

**Pharmacy Prior Authorization
Opioid Guideline – Clinical Guideline**

Note: Except for special cases (noted below) opioids should only be approved for those 18 years of age or older.

Eligible plans: Pennsylvania CHIP

All Long-Acting opioids require Prior Authorization.

All Short Acting opioids have a seven-day supply limit.

All opioids will be limited to 90 Morphine Milligram Equivalents per day.

Members with pain due to active cancer, palliative care, or end-of-life care will be exempt from guideline requirements for all *preferred* medications.

A signed treatment plan along with completed Opioid Prior Authorization form must be submitted.

Note: Short Acting Mucosal Fentanyl agents are not subject to this guideline and have a separate Prior Authorization guideline

General Authorization Criteria:

Provider attests to all the following prior to initiating treatment:

1. For the treatment of chronic pain, non-pharmacologic therapy (for example physical therapy, exercise, Cognitive Behavioral Therapy, weight loss), and non-opioid therapy (for example topical diclofenac, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Tri-Cyclic Antidepressants (TCAs), and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) or anticonvulsants) were tried before prescribing opioids.
2. Established treatment plan with realistic goals for pain and function (for example, pain may persist while function has improved), and when treatment will be stopped.

The treatment plan must also address the following:

- a. Consequences of lost medication
- b. Consequences of obtaining controlled substances from other prescribers
- c. Member agreement to only use one pharmacy

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3. Addresses harm and benefits before treatment, and periodically during treatment (increased risks of respiratory depression, combination use with benzodiazepines, risks to other household members including children, cognitive limitations and side effects).
4. Treatment will be prescribed at the lowest effective dose. Prescriber should calculate Morphine Milligram Equivalents per day of current prescribed dose
5. The treatment plan is reviewed within 1 to 4 weeks of starting opioid therapy for chronic pain, and with any dose escalation, and re-evaluated every three months.
6. Provider has performed the following risk assessment:
 - Checked the state’s Prescription Monitoring Program/Prescription Drug Monitoring Program for controlled substances with focus on opioid dosages and dangerous combinations
 - Reviewed a urine drug screen, or serum medication level prior to initiating treatment with short acting opioids and/or long acting opioids. Attest or comment in notes that urine drug screen is consistent with prescribed controlled substances.
 - Offered a prescription for, and counseled member, or household member on use of naloxone, if member has risk factors for overdose such as prior overdose, substance use disorder, doses of 50 Morphine Milligram Equivalents or greater per day, or concomitant benzodiazepine use.
 - If evidence of substance use disorder, prescriber will offer, or arrange for evidence-based treatment (for example, Medication-Assisted Treatment)
7. Females of reproductive age should be counseled about opioid use during pregnancy, and neonatal abstinence syndrome.

Additional Prior Authorization Criteria:

Long Acting Opioids

Preferred Agents: Fentanyl patch, morphine sulfate extended release, methadone, buprenorphine patches and oxymorphone extended release

Documentation is required to support medical necessity of exceeding the recommended limit of 90 Morphine Milligram Equivalents per day.

A Pain Specialist consult is warranted if more than 90 Morphine Milligram Equivalents per day is needed.

Member must meet the following:

1. Treatment is for chronic pain

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2. Provider has initiated treatment with an immediate release opioid for at least two weeks before considering extended release/long acting opioids; use should be reserved for severe, continuous pain, and not for intermittent use.
3. For oxymorphone extended release:
 - Member had inadequate response, or intolerance, to at least 2 formulary long-acting opioids (fentanyl patch, morphine sulfate extended release, methadone); trials of formulary agents were for at least 2 weeks.
4. For buprenorphine weekly patches:
 - Provider has documented need for opioid with lower-risk for abuse and noted concern that member, or member's household is at risk for abuse and diversion (buprenorphine has lower abuse potential compared to other long-acting formulary products)
5. For non-formulary agents, member had inadequate response, or intolerance, to oxymorphone extended release, and at least 2 formulary long-acting opioids for at least 2 weeks (for example fentanyl patch, morphine sulfate extended release, or methadone)
6. For Abuse-Deterrent product requests:
 - Documentation member has tried and failed buprenorphine patches for at least 2 weeks
 - Provider has documented need for abuse deterrent agent and noted concern that member, or member's household is at risk for abuse and diversion

