL of the following criteria are met:

1. ONE of the following:

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 non-cancer pain and ALL of the following:

i. 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

ii. Clinical documentation including but not limited to chart notes of the treatment plan that addresses the patient specific goals of opioid therapy. (The treatment plan includes but is not limited to an individualized plan to get to the lowest effective opioid dose in the shortest time feasible.)

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

III. Administration and Authorization Period

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

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

1. **Grace Fill:** Allow up to one grace fill within a 60-day period, providing up to an additional seven days of therapy. To obtain a grace fill, the dispensing pharmacy/pharmacist may call the number provided at the point-of-sale rejection messaging. (This is the message given when the prescription is submitted online from the pharmacy and the claim is denied).

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. 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. Authorization shall be reviewed as follows:

i. **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 1d.).

ii. **Acute episodic pain associated with sickle cell disease (SCD):** Authorization may be reviewed every 12 months.

iii. **Non-cancer pain:**

1. **Initial Authorization**: Authorization shall be reviewed at 6 months.

2. **Continued Authorization**: Authorization shall be reviewed at least every six months. Current clinical documentation (including, but not limited to chart notes) must be provided to confirm that current medical necessity criteria are met, including:
   - **a.** The comprehensive pain management treatment plan has been assessed and updated.
   - **b.** The patient is making progress toward the stated goals of opioid therapy.

Position Summary

Summary

- The intent of this policy is to facilitate the best possible medical care for patients with non-cancer pain. The extended duration 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 episodes of acute pain associated with sickle cell disease or buprenorphine therapy as medication assisted therapy (MAT) for treatment of opioid addiction.
- The intent of the Immediate-Release (IR) Opioids Pre-Authorization (PA) policy is to help direct appropriate use of immediate-release (IR) ("short acting") opioids and ensure appropriate selection of patients for treatment of pain severe enough to require extended duration opioid treatment (for which alternative treatment options are inadequate) based on product labeling and/or based on CDC guideline recommendation on the duration of opioid use.
- The policy allows for access to opioids for up to fourteen days of therapy in 30 days without pre-authorization review. Requests for treatment of non-cancer pain beyond fourteen days will result in an alert to patients to seek pre-authorization for extended therapy.
- The policy allows up to one grace fill, up to seven days of therapy, of the requested agent to help prevent opioid withdrawal during the pre-authorization submission and review process.
- The policy will allow for approval for patients with diagnosis of pain due to active malignancies or who are in hospice care or who have episodic acute pain associated with sickle cell disease.
- The policy will also allow for approval in extended-duration (chronic) non-cancer pain when the prescriber has provided documentation for a formal consultative evaluation which includes diagnosis and complete medical history; the prescriber has confirmed that a patient-specific pain management plan is on file; and the prescriber has assessed the patient's risk for diversion.
- 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 5*).

- 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.
- Extended-duration use of immediate-release (IR) 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 the shortest amount of time as necessary.
    * If patients have prolonged severe pain, the patient should be evaluated for management of extended duration (chronic) pain and associated extended duration opioid use.
    * 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.
- The Center for Disease Control and Prevention recommends that when opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. [1]
- All requests for coverage of ongoing IR 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 Extended-Duration (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.

<u>MANAGEMENT OF POST-OPERATIVE PAIN [1]</u>

- Short-acting ["immediate-release' (IR)] opioids should be used for management of acute pain and use of non-opioid therapies should be maximized, to limit the need for opioids.
- In addition, the CDC guidance calls out the use of long-acting ["extended-release" (ER)] opioids should be reserved for severe, continuous pain and that IR products should be used instead when starting opioid therapy.
- A systematic review found NSAIDs to be more effective than opioids for surgical dental pain and kidney stone pain, and similarly effective to opioids for low back pain; acetaminophen was more effective than opioids for kidney stone pain. [2]
- The American College of Physicians (ACP) recommends nonopioid medications for acute low back pain and recommends against opioids for musculoskeletal injury.[3]
- The American Dental Association (ADA) recommends NSAIDs as 1st line therapy for acute pain management.[4]

LONG-TERM (EXTENDED-DURATION)/CHRONIC OPIOID THERAPY[1]

