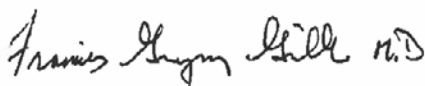


## Prior Authorization Review Panel

### 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.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: N/A</b>
<b>Policy Number: PHW.PDL.110</b>	<b>Effective Date: 01/01/2020</b> <b>Revision Date: 07/2020</b>
<b>Policy Name: Analgesics, Opioid Long-Acting</b>	
<p><b>Type of Submission – <u>Check all that apply</u>:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> New Policy</li> <li><input type="checkbox"/> Revised Policy*</li> <li><input checked="" type="checkbox"/> Annual Review - No Revisions</li> <li><input checked="" type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i></li> </ul>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p style="margin-top: 20px;">Q3 2020 annual review: no changes.</p>	
<b>Name of Authorized Individual (Please type or print):</b>  <b>Francis G. Grillo, MD</b>	<b>Signature of Authorized Individual:</b>  

## **Clinical Policy: Analgesics, Opioid Long-Acting**

Reference Number: PHW.PDL.110

Effective Date: 01/01/2020

Last Review Date: 07/2020

[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 the following:

1. For all non-preferred Analgesics, Opioid Long Acting, whether the beneficiary has a documented history of intolerance, a contraindication to, or therapeutic failure of the preferred Analgesics, Opioid Long Acting.

**AND**

2. For a preferred or non-preferred Analgesic, Opioid Long Acting for a beneficiary with a concurrent prescription for a Buprenorphine Agent with a Food and Drug Administration (FDA) approved indication for opioid dependence or naltrexone for extended-release injectable suspension (Vivitrol), the physician reviewer will consider whether:

- a. Both of the prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s)

**AND**

- b. The beneficiary 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. Whether the beneficiary:

- a. Is under 18 years of age, has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome, or is receiving palliative care or hospice services, and the Analgesic, Opioid Long Acting does not contain codeine or tramadol.

**OR**

- b. Is 18 years of age or older and has a diagnosis of active cancer or sickle cell with crisis, or is receiving palliative care or hospice services

**OR**

4. For a prescription for either a preferred or non-preferred Analgesic, Opioid Long Acting when prescribed for a beneficiary under 21 years of age who does not meet the guidelines in #3 above, whether the beneficiary:

- a. Has documentation of pain that is:
  - i. Caused by a medical condition

**AND**

- ii. Not neuropathic or migraine in type

**AND**

- iii. Severe, as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale)

**AND**

- b. Has documentation of the anticipated duration of therapy

**AND**

- c. Has documentation of therapeutic failure, contraindication, or intolerance to the following pain management modalities:
  - i. Non-pharmacologic techniques (i.e., behavioral, cognitive, physical, and/or supportive therapies)

**AND**

- ii. Non-opioid analgesics (e.g., acetaminophen, NSAIDs)

**AND**

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

**AND**

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

**AND**

- f. Is opioid-tolerant

**AND**

- g. Is prescribed a medication and dose that is appropriate based on the beneficiary's age, weight, and concurrent medical conditions as listed in:

- i. The FDA-approved package insert

**OR**

- ii. Nationally recognized compendia for medically-accepted indications for off-label use

**OR**

- iii. Medically accepted standards of care that corroborate use, such as peer-reviewed literature or national treatment guidelines

**AND**

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

**AND**

- i. Has documentation that the beneficiary or parent/guardian has been educated on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse, and addiction

**AND**

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

**AND**

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

**AND**

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

**AND**

- m. Has a recent urine drug screen (UDS) (including testing for licit and illicit drugs with the potential for abuse; must include specific testing for oxycodone, fentanyl, tramadol, and carisoprodol) that is consistent with prescribed controlled substances

**AND**

- 5. For a prescription for either a preferred or non-preferred Analgesic, Opioid Long Acting when prescribed for an adult 21 years of age or older who does not meet the guidelines in #3 above, whether the beneficiary:

