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Medication Policy Manual | **Policy No:** dru516

Topic: Immediate-release (IR) Opioid Medication Products for Pain | **Date of Origin:** January 1, 2018

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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, methadone, 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 (as listed in *Appendices 3 and 4*) prescribed for more than seven (7) days use. Use of IR opioids beyond seven days total in 60 days is considered "extended-duration opioid therapy" and coverable only when criteria for treatment of chronic pain are met.

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

Policy/Criteria

I. Most contracts require pre-authorization approval of immediate-release (IR) opioids (as listed in *Appendix 1,* including commercial and extemporaneously compounded opioids) prior to coverage. **Immediate-release (IR) opioid therapy** (defined as treatment with any IR opioid beyond seven days total in 60 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 2)*

OR

c. The patient is undergoing treatment of extended-duration (long-term) non-cancer pain and ALL of the following:

i. The prescriber has provided documentation in support of use of immediate release (IR) or combination opioids for an extended duration

AND

ii. The prescriber provides clinical documentation (including, but not limited to chart notes) of a formal, consultative evaluation including:

1. Diagnosis

AND

2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

iii. 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 in clinical documentation (including, but not limited to chart notes), 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:

i. Exercise, such as regular walks, swimming, stretching, yoga, physical therapy, and physical rehabilitation.

ii. Relaxation techniques, such as meditation, yoga, Tai chi, deep breathing, visualization, listening to soothing music, and progressive muscle relaxation.

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

AND

iv. The prescriber has confirmed that a patient-specific comprehensive pain management treatment plan that addresses goals of opioid therapy and a plan to get to the lowest effective opioid dose in the shortest time is on file for the patient (NOTE: the expectation is this comprehensive plan will be addressed at patient evaluations, at least every six months).

II. Administration and Authorization Period

A. Regence Pharmacy Services considers immediate-release (IR) opioids (oral, nasal, and topical) to be 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 two grace fills within a 60-day period, with each grace fill 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 1c.).

ii. **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. Clinical documentation

(including, but not limited to chart notes) must be provided to confirm that current medical necessity criteria are met, including that the comprehensive pain management treatment plan has been assessed and updated, the patient is making progress toward the stated goals of opioid therapy, the lowest effective opioid is being used, and that the opioid medication is effective for long-term non-cancer pain.

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 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 acute opioid use.
- The policy allows for access to opioids for up to seven days of therapy in 60 days without pre-authorization review. Requests for treatment of non-cancer pain beyond seven days will result in an alert to patients to seek pre-authorization for extended therapy.
- The policy allows up to two grace fills, each 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.
- 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 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 9*).
- 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 (beyond seven days), 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. Three days or less will often be sufficient; more than seven days will rarely be needed. [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), Agency Medical Director's Group (ADMG), Washington State Health Care Authority, and the Federation of State Medical Boards (FSMB).

MANAGEMENT OF POST-OPERATIVE PAIN [1,3,10]

- While the scope of the CDC guidance is to help clinicians manage chronic pain, there are embedded recommendations regarding the management of acute pain. Specifically, short-acting ["immediate-release' (IR)] opioids should be used for management of acute pain for less than three days (and rarely for greater than seven days) and use of non-opioid therapies should be maximized, to limit the need for opioids.
- In addition, the guidance calls out the use of long-acting ["extended-release" (ER)] opioids for acute pain is listed as a "high-risk prescribing practice" that has contributed to the opioid epidemic, as a greater amount of early opioid exposure is associated with greater risk for long-term use.
- While the CDC guidance admits that the management of post-op pain is outside of the specific scope of their guidelines, they are clear that acute pain still can be managed without ER opioids. Supporting guidance from Washington Agency Medical Directors' Group (WAMDG) Interagency Guidelines and the American Society of Anesthesiologists (ASA) state the following on peri- and post-operative pain management: [3, 10]
    * The WAMDG guidelines support the use of immediate-release (IR) opioids as "the foundation" for acute, severe post-op pain in opioid naïve patients. For opioid tolerant patients, "baseline" pre-operative opioids may be continued per the outpatient regimens, with IR opioids used for the acute pain. The WAMDG guidelines specifically state that extended-release (ER) opioids should not be added or increased in the acute post-op phase. [The ASA guidelines are focused on the use of inpatient pain management with epidurals, patient-controlled analgesia (PCA) pumps, and regional anesthesia techniques].

* Both guidelines encourage the use of non-opioids for more steady analgesia, with use of medications such as NSAIDs, COX2 inhibitors, and acetaminophen.

LONG-TERM (EXTENDED-DURATION) OPIOID THERAPY (more than seven days) [1-4]

- Long-term (more than seven days) 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. Accordingly, current pain management guidelines for non-cancer pain recommend restriction of opioid use in all pain requiring opioids beyond seven days. [1]
- 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. [1]
- Most acute pain can be managed with three days or less of opioids. For severe acute pain seen in the primary care setting, use of opioids beyond seven days is rarely needed. [1] 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: [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, substance abuse disorder, 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 4*).
- 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. [1,2,5]
- Ongoing use of non-opioid medications and non-pharmacologic therapies should be continued along with opioids, for comprehensive pain management.
- Opioid doses needed for the treatment of non-cancer pain are often smaller than those used in cancer-related pain. [5] 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.
- Dose escalation above 50 MEDs must include careful evaluation and documentation of the benefits versus risks for each patient. Use of greater than 90 MEDs should be avoided, except for specific acute medical conditions, but not for the typical patient with acute pain. [1]

- 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]
- Random urinalysis testing is recognized as a standard monitoring tool, to identify use of undisclosed substances, uncover diversion, and evaluate compliance with opioid therapy.

