

Clinical Policy: Analgesics, Opioid Short-Acting

Reference Number: PHW.PDL.109

Effective Date: 01/01/2020

Last Review Date: 07/2023

[Revision Log](#)

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 beneficiary 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 beneficiary under 18 years of age and at least **one** of the following:
 - a. More than a 5-day supply is prescribed.
 - b. The beneficiary 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 beneficiary 18 years of age or older and at least **one** of the following:

- a. More than a 10-day supply is prescribed.
- b. The beneficiary 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 beneficiary:

1. For a transmucosal fentanyl product, **all** of the following:
 - a. Has a diagnosis of cancer,
 - b. Is opioid-tolerant,¹
 - 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-tolerant¹
 - 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

¹ 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 beneficiary 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 beneficiary 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 beneficiary 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) Not migraine in type,
- c) Moderate to severe,

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 beneficiary'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 beneficiaries 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 beneficiary under 18 years of age, is prescribed a medication and dose that is appropriate based on the beneficiary'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 beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting;
 - b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary 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 beneficiary:

- 1. **One** of the following:
 - a. **One** of the following:
 - i. For a beneficiary 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 beneficiary 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 beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting;
 - b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary 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 beneficiary.

D. Dose and Duration of Therapy

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

E. References:

1. Cytochrome P450 drug interactions. Pharmacist's Letter/Prescriber's Letter. 2006;22(2):220233.
2. Subutex [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006.
3. Suboxone [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006.
4. Suboxone/Subutex. Pharmacist's Letter/Prescriber's Letter. 2009;25(1) 250101.
5. Hauer J, Jones BL. Evaluation and management of pain in children. Waltham, MA: UpToDate Inc. Accessed August 12, 2013.
6. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification, and management. Waltham, MA: UpToDate Inc. Accessed August 12, 2013.
7. National Institute on Drug Abuse, Topics in Brief: Prescription Drug Abuse. Revised December 2011.
8. American News Report, Should Children Take Opioid Painkillers? July 10, 2012.
9. Chou R, Fanciullo GJ, Fine PG, et al for the American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. Journal of Pain. 2009;10(2):113-130.
10. FDA News Release: FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. September 10, 2013. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm367726.htm>. Accessed February 12, 2014.
11. Government Accountability Office. Prescription Pain Reliever Abuse. GAO-12-115. December 2011. Available at www.gao.gov/assets/590/587301.pdf. Accessed on January 31, 2014.

12. Kirschner N, Ginsburg J, Sulmasy LS for the Health and Public Policy Committee of the American College of Physicians. Prescription Drug Abuse: Executive Summary of a Policy Position Paper from the American College of Physicians. *Annals of Internal Medicine*. 2014;160(3):198-200.
13. Nuckols TK, Anderson L, Popescu I, et al. Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain. *Annals of Internal Medicine*. 2014;160(1):38-47.
14. Policy Impact: Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. Available at <http://www.cdc.gov/homeandrecreationalafety/rxbrief>. Accessed February 12, 2014.
15. Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. Available at <http://www.cdc.gov/injury/about/focus-rx.html>. Accessed February 12, 2014.
16. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification, and management. Waltham, MA: UpToDate Inc. Accessed February 12, 2014.
17. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep*. 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.
18. Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain. Available at: <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Documents/PAGuidelinesonOpioids.pdf>. Accessed January 31, 2017.
19. Smith JH. Acute treatment of migraine in adults. Swanson JW, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated August 1, 2019. Accessed August 27, 2019.
20. Becker WJ, Findlay T, Moga C, Scott NA, Harstall C, Taenzer P. Guideline for primary care management of headache in adults. *Can Fam Physician*. 2015;61:670-679.
21. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
22. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. *MMWR Recomm Rep*. 2022 Nov 4;71(3):1-95. doi: 10.15585/mmwr.rr7103a1. PMID: 36327391; PMCID: PMC9639433.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q3 2023: policy revised according to DHS revisions effective 07/10/2023	07/2023