Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

# 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. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Opioid Short-Acting at: https://papdl.com/preferred-drug-list.

2. 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 in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

3. 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 dependence OR naltrexone for extended-release injectable suspension (Vivitrol).

4. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.

5. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary 18-20 years of age and at least **one** of the following:

    a. More than a 3-day supply is prescribed
    b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 365 days.

6. An Analgesic, Opioid Short-Acting that does not contain codeine or tramadol when prescribed for a beneficiary under 21 years of age and at least **one** of the following:

    a. More than a 3-day supply is prescribed
    b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 365 days.

7. An Analgesic, Opioid Short-Acting when prescribed for a beneficiary 21 years of age or older 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.

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:

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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-tolerant

   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 of 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 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 following preventive therapies:
            (i) Anticonvulsants,
            (ii) Beta blockers,
            (iii) Botulinum toxin (for a diagnosis of chronic migraine only),
            (iv) Calcitonin gene-related peptide inhibitors/antagonists,
            (v) Calcium channel blockers,
            (vi) Serotonin-norepinephrine reuptake inhibitors,
            (vii) Tricyclic antidepressants;

[1] Opioid tolerant 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 equianalgesic dose of another opioid for one (1) week or longer.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

**AND**

3. For a combination agent containing a barbiturate, also meets the guidelines in the Analgesics, Non-Opioid Barbiturate Combinations Policy; **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), **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 an acute need for therapy with an Analgesic, Opioid Short-Acting, and the other therapy will be suspended during the treatment for acute pain;

    **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
            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 pain that is **all** of the following:

            a) Caused by a medical condition,
            b) Not migraine in type,
            c) **One** of the following:

(i) For a beneficiary under 21 years of age, severe as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale)
(ii) For a beneficiary 21 years of age or older, moderate-to-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 (e.g., 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 Short-Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy,

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

vi. **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,

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 recent use (within the past 60 days) of an opioid,

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

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

xi. 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**

8. **One** of the following:

   a. Meets the guidelines in B.7.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 Short-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**

9. 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 **all** of the following:

   a. **One** of the following:

      i. For a beneficiary under 21 years of age, has severe pain as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale)
      ii. For a beneficiary 21 years of age or older, has moderate-to-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 Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting,

   d. 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.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 level of functioning while on the requested agent,

        ii. Has documentation that the Analgesic, Opioid Short-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 as 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 to be 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 Short-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 Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account **all** of the following:

   a. **One** of the following:

      i. For a beneficiary under 21 years of age, has severe pain as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale)
      ii. For a beneficiary 21 years of age or older, has moderate-to-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 Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting,

   d. 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.

B. Clinical Review Process

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

C. Dose and Duration of Therapy

Requests for prior authorization of an Analgesic, Opioid Short-Acting will be approved as follows:

1. For a beneficiary with a diagnosis of active cancer, requests will be approved for up to 6 months.
2. For a beneficiary who is receiving palliative care or hospice services, requests will be approved for up to 6 months.
3. For all other beneficiaries:
   a. For a dose of less than 50 MME per day, requests will be approved for up to 6 months.
   b. For a dose of greater than or equal to 50 MME per day, requests will be approved for up to 3 months.

Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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

| | | | |
|---|---|---|---|
| ☐New request ☐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 *(submit documentation)*: | | Dx code (*required*): |
| ***For initial requests for a NON-PREFERRED medication,*** does the beneficiary have a history of trial and failure, contraindication, or intolerance to the preferred Analgesics, Opioid Short-Acting? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred medications in this class.* | | ☐Yes ☐No *Submit documentation of medications tried and treatment outcomes, including intolerances or contraindications.* |
| Is the beneficiary being treated for active cancer, sickle cell with crisis, or neonatal abstinence syndrome OR receiving hospice or palliative care services? | | ☐Yes – *Submit documentation* ☐No – ***Continue with form.*** |
| What is the anticipated duration of therapy with opioid analgesics? | | Duration: _____ *Submit documentation.* |
| 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? | | ☐Yes ☐No *Submit documentation.* |
| Is the beneficiary taking a benzodiazepine? ***Submit beneficiary's current medication list.*** | | ☐Yes – specify: _____ ☐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/imagining 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

☐Was assessed for the potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescriber

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

- ☐ 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 guarding 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
- ☐ The requested medication is a **transmucosal fentanyl product**
  - ☐ Has a diagnosis of cancer
  - ☐ Is opioid-tolerant
  - ☐ Is prescribed transmucosal fentanyl by a specialist certified in pain medicine, oncology, or hospice and palliative medicine
  - ☐ Has a contraindication to the preferred Analgesics, Opioid Short-Acting *(refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred medications in this class)*
- ☐ The requested medication is a **nasal butorphanol product**
  - ☐ Is not opioid-tolerant
  - ☐ Is being treated for **migraine**
    - ☐ Is prescribed nasal butorphanol by a neurologist or headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties
    - ☐ Tried and failed or has a contraindication or intolerance to the following abortive medications:
      - ☐ Acetaminophen ☐ Triptans
      - ☐ NSAIDs ☐ Dihydroergotamine
    - ☐ Tried and failed or has a contraindication or intolerance to the following preventive medications:
      - ☐ Anticonvulsants ☐ Botulinum toxins ☐ Calcium channel blockers ☐ tricyclic antidepressants
      - ☐ Beta blockers ☐ CGRP inhibitors ☐ SNRIs
  - ☐ Is being treated for **non-migraine pain**
    - ☐ Is prescribed nasal butorphanol by a specialist certified in neurology, pain medicine, oncology, or hospice and palliative care medicine
    - ☐ Tried and failed or has a contraindication or intolerance to at least 3 unrelated (ie, different opioid ingredient) preferred Analgesics, Opioid Short-Acting

**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: |
|---|---|