CHRONIC OPIOID THERAPY (more than 30 days) [1,3,5]

- All patients continuing on opioid therapy beyond 30 days should be evaluated for long-term pain, as detailed in the section above.
- 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.
- The safety and efficacy of chronic administration of chronic opioids for chronic non-cancer pain has yet to be established despite increasing commercial pressure to routinely use these medications.
- 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.
- Many people with chronic pain require little or no dose escalation in chronic opioid therapy.
- Lack of knowledge about pain management by the patient or the patient's physician may result in inadequate pain control.

MEDICATION ASSISTED THERAPY (MAT) FOR OPIOID ADDICTION

- Opioid treatment programs (OTPs) provide medication assisted therapy (MAT) for individuals diagnosed with an opioid use disorder. OTPs also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs, potential criminal activity, and/or the spread of infectious disease. OTPs focus on improving the quality of life of those receiving treatment.

  Buprenorphine is partial opioid agonist and can be effective as MAT for opioid addiction, as office-based opioid dependence treatment (OBOT).
  All prescribers of buprenorphine OBOT (see *Appendices 5 and 6*) must have a valid Drug Addiction Treatment Act of 2000 (DATA) waiver. Prescribers must include their DATA 2000 waiver ID number (or "X" number) on prescriptions for opioid addiction treatment medications, in addition the DEA registration number. Dispensing pharmacists verify the XDEA validity per *Appendix 6*. [6]

- 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 IR Opioid Medication Products for Pain Policy.
    * Methadone is a full opioid agonist, dispensed only in specialty regulated clinics for MAT. [8] By law, methadone can only be dispensed through an opioid treatment program (OTP) certified by the federal agency, Substance Abuse and Mental Health Services Administration (SAMHSA). These OTPs are also referred to as a "methadone clinic."
    * Unlike buprenorphine, methadone for MAT may not legally be prescribed for office-based opioid dependence treatment (OBOT).
    * 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.
- First-line non-opioid medication options include acetaminophen, non-steroidal antiinflammatory 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.[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]
- 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.

CDC Guidance [1]

The guideline provides 12 treatment recommendations across three categories.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate. (Recommendation category: A; evidence type: 3)
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and consider how opioid therapy will be discontinued if benefits do not outweigh risks.

   Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. (Recommendation category: A; evidence type: 4)
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy. (Recommendation category: A; evidence type: 3)

Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release long-acting (ER/LA) opioids. (Recommendation category: A; evidence type: 4)

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day. (Recommendation category: A; evidence type: 3)
6. Long-term opioid use often begins with treatment of acute pain. 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. Three days or less will often be sufficient; more than 7 days will rarely be needed. (Recommendation category: A; evidence type: 4)
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. (Recommendation category: A; evidence type: 4)

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50MME/d), or concurrent benzodiazepine use, are present. (Recommendation category: A; evidence type: 4)
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. (Recommendation category: A; evidence type: 4)
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. (Recommendation category: B; evidence type: 4)
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible. (Recommendation category: A; evidence type: 3)
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder. (Recommendation category: A; evidence type: 2)

Other Guidelines

- The National Comprehensive Cancer Network (NCCN) Guidelines: Adult Cancer Pain recommend that in a patient who has not been exposed to opioids in the past morphine is generally considered the standard starting drug of choice. Oral administration is the preferred route. Patients presenting with severe pain needed urgent relief should be treated with parenteral opioids. [11]
- The Evidence-based Guideline: Treatment of painful diabetic neuropathy (DPN) from the American Academy of Neurology (AAN), the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation state the following: Dextromethorphan, morphine, tramadol, and oxycodone should be considered for the treatment of DPN, but data is insufficient to recommend one agent over the other, but are not considered as first line therapy. Tapentadol has a similar mechanism of action as tramadol, with indications for treatment of moderate to severe pain in adults as well as for the treatment of diabetic peripheral neuropathy, but is not recommended by any guidelines. [12]
- The AAN states that although there is evidence for significant pain relief with opioids in the short term (average duration of trials 5 weeks, range 1-16 weeks), there is no substantial evidence for maintenance of pain relief over longer periods of time, or significant evidence for improved physical function. [13]
- The World Health Organization (WHO) Pain Relief Ladder for cancer pain relief states: [14] If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and acetaminophen); then, as necessary, mild opioids (codeine); then strong opioids such as morphine.
- The American Society for Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain (2012) states the following: While there is significant short-term evidence available for all opioids, the evidence for long-term effectiveness is inconclusive due to relatively short (3 months) duration of studies and lack of quality studies. The ASIPP also recommends the following when prescribing opioids for chronic use: [15]
    * Before initiating opioid therapy, a comprehensive assessment and documentation which includes comprehensive history, general medical condition, psychosocial history, psychiatric status, and substance use history.
    * Screening for opioid use.
    * Implement prescription monitoring program.
    * Establish appropriate physical diagnosis and psychological diagnosis if available prior to initiating therapy.
    * Establish medical necessity for initiating and maintaining therapy.
    * Establish treatment goals.
    * Establish a robust agreement with patient to prevent overuse, misuse, abuse, and diversion.
    * A pain management consultation, may assist non-pain physicians, if high-dose opioid therapy is utilized.

