Pharmacy Management Drug Policy

SUBJECT: Opioid Management Health and Safety Program
POLICY NUMBER: PHARMACY-34
EFFECTIVE DATE: 06/2007
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If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

General Background Center for Disease Control and Prevention (CDC)

In 2022, the Centers for Disease Control and Prevention (CDC) published the Clinical Practice Guideline for Prescribing Opioids for Pain as it had updated the CDC Guideline for Prescribing Opioids for Chronic Pain from 2016. The guideline provides recommendations for those clinicians providing pain care, including those prescribing opioids, for outpatients aged ≥18 years. These clinicians include primary care providers, dentists, pain medicine and orthopedic providers. It includes recommendations for managing acute (duration of <1 month), subacute (duration of 1–3 months), and chronic (duration of >3 months) pain. These guideline recommendations do not apply to pain related to sickle cell disease, cancer, palliative care, and end-of-life care. The scope of this coverage policy similarly excludes these diagnoses due to the complex nature of pain management in these conditions. For more information pertaining to pain management in these conditions please refer to the following resources: for cancer related pain management refer to the National Comprehensive Cancer Network Clinical Practice Guidelines, for palliative and end-of-life care please refer to the American Academy of Family Physicians or National Institutes of Health, for pain management related to sickle cell disease refer to the American Society of Hematology (ASH) 2020 Guidelines for Sickle Cell Disease: Management of Acute and Chronic Pain. (Dowell, 2022).

The guidelines provide statistical information related to pain and the utilization of opioid medications for the treatment of pain in the United States. Approximately one in five U.S. adults had chronic pain in 2019 and approximately one in 14 adults experienced "high impact" chronic pain, defined as having pain on most days or every day during the past 3 months that limited life or work activities. Pain, especially chronic pain, can affect almost every aspect of a person's life, leading to impaired physical functioning, poor mental health, and reduced quality of life, and contributes to substantial morbidity each year. In 2011, the economic costs of chronic pain were estimated to range from $560 to $635 billion in annual direct medical costs, lost productivity, and disability. Because of the clinical, psychological, and social consequences associated with pain, it is essential that clinicians have the resources to provide appropriate and compassionate care for patients with pain. An important aim of pain management is the provision of patient-centered care built on trust between patients and clinicians. (Dowell, 2022)

The 2022 guideline includes recommendations for prescribing opioids to outpatients aged ≥18 years with acute (duration of <1 month), subacute (duration of 1–3 months), or chronic (duration of >3 months) pain but are not intended to be absolute limits of practice. Flexibility for clinicians and patients is paramount when making patient-centered clinical treatment decisions. The key areas covered in the guideline are

determining whether or not to initiate opioids for pain, selecting opioids and determining opioid dosages, deciding duration of initial opioid prescriptions, conducting follow-up, assessing risk, and addressing potential harms of opioid use. (Dowell, 2022).

In addition to updating recommendations on the basis of new evidence regarding management of chronic pain, the clinical practice guideline is intended to assist clinicians in weighing benefits and risks of prescribing opioid pain medication for painful acute conditions (e.g., low back pain, neck pain, other musculoskeletal pain, neuropathic pain, dental pain, kidney stone pain, and acute episodic migraine) and pain related to procedures (e.g., postoperative pain and pain from oral surgery). Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy if benefits are anticipated to outweigh risks to the patient. Nonopioid therapies are at least as effective as opioids for many common types of acute pain (such as sprains, tendonitis, dental pain, headaches) and preferred for subacute and chronic pain (such as osteoarthritis and fibromyalgia). Nonopioid pharmacologic therapies include topical/oral NSAIDs, acetaminophen, muscle relaxants, triptans, and selected antidepressants and anticonvulsants. Nonpharmacologic therapies include ice, heat, acupuncture, physical therapy, massage, and exercise. (Dowell, 2022)

Opioids are associated with significant risks necessitating their judicious use. In addition to common adverse events, opioids are associated with severe risks including dependence, addiction, respiratory depression, overdose, and death. The CDC guidelines offer multiple strategies intended to mitigate the risks associated with opioid therapy. They recommend treating pain at the lowest possible dose and only for the expected duration of the pain. For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage. If benefits outweigh risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy. Clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. (Dowell, 2022).

