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: April 25, 2019 | **Next Review Date:** January 2020

Effective Date: July 1, 2019

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).

This policy applies to all extended-release (ER) opioids prescribed for any quantity.

NOTE: Immediate-release (IR) opioids are covered in a separate policy.

Policy/Criteria

I. Most contracts require pre-authorization approval of extended-release (ER) opioids (as listed in *Appendix 1,* including commercial and extemporaneously compounded opioids) prior to coverage. **Extended-release (ER) opioid therapy** 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 chronic non-cancer pain and ALL of the following are met:
      i. 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

      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 in clinical documentation (including, but not limited to chart notes), including both criteria a. and b. 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

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

AND

iv. ONE of the following:

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

OR

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

AND

v. 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. Patient. (NOTE: the expectation is this comprehensive plan will be addressed at patient evaluations, at least every six months)

AND

2. The patient does not have any FDA labeled contraindication(s) to the requested agent (see *Appendix 3*)

AND

3. ONE of the following:

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

II. Administration and Authorization Period

A. Regence Pharmacy Services considers extended-release (ER) opioids (oral, nasal, and topical) to be 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 daily quantity defined in *Appendix 4* based on MEDs and prescribing information.
    b. Quantities above the policy quantity limit (as defined in *Appendix 4*) may be approved when BOTH of the following are met:
        i. The requested dose cannot be achieved using a lesser quantity of a higher strength

        AND

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

            OR

            b. 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. **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 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, for up to the daily quantity defined in *Appendix 4*.

III. 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 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 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 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 10*).
- 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.
- The policy will not be approved for those with FDA labeled contraindication(s) to the requested agent.

- 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), 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 < 3 days (and rarely for >7 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 5*).
- 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 *Appendix 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 7*. [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 ER 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: 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. [14]
- 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 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 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. [10]
- PDMPs are monitored for safe use of opioids and other controlled substances. (See *Appendix 10* for more information).

Appendix 1: Opioids covered in this policy [a] FDA APPROVED INDICATIONS AND DOSAGE [7,19]		
Brand/Generic Name	**Dosing Frequency** **(Maximum Labeled Dose)**	**Indication and Usage**
Narcotics		
Arymo ER (morphine sulfate ER) 15, 30, 60 mg	Two or three times daily	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • Product is not indicated as an as-needed (prn) analgesic.
Avinza **morphine sulfate ER** 30, 45, 60, 75, 90, 120 mg	Once daily (1600 mg daily)	
Belbuca (buprenorphine buccal film) 75, 150, 300, 450, 600, 750, 900 mcg	Twice daily (1800 mcg daily)	
Butrans (buprenorphine transdermal) 5, 7.5, 10, 15, 20 mcg/hour system	1 transdermal system weekly (20 mcg/hr)	
Duragesi (fentanyl transdermal patch) 12, 25, 50, 75, 100 mcg/hour	15 patches per month	
Embeda (morphine/naltrexone ER) 20-0.8, 30-1.2, 50-2, 60-2.4, 80-3.2, 100-4 mg	Once or twice daily	
Exalgo (hydromorphone ER) [a] 8, 12, 16, 32 mg	Once daily	
Fentanyl transdermal patch 37.5, 62.5, 87.5 mcg/hour	15 patches per month	
Hysingla ER (hydrocodone ER) 20, 30, 40, 60, 80, 100, 120 mg	Once daily	
Kadian [a] (morphine ER) 10, 20, 30, 40, 50, 60, 70, 80, 100, 130, 150, 200 mg	Once or twice daily	

