pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
April 26, 2018	April 26, 2018	*See below

SUBJECT

Prior Authorization of Analgesics, Opioid Long Acting – Pharmacy Services

BY

Sally A. Kozak, Acting 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: 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 additions to the type of information needed to evaluate the medical necessity of prescriptions for Analgesics, Opioid Long Acting submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to Analgesics, Opioid Long Acting to the appropriate managed care organization.

*01-18-07	09-18-08	27-18-07	33-18-08
02-18-05	11-18-05	30-18-05	
03-18-05	14-18-06	31-18-08	
08-18-08	24-18-05	32-18-05	

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

BACKGROUND:

As part of the ongoing effort to address the opioid crisis in the Commonwealth but continue to provide access to beneficiaries who have a medical need for Analgesics, Opioid Long Acting, the Department of Human Services (Department) is revising the requirements for prior authorization and the guidelines to evaluate the medical necessity of prescriptions for Analgesics, Opioid Long Acting submitted for prior authorization.

DISCUSSION:

The Department is revising the requirements and the guidelines as follows:

- Additions to the clinical review guidelines to determine medical necessity:
    - Whether the beneficiary:
        a. Is under 18 years of age, has a diagnosis of active cancer, sickle cell with crisis or neonatal abstinence syndrome, or is receiving palliative care or hospice services, and the Analgesic, Opioid Long Acting does not contain codeine or tramadol

        OR

        b. Is 18 years of age or older and has a diagnosis of active cancer or sickle cell with crisis, or is receiving palliative care or hospice services

    - Whether the beneficiary is prescribed a medication and dose that is appropriate based on the beneficiary's age, weight, and concurrent medical conditions as listed in:
        a. The Food and Drug Administration (FDA) approved package insert

        OR

        b. Nationally recognized compendia for medically-accepted indications for off-label use

        OR

        c. Medically accepted standards of care that corroborate use, such as peer-reviewed literature or national treatment guidelines

- Addition to the provisions for automated prior authorization:

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 receipt of palliative care or hospice services

The proposed revisions were shared with the Medical Assistance Advisory Committee and were subject to public review and comment.

PROCEDURE:

The procedures for prescribers to request prior authorization of Analgesics, Opioid Long 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 Long 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 Long Acting

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:

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

2. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm

B. 5-Day Supplies

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 Long 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 Long Acting that contains 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 Long Acting, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For all non-preferred Analgesics, Opioid Long Acting, whether the beneficiary has a documented history of intolerance, a contraindication to, or therapeutic failure of the preferred Analgesics, Opioid Long Acting.

AND

2. For a preferred or non-preferred Analgesic, Opioid Long Acting for a beneficiary with a concurrent prescription for a Buprenorphine Agent with a Food and Drug Administration (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 a need for therapy with an Analgesic, Opioid Long Acting and the other therapy will be suspended during the treatment for pain

AND

3. Whether the beneficiary:

   a. Is under 18 years of age, has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome, or is receiving palliative care or hospice services, and the Analgesic, Opioid Long Acting does not contain codeine or tramadol.

   OR

   b. Is 18 years of age or older and has a diagnosis of active cancer or sickle cell with crisis, or is receiving palliative care or hospice services

   OR

4. For a prescription for either a preferred or non-preferred Analgesic, Opioid Long Acting when prescribed for a beneficiary under 21 years of age who does not meet the guidelines in #3 above, 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 Long Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy

AND

e. Has documentation of a trial of Analgesics, Opioid Short Acting

AND

f. Is opioid-tolerant

AND

g. 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

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

AND

i. 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

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

AND

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

AND

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

AND

m. Has a recent urine drug screen (UDS) (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

5. For a prescription for either a preferred or non-preferred Analgesic, Opioid Long Acting when prescribed for an adult 21 years of age or

older who does not meet the guidelines in #3 above, 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 Long Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy

AND

e. Has documentation of a trial of Analgesics, Opioid Short Acting

AND

f. Is opioid-tolerant (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)

AND

g. 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

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

AND

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

AND

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

AND

k. 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

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

AND

m. Has a recent UDS (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

6. For all Analgesics, Opioid Long Acting, 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 Long Acting

Quantity Limits - In addition, if the quantity of a prescription for either a preferred or non-preferred Analgesic, Opioid Long 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 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 the following:

a. Pain is inadequately controlled at the current quantity limit

AND

b. Pain is inadequately controlled by other Analgesics, Opioid Long Acting

OR

c. The beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long Acting

AND

4. For doses that exceed the FDA-approved starting dose, there is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid-containing medications

AND

5. The requested dosing frequency does not exceed the maximum FDA-approved dosing frequency

NOTE: As described in Section E, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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 PRESCRIPTIONS FOR ANALGESICS, OPIOID LONG ACTING: Requests for prior authorizations of renewals for Analgesics, Opioid Long 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 Long 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 the 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; and 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 Long Acting

NOTE: As described in Section E, 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.

D. Automated Prior Authorization

Prior authorization of a prescription for a preferred Analgesic, Opioid Long 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 neonatal abstinence syndrome, or is receiving palliative care or hospice services, for a beneficiary under 18 years of age and the Analgesic, Opioid Long-Acting does not contain tramadol

OR

2. A diagnosis of active cancer or sickle cell with crisis, or is receiving palliative care or hospice services, 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 Long 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 Long Acting to three (3) months of therapy**.**

References:

1. Methadone: focus on safety. Pharmacist's Letter/Prescriber's Letter 2006; 22(9):220902
2. Cytochrome P450 drug interactions. Pharmacist's Letter/Prescriber's Letter 2006; 22(2):220233
3. Subutex [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006
4. Suboxone [package insert]. South San Francisco, CA: Genentech, Inc.; September 2006
5. Suboxone/Subutex Pharmacist’s Letter/Prescriber’s Letter 2009;25(1):250101.

6. Hauer J, Jones BL. Evaluation and management of pain in children, UpToDate. Accessed August 12, 2013.
7. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification, and management, UpToDate. Accessed August 12, 2013.
8. National Institute on Drug Abuse, Topics in Brief: Prescription Drug Abuse, Revised December 2011
9. American News Report, Should Children Take Opioid Painkillers? July 10, 2012
10. Chou R, Fanciullo GJ, Fine PG, et al for the American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. Journal of Pain 2009;10(2):113-130.
11. FDA News Release: FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics; September 10, 2013. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm367726.htm. Accessed February 12, 2014.
12. Government Accountability Office. Prescription Pain Reliever Abuse. GAO-12-115, December 2011. Available at www.gao.gov/assets/590/587301.pdf. Accessed on January 31, 2014.
13. Kirschner N, Ginsburg J, Sulmasy LS for the Health and Public Policy Committee of the American College of Physicians. Prescription Drug Abuse: Executive Summary of a Policy Position Paper from the American College of Physicians. Annals of Internal Medicine 2014;160(3):198-200.
14. Nuckols TK, Anderson L, Popescu I, et al. Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain. Annals of Internal Medicine 2014;160(1):38-47.
15. Policy Impact: Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. Available at http://www.cdc.gov/homeandrecreationalsafety/rxbrief. Accessed February 12, 2014.
16. Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. Available at http://www.cdc.gov/injury/about/focus-rx.html. Accessed February 12, 2014.
17. Wilford BB, Parran TV, DuPont RL. Prescription drug abuse and addiction: prevention, identification and management, UpToDate. Accessed February 12, 2014.
18. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.
19. Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain. Accessed January 31, 2017, http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Documents/PAGuidelinesonOpioids.pdf.