- The CDC guideline for opioid prescribing states that although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use non-pharmacologic and non-opioid pharmacologic pain treatments as appropriate and consider consulting a pain specialist as needed to provide optimal pain management. [1]

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.
* Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

Urinalysis

- Random urinalysis testing can provide useful clinical information to prescribers of long-term opioids for non-cancer pain. Random urinalysis testing is recognized as a useful tool in the monitoring of these patients by all current guidelines [1-4]
- In clinical practice, urine drug tests are used to identify use of undisclosed substances, to uncover diversion, and to evaluate compliance with prescribed controlled substance therapies.

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.
- Opioid therapy may be accompanied by troublesome adverse side effects including sedation, nausea, vomiting, pruritus, constipation, physical dependence, and aberrant behavior.
- In clinical trials, 1 of 4 (or more) patients drop out due to adverse effects.
- Constipation is one of the most common adverse effects and does not improve over time.
- Adverse effects resulting from long-term use include immunologic effects, hormonal changes, and hyperalgesia.
- 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. [1]

- In September 2013 the FDA issued a safety bulletin. In an effort to combat the rising rate of opioid-related deaths, the FDA will require safety label changes on all extended release and long-acting opioid analgesics (extended-release and long-acting opioids include hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol).[16]
    * The new safety information will emphasize 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 will also indicate that the drugs should not be used on an "as-needed" pain relief basis.
    * The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts.
    * In addition, the FDA is notifying ER/LA opioid analgesic application holders of the need for changes to the following sections of drug labeling: Dosage and Administration; Warnings and Precautions; Drug Interactions; Use in Specific Populations; Patient Counseling Information, and the Medication Guide.
    * Once the safety labeling changes are finalized, modifications will also be made to the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), to reflect the updated information.
    * 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.
- Hydrocodone combination products have been reclassified to Schedule II by the Drug Enforcement Administration (DEA) effective October 2014. This change followed the recommendation out of the FDA Advisory Committee meeting that occurred in January 2013 where the committee voted 19 to 10 to reschedule these products. [17]
- 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. [7]
- PDMPs are monitored for safe use of opioids and other controlled substances. (See *Appendix 9* for more information).

Appendix 1: Opioids covered in this policy [a] **FDA Approved Indications and Dosage [7]**		
Immediate Release Opioid Agents		
Product	**Indication**	**Dosage & Administration**
butorphanol nasal spray[a]	10 mg/mL nasal spray	The usual recommended initial dose is 1 mg (1 spray in one nostril). If adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given. The initial dose sequence outlined above may be repeated in 3 to 4 hours as required after the second dose of the sequence. Depending on the severity of the pain, an initial dose of 2 mg (1 spray in each nostril) may be used in patients who will be able to remain recumbent in the event drowsiness or dizziness occurs. In such patients single additional 2 mg doses should not be given for 3 to 4 hours.
codeine[a]	15 mg tablet	15 mg to 60 mg repeated up to every four hours as needed for pain. The maximum 24 hour dose is 360 mg.
codeine[a]	30 mg tablet	15 mg to 60 mg repeated up to every four hours as needed for pain. The maximum 24 hour dose is 360 mg.
codeine[a]	60 mg tablet	15 mg to 60 mg repeated up to every four hours as needed for pain. The maximum 24 hour dose is 360 mg.
Demerol[a] (meperidine)	50 mg tablet	Every 3-4 hours
Demerol[a] (meperidine)	100 mg tablet	Every 3-4 hours
Demerol (meperidine)	50 mg/5 mL solution	Every 3-4 hours
Dilaudid[a] (hydromorphone)	2 mg tablet	Every 4-6 hours
Dilaudid[a] (hydromorphone)	4 mg tablet	Every 4-6 hours

Appendix 1: Opioids covered in this policy [a] **FDA Approved Indications and Dosage [7]**		
Immediate Release Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Dilaudid[a] (hydromorphone)	8 mg tablet	Every 4-6 hours
Dilaudid[a] (hydromorphone)	1 mg/mL liquid	Every 3-6 hours
Dolophine[a] (methadone)	5 mg tablet	Every 8-12 hours
Dolophine[a] (methadone)	10 mg tablet	Every 8-12 hours
Levorphanol	2 mg tablet	Every 6-8 hours
Methadose[a] (methadone)	40 mg soluble tablet	80-120 mg daily
Methadone[a]	5 mg/5mL solution	Every 8-12 hours
Methadone[a]	10 mg/5 mL solution	Every 8-12 hours
Methadose[a] (methadone)	10 mg/mL concentrate	Every 8-12 hours
Morphine	15 mg tablet	Every 4 hours
morphine[a]	30 mg tablet	Every 4 hours
morphine[a]	10 mg/5 mL solution	Every 4 hours
morphine[a]	20 mg/5 mL solution	Every 4 hours
morphine[a]	20 mg/mL concentrate	Every 4 hours
oxycodone[a]	5 mg capsule	Every 4-6 hours
RoxyBond[a] abuse deterrent (oxycodone)	5 mg tablet 15 mg tablet 30 mg tablet	Every 4-6 hours
Roxyicodone[a] (oxycodone)	5 mg tablet	Every 4-6 hours
oxycodone[a]	10 mg tablet	Every 4-6 hours
Roxyicodone[a] (oxycodone)	15 mg tablet	Every 4-6 hours
oxycodone[a]	20 mg tablet	Every 4-6 hours