Appendix 1: Opioids covered in this policy [a] **FDA APPROVED INDICATIONS AND DOSAGE** [7,19]		
Brand/Generic Name	**Dosing Frequency** **(Maximum Labeled Dose)**	**Indication and Usage**
MorphaBond ER Abuse Deterrent (morphine sulfate ER) 15, 30, 60, 100 mg	Twice daily	
MS Contin [a] (morphine sulfate ER) 15, 30, 60, 100, 200 mg	Twice daily with some patients requiring three times daily	
Opana ER (oxymorphone ER) 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg	Twice daily	
Oramorph SR (morphine ER) 15, 30, 60, 100 mg	Twice daily with some patients requiring three times daily	
OxyContin (oxycodone ER)	Twice daily	
Troxyca ER (oxycodone/naltrexone) ER cap	Twice daily	
Xtampza ER (oxycodone ER) 9, 13.5, 18, 27, 36 mg capsules	Twice daily (288 mg)	
Zohydro ER (hydrocodone ER) 10, 15, 20, 30, 40, 50 mg capsules	Twice daily	
Zohydro ER Abuse Deterrent (hydrocodone ER) 10, 15, 20, 30, 40, 50 mg capsules	Twice daily	
Xartemis XR (oxycodone/acetaminophen ER) 7.5 mg/325 mg tablet	Twice daily	Management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. Limitations of Use: Because of the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, reserve oxycodone/acetaminophen ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate

Appendix 1: Opioids covered in this policy [a] **FDA APPROVED INDICATIONS AND DOSAGE** [7,19]		
Brand/Generic Name	**Dosing Frequency** **(Maximum Labeled Dose)**	**Indication and Usage**
Tapentadol, Tramadol		
Nucynta ER (tapentadol ER) 50, 100, 150, 200, 250 mg	Twice daily (500 mg daily)	Pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve tapentadol ER for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Tapentadol ER is not indicated as an as-needed (prn) analgesic.
Conzip (tramadol SR biphasic) 100, 200, 300 mg	Once daily (300 mg daily)	Management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time
Ryzolt [a] (tramadol ER) 100, 200, 300 mg	Once daily (300 mg daily)	
Tramadol SR Biphasic (tramadol SR biphasic) 150 mg	Once daily (300 mg daily)	

Appendix 1: Opioids covered in this policy [a] FDA APPROVED INDICATIONS AND DOSAGE [7,19]		
Brand/Generic Name	**Dosing Frequency** **(Maximum Labeled Dose)**	**Indication and Usage**
Ultram ER [a] (tramadol ER) 100, 200, 300 mg	Once daily (300 mg daily)	

a - generic available, and targeted by the 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: FDA Labeled Contraindication(s) [7]	
Agent	**Contraindication(s)**
Arymo ER morphine sulfate ER	• Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Concurrent use of monoamine oxidase inhibitors (MAOIs) or use within 14 days • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to morphine
Avinza morphine sulfate ER	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known of suspected paralytic ileus • Hypersensitivity (e.g. anaphylaxis) to morphine
Belbuca (buprenorphine buccal film)	Patients with: • Significant respiratory depression Acute or severe bronchial asthma • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to buprenorphine

Appendix 3: FDA Labeled Contraindication(s) [7]	
Agent	**Contraindication(s)**
Butrans (buprenorphine transdermal)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known of suspected paralytic ileus • Hypersensitivity (e.g. anaphylaxis) to buprenorphine
Duragesic (fentanyl transdermal system)	• Opioid non-tolerant patients. • Acute or intermittent pain, postoperative pain, mild pain. • Respiratory compromise, acute or severe asthma. • Paralytic ileus. • Known hypersensitivity to fentanyl or any of the components of the transdermal system.
Embeda (morphine/naltrexone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known of suspected paralytic ileus • Hypersensitivity (e.g. anaphylaxis) to morphine or naltrexone
Exalgo (hydromorphone ER)	• Opioid non-tolerant patients. • Patients with o Significant respiratory depression o Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment o Known or suspected paralytic ileus o surgical procedures and/or underlying disease resulting in narrowing of the gastrointestinal tract, or have "blind loops" of the gastrointestinal tract or gastrointestinal obstruction o Hypersensitivity (e.g. anaphylaxis) to hydromorphone or sulfite-containing medications
Fentanyl transdermal system	• Opioid non-tolerant patients. • Acute or intermittent pain, postoperative pain, mild pain. • Respiratory compromise, acute or severe asthma. • Paralytic ileus. • Known hypersensitivity to fentanyl or any of the components of the transdermal system.

