pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 12, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Opioid Dependence 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 Dependence 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 Dependence Treatments 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 Opioid Dependence Treatments to the appropriate MCO.

BACKGROUND:

*01-21-36	09-21-35	27-21-27	33-21-35
02-21-23	11-21-25	30-21-30	
03-21-23	14-21-26	31-21-38	
08-21-38	24-21-33	32-21-23	

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.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical 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 September 15, 2021, meeting, the P&T Committee recommended the following revision to the guidelines to determine medical necessity of Opioid Dependence Treatments:

- Addition of a guideline for Lucemyra (lofexidine), that the beneficiary is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The revision to the guidelines to determine medical necessity of prescriptions for Opioid Dependence Treatments submitted for prior authorization, as recommended by the P&T Committee, was subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Opioid Dependence 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 Dependence 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 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 Opioid Dependence Treatments

A. Prescriptions That Require Prior Authorization

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

1. An oral buprenorphine Opioid Dependence Treatment without naloxone.

2. A non-preferred Opioid Dependence Treatment. See the Preferred Drug List (PDL) for the list of preferred Opioid Dependence Treatments at: https://papdl.com/preferred-drug-list.

3. An Opioid Dependence 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 Dependence 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 Dependence Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Opioid Dependence Treatment for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-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 an oral buprenorphine Opioid Dependence Treatment that does not contain naloxone, **one** of the following:

   a. Is prescribed the agent for induction therapy,
   b. Is pregnant,

c. Is breastfeeding,
d. Has a history of contraindication or intolerance to naloxone;

AND

4. For a non-preferred Opioid Dependence Treatment, **one** of the following:

   a. For an oral buprenorphine Opioid Dependence Treatment, has a history of therapeutic failure, contraindication, or intolerance of the preferred oral buprenorphine Opioid Dependence Treatments,
   b. For an alpha-2 adrenergic agonist Opioid Dependence Treatment, has a history of therapeutic failure, contraindication, or intolerance of the preferred alpha-2 adrenergic agonist Opioid Dependence Treatments,
   c. For a non-oral buprenorphine Opioid Dependence Treatment, has a history of therapeutic failure, contraindication, or intolerance of the preferred non-oral buprenorphine Opioid Dependence Treatments;

   AND

5. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary's controlled substance prescription history; **AND**

6. If a prescription for an Opioid Dependence 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; **AND**

7. If a prescription for an oral buprenorphine Opioid Dependence Treatment is for a daily dose that exceeds 24 mg/day, **all** of the following:

   a. Whether the beneficiary is prescribed a daily dose consistent with medically accepted prescribing practices and standards of care,

   b. Whether the beneficiary has documentation of an evaluation to determine the recommended level of care,

   c. Whether the beneficiary has documentation of participation in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program,

   d. Whether the beneficiary has a recent urine drug screen for drugs with the potential for abuse,

   e. For a beneficiary already established on buprenorphine, whether the beneficiary has a recent urine drug screen that is positive for buprenorphine and norbuprenorphine.

   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 Dependence 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 the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

E. 5-Day Supply

The Department will cover a 5-day supply of the prescribed oral Opioid Dependence Treatment 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 oral Opioid Dependence Treatment that the Department will cover without prior authorization is one 5-day supply per beneficiary during a 6-month period.

The Department does not consider a delay in the receipt of a buprenorphine implant or injection to present an immediate need and, therefore, will not cover 5-day supplies of a buprenorphine implant or injection pending approval of a request for prior authorization.

F. References

1. SUBOXONE® [package insert]. North Chesterfield, VA: Indivior Inc., February 2018.
2. SUBUTEX® [package insert]. North Chesterfield, VA: Indivior Inc., February 2018.
3. *Psychiatric Services* in Advance, November 18, 2013; doi:10.1176/appi.ps.201300256.
4. Nuckols TK, Anderson L, Popescu I., Diamant AL, Doyle B, Di Capua P, Chou R. “Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain.” Annals of Internal Medicine, Volume 160, Number 1 (January 7, 2014).
5. “At Clinics, Tumultuous Lives and Turbulent Care,” New York Times, 18 November 2013. http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html. http://www.nytimes.com/2013/11/18/health/at-clinics-tumultuous-lives-and-turbulent-care.html?hp&_r=0.