Appendix 1: Opioids covered in this policy [a] **FDA Approved Indications and Dosage [7]**		
Immediate Release Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Roxyicodone[a] (oxycodone)	30 mg tablet	Every 4-6 hours
oxycodone[a]	5 mg/5mL solution	Every 4-6 hours
oxycodone[a]	20 mg/mL concentrate	Every 4-6 hours
Oxaydo (oxycodone)	5 mg tablet	Every 4-6 hours
Oxaydo (oxycodone)	7.5 mg tablet	Every 4-6 hours
Opana (oxymorphone)	5 mg tablet	Every 4-6 hours
Opana (oxymorphone)	10 mg tablet	Every 4-6 hours
Nucynta (tapentadol)	50 mg tablet	Every 4-6 hours. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.
Nucynta (tapentadol)	75 mg tablet	Every 4-6 hours. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.
Nucynta (tapentadol)	100 mg tablet	Every 4-6 hours. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.
Ultram[a] (tramadol)	50 mg tablet	Every 4 to 6 hours not to exceed 400 mg/day

[a] Generic available, and targeted by this policy

Appendix 1: Opioids covered in this policy (continued) [a] **FDA Approved Indications and Dosage** [7]		
Combination Opioid Agents		
Product	**Indication**	**Dosage & Administration**
oxycodone/ ibuprofen	5 mg/400 mg tablet	Should not exceed 4 tablets (20 mg/1600 mg) in a 24-hour period and should not exceed 7 days.
Reprexain, Ibudone (hydrocodone/ ibuprofen)	2.5 mg/200 mg tablet 5 mg/200 mg tablet 10 mg/200 mg tablet	One tablet every 4 to 6 hours, as necessary. Dosage should not exceed 5 tablets (40 mg/1000 mg) in a 24-hour period.
Vicoprofen (hydrocodone/ ibuprofen)	7.5 mg/200 mg tablet	One tablet every 4 to 6 hours, as necessary. Dosage should not exceed 5 tablets (37.5 mg/1000 mg) in a 24-hour period.
Ultracet (tramadol/ acetaminophen)	37.5 mg/325 mg tablet	2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets (300 mg/2600 mg) per day for up to 5 days.
Percodan, Endodan (oxycodone/ aspirin)	4.8355 mg/325 mg tablet	One tablet every 6 hours as needed for pain. The maximum daily dose of aspirin should not exceed 4 grams or 12 tablets.
Synalgos-DC, Aspirin/Caffeine/ Dihydrocodeine	356.4 mg/30 mg/16 mg capsule	Two capsules every 4 hours as need-ed for pain. Maximum 12 capsules (4,276.8 mg/360 mg/192 mg) per day
Percocet, Endocet (oxycodone/ acetaminophen)	2.5 mg/325 mg tablet	Maximum 12 tablets (30 mg/3,900) per day
Percocet, Endocet, Roxicet (oxycodone/ acetaminophen)	5 mg/325 mg tablet	Maximum 12 tablets (60 mg/3,900 mg) per day
Percocet, Endocet (oxycodone/ acetaminophen)	7.5 mg/325 mg tablet	Maximum 8 tablets (60 mg/2,600) per day
Percocet, Endocet (oxycodone/ acetaminophen)	10 mg/325 mg tablet	Maximum 6 tablets (60 mg/1950 mg) per day

Appendix 1: Opioids covered in this policy (continued) [a] **FDA Approved Indications and Dosage** [7]		
Combination Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Percocet, Endocet (oxycodone/ acetaminophen)	7.5 mg/500 mg tablet	Maximum 8 tablets (60 mg/4,000 mg) per day
Percocet, Endocet (oxycodone/ acetaminophen)	10 mg/650 mg tablet	Maximum 6 tablets (60 mg/3,900 mg) per day
Primlev (oxycodone/ acetaminophen)	5 mg/300 mg tablet	Maximum 12 tablets (60 mg/3,600 mg) per day
Primlev (oxycodone/ acetaminophen)	7.5 mg/300 mg tablet	Maximum 8 tablets (60 mg/2,400mg) per day
Primlev (oxycodone/ acetaminophen)	10 mg/300 mg tablet	Maximum 6 tablets (60 mg/1800 mg) per day
Roxicet (oxycodone/ acetaminophen)	5 mg/500 mg tablet	Maximum 8 tablets (40 mg/4000 mg) per day
Roxicet (oxycodone/ acetaminophen)	5 mg/325 mg/5 mL solution	Maximum 60 mLs (60 mg/3,900mg) per day
Tylox (oxycodone/ acetaminophen)	5 mg/500 mg capsule	Maximum 8 tablets (40 mg/4000 mg) per day
Xolox (oxycodone/ acetaminophen)	10 mg/500 mg tablet	Maximum 8 tablets (80 mg/4000 mg) per day
Capital and Codeine (acetaminophen/ codeine)	120 mg/12 mg/5 mL suspension	Pediatric: 5-10 mLs 3-4 times daily. Maximum 80 mLs (1,920 mg/192 mg) per day Adults: 15 mLs every 4 hours as needed. Maximum 90 mLs (2,160/216 mg) per day