Appendix 3: FDA Labeled Contraindication(s) [7]	
Agent	**Contraindication(s)**
Hysingla ER (hydrocodone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known of suspected paralytic ileus or gastrointestinal obstruction • Hypersensitivity to any component of Hysingla ER or the active ingredient, hydrocodone bitartrate
Kadian (morphine ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus • Hypersensitivity (e.g. anaphylaxis) to morphine
MorphaBond ER Abuse Deterrent (morphine sulfate ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to morphine
MS Contin (morphine sulfate ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus • Hypersensitivity (e.g., anaphylaxis) to morphine
Oramorph SR (morphine ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus • Hypersensitivity (e.g. anaphylaxis) to morphine
Opana ER (oxymorphone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment • Hypersensitivity to oxymorphone • Moderate or severe hepatic impairment • Known or suspected gastrointestinal obstruction, including paralytic ileus

Appendix 3: FDA Labeled Contraindication(s) [7]	
Agent	**Contraindication(s)**
OxyContin (oxycodone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma • Known or suspected paralytic ileus and GI obstruction • Hypersensitivity to oxycodone
Xartemis XR (oxycodone/acetaminophen ER)	• Patients who have known hypersensitivity to oxycodone, acetaminophen or any other components of the product. • Patients who have significant respiratory depression. • Patients who have acute or severe bronchial asthma or hypercarbia. • Patients who have suspected or known paralytic ileus.
Xtampza ER (oxycodone ER)	• Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity (e.g., anaphylaxis) to oxycodone.
Zohydro ER (hydrocodone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma or hypercarbia • Known or suspected paralytic ileus • Hypersensitivity to hydrocodone bitartrate or any other ingredients in Zohydro ER
Zohydro ER Abuse Deterrent (hydrocodone ER)	Patients with: • Significant respiratory depression • Acute or severe bronchial asthma or hypercarbia • Known or suspected paralytic ileus • Hypersensitivity to hydrocodone bitartrate or any other ingredients in Zohydro ER
ConZip (tramadol SR biphasic ER)	• Patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids • Patients with significant respiratory depression in unmonitored settings or the absence of resuscitative equipment • Patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment • All other opioid contraindications, including intoxication with alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs

Appendix 3: FDA Labeled Contraindication(s) [7]	
Agent	**Contraindication(s)**
Nucynta ER (tapentadol ER)	• Significant respiratory depression • Acute or severe bronchial asthma • Known or suspected paralytic ileus • Hypersensitivity to tapentadol or to any other ingredients of the product • Concurrent use of monoamine oxidase inhibitors (MAOI) or use within the last 14 days
Ryzolt (tramadol ER)	• Patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. • Patients with significant respiratory depression in unmonitored settings or the absence of resuscitative equipment. • Patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment.
Tramadol ER (tramadol SR biphasic)	• Patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. • Contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. Tramadol ER may worsen central nervous system and respiratory depression in these patients
Ultram ER (tramadol ER)	• Patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. • Contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. Tramadol ER may worsen central nervous system and respiratory depression in these patients

