

ISSUE DATE November 6, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *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 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 Long-Acting to the appropriate managed care organization.

BACKGROUND:

*01-20-12	09-20-11	27-20-07	33-20-08
02-20-05	11-20-05	30-20-04	
03-20-05	14-20-06	31-20-12	
08-20-15	24-20-06	32-20-04	

<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>

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 Long-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;
- Addition of a guideline for prescriptions for Analgesics, Opioid Long-Acting that represent therapeutic duplication;
- Revisions to the guidelines for initial requests that exceed the quantity limit to align with the guidelines in the Analgesics, Opioid Short-Acting chapter and the addition of these guidelines to the guidelines for requests for renewal of prior authorizations for Analgesics, Opioid Long-Acting;
- Revision to the guideline for urine drug screening to remove screening for carisoprodol; and
- Revision to the Dose and Duration of Therapy to allow for approval of requests for prior authorization for up to 6 months.

The revisions to the guidelines to determine medical necessity of Analgesics, Opioid Long-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 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

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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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, has a history of therapeutic failure, contraindication, or intolerance of 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), **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 a need for therapy with an Analgesic, Opioid Long-Acting, and the other therapy will be suspended during the treatment for pain;

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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a) Caused by a medical condition,
 - b) Not migraine in type,
 - c) 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 (i.e., behavioral, cognitive, physical, and/or supportive therapies)
 - b) Non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants),
 - iv. Has documentation that the Analgesic, Opioid Long Acting will be used in combination with tolerated non-pharmacologic therapy and non-opioid pharmacologic therapy,
 - v. Has documentation of a trial of Analgesics, Opioid Short-Acting,
 - vi. 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),
 - 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 potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,
 - ix. **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,
 - x. Was evaluated for risk factors for opioid-related harm; if beneficiary is identified to be at high risk for opioid-related harm, the prescriber considered prescribing naloxone,

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- xi. Was assessed for recent use (within the past 60 days) of an opioid,
- xii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined medically necessary,
- xiii. 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

- 4. **One** of the following:
 - a. Meets the guidelines in B.3.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 Long-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

- 5. 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

- 6. 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. The beneficiary has severe pain as documented by a pain assessment tool measurement (e.g., a numeric or visual analog scale),

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
- d. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,
- e. 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.

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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- i. Has documentation of improvement in pain control and/or level of functioning while on the requested agent,
- ii. Has documentation that the Analgesic, Opioid Long-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 at 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 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

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 Long-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;

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

3. 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. The beneficiary has 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 Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,
 - d. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,
 - e. 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.

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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. Automated Prior Authorization

Prior authorization of a prescription for a preferred Analgesic, Opioid Long-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.

F. 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.

G. 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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/homeandrecreationalafety/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>.