Appendix 1: Opioids covered in this policy (continued) [a] **FDA Approved Indications and Dosage** [7]		
Combination Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/15 mg tablet	Maximum 12 tablets (3600 mg/180 mg) per day
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/30 mg tablet	Maximum 12 tablets (3600 mg/360 mg) per day
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/60 mg tablet	Maximum 6 tablets (1800 mg/360 mg) per day
Hycet (hydrocodone/ acetaminophen)	7.5 mg/325 mg/15 mL solution	Maximum 90 mLs (45 mg/1,950 mg) per day
Hydrocodone/ acetaminophen	2.5 mg/325 mg tablet	One or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 12 tablets (30 mg/3,900 mg).
Hydrocodone/ acetaminophen	2.5 mg/500 mg tablet	One or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 8 tablets (20 mg/4000 mg).
Lorcet, Lorcet Plus (hydrocodone/ acetaminophen)	7.5 mg/650 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets (45 mg/3,900 mg).
Lorcet, Lorcet Plus (hydrocodone/ acetaminophen)	10 mg/650 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 5 tablets (50 mg/3,250 mg).
Lortab (hydrocodone/ acetaminophen)	5 mg/500 mg tablet	One or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 8 tablets (40 mg/4000 mg).
Lortab (hydrocodone/ acetaminophen)	7.5 mg/500 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets (45 mg/3000mg).

Appendix 1: Opioids covered in this policy (continued) [a] **FDA Approved Indications and Dosage** [7]		
Combination Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Lortab (hydrocodone/ acetaminophen)	10 mg/500 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 5 tablets (50 mg/2500 mg).
Lortab (hydrocodone/ acetaminophen)	7.5 mg/500 mg/15 mL solution	Maximum 90 mLs (45 mg/3000 mg) per day.
Maxidone (hydrocodone/ acetaminophen)	10 mg/750 mg tablet	One table every four to six hours as needed for pain. The total daily dosage should not exceed 5 tablets (50 mg/3,750 mg).
Norco (hydrocodone/ acetaminophen)	5 mg/325 mg tablet	One or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 8 tablets (40 mg/2,600 mg).
Norco (hydrocodone/ acetaminophen)	7.5 mg/325 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets (45 mg/1,950 mg).
Norco (hydrocodone/ acetaminophen)	10 mg/325 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 5 tablets (50 mg/1,625 mg).
Xodol (hydrocodone/ acetaminophen)	5 mg/300 mg tablet	One or two tablets every four to six hours as needed for pain. The total daily dosage should not exceed 8 tablets (40 mg/2400 mg).
Xodol (hydrocodone/ acetaminophen)	7.5 mg/300 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets (45 mg/1,800 mg).
Xodol (hydrocodone/ acetaminophen)	10 mg/300 mg tablet	One tablet every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablets (60 mg/1,800 mg).

Appendix 1: Opioids covered in this policy (continued) [a] **FDA Approved Indications and Dosage** [7]		
Combination Opioid Agents		
Product	**Indication**	**Dosage & Administration**
Zamicet (hydrocodone/ acetaminophen)	10 mg/325 mg/15 mL solution	One tablespoonful (15 mL) every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablespoonfuls (90 mLs) (60 mg/1,950 mg).
Zolvit/Lortab (hydrocodone/ acetaminophen)	10 mg/300 mg/15 mL solution	Maximum 67.5 mL (45 mg/1,350 mg) per day
Trezix (acetaminophen/ caffeine/ dihydrocodeine)	320.5 mg/30 mg/16 mg capsule	Two capsules orally every four hours, as needed. No more than two capsules should be taken in a 4-hour period. No more than five doses, or ten capsules (3,205 mg/300mg/160 mg) should be taken in a 24-hour period.
Acetaminophen/Caffeine/ Dihydrocodeine	325 mg/30 mg/16 mg tablet	Two tablets every four hours, as needed. No more than two tablets should be taken in a 4-hour period. No more than 5 doses, or ten tablets, should be taken in a 24-hour period.
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)	50 mg/325 mg/40 mg/30 mg capsule	One or 2 tablets every 4 hours as needed. Total daily dosage should not exceed 6 tablets (300mg/1,950mg/240mg/180mg).
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)	50 mg/300 mg/40 mg/30 mg capsule	One or 2 capsules every 4 hours. Total daily dosage should not exceed 6 capsules (300 mg/1800 mg/240 mg).
Fiorinal w/Codeine (butalbital/ aspirin/ caffeine/ codeine)[a]	50 mg/325 mg/40 mg/30 mg capsule	One or 2 tablets every 4 hours as needed. Total daily dosage should not exceed 6 tablets (300mg/1,950mg/240mg/180mg).