Appendix 4: Pre-Authorization and Quantity Limit Target Drugs – Recommended Limits		
Brand (generic)	**GPI**	**Quantity Per Day Limit**
Narcotic Analgesics		
Arymo ER (morphine sulfate)		
15 mg extended release tablet	6510005510A620	3 tablets
30 mg extended release tablet	6510005510A630	3 tablets
60 mg extended release tablet	6510005510A640	3 tablets
Avinza, morphine sulfate ER		
30 mg sustained-release capsule	65100055207020	1 capsule
45 mg sustained-release capsule	65100055207025	1 capsule
60 mg sustained-release capsule	65100055207030	1 capsule
75 mg sustained-release capsule	65100055207035	1 capsule
90 mg sustained-release capsule	65100055207040	1 capsule
120 mg sustained-release capsule	65100055207050	1 capsule
Belbuca (buprenorphine buccal film)		
75 mcg buccal film	65200010108210	2 films
150 mcg buccal film	65200010108220	2 films
300 mcg buccal film	65200010108230	2 films
450 mcg buccal film	65200010108240	2 films
600 mcg buccal film	65200010108250	2 films
750 mcg buccal film	65200010108260	2 films
900 mcg buccal film	65200010108270	2 films
Butrans, (buprenorphine transdermal)		
5 mcg/hour transdermal system	65200010008820	1 system/week
7.5 mcg/hour transdermal system	65200010008825	1 system/week
10 mcg/hour transdermal system	65200010008830	1 system/week
15 mcg/hour transdermal system	65200010008835	1 system/week
20 mcg/hour transdermal system	65200010008840	1 system/week
Duragesic (fentanyl transdermal patch)		
12 mcg/hr transdermal patch	65100025008610	15 patches/month
25 mcg/hr transdermal patch	65100025008620	15 patches/month
50 mcg/hr transdermal patch	65100025008630	15 patches/month
75 mcg/hr transdermal patch	65100025008640	15 patches/month
100 mcg/hr transdermal patch	65100025008650	15 patches/month
Embeda (morphine/naltrexone ER)		
20 mg/0.8 mg controlled-release capsule	65100055700220	2 capsules
30 mg/1.2 mg controlled-release capsule	65100055700230	2 capsules
50 mg/2 mg controlled-release capsule	65100055700240	2 capsules
60 mg/2.4 mg controlled-release capsule	65100055700250	2 capsules
80 mg/3.2 mg controlled-release capsule	65100055700260	2 capsules
100 mg/4 mg controlled-release capsule	65100055700270	2 capsules
Exalgo (hydromorphone ER)		
8 mg extended-release tablet[a]	6510003510A820	1 tablet
12 mg extended-release tablet[a]	6510003510A830	1 tablet
16 mg extended-release tablet[a]	6510003510A840	1 tablet
32 mg extended-release tablet	6510003510A855	1 tablet
Fentanyl transdermal patch		
37.5 mcg/hr transdermal patch	65100025008626	15 patches/month
62.5 mcg/hr transdermal patch	65100025008635	15 patches/month
87.5 mcg/hr transdermal patch	65100025008645	15 patches/month
Hysingla ER (hydrocodone ER)		
20 mg extended-release tablet	6510003010A810	1 tablet