In addition to overall guidance regarding opioid therapy, the CDC guidelines also make recommendations for opioid selection. When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release instead of extended-release and long-acting (ER/LA) opioids. ER/LA opioids should be reserved for severe, continuous pain. The FDA has noted that some ER/LA opioids should be considered only for patients who have received certain dosages of immediate-release opioids daily for at least 1 week. Additionally, specific concerns regarding methadone and fentanyl are acknowledged by the guidelines. It is stated that methadone should not be the first choice for an extended-release opioid in pain management due to risks of overdose and QT prolongation. Fentanyl is also specifically recognized as a complex extended-release opioid due to dosing, absorption, and pharmacodynamics properties. (Dowell, 2022)

The risk of overdose and death can be reduced by avoiding dose escalations. Many patients do not experience benefit in pain or function from increasing opioid dosages to ≥50 MME/day but are exposed to progressive increases in risk as dosage increases. A tool to assist with calculating morphine milligram equivalent dosages can be found in Appendix A. When doses exceed 50 MME the guidelines recommend implementing additional precautions including providing educational resources for individuals and household members intended to reduce the risk of overdose, prescribing naloxone, and increasing the frequency of appointments. When benefits (including avoiding risks of tapering) do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to a reduced opioid dosage or, if warranted based on the individual clinical circumstances of the patient, appropriately taper, and discontinue opioid therapy. (Dowell, 2022)

The guidelines advocate for frequent appointments for all individuals on opioid therapy. Patients should be evaluated at least every 2 weeks if they continue to receive opioids for acute pain. Clinicians should evaluate benefits and risks with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or for dosage escalation. The guidelines suggest clinicians should regularly reassess all patients receiving long-term opioid therapy every 3 months or more frequently for most patients. Clinicians are recommended to communicate all expectations of therapy, including responsibilities of both the prescriber and patient, to the individual. A commonly used tool to aid in this communication is a medication use agreement. (Dowell, 2022)

Medication Use Agreements

A medication use agreement is a tool used by clinicians to clearly communicate roles and responsibilities of the individual patient and prescribing clinician in relation to controlled substance prescriptions. The agreement outlines clinician expectations of the patient including circumstances of treatment discontinuation. Several national organizations, including National Institutes of Health and American Academy of Family Physicians, have published such agreements and allow for their use by prescribing clinicians.

- The National Institute on Drug Abuse division of the National Institutes of Health provides two sample medications use agreement forms for public use. One form provided by the National Institute on Drug Abuse is adapted from the American Academy of Pain Medicine. Both medication-use agreements can be found online at https://nida.nih.gov/sites/default/files/SamplePatientAgreementForms.pdf

- The American Academy of Family Physicians has also published a medication use agreement for public use. The medication use agreement can be found online at www.aafp.org/dam/AAFP/documents/patient_care/pain_management/agreement.pdf

COVERAGE POLICY:

Opioid Therapy Management includes criteria for ALL the following:

- Immediate-Release/Extended-Release opioids exceeding a cumulative daily dose of 200 Morphine-Milligram Equivalents (MME)
- New Immediate-Release opioid analgesics exceeding a 7-day supply without prior history of opioid use
- New starts of Extended-Release Opioids
- Transmucosal immediate-release fentanyl (TIRF) medications and their quantity limits
- Cough & cold medications containing opioid ingredients, such as codeine and hydrocodone, for children less than 18 years of age.
- The concurrent use of buprenorphine and opioid medications
- Prior authorization of levorphanol
- Opioid drugs that require step therapy: Oxycontin
- Prolate solution and generic oxycodone-APAP 10-300MG/5mL
- Prolate Tablets, Primlev, Nalocet and generic oxycodone-APAP 5mg /300mg and oxycodone-APAP 10mg /300mg and oxycodone-APAP 2.5mg /300mg
- Roxybond and Oxaydo Tablets

