pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 28, 2023	July 10, 2023	*See below

SUBJECT

Prior Authorization of Analgesics, Opioid Long-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 Long-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 Long-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 Long-Acting to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR)

*01-23-10	09-23-10	27-23-04	33-23-10
02-23-03	11-23-03	30-23-07	
03-23-03	14-23-03	31-23-11	
08-23-14	24-23-09	32-23-03	

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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the April 26, 2023, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Analgesics, Opioid Long-Acting:

- Revision of the guideline for non-preferred Analgesics, Opioid Long-Acting to include specific guidelines for non-preferred buprenorphine- and tramadol-containing products.
- Deletion of the guideline for an Analgesic, Opioid Long-Acting when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol) that the beneficiary has a need for therapy with an Analgesic, Opioid Long-Acting and the other therapy will be suspended.
- Revision of the guideline related to the severity of the beneficiary's pain.
- Deletion of the guideline that the beneficiary has documentation of the anticipated duration of therapy.
- Revisions to the guidelines for a history of therapeutic failure of or a contraindication or an intolerance to other pain management modalities.
- Deletion of the guidelines that the Analgesic, Opioid Long-Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy.
- Revision of the guideline related to an appropriate medication and dose.
- Revision of the guideline that the beneficiary was assessed for potential risk of opioid misuse, abuse, or addiction.
- Deletion of the guidelines related to education about the potential adverse effects of opioid analgesics.
- Deletion of the guidelines that the beneficiary was evaluated for risk factors for opioid related harm.
- Deletion of the guideline that the beneficiary was assessed for recent use of an opioid.
- Clarification that the guideline related to urine drug screens includes specific testing for buprenorphine.
- Addition of a guideline that a beneficiary under 18 years of age is prescribed an appropriate medication and dose.
- Deletion of the guidelines related to documentation that the prescriber or prescriber's delegate conducted a search of the Prescription Drug Monitoring Program.
- Revision of the guidelines related to a request for an Analgesic, Opioid Long-Acting that exceeds the quantity limit.
- Addition of notes related to 1-month approvals for beneficiaries who do not meet the medical necessity guidelines but are receiving ongoing opioid therapy.

- Deletion of the guideline for renewals of prior authorization that the beneficiary is being monitored by the prescriber for adverse effects and warning signs for serious problems, such as overdose and opioid use disorder.
- Revision of the guideline for renewals of prior authorization related to urine drug screens.
- Deletion of the section related to automated prior authorization.

The revisions to the guidelines to determine medical necessity of prescriptions for Analgesics, Opioid Long-Acting submitted for prior authorization, as recommended by the DUR Board, 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 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 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.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

I. 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.

B. 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 whether the beneficiary:

1. For a non-preferred Analgesic, Opioid Long-Acting, **one** of the following:

    a. For a non-preferred buprenorphine product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing buprenorphine,
    b. For a non-preferred tramadol product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing tramadol,
    c. For all other non-preferred Analgesics, Opioid Long-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting

    See the Preferred Drug List for the list of preferred Analgesics, Opioid Long-Acting at: https://papdl.com/preferred-drug-list; **AND**

2. For an Analgesic, Opioid Long-Acting when the beneficiary has 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**

3. **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 Long-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) Severe,

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

iv. Is opioid-tolerant (for adults, 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 equi-analgesic dose of another opioid for one week or longer),

v. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

vi. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,

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

viii. 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,

ix. For a beneficiary under 18 years of age, 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;

AND

4. For therapeutic duplication, **one** of the following:

a. Is being transitioned to or from another Analgesic, Opioid Long-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

5. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter and **all** 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 Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

    b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

    c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

        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.

    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 1-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 LONG-ACTING: The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Long-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 Long-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 agent,

ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined 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 Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter and **all** 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 Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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.

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 1-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 Long-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

Requests for prior authorization of an Analgesic, Opioid Long-Acting will be approved for up to 6 months.

E. 5-Day Supplies

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 Long-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 Long-Acting that contains codeine or tramadol when prescribed for a child under 18 years of age.

F. 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.
20. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. MMWR Recomm Rep. 2022 Nov 4;71(3):1-95. doi: 10.15585/mmwr.rr7103a1. PMID: 36327391; PMCID: PMC9639433.