- Long-term administration of opioid analgesics may be a necessary component of comprehensive care for some patients with non-cancer pain, including those with chronic (more than 30 days) of pain.
- However, overprescribing of opioids for pain have led to an epidemic of opioid abuse. Long-term opioid use commonly begins with treatment of acute pain.
- Prescribing of the lowest effective dose of a short-acting (also known as "immediate-release," IR) opioid for the shortest amount of time is recommended when initiating opioids.
- An increased length of opioid therapy for treatment of acute pain is associated with an increased risk of opioid abuse disorder.
- Guidelines recommend use of long-term opioids only when a comprehensive pain management plan is ineffective for controlling pain. Key elements include:
    * 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 2*).
- Long-term opioids should be considered only when other conservative measures, including non-opioid medications and non-pharmacologic therapies have failed and the patient has demonstrated sustained functional improvement with previous opioid trials.
- Ongoing use of non-opioid medications and non-pharmacologic therapies should be continued along with opioids, for comprehensive pain management.
- In opioid-naïve patients, opioid doses should not exceed 50 morphine milligram equivalents per day (MEDs). Use of higher doses are associated with poorer health outcomes.
- Benefits of high-dose opioids for pain are not well established. Few trials evaluated opioid dosages of ≥90 MME/day.[1] Dosages > 50 MME/day often do not provide additional benefit in pain or function but are associated with increased risks of misuse, overdose, and death.
- 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. Use of ongoing opioids without documentation of clinically meaningful improvement in pain is considered not medically necessary.

- The use of chronic opioid therapy for patients with chronic non-cancer pain remains controversial, and in some cases can worsen pain syndromes and cause adverse sequelae.
- Chronic opioid therapy has not been shown to improve overall patient quality of life in non-cancer pain despite reported improvement in pain.
- Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.
- In 2023, the FDA determined that a new warning about opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia) be added to both IR and ER opioids. Although OIH can occur at any opioid dosage, it may occur more often with higher doses and longer-term use.

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. [5]

Efficacy *[1][6]*

- 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).

- First-line non-opioid medication options include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, and antiepileptics. Topical agents (such as topical NSAIDs, capsaicin, or lidocaine) may be used in select patients.
- 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.
- Narcotic analgesics and combinations are indicated for the treatment of mild to moderate to severe pain. 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.[7] Tramadol has been found to be efficacious in several randomized trials for the treatment of neuropathic pain, chronic non-cancer pain, and osteoarthritis pain.[5]
- 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.

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 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.[8]
- 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.[7]

Safety[1 5]

- 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 my 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.
- Hydrocodone combination products were reclassified to Schedule II by the Drug Enforcement Administration (DEA) effective October 2014. [9]
- Concomitant use of tramadol with MAO inhibitors or selective serotonin reuptake inhibitors (SSRIs) increases the risk of adverse events such as seizures and serotonin syndrome. Withdrawal symptoms may occur if tramadol is discontinued abruptly. [5]
- PDMPs are monitored for safe use of opioids and other controlled substances. (See *Appendix 5* 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: 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 3: Buprenorphine for use as Medication Assisted Therapy (MAT) for Office-based Opioid Dependence Treatment (OBOT) [5]	
Buprenorphine	buprenorphine SL tablet (generic) buprenorphine/naloxone SL tablet (generic, Zubsolv), SL film (Suboxone film), buccal film (Bunavail) buprenorphine subdermal implant (Probuphine)

Appendix 4: Pain contracts, treatment agreements
Federation of State Medical Boards Model Pain Guidelines:[10] "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; and - number and frequency of all prescription refills; and - reasons for which drug therapy may be discontinued (i.e., violation of agreement)."

Appendix 5: 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-https://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
Extended-release (ER) Opioid Medication Products for Pain, Medication Policy Manual, Policy No. dru515

References

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Revision History

Revision Date	Revision Summary
12/12/2024	• No changes to policy with this annual update.
12/7/2023	• Updated policy to apply to IR opioid supplies greater than 14 days total in 30 days. • Simplified criteria by removing criterion D (regarding acute pain), Ei (regarding extended use of IR opioids), and Eii (regarding pain evaluation).
9/14/2023	Removed methadone from policy (no longer requires PA) effective 12/1/2023.
6/15/2023	Update to note that Appendix 1 was removed with the 12/9/2023 update to policy. No other changes.
12/9/2022	No change to criteria with this annual update.
1/20/2021	Added Apadaz (benzhydrocodone/acetaminophen) to policy. No other changes to policy with this annual update.
4/22/2020	Added Prolate (oxycodone/acetaminophen) to policy.
1/22/2020	• Added coverage for pain associated with sickle cell disease. • Clarified intent and added specific coverage pathway for additional acute pain treatment. • 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) and intent of step therapy with non-opioid treatments and PDMP review.
1/30/2018	Clarified position statement, to include statements on the use of opioids (IR and ER formulations) for management of post-operative pain.
12/15/2017	Updated Target Agents to match intent.
11/10/2017	Clarified wording for intent- 7 days total of any IR opioid and 12-month authorization for cancer-related pain.

Revision Date	Revision Summary
8/11/2017	New policy; for all immediate-release partial and full 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.

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