Morphine Milligram Equivalents (MME)
Members will be limited to the following MME doses for all active opioids (short and long acting): • New starts to opioid therapy: 90 MME • Existing opioid users: 200 MME A coverage review is required if the patient exceeds the above listed MME's. *See Appendix A (on page 7) for conversion chart and dosing calculation formula. Approval will be granted for 1 year for any of the following criteria: 1. Patient has been diagnosed with cancer and appropriate pain management requires dosing that exceeds the restricted amount. 2. Patient has a terminal illness and appropriate pain management requires dosing that exceeds the restricted amount 3. The provider states that based on the patient's clinical circumstances, the amount of opioid and dose prescribed is warranted in order to adequately manage the patient's pain.

Opioid-naïve ADULT 7-day supply for first FOUR fills limit
The first **four** fills of short acting opioid medications will be limited to 7-day supplies for members who are opioid-naïve. Coverage of the first four fills for short acting opioids that exceed a 7-day supply in opioid-naïve patients will be allowed if: 1. Patient has been diagnosed with cancer or is being treated for a diagnosis of cancer related pain 2. Patient is being treated for pain related to a terminal illness 3. There is documentation that the patient is not opioid-naïve and has filled/taken 28 or more days of opioids within the past 130 days. a. Examples include (but not limited to): individuals who are new to plan, had previous claims paid for under workers compensation or received as inpatient or rehabilitation facility. 4. If approvable, the authorization is for 120 days.

Opioid-naïve PEDIATRIC 3-day supply for first FOUR fills limit
The first **four** fills of short acting opioid medications for pediatric patients (< 18 y/o) will be limited to 3-day supplies for members who are opioid-naïve. Coverage of the first four fills for short acting opioids that exceed a 3-day supply in pediatric opioid-naïve patients will be allowed if: 1. Patient has been diagnosed with cancer or is being treated for a diagnosis of cancer related pain 2. Patient is being treated for pain related to a terminal illness 3. There is documentation that the patient is not opioid-naïve (has been taking an opioid within the past 130 days). a. Examples include (but not limited to): individuals who are new to plan, had previous claims paid for under workers compensation or received as inpatient or rehabilitation facility. 4. If approvable, the authorization is for 120 days.

Extended-release (long-acting) opioids

Prior authorization is required on all long-acting opioids that are on formulary. Please refer to the formulary list specific to the patient to see which are covered.

Coverage of extended-release (long-acting) opioids is recommended in those who meet the following criteria:

1. **Pain Severe Enough to Require Daily, Around-the-Clock, Long-Term Opioid Treatment.** Approve for 1 year if the patient meets **ONE** of the following criteria (A, B, or C):

   A. The patient has a cancer diagnosis or request is from hematologist, oncologist or palliative care provider, **OR**
   B. The patient is in a hospice program, end-of-life care, or palliative care, **OR**
   C. The patient has chronic non-cancer pain (chronic pain is defined as pain that persists for greater than a 3-month period). Approve for 1 year if the patient meets **ALL** the following criteria (i, ii, iii, iv, v, vi, vii):
      i. Non-opioid therapies (e.g., non-opioid medications [e.g., nonsteroidal anti- inflammatory drugs {NSAIDs}, tricyclic antidepressants, serotonin, and norepinephrine reuptake inhibitors {SNRIs}, anticonvulsants], and non- pharmacological therapies {such as exercise therapy, weight loss, cognitive behavioral therapy}) have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician; **AND**
      ii. The patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescribing physician; **AND**
      iii. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the patient according to the prescribing physician; **AND**
      iv. Medication Agreement/Pain Contract and Treatment plan (including goals for pain and function) is in place and reassessments (including pain levels and function) are scheduled at regular intervals according to the prescribing physician.
      vi. Only one long-acting agent will be authorized at a time.
      vii. Patient is not naïve to opioid treatment.

