

Clinical Policy: Analgesics, Opioid Long-Acting

Reference Number: PHW.PDL.110

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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 Long-Acting Opioid Analgesics are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Analgesics, Opioid Long Acting

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Opioid Long Acting must be prior authorized:

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

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

1. For a non-preferred Analgesic, Opioid Long-Acting, **one** of the following:
 - a. For a non-preferred buprenorphine product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing buprenorphine,
 - b. For a non-preferred tramadol product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing tramadol,
 - c. For all other non-preferred Analgesics, Opioid Long-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting
2. For an Analgesic, Opioid Long-Acting when the member has 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**
3. **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 Long-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 pain that is **all** of the following:
 - a) Caused by a medical condition,
 - b) Not migraine in type,
 - c) 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 member's condition,
 - iii. For all Analgesics, Opioid Long-Acting except buprenorphine products, has documentation of a trial of Analgesics, Opioid Short-Acting,
 - iv. For all Analgesics, Opioid Long-Acting except buprenorphine products, is opioid-tolerant (for adults, is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equi-analgesic dose of another opioid for one week or longer),
 - v. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - vi. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,
 - vii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
 - viii. 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,

- ix. 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;

AND

- 4. For therapeutic duplication, **one** of the following:
 - a. Is being transitioned to or from another Analgesic, Opioid Long-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

- 5. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override and **all** 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 Long-Acting or the member has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
 - b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,
 - c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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 PRESCRIPTIONS FOR ANALGESICS, OPIOID LONG ACTING: The determination of medical necessity of a request for renewal of a prior

authorization for an Analgesic, Opioid Long-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 Long-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 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 Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override and **all** 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 Long-Acting or the member has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
 - b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

- c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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 Long-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. Approval Duration:

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

References:

1. Methadone: focus on safety. Pharmacist's Letter/Prescriber's Letter 2006; 22(9):220902
2. Cytochrome P450 drug interactions. Pharmacist's Letter/Prescriber's Letter 2006; 22(2):220233
3. Subutex [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006
4. Suboxone [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006
5. Suboxone/Subutex Pharmacist's Letter/Prescriber's Letter 2009;25(1):250101.
6. Hauer J, Jones BL. Evaluation and management of pain in children, UpToDate. Accessed August 12, 2013.
7. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification, and management, UpToDate. Accessed August 12, 2013.
8. National Institute on Drug Abuse, Topics in Brief: Prescription Drug Abuse, Revised December 2011
9. American News Report, Should Children Take Opioid Painkillers? July 10, 2012

10. 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.
11. 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.
12. 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.
13. 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.
14. 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.
15. Policy Impact: Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. Available at <http://www.cdc.gov/homeandrecreationalsafety/rxbrief>. Accessed February 12, 2014.
16. 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.
17. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification and management, UpToDate. Accessed February 12, 2014.
18. 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>.
19. Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain. Accessed January 31, 2017, <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Documents/PAGuidelinesonOpioids.pdf>.
20. 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
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Reviews, Revisions, and Approvals	Date
Q1 2024 annual review: no changes.	11/2023
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