[a] Generic available, and targeted by this policy

Appendix 2: 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 3: Target Agents					
Immediate Release Agents					
Product	**Strength**	**GPI**	**Brand, Generic Availability**	**Multi-source Code**	**Quantity vs. Time (QvT)**
butorphanol	10 mg/mL nasal spray	65200020102050	G	M,N,O,Y	7 days/ 60 days[a]
Codeine	15 mg tablet	65100020200305	BG	M,N,O,Y	7 days/ 60 days[a]
Codeine	30 mg tablet	65100020200310	BG	M,N,O,Y	7 days/ 60 days[a]
Codeine	60 mg tablet	65100020200315	BG	M,N,O,Y	7 days/ 60 days[a]
Hydromorphone, Dilaudid	2 mg tablet	65100035100310	BG	M,N,O,Y	7 days/ 60 days[a]
Hydromorphone, Dilaudid	4 mg tablet	65100035100320	BG	M,N,O,Y	7 days/ 60 days[a]
Hydromorphone, Dilaudid	8 mg tablet	65100035100330	BG	M,N,O,Y	7 days/ 60 days[a]
Hydromorphone, Dilaudid	1 mg/mL liquid	65100035100920	BG	M,N,O,Y	7 days/ 60 days[a]
Levorphanol, Levodromoran	2 mg tablet	65100040100305	B	M,N,O,Y	7 days/ 60 days[a]
Meperidine, Demerol	50 mg tablet	65100045100305	BG	M,N,O,Y	7 days/ 60 days[a]
Meperidine, Demerol	100 mg tablet	65100045100310	BG	M,N,O,Y	7 days/ 60 days[a]
Meperidine, Demerol	50 mg/5 mL solution	65100045102060	B	M,N,O,Y	7 days/ 60 days[a]
Methadone, Dolophine, Methadose	5 mg tablet	65100050100305	BG	M,N,O,Y	7 days/ 60 days[a]
Methadone, Dolophine, Methadose	10 mg tablet	65100050100310	BG	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Methadone, Dolophine, Methadose	40 mg soluble tablet	65100050107320	G	M,N,O,Y	7 days/ 60 days[a]
Methadone, Dolophine, Methadose	5 mg/5mL solution	65100050102010	BG	M,N,O,Y	7 days/ 60 days[a]
Methadone, Dolophine, Methadose	10 mg/5 mL solution	65100050102015	BG	M,N,O,Y	7 days/ 60 days[a]
Methadone, Dolophine, Methadose	10 mg/mL concentrate	65100050101310	BG	M,N,O,Y	7 days/ 60 days[a]
Morphine	15 mg tablet	65100055100310	B	M,N,O,Y	7 days/ 60 days[a]
Morphine	30 mg tablet	65100055100315	B	M,N,O,Y	7 days/ 60 days[a]
Morphine	10 mg/5 mL solution	65100055102065	G	M,N,O,Y	7 days/ 60 days[a]
Morphine	20 mg/5 mL solution	65100055102070	G	M,N,O,Y	7 days/ 60 days[a]
Morphine	20 mg/mL concentrate	65100055102090	G	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	5 mg capsule	65100075100110	G	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	5 mg tablet	65100075100310	BG	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	10 mg tablet	65100075100320	G	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	15 mg tablet	65100075100325	BG	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	20 mg tablet	65100075100330	G	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	30 mg tablet	65100075100340	BG	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	5 mg/5mL solution	65100075102005	G	M,N,O,Y	7 days/ 60 days[a]
Oxycodone, OxyIR, Roxyicodone intensol	20 mg/mL concentrate	65100075101320	G	M,N,O,Y	7 days/ 60 days[a]
Oxecta, Oxaydo (oxycodone)	5 mg tablet	6510007510A510	B	M,N,O,Y	7 days/ 60 days[a]
Oxecta, Oxaydo (oxycodone)	7.5 mg tablet	6510007510A520	B	M,N,O,Y	7 days/ 60 days[a]
Oxymorphone, Opana	5 mg tablet	65100080100305	BG	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Oxymorphone, Opana	10 mg tablet	65100080100310	BG	M,N,O,Y	7 days/ 60 days[a]
Nucynta (tapentadol)	50 mg tablet	65100091100320	B	M,N,O,Y	7 days/ 60 days[a]
Nucynta (tapentadol)	75 mg tablet	65100091100330	B	M,N,O,Y	7 days/ 60 days[a]
Nucynta (tapentadol)	100 mg tablet	65100091100340	B	M,N,O,Y	7 days/ 60 days[a]
Rybix ODT (tramadol)	50 mg orally disintegrating tablet	65100095107220	DC	M,N,O,Y	7 days/ 60 days[a]
Ultram (tramadol)	50 mg tablet	65100095100320	BG	M,N,O,Y	7 days/ 60 days[a]
Combination Agents					
Oxycodone/ Ibuprofen	5 mg/400 mg tablet	65990002260320	B	M,N,O,Y	7 days/ 60 days[a]
Reprexain (hydrocodone/ ibuprofen)	2.5 mg/200 mg tablet	65991702500310	BG	M,N,O,Y	7 days/ 60 days[a]
Reprexain, Ibudone (hydrocodone/ ibuprofen)	5 mg/200 mg tablet	65991702500315	BG	M,N,O,Y	7 days/ 60 days[a]
Reprexain, Ibudone, Xylon (hydrocodone/ ibuprofen)	10 mg/200 mg tablet	65991702500330	BG	M,N,O,Y	7 days/ 60 days[a]
Vicoprofen (hydrocodone/ ibuprofen)	7.5 mg/200 mg tablet	65991702500320	BG	M,N,O,Y	7 days/ 60 days[a]
Ultracet (tramadol/ acetaminophen)	37.5 mg/325 mg tablet	65995002200320	BG	M,N,O,Y	7 days/ 60 days[a]
Percodan, Endodan (oxycodone/ aspirin)	4.8355 mg/325 mg tablet	65990002220340	BG	M,N,O,Y	7 days/ 60 days[a]
Synalgos-DC, Aspirin/Caffeine/Dihydrocodeine	356.4 mg/30 mg/16 mg capsule	65991303100115	B	M,N,O,Y	7 days/ 60 days[a]
Magnacet (oxycodone/ acetaminophen)	5 mg/400 mg tablet	65990002200315	DC	M,N,O,Y	7 days/ 60 days[a]
Magnacet (oxycodone/ acetaminophen)	7.5 mg/400 mg tablet	65990002200328	DC	M,N,O,Y	7 days/ 60 days[a]
Magnacet (oxycodone/ acetaminophen)	10 mg/400 mg tablet	65990002200336	DC	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Percocet, Endocet (oxycodone/ acetaminophen)	2.5 mg/325 mg tablet	65990002200305	BG	M,N,O,Y	7 days/ 60 days[a]
Percocet, Endocet, Roxicet (oxycodone/ acetaminophen)	5 mg/325 mg tablet	65990002200310	BG	M,N,O,Y	7 days/ 60 days[a]
Percocet, Endocet (oxycodone/ acetaminophen)	7.5 mg/325 mg tablet	65990002200327	BG	M,N,O,Y	7 days/ 60 days[a]