Appendix 4: Pre-Authorization and Quantity Limit Target Drugs – Recommended Limits		
Brand (generic)	**GPI**	**Quantity Per Day Limit**
30 mg extended-release tablet	6510003010A820	1 tablet
40 mg extended-release tablet	6510003010A830	1 tablet
60 mg extended-release tablet	6510003010A840	1 tablet
80 mg extended-release tablet	6510003010A850	1 tablet
100 mg extended-release tablet	6510003010A860	1 tablet
120 mg extended-release tablet	6510003010A870	1 tablet
Kadian (morphine sulfate ER)		
10 mg sustained-release capsule[a]	65100055107010	2 capsules
20 mg sustained-release capsule[a]	65100055107020	2 capsules
30 mg sustained-release capsule[a]	65100055107030	2 capsules
40 mg sustained-release capsule	65100055107035	2 capsules
50 mg sustained-release capsule[a]	65100055107040	2 capsules
60 mg sustained-release capsule[a]	65100055107045	2 capsules
70 mg sustained-release capsule	65100055107047	2 capsules
80 mg sustained-release capsule[a]	65100055107050	2 capsules
100 mg sustained-release capsule[a]	65100055107060	2 capsules
130 mg sustained-release capsule	65100055107070	2 capsules
150 mg sustained-release capsule	65100055107074	2 capsules
200 mg sustained-release capsule	65100055107080	2 capsules
MorphaBond ER (morphine sulfate ER)[a]		
15 mg sustained-release tablet	6510005510A720	2 tablets
30 mg sustained-release tablet	6510005510A730	2 tablets
60 mg sustained-release tablet	6510005510A740	2 tablets
100 mg sustained-release tablet	6510005510A760	2 tablets
MS Contin (morphine sulfate ER)[a]		
15 mg sustained-release tablet	65100055100415	3 tablets
30 mg sustained-release tablet	65100055100432	3 tablets
60 mg sustained-release tablet	65100055100445	3 tablets
100 mg sustained-release tablet	65100055100460	3 tablets
200 mg sustained-release tablet	65100055100480	3 tablets
Opana ER (oxymorphone ER)		
5 mg extended-release tablet	6510008010A705	2 tablets
7.5 mg extended-release tablet	6510008010A707	2 tablets
10 mg extended-release tablet	6510008010A710	2 tablets
15 mg extended-release tablet	6510008010A715	2 tablets
20 mg extended-release tablet	6510008010A720	2 tablets
30 mg extended-release tablet	6510008010A730	2 tablets
40 mg extended-release tablet	6510008010A740	2 tablets
Oramorph SR (morphine sulfate ER)		
15 mg sustained-release tablet	65100055107415	3 tablets
30 mg sustained-release tablet	65100055107430	3 tablets
60 mg sustained-release tablet	65100055107445	3 tablets
100 mg sustained-release tablet	65100055107460	3 tablets
OxyContin (oxycodone ER)		
5 mg extended release tablet	6510007510A705	2 tablets
10 mg extended release tablet	6510007510A710	2 tablets
15 mg extended release tablet	6510007510A715	2 tablets
20 mg extended release tablet	6510007510A720	2 tablets
30 mg extended release tablet	6510007510A730	2 tablets
40 mg extended release tablet	6510007510A740	2 tablets

Appendix 4: Pre-Authorization and Quantity Limit Target Drugs – Recommended Limits		
Brand (generic)	**GPI**	**Quantity Per Day Limit**
60 mg extended release tablet	6510007510A760	4 tablets
80 mg extended release tablet	6510007510A780	4 tablets
oxymorphone ER		
5 mg extended-release tablet	65100080107405	2 tablets
7.5 mg extended-release tablet	65100080107407	2 tablets
10 mg extended-release tablet	65100080107410	2 tablets
15 mg extended-release tablet	65100080107415	2 tablets
20 mg extended-release tablet	65100080107420	2 tablets
30 mg extended-release tablet	65-10-00-80-10-74-30	2 tablets
40 mg extended-release tablet	65-10-00-80-10-74-40	2 tablets
Xartemis XR (oxycodone/acetaminophen ER)		
7.5 mg/325 mg extended release tablet	65990002200430	4 tablets
Xtampza ER (oxycodone ER)		
9 mg capsule	6510007500A310	2 capsules
13.5 mg capsule	6510007500A315	2 capsules
18 mg capsule	6510007500A320	2 capsules
27 mg capsule	6510007500A330	2 capsules
36 mg capsule	6510007500A340	2 capsules
Zohydro ER (hydrocodone ER)		
10 mg sustained-release capsule	65100030106910	2 capsules
15 mg sustained-release capsule	65100030106915	2 capsules
20 mg sustained-release capsule	65100030106920	2 capsules
30 mg sustained-release capsule	65100030106930	2 capsules
40 mg sustained-release capsule	65100030106940	2 capsules
50 mg sustained-release capsule	65100030106950	2 capsules
Zohydro ER Abuse Deterrent (hydrocodone ER)		
10 mg sustained-release capsule	6510003010A310	2 capsules
15 mg sustained-release capsule	6510003010A315	2 capsules
20 mg sustained-release capsule	6510003010A320	2 capsules
30 mg sustained-release capsule	6510003010A330	2 capsules
40 mg sustained-release capsule	6510003010A340	2 capsules
50 mg sustained-release capsule	6510003010A350	2 capsules
Tramadol, Tapentadol		
ConZip (tramadol SR biphasic ER)		
100 mg sustained-release capsule	65100095107070	1 capsule
200 mg sustained-release capsule	65100095107080	1 capsule
300 mg sustained-release capsule	65100095107090	1 capsule
Nucynta ER (tapentadol ER)		
50 mg extended-release tablet	65100091107420	2 tablets
100 mg extended-release tablet	65100091107430	2 tablets
150 mg extended-release tablet	65100091107440	2 tablets
200 mg extended-release tablet	65100091107450	2 tablets
250 mg extended-release tablet	65100091107460	2 tablets
Ryzolt (tramadol ER)[a]		
100 mg sustained-release tablet	65100095107560	1 tablet
200 mg sustained-release tablet	65100095107570	1 tablet
300 mg sustained-release tablet	65100095107580	1 tablet
Tramadol ER (tramadol SR biphasic)		
150 mg sustained-release capsule	65100095107075	1 capsule

