

ISSUE DATE November 6, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Analgesics, Opioid Short-Acting – Pharmacy Services		BY  Sally A. 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.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

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 delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Analgesics, Opioid Short-Acting to the appropriate managed care organization.

*01-20-13	09-20-12	27-20-08	33-20-09
02-20-06	11-20-06	30-20-05	
03-20-06	14-20-07	31-20-13	
08-20-16	24-20-07	32-20-05	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p>

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 11, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Analgesics, Opioid Short-Acting:

- Clarification of the guideline for alternative pain management modalities that are commonly used to treat neuropathic pain to add examples of non-opioid analgesics (e.g., gabapentinoids, duloxetine, and tricyclic antidepressants);
- Revision to the guideline related to the Prescription Drug Monitoring Program (PDMP) for a beneficiary with a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services; and
- Revision to the Dose and Duration of Therapy to limit approval of requests to three months for beneficiaries who do not have a diagnosis of active cancer and who are not receiving palliative care or hospice services when the total daily opioid dose is equal to or greater than 50 morphine milligram equivalents.

The revisions to the guidelines to determine medical necessity of Analgesics, Opioid Short-Acting, as recommended by the P&T Committee, 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 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

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

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

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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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
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 dependence 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 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.
7. 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.
8. An Analgesic, Opioid Short-Acting when prescribed for a beneficiary 21 years of age or older and at least **one** of the following:

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- 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:

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,

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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- 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 the 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 guidelines in the provider handbook pages in the SECTION II chapter related to Analgesics, Non-Opioid Barbiturate Combinations; **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:

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- 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),

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- 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,

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- 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 the guidelines set forth in the Quantity Limits Chapter and **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.

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:

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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

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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 the guidelines set forth in the Quantity Limits Chapter and **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

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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

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.

D. Automated Prior Authorization

Prior authorization of a prescription for a preferred Analgesic, Opioid Short-Acting that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale Online Claims Adjudication System verifies a record of a paid claim(s) within 365 days prior to the date of service that documents **one** of the following:

1. For a beneficiary under 18 years of age, **both** of the following:
 - a. The beneficiary 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
2. For a beneficiary 18 years of age or older, the beneficiary has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services.

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E. 5-Day Supply

The Department will cover a 5-day supply of the prescribed medication without prior authorization if, in the professional judgment of the dispensing pharmacist, the beneficiary has an immediate need for the medication, unless the dispensing 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. The maximum number of 5-day supplies of a prescription for an Analgesic, Opioid Short-Acting that the Department will cover without prior authorization is one 5-day supply per beneficiary during a 6-month period.

In response to health and safety concerns, the Department will not cover a 5-day supply of an Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.

F. References:

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