


ISSUE DATE February 6, 2024	EFFECTIVE DATE February 6, 2024	NUMBER *See below
SUBJECT Prior Authorization of Opioid Use Disorder Treatments – 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 Opioid Use Disorder Treatments 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 Opioid Use Disorder Treatments 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 Opioid Use Disorder Treatments to the appropriate managed care organization.

BACKGROUND:

Fentanyl is a synthetic opioid that is approximately 50 times more potent than heroin

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

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>.

and 100 times more potent than morphine. The U.S. Centers for Disease Control and Prevention estimates that the rate of overdose deaths in the U.S. involving synthetic opioids like fentanyl was almost 22 times higher in 2021 than in 2013, and the rate of overdose deaths involving synthetic opioids (other than methadone) increased by over 22% from 2020 to 2021. Most recent cases of fentanyl-related harm, overdose, and death are linked to illegally made fentanyl that is often sold through illegal drug markets for its heroin-like euphoric effect.

Buprenorphine is partial opioid agonist that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid use disorder (OUD). Unlike methadone, buprenorphine for the treatment of OUD can be prescribed in physician offices and dispensed in physician offices and community pharmacies, significantly increasing access to treatment for OUD. The Substance Abuse and Mental Health Services Administration highlights the pharmacological properties of buprenorphine that contribute to its integral role in the treatment of OUD, such as its ability to diminish the effects of physical dependence to opioids, such as withdrawal symptoms and cravings, increased safety in cases of overdose compared to other opioids, and lower potential for misuse compared to other opioids.

Current FDA guidance recommends a target buprenorphine dose of 16 mg per day and a dose range of 4 mg to 24 mg per day for the treatment of OUD. However, recent medical literature supports higher doses of buprenorphine in some scenarios as well as the importance of allowing prescribers to individualize buprenorphine doses for their patients.

A study funded by the National Institutes of Health's National Institute of Drug Abuse (NIDA) and published by the American Medical Association's JAMA Network in 2023 found that patients who were prescribed higher doses of buprenorphine remained in treatment longer than patients prescribed 16 mg of buprenorphine per day and concluded that "the value of higher buprenorphine doses than currently recommended needs to be considered for improving retention in treatment." In response to these findings, Dr. Nora Volkow, Director of the NIDA, reiterated, "Effective treatment can save lives, but our proven treatments for opioid use disorders must evolve to match the challenges posed by the fentanyl crisis" and recommended, "If science continues to demonstrate that a higher dosage of buprenorphine increases treatment retention, we must re-evaluate clinical guidelines to optimize treatment and help people achieve recovery."

DISCUSSION:

Prescriptions for a sublingual buprenorphine Opioid Use Disorder Treatment that exceed the quantity limits require prior authorization. The Department of Human Services (Department) is updating the medical necessity guidelines for Opioid Use Disorder Treatments to remove the guidelines related to a prescription for a sublingual buprenorphine Opioid Use Disorder Treatment that exceeds a daily dose of 24 mg/day. The Department will be updating the quantity limits to support the change in the guidelines.

PROCEDURE:

The procedures for prescribers to request prior authorization of Opioid Use Disorder

Treatments 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 Opioid Use Disorder Treatments) 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>

REFERENCES:

U.S. Drug Enforcement Administration – Fentanyl

<https://www.dea.gov/factsheets/fentanyl>

Centers for Disease Control and Prevention – Fentanyl

<https://www.cdc.gov/opioids/basics/fentanyl.html>

Substance Abuse and Mental Health Services Administration – Buprenorphine

<https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine>

Journal of Addiction Medicine (American Society of Addiction Medicine) – Evidence of Buprenorphine Dose Limits: A Review.

https://journals.lww.com/journaladdictionmedicine/fulltext/2023/09000/evidence_on_buprenorphine_dose_limits_a_review.4.aspx

JAMA Network Open (American Medical Association) – Buprenorphine Dose and Time to Discontinuation Among Patients With Opioid Use Disorder in the Era of Fentanyl

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809633?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=091823

National Institutes of Health – National Institute on Drug Abuse – Higher buprenorphine doses associated with improved retention in treatment for opioid use disorder

<https://nida.nih.gov/news-events/news-releases/2023/09/higher-buprenorphine-doses-associated-with-improved-retention-in-treatment-for-opioid-use-disorder>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Opioid Use Disorder Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Opioid Use Disorder Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Opioid Use Disorder Treatment. See the Preferred Drug List (PDL) for the list of preferred Opioid Use Disorder Treatments at: <https://papdl.com/preferred-drug-list>.
2. An Opioid Use Disorder Treatment 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>.

REMINDER: A prescription for a benzodiazepine, opioid analgesic, controlled substance sedative hypnotic, or carisoprodol requires prior authorization when a beneficiary has a concurrent prescription for a buprenorphine Opioid Use Disorder Treatment. Refer to the specific individual handbook chapters (e.g., Analgesics, Opioid Long-Acting, Analgesics, Opioid Short-Acting, Anticonvulsants, Anxiolytics, Skeletal Muscle Relaxants, Sedative Hypnotics) for corresponding prior authorization guidelines.

REMINDER: A prescription for an opioid analgesic requires prior authorization when a beneficiary has a concurrent prescription for Vivitrol.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Opioid Use Disorder Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Opioid Use Disorder Treatment for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. For Lucemyra (lofexidine), is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. For a non-preferred Opioid Use Disorder Treatment, **one** of the following:
 - a. For a sublingual buprenorphine Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred sublingual buprenorphine Opioid Use Disorder Treatments,
 - b. For an alpha-2 adrenergic agonist Opioid Use Disorder Treatment, has a history of

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therapeutic failure of or a contraindication or an intolerance to the preferred alpha-2 adrenergic agonist Opioid Use Disorder Treatments,

- c. For a non-sublingual buprenorphine Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-sublingual buprenorphine Opioid Use Disorder Treatments;

AND

4. If a prescription for an Opioid Use Disorder Treatment 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.

NOTE: If the beneficiary does not meet the clinical review guidelines and 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.

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 Opioid Use Disorder Treatment. 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 Lucemyra (lofexidine) will be approved for a dose and duration of therapy consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.