Appendix 4: Pre-Authorization and Quantity Limit Target Drugs – Recommended Limits		
Brand (generic)	**GPI**	**Quantity Per Day Limit**
Ultram ER (tramadol ER)[a]		
100 mg sustained-release tablet	65100095107520	1 tablet
200 mg sustained-release tablet	65100095107530	1 tablet
300 mg sustained-release tablet	65100095107540	1 tablet

a – generic available, included in quantity limit policy

Appendix 5: 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 6: 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 7: 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 8: 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 9: 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 10: State Prescription Drug Monitoring Programs, Guidelines, Administrative Rules, and Statues Regarding Chronic Opioid Therapy for Non-Malignant Pain.
IDAHO www.healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/LongActingNarcoticAnalgesics.pdf https:/idaho.pmpaware.net/login
OREGON www.oregon.gov/omb/Topics-of-Interest/Pages/Pain-Management.aspx www.orpdmp.com/health-care-provider/ www.oregonpainguidance.org/clinical-tools
UTAH health.utah.gov/prescription/pdf/guidelines/final04.09opioidGuidlines_summary%20WEB.pdf www.dopl.utah.gov/programs/csdb/index.html
WASHINGTON www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement.aspx /www.wapmp.org/ www.agencymeddirectors.wa.gov/guidelines.asp www.hca.wa.gov/billers-providers/programs-and-services/opioids
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
Immediate-release (IR) Opioid Medication Products for Pain, Medication Policy Manual, Policy No. dru516

Codes	Number	Description
N/A		

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. *MMWR Recomm Rep*. 2016 Mar 18;65(1):1-49. PMID: 26987082.[cited 3/26/2018] Available at: http://www.cdc.gov/drugoverdose/prescribing/guideline.html
2. Agency Medical Director's Group. Interagency Guideline on Prescribing Opioids for Pain 3rd Edition. AMDG. Olympia, WA. June 2015. [cited 3/26/2018] Available at: http://www.agencymeddirectors.wa.gov/guidelines.asp
3. Federation of State Medical Boards (FSMB). Model Policy for the Use of Controlled Substances for the Treatment of Pain. Washington, DC: The Federation, July 2013. [cited 3/26/2018] Available at: http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf
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 3/26/2018] Available at: https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/verify-physician-waivers
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 3/26/2018] 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. The World Health Organization. Pain relief Ladder. [cited 3/26/2018] Available at: http://www.who.int/cancer/palliative/painladder/en/ .
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. CMS. Opioid Morphine Equivalent Conversion Factors.docx. [cited 3/26/2018] Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-March-2015.pdf
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

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), 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.