2. Authorization will **NOT** be granted (on initial or recertification) for the following:
   A. Individual has a known current substance abuse issue (does not apply to buprenorphine products such as patch/film)
   B. Individual is currently taking a buprenorphine product for addiction therapy (e.g., Bunavail, Suboxone, Subutex, Zubsolv)
   C. Acute pain conditions (such as tonsillectomy, orthopedic surgery, or general post-op pain)

3. **Recertification** after 1 year will require:
   A. Physician attestation documenting effective pain control, no aberrant behavior and no signs of abuse or misuse
   B. If treatment is no longer deemed medically necessary, further therapy will not be authorized

Transmucosal Immediate-Release Fentanyl (TIRF) medications
Prior authorization is required for **Abstral, Actiq, Fentora, Lazanda, Subsys** and equivalent generics. A. Patients must have a diagnosis of cancer related pain **AND** B. Must be prescribed by an oncologist, hematologist, or palliative care. C. Severe intolerance or therapeutic failure of at least two other opioid medications. D. If approvable, an authorization is granted for 1 year. E. Quantity limit of TIRF agents is as follows: 120 units per 30-day supply for Fentora, Actiq, Abstral and Subsys 30 units per 30-day supply for Lazanda. **Recertification** after 1 year will require: A. Recent progress notes documenting effective pain control, no aberrant behavior and no signs of abuse or misuse B. If treatment is no longer deemed medically necessary, further therapy will not be authorized.

Opioid cough and cold medicines
Opioid cough and cold medicines containing codeine or hydrocodone require prior authorization in children younger than 18 years of age. Due to the risk of adverse effects (slowed or difficult breathing, misuse, abuse, addiction, overdose, and death), the FDA in January 2018 recommended against routine use of codeine/hydrocodone containing cough/cold products for patients < 18 years of age and that future manufacturer labeling for these products include a contraindication in this population. A. Based on FDA labeling changes due to serious risks of these medicines outweighing their potential benefits, the following medications are considered not medically necessary and will not be covered for children less than 18 years of age. i. If the provider requests an exception to the policy for a child less than 18 years of age, they will need to attest that the benefit of the drug outweighs the risk for their patient. B. The opioid cough & cold medications included in this edit are in the following drug categories: Narcotic antitussive - anticholinergic combination Narcotic antitussive - 1st generation antihistamine combination Narcotic antitussive - 1st generation antihistamine – decongestant combination Narcotic antitussive - decongestant combination Narcotic antitussive - decongestant - expectorant combination Narcotic antitussive - expectorant combination

