

## Clinical Policy: Analgesics, Opioid Short-Acting

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### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health and Wellness® that Short-acting Opioid Analgesics are **medically necessary** when the following criteria are met:

### I. Requirements for Prior Authorization of Analgesics, Opioid Short-Acting

#### A. Prescriptions That Require Prior Authorization

Prescriptions for Analgesics, Opioid Short-Acting that meet any of the following conditions must be prior authorized:

1. A non-preferred Analgesic, Opioid Short-Acting.
2. An Analgesic, Opioid Short-Acting with a prescribed quantity that exceeds the quantity limit.
3. An Analgesic, Opioid Short-Acting when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs (therapeutic duplication).
4. An Analgesic, Opioid Short-Acting when a member has a concurrent prescription for a buprenorphine agent with a U.S. Food and Drug Administration (FDA)-approved indication for opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol).
5. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a child under 18 years of age.
6. An Analgesic, Opioid Short-Acting that does not contain codeine or tramadol when prescribed for a member under 18 years of age and at least **one** of the following:
  - a. More than a 5-day supply is prescribed.
  - b. The member has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.
7. An Analgesic, Opioid Short-Acting when prescribed for a member 18 years of age or older and at least **one** of the following:

- a. More than a 10-day supply is prescribed.
- b. The member has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.

**B. Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for an Analgesic, Opioid Short-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a transmucosal fentanyl product, **all** of the following:
  - a. Has a diagnosis of cancer,
  - b. Is opioid-tolerant,<sup>1</sup>
  - c. Is prescribed the requested transmucosal fentanyl product by a specialist certified in pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
  - d. Has a history of a contraindication to the preferred Analgesics, Opioid Short-Acting;

**AND**

2. For nasal butorphanol, **both** of the following:
  - a. Is not opioid-tolerant<sup>1</sup>
  - b. **One** of the following:
    - i. **All** of the following:
      - a) Has a diagnosis of pain,
      - b) Is being prescribed nasal butorphanol by a specialist certified in neurology, pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
      - c) Has a history of therapeutic failure, contraindication, or intolerance to at least 3 unrelated (i.e., different opioid ingredient) preferred Analgesics, Opioid Short-Acting (single-entity or combination products),
    - ii. **All** of the following:
      - a) Has a diagnosis of migraine,
      - b) Is prescribed nasal butorphanol by a neurologist or headache specialist who is

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<sup>1</sup> Opioid tolerant is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/h, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equianalgesic dose of another opioid for one (1) week or longer.

certified in headache medicine by the United Council for Neurologic Subspecialties,

- c) Has a history of therapeutic failure, contraindication, or intolerance of **all** of the following abortive therapies:
  - (i) Acetaminophen,
  - (ii) Non-steroidal anti-inflammatory drugs (NSAIDs),
  - (iii) Triptans,
  - (iv) Dihydroergotamine,
- d) Has a history of therapeutic failure, contraindication, or intolerance of **all** of the following preventive therapies:
  - (i) Anticonvulsants,
  - (ii) Beta blockers,
  - (iii) Botulinum toxin (for a diagnosis of chronic migraine only),
  - (iv) Calcitonin gene-related peptide (CGRP) inhibitors/antagonists,
  - (v) Calcium channel blockers,
  - (vi) Serotonin-norepinephrine reuptake inhibitors (SNRIs),
  - (vii) Tricyclic antidepressants;

**AND**

- 3. For a combination agent containing a barbiturate, also meets the prior authorization guidelines in PHW.PDL.692 Analgesics, Non-Opioid Barbiturate Combinations; **AND**
- 4. For a non-preferred Analgesic, Opioid Short-Acting, has a history of therapeutic failure, contraindication, or intolerance of the preferred Analgesics, Opioid Short-Acting; **AND**
- 5. For a member with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s);

**AND**

- 6. For therapeutic duplication, **one** of the following:
  - a. Is being transitioned to or from another Analgesic, Opioid Short-Acting with the intent of discontinuing one of the medications;
  - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

**AND**

**7. One of the following:**

**a. One of the following:**

- i. For a member under 18 years of age, both of the following:**
  - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury;**
  - b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol;**
- ii. For a member 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury;**

**b. All of the following:**

- i. Has documentation of pain that is all of the following:**
  - a) Caused by a medical condition,**
  - b) Moderate to severe,**
  - c) For all Analgesics, Opioid Short-Acting except nasal butorphanol, not migraine in type,**
- ii. Has a history of therapeutic failure of or a contraindication or an intolerance to non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants) appropriate for the member's condition,**
- iii. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,**
- iv. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,**
- v. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,**
- vi. For members who have received opioid treatment for the past 3 months, has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone,**

fentanyl, buprenorphine, and tramadol) that is consistent with prescribed controlled substances;

vii. For a member under 18 years of age, is prescribed a medication and dose that is appropriate based on the member's age, weight, and concurrent medical conditions and is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

8. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override and **both** of the following:

- a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:
  - i. Pain is inadequately controlled at the current quantity limit
  - ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the member has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting;
- b. The member would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved. When the above guidelines are not met but the member is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANALGESICS, OPIOID SHORT-ACTING:** The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Short-Acting that was previously approved will take into account whether the member:

1. **One** of the following:
  - a. **One** of the following:
    - i. For a member under 18 years of age, **both** of the following:
      - a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services;

- b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol;
- ii. For a member 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services;

b. All of the following;

- i. Has documentation of improvement in pain control and/or level of functioning while on the requested agent,
- ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
- iii. Has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) at least every 12 months that is consistent with prescribed controlled substances;

**AND**

2. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override and **both** of the following:
  - a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least **one** of the following:
    - i. Pain is inadequately controlled at the current quantity limit;
    - ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the member has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting;
  - b. The member would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved. When the above guidelines are not met but the member is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Opioid Short-Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

**D. Dose and Duration of Therapy**

Requests for prior authorization of an Analgesic, Opioid Short-Acting will be approved for up to 6 months

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Reviews, Revisions, and Approvals	Date
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