Percocet, Endocet (oxycodone/ acetaminophen)	7.5 mg/500 mg tablet	65990002200330	DC	M,N,O,Y	7 days/ 60 days[a]
Percocet, Endocet (oxycodone/ acetaminophen)	10 mg/325 mg tablet	65990002200335	BG	M,N,O,Y	7 days/ 60 days[a]
Percocet, Endocet (oxycodone/ acetaminophen)	10 mg/650 mg tablet	65990002200340	DC	M,N,O,Y	7 days/ 60 days[a]
Primlev (oxycodone/ acetaminophen)	5 mg/300 mg tablet	65990002200308	B	M,N,O,Y	7 days/ 60 days[a]
Primlev (oxycodone/ acetaminophen)	7.5 mg/300 mg tablet	65990002200325	B	M,N,O,Y	7 days/ 60 days[a]
Primlev (oxycodone/ acetaminophen)	10 mg/300 mg tablet	65990002200333	B	M,N,O,Y	7 days/ 60 days[a]
Roxicet (oxycodone/ acetaminophen)	5 mg/500 mg tablet	65990002200320	DC	M,N,O,Y	7 days/ 60 days[a]
Roxicet (oxycodone/ acetaminophen)	5 mg/325 mg/5 mL solution	65990002202005	B	M,N,O,Y	7 days/ 60 days[a]
Tylox (oxycodone/ acetaminophen)	5 mg/500 mg capsule	65990002200120	DC	M,N,O,Y	7 days/ 60 days[a]
Xolox (oxycodone/ acetaminophen)	10 mg/500 mg tablet	65990002200337	DC	M,N,O,Y	7 days/ 60 days[a]
Capital and Codeine (acetaminophen/codeine)	120 mg/12 mg/5 mL suspension	65991002051805	B	M,N,O,Y	7 days/ 60 days[a]
Acetaminophen/codeine	120 mg/12 mg/5 mL solution	65991002052020	G	M,N,O,Y	7 days/ 60 days[a]
Cocet (acetaminophen/codeine)	650 mg/30 mg tablet	65991002050325	DC	M,N,O,Y	7 days/ 60 days[a]
Cocet Plus (acetaminophen/codeine)	650 mg/60 mg tablet	65991002050327	DC	M,N,O,Y	7 days/ 60 days[a]
Tylenol w/Codeine (acetaminophen/codeine)	300 mg/15 mg tablet	65991002050310	BG	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Tylenol w/Codeine (acetaminophen/codeine)	300 mg/30 mg tablet	65991002050315	BG	M,N,O,Y	7 days/ 60 days[a]
Tylenol w/Codeine (acetaminophen/codeine)	300 mg/60 mg tablet	65991002050320	BG	M,N,O,Y	7 days/ 60 days[a]
Hycet (hydrocodone/ acetaminophen)	7.5 mg/325 mg/15 mL solution	65991702102015	BG	M,N,O,Y	7 days/ 60 days[a]
Hydrocodone/ acetaminophen	2.5 mg/325 mg tablet	65991702100302	G	M,N,O,Y	7 days/ 60 days[a]
Hydrocodone/ acetaminophen	2.5 mg/500 mg tablet	65991702100307	DC	M,N,O,Y	7 days/ 60 days[a]
Lorcet, Lorcet Plus (hydrocodone/ acetaminophen)	7.5 mg/650 mg tablet	65991702100340	DC	M,N,O,Y	7 days/ 60 days[a]
Lorcet, Lorcet Plus (hydrocodone/ acetaminophen)	10 mg/650 mg tablet	65991702100345	DC	M,N,O,Y	7 days/ 60 days[a]
Lortab (hydrocodone/ acetaminophen)	5 mg/500 mg tablet	65991702100310	DC	M,N,O,Y	7 days/ 60 days[a]
Lortab (hydrocodone/ acetaminophen)	7.5 mg/500 mg tablet	65991702100325	DC	M,N,O,Y	7 days/ 60 days[a]
Lortab (hydrocodone/ acetaminophen)	10 mg/500 mg tablet	65991702100327	DC	M,N,O,Y	7 days/ 60 days[a]
Lortab (hydrocodone/ acetaminophen)	7.5 mg/500 mg/15 mL solution	65991702102020	B	M,N,O,Y	7 days/ 60 days[a]
Maxidone (hydrocodone/ acetaminophen)	10 mg/750 mg tablet	65991702100353	DC	M,N,O,Y	7 days/ 60 days[a]
Norco (hydrocodone/ acetaminophen)	5 mg/325 mg tablet	65991702100356	BG	M,N,O,Y	7 days/ 60 days[a]
Norco (hydrocodone/ acetaminophen)	7.5 mg/325 mg tablet	65991702100358	BG	M,N,O,Y	7 days/ 60 days[a]
Norco (hydrocodone/ acetaminophen)	10 mg/325 mg tablet	65991702100305	BG	M,N,O,Y	7 days/ 60 days[a]
Stagesic, Hydrogesic, Polygesic (hydrocodone/ acetaminophen)	5 mg/500 mg capsule	65991702100110	DC	M,N,O,Y	7 days/ 60 days[a]
Vicodin, Vicodin ES, Vicodin HP (hydrocodone/ acetaminophen)	7.5 mg/750 mg tablet	65991702100350	DC	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Vicodin, Vicodin ES, Vicodin HP (hydrocodone/ acetaminophen)	10 mg/660 mg tablet	65991702100346	DC	M,N,O,Y	7 days/ 60 days[a]
Xodol (hydrocodone/ acetaminophen)	5 mg/300 mg tablet	65991702100309	BG	M,N,O,Y	7 days/ 60 days[a]
Xodol (hydrocodone/ acetaminophen)	7.5 mg/300 mg tablet	65991702100322	BG	M,N,O,Y	7 days/ 60 days[a]
Xodol (hydrocodone/ acetaminophen)	10 mg/300 mg tablet	65991702100375	BG	M,N,O,Y	7 days/ 60 days[a]
hydrocodone/ acetaminophen solution	10 mg/325 mg/15 mL solution	65991702102025	BG	M,N,O,Y	7 days/ 60 days[a]
Zolvit/Lortab (hydrocodone/ acetaminophen)	10 mg/300 mg/15 mL solution	65991702102024	B	M,N,O,Y	7 days/ 60 days[a]
Zydone (hydrocodone/ acetaminophen)	5 mg/400 mg tablet	65991702100360	DC	M,N,O,Y	7 days/ 60 days[a]
Zydone (hydrocodone/ acetaminophen)	7.5 mg/400 mg tablet	65991702100365	DC	M,N,O,Y	7 days/ 60 days[a]
Zydone (hydrocodone/ acetaminophen)	10 mg/400 mg tablet	65991702100370	DC	M,N,O,Y	7 days/ 60 days[a]
Trezix (acetaminophen/caffeine/ dihydrocodeine)	320.5 mg/30 mg/16 mg capsule	65991303050115	BG	M,N,O,Y	7 days/ 60 days[a]
Trezix (acetaminophen/caffeine/ dihydrocodeine)	356.4 mg/30 mg/16 mg capsule	65991303050120	DC	M,N,O,Y	7 days/ 60 days[a]
Acetaminophen/Caffeine/Dihydrocodeine	325 mg/30 mg/16 mg tablet	65991303050320	B	M,N,O,Y	7 days/ 60 daysa
Panlor SS, ZerLor (acetaminophen/caffeine/ dihydrocodeine)	712.8 mg/60 mg/32 mg tablet	65991303050340	DC	M,N,O,Y	7 days/ 60 days[a]
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)	50 mg/325 mg/40 mg/30 mg capsule	65991004100115	BG	M,N,O,Y	7 days/ 60 days[a]
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)	50 mg/300 mg/40 mg/30 mg capsule	65991004100113	BG	M,N,O,Y	7 days/ 60 days[a]
Fiorinal w/Codeine (butalbital/ aspirin/caffeine/ codeine)	50 mg/325 mg/40 mg/30 mg capsule	65991004300115	BG	M,N,O,Y	7 days/ 60 days[a]

