




Medical Assistance BULLETIN

ISSUE DATE November 7, 2024	EFFECTIVE DATE January 6, 2025	NUMBER *See below	
SUBJECT Prior Authorization of Analgesics, Opioid Short-Acting – Pharmacy Services		BY  Sally Kozak Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Analgesics, Opioid Short-Acting submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Analgesics, Opioid Short-Acting will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Analgesics, Opioid Short-Acting to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Analgesics, Opioid Short-Acting to address the use of nasal butorphanol for treatment of migraine pain. There are no other changes to the medical necessity guidelines.

*01-25-03	09-25-03	27-25-03	33-25-03
02-25-03	11-25-03	30-25-03	
03-25-03	14-25-03	31-25-03	
08-25-04	24-25-03	32-25-03	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:

<https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html>

The revisions to the guidelines to determine medical necessity of prescriptions for Analgesics, Opioid Short-Acting were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Analgesics, Opioid Short-Acting are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Analgesics, Opioid Short-Acting) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. 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).
4. 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 use disorder OR naltrexone for extended-release injectable suspension (Vivitrol).
5. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.
6. An Analgesic, Opioid Short-Acting that does not contain codeine or tramadol when prescribed for a beneficiary under 18 years of age and at least **one** of the following:
 - a. More than a five-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.
7. An Analgesic, Opioid Short-Acting when prescribed for a beneficiary 18 years of age or older and at least **one** of the following:
 - a. More than a 10-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

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Short-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

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-tolerant¹
 - 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 of or a contraindication or an intolerance to at least three 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 of or a contraindication or an intolerance to **all** of the following abortive therapies:
 - (i) Acetaminophen,
 - (ii) Non-steroidal anti-inflammatory drugs (NSAIDs),

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.

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- (iii) Triptans,
 - (iv) Dihydroergotamine,
- d) Has a history of therapeutic failure of or a contraindication or an intolerance to **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;

AND

- 3. For a combination agent containing a barbiturate, also meets the prior authorization guideline related to Analgesics, Non-Opioid Barbiturate Combinations; **AND**
- 4. For a non-preferred Analgesic, Opioid Short-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to 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), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s);

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 drugs
 - b. Has a medical reason for concomitant use of the requested drugs 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:

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- a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury
 - 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 or is receiving treatment post-operatively or following a traumatic injury
- b. **All** of the following:
- i. Has documentation of pain that is **all** of the following:
 - a) Caused by a medical condition,
 - b) Moderate to severe,
 - c) For all Analgesics, Opioid Short-Acting except nasal butorphanol, not migraine in type,
 - 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 beneficiary's condition,
 - iii. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,
 - iv. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - v. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
 - vi. For beneficiaries who have received opioid treatment for the past three months, 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,
 - vii. For a beneficiary under 18 years of age, is prescribed a drug 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;

AND

8. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the

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quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and **both** 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 Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting
- b. 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. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a one-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

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/or level of functioning while on the requested drug,

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- ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be 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 Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and **both** 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 Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting
 - b. 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. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a one-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 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.

D. Dose and Duration of Therapy

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

E. Five-Day Supply

The Department will cover a five-day supply of the prescribed drug without prior authorization if, in the professional judgment of the dispensing pharmacist, the beneficiary has an immediate need for the drug, unless the dispensing pharmacist determines that taking the drug either alone or along with other drugs that the beneficiary may be taking would jeopardize the health and safety of the beneficiary. The maximum number of five-day supplies of a prescription for an Analgesic, Opioid Short-Acting that the Department will cover without prior authorization is one five-day supply per beneficiary during a six-month period.

In response to health and safety concerns, the Department will not cover a five-day supply of an Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.

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