Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2020**
Policy Number: PHW.PDL.110	**Effective Date: 01/01/2020** **Revision Date: 11/2020**
Policy Name: Analgesics, Opioid Long-Acting	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021: policy revised according to DHS revisions effective 01/05/2021

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Name of Authorized Individual (Please type or print):** **Auren Weinberg, MD**

Clinical Policy: Analgesics, Opioid Long-Acting

Reference Number: PHW.PDL.110
Effective Date: 01/01/2020
Last Review Date: 11/2020

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 health plans affiliated with 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 beneficiary:

1. For a non-preferred Analgesic, Opioid Long-Acting, has a history of therapeutic failure, contraindication, or intolerance of the preferred Analgesics, Opioid Long-Acting; **AND**

2. For an Analgesic, Opioid Long-Acting when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), **both** of the following:

    a. Is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
    b. Has a need for therapy with an Analgesic, Opioid Long-Acting, and the other therapy will be suspended during the treatment for pain;

    AND

3. **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 Long-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 pain that is **all** of the following:

      a.) Caused by a medical condition,
      b.) Not migraine in type,
      c.) Severe as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale),

   ii. Has documentation of the anticipated duration of therapy,

   iii. Has documentation of therapeutic failure, contraindication, or intolerance to **both** of the following pain management modalities:

      a.) Non-pharmacologic techniques (i.e., behavioral, cognitive, physical, and/or supportive therapies)
      b.) Non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants),

   iv. Has documentation that the Analgesic, Opioid Long Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy,

   v. Has documentation of a trial of Analgesics, Opioid Short-Acting,

   vi. 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),

   vii. 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,

   viii. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,

ix. **One** of the following:

a.) For a beneficiary under 21 years of age, has documentation that the beneficiary or parent/guardian has been educated about the potential adverse effects of opioid analgesics, including the risk for misuse, abuse, and addiction
b.) For a beneficiary 21 years of age or older, has documentation of education about the potential adverse effects of opioid analgesics, including the risk for misuse, abuse, and addiction,

x. Was evaluated for risk factors for opioid-related harm; if beneficiary is identified to be at high risk for opioid-related harm, the prescriber considered prescribing naloxone,

xi. Was assessed for recent use (within the past 60 days) of an opioid,

xii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined medically necessary,

xiii. 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, and tramadol) that is consistent with prescribed controlled substances;

AND

4. **One** of the following:

a. Meets the guidelines in B.3.a. and **all** of the following:

i. Does not have a concomitant prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol),
ii. Is not prescribed an Analgesic, Opioid Long-Acting that represents a therapeutic duplication,
iii. Is not prescribed a quantity that exceeds the quantity limit

b. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history;

AND

5. 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

6. 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. The beneficiary has severe pain as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale),

   b. The medication is being prescribed by an appropriate specialist or in consultation with an appropriate specialist,

   c. 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 beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

   d. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

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

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.

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 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 Long-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. Has documentation that the Analgesic, Opioid Long-Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy,

iii. Is being monitored by the prescriber for adverse events and warning signs for serious problems, such as overdose and opioid use disorder,
iv. Was evaluated for risk factors for opioid-related harm; if the beneficiary is identified at high risk for opioid-related harm, the prescriber considered prescribing naloxone,

v. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined medically necessary,

vi. **One** of the following:

a.) If prescribed less than 50 morphine milligram equivalents (MME) per day, has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) every 12 months that is consistent with prescribed controlled substances
b.) If prescribed greater than or equal to 50 MME per day, has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) every 6 months that is consistent with prescribed controlled substances;

AND

2. **One** of the following:
   a. Meets the guidelines in RENEWAL B.1.a. and **all** of the following:

i. Does not have a concomitant prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol),
ii. Is not prescribed an Analgesic, Opioid Long-Acting that represents a therapeutic duplication,
iii. Is not prescribed a quantity that exceeds the quantity limit

b. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history;

AND

3. 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. The beneficiary has severe pain as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale),

   b. The medication is being prescribed by an appropriate specialist or in consultation with an appropriate specialist,

   c. 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 beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

   d. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

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

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.

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 beneficiary.

D. **Approval Duration:**

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

A pharmacist may dispense a 72-hour supply for a newly prescribed medication without prior authorization if, in the professional judgment of the pharmacist, the beneficiary has an immediate need for the medication, unless the pharmacist determines that taking the medication either alone or along with other medications that the beneficiary may be taking, would jeopardize the health and safety of the beneficiary. Similarly, a pharmacist may dispense a 15-day supply of the prescribed medication without prior authorization if it is an ongoing medication.

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.

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