pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 27, 2017	January 8, 2018	*See Below

SUBJECT

Prior Authorization of Analgesics, Opioid Short Acting - Pharmacy Services

BY

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Office of Medical Assistance Programs

New 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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

BACKGROUND:

The DHS Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-37	09-17-36	27-17-34	
02-17-32	11-17-32	30-17-33	
03-17-32	14-17-33	31-17-38	
08-17-39	24-17-33	32-17-32	33-17-37

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

DISCUSSION:

The Food and Drug Administration (FDA) recently published a new safety announcement restricting the use of prescriptions containing codeine and tramadol in children. During the September 20, 2017 DUR Board meeting, the DUR Board recommended a revision to the title of the handbook chapter to more accurately reflect the scope of drugs covered in this class, and revisions to the requirements for prescriptions that require prior authorization, 5-day supplies, medical necessity guidelines, and automated prior authorization to address these new FDA contraindications and warnings. In addition, DHS is limiting the duration of approvals of all request for prior authorization of Analgesics, Opioid Short Acting to three (3) months based on the Centers for Disease Control and Prevention (CDC) recommendation that clinicians should evaluate the benefits and harms of continued therapy with patients every three months or more frequently. The revisions were subject to public review and comment, and subsequently approved for implementation by DHS.

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. DHS 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

SECTION II
Analgesics, Opioid Short Acting

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 prescription for a non-preferred Analgesic, Opioid Short Acting regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Analgesics, Opioid Short Acting at: https://papdl.com/preferred-drug-list

2. A prescription for a preferred Analgesic, Opioid Short Acting with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm

3. A prescription for either a preferred or non-preferred 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 PROMISe, the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. A prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting when a beneficiary has a concurrent prescription for a Buprenorphine Agent with an FDA-approved indication for opioid dependence or naltrexone for extended-release injectable suspension (Vivitrol)

5. A prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting that contains codeine or tramadol when prescribed for a child under 18 years of age.

6. A prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting that contains codeine or tramadol when prescribed for a child 18-20 years of age, and:

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

7. A prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting that does not contain codeine or tramadol when prescribed for a child under 21 years of age, and:

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

8. A prescription for a preferred Analgesic, Opioid Short Acting when prescribed for an adult 21 years of age or older, and

    a. More than a 7-day supply is prescribed, **OR**
    b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short Acting within the past 180 days

B. 5-Day Supply

A pharmacist may dispense a 5-day supply of the 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. The maximum number of 5-day supplies of a prescription for an Analgesic, Opioid Short Acting that can be dispensed without prior authorization is one (1) 5-day supply per beneficiary during a six (6) month period.

In response to health and safety concerns, a pharmacist may not dispense a 5-day supply of an Analgesic, Opioid Short Acting that contains codeine or tramadol when prescribed for a child under 18 years of age.

C. Clinical Review Guidelines and 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 the following:

1. For transmucosal fentanyl products - The beneficiary has a diagnosis of cancer

    AND

    a. The beneficiary is opioid tolerant. (Opioid tolerant is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/h, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equi-analgesic dose of another opioid for one (1) week or longer.)

    AND

b. The prescriber is an American Board of Medical Specialties (ABMS) Certified Oncologist or Pain Specialist

AND

c. The beneficiary has a history of a contraindication to the preferred Analgesics, Opioid Short Acting

AND

2. For Nasal Butorphanol - The beneficiary is not opioid tolerant (Opioid tolerant is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/h, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equi-analgesic dose of another opioid for one (1) week or longer.)

AND

a. Has a diagnosis of pain

AND

b. Has a history of a contraindication, intolerance to or therapeutic failure of at least three unrelated (different opioid ingredient) preferred Analgesics, Opioid Short Acting Medication (single entity or combination products)

AND

c. Is being prescribed nasal butorphanol by a neurologist or pain medication specialist

OR

d. Has a diagnosis of migraine

AND

e. Has a history of a contraindication, intolerance to or therapeutic failure of the triptans for abortive therapy

AND

f. Has a history of a contraindication, intolerance to or therapeutic failure of the following preventative therapies:

i. Beta blockers
ii. Calcium channel blockers
iii. Anticonvulsants
iv. Selective serotonin reuptake inhibitor (SSRI) Antidepressants
v. Tri-cyclic antidepressants
vi. Non-steroidal anti-inflammatories (NSAIDs)

AND

3. For non-preferred Analgesics, Opioid Short Acting – The beneficiary has a history of a contraindication to, intolerance, or therapeutic failure of at least three unrelated (different opioid ingredient) preferred Analgesics, Opioid Short Acting Medication (single entity or combination products for breakthrough pain)

AND

4. When determining medical necessity of a prescription for a preferred or non-preferred Analgesic, Opioid Short Acting for a beneficiary with a concurrent prescription for a Buprenorphine Agent with an 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 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

5. For therapeutic duplication, whether:

a. The beneficiary is being titrated to, or tapered from, a drug in the same class

OR

b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested

AND

6. For a prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting when prescribed for a child under 21 years of age, 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 Short Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy

AND

e. 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

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

AND

g. 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

h. 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

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

AND

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

AND

k. Has a recent urine drug screen (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

l. For a combination agent containing a barbiturate, meets the guidelines in the handbook chapter for Analgesics, Non-Opioid Barbiturate Combinations

AND

7. For a prescription for a preferred or non-preferred Analgesic, Opioid Short Acting when prescribed for a beneficiary 21 years of age and older, 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. Moderate to 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 Short Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy

AND

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

AND

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

AND

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

AND

h. 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

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

AND

j. Has a recent urine drug screen (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

k. For a combination agent containing a barbiturate, meets the guidelines in the handbook chapter for Analgesics, Non-Opioid Barbiturate Combinations

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 Short Acting

OR

9. 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.

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

1. The beneficiary has moderate to 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 one or more of the following:

    a. Pain is inadequately controlled at the current quantity limit

    AND

    b. 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

AND

4. The beneficiary would be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long Acting

OR

5. If the quantity of a prescription for either a preferred or non-preferred Analgesic, Opioid Short Acting exceeds the quantity limit and does not meet the 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.

FOR RENEWALS OF PRESCRIPTIONS FOR ANALGESICS, OPIOID SHORT ACTING: Requests for prior authorizations of renewals for Analgesics, Opioid Short 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 Short 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 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; must include 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 Short Acting

OR

9. 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.

D. Automated Prior Authorization

Prior authorization of a prescription for a preferred Analgesic, Opioid Short Acting will be automatically approved when the PROMISe Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim 365 days prior to the date of service that documents:

1. A diagnosis of active cancer, sickle cell with crisis or newborn drug withdrawal syndrome for a beneficiary under 18 years of age and the Analgesic, Opioid Short Acting does not contain codeine or tramadol.

2. A diagnosis of active cancer or sickle cell with crisis for a beneficiary 18 years of age or older.

E. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above, to assess the medical necessity of the request for a prescription for an Analgesic, Opioid Short Acting. If the guidelines in Section C. 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.

F. Dose and Duration of Therapy

The Department will limit authorization of prescriptions for Analgesics, Opioid Short Acting to three (3) months of therapy.

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