

## 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. 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. See the Preferred Drug List for the list of preferred Analgesics, Opioid Long-Acting at: <https://papdl.com/preferred-drug-list>; **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;

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 **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 PRIOR AUTHORIZATION 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 **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. Dose and Duration of Therapy

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

**ANALGESICS, OPIOID LONG-ACTING PRIOR AUTHORIZATION FORM** (form effective 01/05/2021)

<input type="checkbox"/> New request	<input type="checkbox"/> Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:		NPI:	State license #:	
LTC facility contact/phone:			Street address:	
Beneficiary name:		Suite #:	City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:	

**CLINICAL INFORMATION**

 Refer to <https://papdl.com/preferred-drug-list> for a list of preferred and non-preferred drugs in this class.

Drug requested:	Strength:	Formulation (capsule, tablet, etc.):
Directions:		Weight (if <21 years of age):
Quantity per fill: _____ to last _____ days		Requested duration:
Diagnosis ( <u>submit documentation</u> ):		Dx code ( <u>required</u> ):
<b>For initial requests for a NON-PREFERRED medication</b> , does the beneficiary have a history of trial and failure, contraindication, or intolerance to the preferred Analgesics, Opioid Long-Acting? Refer to <a href="https://papdl.com/preferred-drug-list">https://papdl.com/preferred-drug-list</a> for a list of preferred and non-preferred medications in this class.		<input type="checkbox"/> Yes <i>Submit documentation of medications tried and treatment outcomes, including intolerances or contraindications.</i> <input type="checkbox"/> No
Is the beneficiary being treated for active cancer, sickle cell with crisis, or neonatal abstinence syndrome OR receiving hospice or palliative care services?		<input type="checkbox"/> Yes – <i>Submit documentation</i> <input type="checkbox"/> No – <b>Continue with form.</b>
What is the anticipated duration of therapy with opioid analgesics?		Duration: _____ <i>Submit documentation.</i>
Did the prescriber or prescriber's delegate search the PDMP to review the beneficiary's controlled substance prescription history before issuing this prescription for the requested agent?		<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No
Is the beneficiary taking a benzodiazepine? <u>Submit beneficiary's current medication list.</u>		<input type="checkbox"/> Yes – specify: _____ <input type="checkbox"/> No

**INITIAL requests**

 Complete the sections below that are applicable to the beneficiary and this request and **SUBMIT DOCUMENTATION** for each item.

- Has documentation of a complete physical exam, including diagnostic testing/imaging results, and pain assessment (cause, severity, location, etc.)
- Has tried or cannot try non-drug pain management modalities (eg, behavioral, cognitive, physical, and/or supportive therapies)
- Has tried or cannot try non-opioid drugs for the treatment of pain:
  - acetaminophen
  - Cymbalta (duloxetine)
  - gabapentin
  - NSAIDs (e.g., ibuprofen, naproxen, meloxicam, etc.)
  - Lyrica (pregabalin)
  - tricyclic antidepressants (e.g., amitriptyline, nortriptyline, etc.)
  - other (specify): \_\_\_\_\_
- Will use the requested opioid in combination with tolerated non-drug therapies and non-opioid drugs
- Has documentation of a trial of short-acting opioids
- For new starts of a long-acting opioid, is opioid-tolerant

- Was assessed for the potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescriber
- Was counseled about the potential side effects of opioids, including the risk for misuse, abuse, and addiction OR, if under 21 years of age, a parent or guardian was counseled about these risks
- Was evaluated for risk factors for opioid-related harm
  - Determined to be at high-risk for opioid-related harm
  - The prescriber considered prescribing naloxone for the beneficiary
- Was assessed for recent use of opioids (within the past 60 days)
- 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

**RENEWAL requests**

**Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.**

- Experienced an improvement in pain control and/or level of functioning while on the requested medication
- Will use the requested opioid in combination with tolerated non-drug therapies and non-opioid drugs
- Was recently evaluated by the prescriber for adverse events and warning signs of serious problems, such as overdose and opioid use disorder
- Was evaluated for risk factors for opioid-related harm
  - Determined to be at high-risk for opioid-related harm
  - The prescriber considered prescribing naloxone for the beneficiary
- 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

**PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION**

**Prescriber Signature:**

**Date:**

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