Concurrent use of opioid/buprenorphine products
Concurrent use of **buprenorphine** products (i.e., single agent, buprenorphine/naloxone, Bunavail, Suboxone, or Zubsolv) and opioid analgesics will not be authorized. For individuals who have a claim for any one of the above listed substance abuse medications in the past 30 days, opioid analgesics will reject for prior authorization. A. If an individual requires short-term pain medication (post-op surgery, acute pain condition, etc.), a provider may request an override if there is a treatment plan in place. The expectation is that the opioid prescriber is in contact with the Substance Abuse provider for coordination of care. B. The override can be requested prospectively (for known scheduled procedures) or at the time of dispensing for situations that are urgent and require immediate treatment. C. The request can be made verbally or via a standard prior authorization form. The request may come from the substance abuse provider, the opioid prescriber, or the dispensing pharmacist. Authorizations will not be given based on information obtained from the member. D. Opioid therapy will not be authorized if an individual fails to disclose that they are receiving buprenorphine therapy or if the substance abuse provider does not support the use of an opioid agent. E. If the request is approvable based on a short-term need, the authorization can be placed for a 2-day window to allow current claim to pay. **If both pain and substance abuse drug therapies are prescribed and requested by the same provider who specializes in psychiatry, addiction or pain and the request is approvable, the reviewer may use their clinical judgment and allow for a longer approval.
Levorphanol
Prior authorization is required for Levorphanol. A. Prior authorization will be bypassed for oncologists, hematologists, and palliative care providers only. Approval will be for 1 year. B. Coverage of Levorphanol is recommended for management of moderate to severe pain for 1 year in those who meet **ALL** the following criteria (i, ii, iii, iv): i. Patient MUST have documentation of an adequate trial of at least one non-opioid product (such as NSAIDs, agents for neuropathic pain {ex: tricyclic antidepressants, duloxetine, pregabalin and gabapentin}) **AND** one opioid combination product (such as hydrocodone/APAP, tramadol/APAP, oxycodone/APAP). Recent progress notes **ARE** required; **AND** ii. The patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescribing physician; **AND** iii. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the patient according to the prescribing physician; **AND** iv. Medication Agreement/Pain Contract and Treatment plan (including goals for pain and function) is in place and reassessments (including pain levels and function) are scheduled at regular intervals according to the prescribing physician C. Authorization will **NOT** be granted for the following: i. Patient has known current substance abuse issues ii. Patient is currently taking a buprenorphine product for addiction therapy D. Recertification approval will be granted for one year in those who meet the following criteria: i. Recertification will require documentation of effective pain control, no aberrant behavior and no signs of abuse or misuse. Recent progress notes will be required. ii. If treatment is no longer deemed medically necessary, further therapy will not be authorized.

Opioid drugs that require step therapy	
Step therapy requires members try certain first-line options before other medications will be considered medically necessary for treatment of a specific condition. Step therapy requirements may apply to both brand and generics. Typically, first-line medications are classified as generics, but there are instances where brand-name medications may be preferred. The following list of drugs requires step therapy. Based upon our review and assessment of the peer-reviewed literature, these medications have been medically proven to be effective and, therefore, medically necessary if the request meets the following criteria:	
Oxycontin	Coverage requires documentation of severe intolerance or therapeutic failure with generic oxycodone ER or Xtampza.

Prolate Solution and generic oxycodone-APAP 10-300MG/5mL
Based on comparable indications, efficacy, and safety profiles of generic oxycodone-APAP and hydrocodone-APAP products, the patient will be required to use generic oxycodone-APAP (except oxycodone10-300mg/5ml) and hydrocodone-APAP products unless there is adequate justification as to why this formulation is not appropriate. 1. In addition, requests for Prolate solution will require that the patient has a swallowing disorder (a swallowing evaluation must be submitted to confirm)
Prolate Tablets, Primlev, Nalocet and generic oxycodone-APAP 5mg/300mg, oxycodone-APAP 7.5/300, oxycodone-APAP 10mg /300mg and oxycodone-APAP 2.5mg /300mg
Based on comparable indications, efficacy, and safety profiles of generic oxycodone-APAP and hydrocodone-APAP products, the patient will be required to use generic oxycodone-APAP (except oxycodone/APAP 2.5/300, 5/300, 7.5/300, 10/300) and hydrocodone-APAP products unless there is adequate justification as to why this formulation is not appropriate.

Roxybond and Oxaydo Tablets
Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the lower cost generic alternatives such as generic oxycodone unless there is medical justification as to why these formulations are medically necessary. -Requests will be approved for 3 months at a time.