Short-Acting Opioids

Preferred Agents: Hydromorphone, morphine sulfate immediate release, oxycodone, oxycodone-acetaminophen, oxycodone-aspirin, tramadol, tramadol-acetaminophen, Endocet, hydrocodone-acetaminophen, hydrocodone ibuprofen, Lorcet, Ibudone, codeine sulfate, butalbital-aspirin-caffeine-codeine, butalbital-acetaminophen-caffeine-codeine, acetaminophen-codeine, ascomp-codeine

Member must meet the following:

- Documentation to support medical necessity of exceeding recommended Morphine Milligram Equivalents, or day supply limit
- Documentation to support continued use of short acting agent beyond 30 days and when used in combination with a long-acting agent. Comments need to address regular use of short acting agent and lack of pain control with the long acting agent and other pain management modalities
- In addition, for all non-formulary agents, member had an inadequate response or intolerance to at least 2 formulary short-acting opioids

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Authorization Criteria for Acute Pain in Pediatric Members (less than 18 years of age):

- Request is for acute pain (for example, post-dental procedure)
- Pain assessment was completed
- Member and their parent(s)/guardian(s) have been screened for previous and current opioid use
- Provider has checked the state's Prescription Monitoring Program/Prescription Drug Monitoring Program for controlled substances with focus on opioid dosages and dangerous combinations
- Concomitant use with benzodiazepines has been appropriately addressed if present
- Combination therapy with acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) were tried and failed or there are contraindications present for the use of both
- Opioid therapy will be used in combination with acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) unless there are contraindications present for the use of both
- Member is not less than 12 years of age if medication prescribed is codeine or tramadol (NOTE: the use of these medications is contraindicated in children younger than 12 and not recommended in those aged 12 – 17.)
- Prescription will be limited to 8 – 12 tablets
- Immediate-release opioids will be prescribed, limited to the lowest effective dose, and no quantity greater than the expected pain duration that is severe enough to require opioids will be given (NOTE: Three days or fewer is recommended by the CDC. More than seven days will rarely be required.)

Initial Approval Duration:

- Cancer, End-of-Life, Palliative Care: 1 year
- Chronic Pain: 3 months
- Acute Pain: 30 days or less
- Acute Pain in Pediatric Members: 3 days or less
 - Total treatment duration should not exceed 7 days

*Medications with more than 200 Morphine Milligram Equivalents per day will require a Medical Director Review

Renewals:

Documentation to support the following:

- Sustained improvement in Pain or Function (for example, pain average, interference with enjoyment of life, and interference with general activity assessment scale of a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment of current medication
- Performed a urine drug screen test at least annually
- Reviewed and verified the state's Prescription Monitoring Program for prescriptions from other providers, benzodiazepines use, or extended release/long acting use for acute pain, upon writing prescription for opioid, and no less often than every 90 days. Clinical notes document that urine drug screen is consistent with prescribed controlled substances.

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- Calculated Morphine Milligram Equivalents per day: For doses of 50 or more Morphine Milligram Equivalents per day, provider has offered Naloxone to the member; For doses of more than 90 Morphine Milligram Equivalents per day, a referral to a Pain Specialist is required.

Note: Naloxone is available on the formulary without Prior Authorization.

- For continued concomitant use of opioid and benzodiazepines, the provider has counseled member on Food and Drug Administration (FDA) Black Box Warning dangers of prescribing opioids in combination with benzodiazepines and will prescribe at the lowest effective dosage and duration.

Renewal Approval Duration:

- Chronic Pain: 6 months
- Acute Pain: 30 days or less
- Acute Pain in Pediatric Members: 3 days or less
 - Total treatment duration should not exceed 7 days

Additional information:

Food and Drug Administration (FDA) Black Box Warning on concomitant use with benzodiazepines:

Food and Drug Administration (FDA) Black Box Warning: Health care professionals should limit prescribing opioid pain medicines with benzodiazepines, or other Central Nervous System depressants only to patients for whom alternative treatment options are inadequate.

If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation and the associated signs and symptoms.

Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other Central Nervous System depressants, including alcohol.

www.fda.gov/Drugs/DrugSafety/ucm518473.htm

References:

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