6. IRETA. (2012, October 18). *Best Practices in the Use of buprenorphine: Final Expert Panel Report Prepared for Community Care Behavioral Health Organization*.
7. Community Care Behavioral Health Organization. (January 2013*) Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for buprenorphine and Suboxone.*
8. Ling et all 1998. *Addiction* 93:475-86.
9. *Treatment of Opioid Dependence,* 2006. JHpress.
10. Drug Information Online. "Buprenorphine Dosage"http://www.drugs.com/dosage/buprenorphine.html#Usual_Adult_Dose_for Opiate Dependence.
11. CSAT's TIP 42: Substance Abuse Treatment for Persons With Co-Occurring Disorders; 2005.
12. Bart G. Maintenance Medication for Opiate Addiction: The Foundation of Recovery. *J Addict Dis.* 2012;31(3):207-225.
13. Ling W, Mooney L, Wu L. Advances in Opioid Antagonist Treatment for Opioid Addiction. *Psychiatr Clin North Am*. 2012; 35(2):297-308.
14. SAMHSA Advisory: An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence. Winter 2012. http://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf.
15. SAMHSA Advisory: Naltrexone for Extended-Release Injectable Suspension for Treatment of Alcohol Dependence. Spring 2007. http://store.samhsa.gov/product/Naltrexone-for-Extended-Release-Injectable-Suspension-for-Treatment-of-Alcohol-Dependence/SMA07-4267.
16. SAMHSA: The Facts About Naltrexone. 2012. http://store.samhsa.gov/shin/content/SMA12-4444/SMA12-4444.pdf.
17. SAMHSA TIP49: Incorporating Alcohol Pharmacotherapies into Medical Practice. May 2009. http://www.ncbi.nlm.nih.gov/books/NBK64041/pdf/TOC.pdf.
18. Strain E. Treatment of opioid use disorder. In UpToDate, Saxon AJ (ed), UpToDate, Waltham MA. (Accessed February 2, 2015).
19. Vivitrol (naltrexone injection) for Opioid Dependence. 2010; Detail-Document #261208. http://pharmacistsletter.therapeuticresearch.com/pl/ArticleDD.aspx?nidchk=1&cs=&s=PL&pt=6&fpt=31&dd=261208&pb=PL&searchid=50550135. Accessed February 25, 2015.
20. Vivitrol prescribing information, Alkermes. July 2013.
21. Probuphine prescribing information, Braeburn Pharmaceuticals, Inc. May 2016**.**
22. Rosenthal RN, Lofwall MR, Kim S, et al. Effect of buprenorphine Implants on Illicit Opioid Use Among Abstinent Adults with Opioid Dependence Treated with Sublingual buprenorphine. *JAMA.* 2016;316(3):282-290.
23. American Society of Addiction Medicine. National practice guideline for the use of medications in the treatment of addiction involving opioid use. https://www.asam.org/docs/default-source/practice-support/guidelines- and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Published June 1, 2015. Accessed February 23, 2018.
24. American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Opioid use and opioid use disorder in pregnancy. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Opioid-Use-and-Opioid-Use- Disorder-in-Pregnancy. Published August 2017. Accessed February 23, 2018.
25. Berghella V, Seligman NS, Cleary BJ. Buprenorphine substitution therapy of opioid use disorder during pregnancy. In: UpToDate [Internet Database]. Simpson LL, Saxon AJ, Barss VA, eds. Waltham, MA: UpToDate. Updated October 31, 2017. Accessed February 23, 2018.
26. Providers' Clinical Support System for Medication Assisted Treatment. Pregnancy and buprenorphine treatment. http://pcssnow.org/wp- content/uploads/2014/06/PCSS-MATGuidancePregnancy-and-Buprenorphine.Martin.pdf. Updated February 4, 2014. Accessed February 23, 2018.
27. Society of Obstetricians and Gynaecologists of Canada. No. 349 – substance use in pregnancy. http://www.jogc.com/article/S1701- 2163(17)30470-X/abstract. Published October 2017. Accessed February 23, 2018.
28. Sublocade [package insert]. North Chesterfield, VA: Indivior Inc., November 2017.
29. *FDA Drug Safety Communication: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks*. Silver Spring, MD: US Food and Drug Administration; September 20, 2017.