Appendix A

Method for calculation of the cumulative daily Morphine Milligram Equivalents (MME) The cumulative daily MME correlates with the risk of dose-related morbidity and mortality. The general algorithm used to calculate the daily MME is as follows:

- # Opioid dosage units per day = (Opioid claim quantity) / (opioid claims days' supply)
- Oral MME daily dose per claim = (#opioid dosage units per day) x (#mg opioid per dosage unit) x (MME conversion factor)
- Cumulative MME: Σ Oral MME daily dose per claim for all opiates received

Table A: Opioid Morphine Equivalent Conversion Factors[1]

Type of Opioid	MME Conversion Factor
Buprenorphine patch[2]	12.6
Buprenorphine tab or film	10
Codeine	0.15
Fentanyl buccal or SL tablets, or lozenge/troche[3]	0.13
Fentanyl film or oral spray[4]	0.18
Fentanyl nasal spray[5]	0.16
Fentanyl patch[6]	7.2
Hydrocodone	1
Hydromorphone	5
Levorphanol tartrate	11
Meperidine hydrochloride	0.1
Methadone	4.7
Oxycodone	1.5
Oxymorphone	3
Tapentadol	0.4
Tramadol	0.2

1. Centers for Disease Control and Prevention, Atlanta, GA. For more information, send an email to Mbohm@cdc.gov.
2. The MME conversion factor for buprenorphine patches is based on the assumption that one milligram of parenteral buprenorphine is equivalent to 75 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24-hour day. Example: 5 ug/hr buprenorphine patch * 24 hrs = 120 ug/day buprenorphine = 0.12 mg/day buprenorphine = 9 mg/day oral morphine milligram equivalent. In other words, the conversion factor not accounting for days of use would be 9/5 or 1.8. However, since the buprenorphine patch remains in place for 7 days, we have multiplied the conversion factor by 7 (1.8 X 7 = 12.6). In this example, MME/day for four 5 µg/hr buprenorphine patches dispensed for use over 28 days would work out as follows: Example: 5 ug/hr buprenorphine patch * (4 patches/28 days) * 12.6 = 9 MME/day. **Changed from 42 to 12.6 in call letter dated 7/11/14**
3. MME conversion factor for Fentanyl buccal tablets, sublingual tablets, and lozenges/troche is 0.13. It is intended to be multiplied by the number of micrograms in a given lozenge/troche
4. The MME conversion factor for fentanyl film and oral spray is 0.18. This reflects a 40% greater bioavailability for films compared to lozenges/tablets and 38% greater bioavailability for oral sprays compared to lozenges/tablets.
5. The MME conversion factor for fentanyl nasal spray is 0.16, which reflects a 20% greater bioavailability for sprays compared to lozenges/tablets.

6. The MME conversion factor for fentanyl patches is based on the assumption that one milligram of parenteral fentanyl is equivalent to 100 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24-hour day. Example: 25 ug/hr fentanyl patch * 24 hrs = 600 ug/day fentanyl = 60 mg/day oral morphine milligram equivalent. In other words, the conversion factor not accounting for days of use would be 60/25 or 2.4. However, since the fentanyl patch remains in place for 3 days, we have multiplied the conversion factor by 3 (2.4 X 3 = 7.2). In this example, MME/day for ten 25 µg/hr fentanyl patches dispensed for use over 30 days would work out as follows: Example: 25 ug/hr fentanyl patch * (10 patches/30 days) * 7.2 = 60 MME/day.

POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Safety Edits are inclusive of all contracts regardless of whether Step Therapy or Prior Authorization is part of the member's benefit.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration;
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
5. Comprehensive assessment and documentation are recommended before initiating opioid therapy, including documentation of comprehensive history, general medical condition, psychosocial history, psychiatric status, and substance use history.
6. Prior to initiating opioid therapy, the prescriber and patient should enter into a treatment agreement which defines expectations for medication use, pharmacy use, receipt of narcotic/controlled substances from other prescribers and prescription drug monitoring.