- a. Has documentation of pain that is:

- i. Caused by a medical condition

**AND**

- ii. Not neuropathic or migraine in type

**AND**

- iii. Severe, as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale)

**AND**

- b. Has documentation of the anticipated duration of therapy

**AND**

- c. Has documentation of therapeutic failure, contraindication, or intolerance to the following pain management modalities:

- i. Non-pharmacologic techniques (i.e., behavioral, cognitive, physical and/or supportive therapies)

**AND**

- ii. Non-opioid analgesics (e.g., acetaminophen, NSAIDs)

**AND**

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

**AND**

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

**AND**

- f. Is opioid-tolerant (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)

**AND**

- g. Is prescribed a medication and dose that is appropriate based on the beneficiary's age, weight, and concurrent medical conditions as listed in:
  - i. The FDA-approved package insert

**OR**

- ii. Nationally recognized compendia for medically-accepted indications for off-label use

**OR**

- iii. Medically accepted standards of care that corroborate use, such as peer-reviewed literature or national treatment guidelines

**AND**

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

**AND**

- i. Has documentation of education on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse, and addiction

**AND**

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

**AND**

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

**AND**

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

**AND**

- m. Has a recent UDS (including testing for licit and illicit drugs with the potential for abuse; and specific testing for oxycodone, fentanyl, tramadol, and carisoprodol) that is consistent with prescribed controlled substances

**AND**

- 6. For all Analgesics, Opioid Long Acting, whether the prescribing provider confirms that he/she, or the prescribing provider's delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history before prescribing the Analgesic, Opioid Long Acting

Quantity Limits - In addition, if the quantity of a prescription for either a preferred or non-preferred Analgesic, Opioid Long Acting exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account whether:

- 1. The beneficiary has severe pain

**AND**

- 2. The medication is being prescribed by an appropriate specialist or in consultation with an appropriate specialist

**AND**

3. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by the following:
  - a. Pain is inadequately controlled at the current quantity limit

**AND**

- b. Pain is inadequately controlled by other Analgesics, Opioid Long Acting

**OR**

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

**AND**

4. For doses that exceed the FDA-approved starting dose, there is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid-containing medications

**AND**

5. The requested dosing frequency does not exceed the maximum FDA-approved dosing frequency

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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:** Requests for prior authorizations of renewals for Analgesics, Opioid Long Acting that were previously approved will take into account whether the beneficiary:

1. Experienced an improvement in pain control and level of functioning while on the requested agent

**AND**

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

**AND**



3. Is being monitored by the prescriber for adverse events and warning signs for serious problems, such as overdose and opioid use disorder

**AND**

4. 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

**AND**

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

**AND**

6. If prescribed less than 50 Morphine Milligram Equivalents (MME) per day, has a UDS (including testing for licit and illicit drugs with the potential for abuse; and specific testing for oxycodone, fentanyl, tramadol, and carisoprodol) every 12 months that is consistent with prescribed controlled substances

**OR**

7. If prescribed greater than or equal to 50 MME per day, has a UDS (including testing for licit and illicit drugs with the potential for abuse; must include specific testing for oxycodone, fentanyl, tramadol, and carisoprodol) every 3 months that is consistent with prescribed controlled substances

**AND**

8. Whether the prescribing provider confirms that he/she, or the prescribing provider's delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history before prescribing the Analgesic, Opioid Long Acting

NOTE: As described in Section C, 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 the request for a

prescription for an Analgesic, Opioid Long Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription.

The prior authorization request will be referred to a physician reviewer for a medical necessity determination when any of the following occur:

1. The guidelines are not met

**OR**

2. The beneficiary is concurrently being prescribed a Buprenorphine Agent with an FDA-approved indication for opioid dependence or naltrexone for extended-release injectable suspension (Vivitrol)

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:**

PA Health & Wellness will limit authorization of prescriptions for Analgesics, Opioid - Long Acting to three (3) months of therapy.

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](http://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