Appendix 3: Target Agents					
Oxycodone/ ibuprofen	5 mg/400 mg tablet	65990002260320	B	M,N,O,Y	7 days/ 60 days[a]
Reprexain (hydrocodone/ ibuprofen)	2.5 mg/200 mg tablet	65991702500310	BG	M,N,O,Y	7 days/ 60 days[a]
Reprexain, Ibudone (hydrocodone/ ibuprofen)	5 mg/200 mg tablet	65991702500315	BG	M,N,O,Y	7 days/ 60 days[a]

Appendix 4: 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 5: 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 6: Verification of DATA 2000 waiver (XDEA) to prescribe buprenorphine office-based opioid dependence treatment (OBOT) for the treatment of opioid addiction [6,8]

- Prescribers must include their DATA 2000 waiver ID number (or "X" number) on prescriptions for opioid addiction treatment medications, in addition the DEA registration number.
- The SAMHSA Buprenorphine Physician Locator Web site lists the physicians in each State who have DATA 2000 waivers. (https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/verify-physician-waivers)
  - * A physician listed on the site can be considered to have a valid DATA 2000 waiver.
  - * The list on the site is not complete, as physicians with a valid waiver may choose not to be listed on the site.
    - A pharmacist may verify that a physician has a valid DATA 2000 waiver by calling SAMHSA at 1-866-287-2728 or by e-mail at info@buprenorphine.samhsa.gov. Pharmacists should convey their DEA registration number with these requests.
- If a prescriber is not listed on the website above, the pharmacy will be called to verify the XDEA is on the written prescription.

Appendix 7: RAND 36-Item Short Form Health Survey (SF-36) [18]

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 8: 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 9: State Prescription Drug Monitoring Programs, Guidelines, Administrative Rules, and Statues Regarding Chronic Opioid Therapy for Non-Malignant Pain.
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/ www.oregonpainguidance.org/clinical-tools
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/guidelines.asp
All other states PDMPs: http://www.namsdl.org/prescription-monitoring-programs.cfm http://missouri.pmpaware.net/

Cross References
Fentanyl-containing Medications (Actiq, Abstral, Fentora, generic lozenges, Lazanda, Onsolis, Subsys), 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

Codes	Number	Description
N/A		

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Revision History

Revision Date	Revision Summary
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 Appendix 3 (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.
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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