7. If aberrant behaviors are demonstrated, counseling should be done to address them and if the behavior is unchanged, opioid use should be seriously reconsidered.
8. Prescriber should monitor adherence through a proven means such as urine drug testing, pill counts, behavioral assessment during visits. When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.
9. Generally, it is believed that patients who do not respond to a low or medium-dose of opioids will not respond to larger doses although individual circumstances also exist.
    - Low dose therapy is defined as ≤40 mg/day morphine equivalent.
    - Moderate dose therapy will be defined as 41 – 90 mg/day morphine equivalent
    - High dose therapy will be defined as >91 mg morphine/day
10. The rate of overdose has been shown to be directly proportional to the prescribed opioid dose
11. Opioid medications must be started at low doses and titrated gradually to higher amounts if necessary. All attempts must be made to maintain patients on lower doses, including use of other drugs. Combinations of short- and long-acting and high doses of long-acting opioids must be prescribed with extreme caution
    - See Table 1 below for dosing recommendations
12. Oral transmucosal, nasal spray and buccal formulation of fentanyl are intended only to be used in the care of opioid-tolerant cancer patients and only by health care providers who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Once a successful dose has been found (i.e., an average episode is treated with a single unit), consumption should be limited to 4 units/day or less. If consumption increases to more than 4 units/day, reevaluate the dose of the long-acting opioid for persistent cancer pain.
13. Methadone may be an appropriate alternative for patients using high dose opioids and/or those with musculoskeletal or neuropathic pain. Methadone should only be prescribed by physicians who are expertly trained to handle dosing of the medication.

Table 1.

Opioid	Recommended Starting Dose for Opioid-Naïve Patients ****	Recommended Starting Dose for Opioid-Exposed Patients with High Doses leading to High Risks	Recommended Maintenance Dose
Hydrocodone	5 to 10mg, 2 to 3 times daily	5 to 10mg, 3 to 4 times daily	30 to 40mg for 24 hours
Morphine			
Immediate Release	Not recommended	10mg, 2 to 3 times daily	30 to 60mg per day
Sustained Release	Not recommended	15 to 30mg twice daily	60 to 90mg daily
Oxycodone			
Immediate Release	5 to 10mg, 2 to 3 times daily	5 to 10mg, 3 to 4 times daily	30 to 40mg per day
Sustained Release	Not recommended	10mg for 12 hours	30 to 60mg for 24 hours
Methadone	Not recommended	2 to 5mg, 2 to 3 times daily	10 to 30mg per day
Transdermal Fentanyl	Not recommended	12.5 to 25mcg q 72 h	25 to 50mcg per 72 hours
Hydromorphone			
Immediate Release	2mg, 2 or 3 times daily	2 to 4mg, 2 to 3 times daily	8 to 16mg per day
Sustained Release	Not recommended	5 to 10mg, 2 times daily	20 to 40mg daily
Codeine	15mg, 2 or 3 times daily	30mg, 2 to 4 times daily	120 to 160mg daily
Oxymorphone			
Immediate Release	5mg 2 or 3 times daily	5 to 10mg, 2 to 3 times daily	30 to 40mg per day
Sustained Release	Not recommended	10mg q 12 h	40 to 60mg per day
Tramadol			
Immediate Release	50mg, 2 or 3 times daily	50mg, 3 to 4 times daily	150 to 300mg per day
Sustained Release	Not recommended	200mg daily	200 to 350mg per day
	****The lowest starting dose for opioid-naïve patients is often equivalent to a single dose of approximately 5–10 MME or a daily dosage of 20–30 MME/day.		

UPDATES:

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04/2024	Reviewed
12/2023	Revised
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05/11/2023	P&T Committee Approval
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09/21	Revised
05/21	Revised
10/20	Reviewed
04/2020	Revision
10/19	Reviewed
08/19	Revision
05/19	Revision
07/18	Revision
05/18	P&T Committee Approval
05/18	Revision
02/18	P&T Committee Approval
08/17	Revision
07/17	Revision
06/17	Revision
04/17	Revision
11/16	Revision
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6/14	Revision
5/14	Revision
4/14	Revision
2/14	Revision
4/13	Revision
11/12	Revision
7/12	Created

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