

Clinical Policy: Opioid Dependence Treatments

Reference Number: PHW.PDL.145.01

Effective Date: 01/01/2020

Last Review Date: 10/2021

[Revision Log](#)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Opioid Dependence Treatments are **medically necessary** when the following criteria are met:

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.

REMINDER: A prescription for a benzodiazepine, opioid analgesic, controlled substance sedative hypnotic, or carisoprodol requires prior authorization when a member 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 member 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 member:

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 member'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 PA.CP.PMN.59 Quantity Limit Override; **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 member is prescribed a daily dose consistent with medically accepted prescribing practices and standards of care,

- b. Whether the member has documentation of an evaluation to determine the recommended level of care,
- c. Whether the member has documentation of participation in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program,
- d. Whether the member has a recent urine drug screen for drugs with the potential for abuse,
- e. For a member already established on buprenorphine, whether the member has a recent urine drug screen that is positive for buprenorphine and norbuprenorphine.

NOTE: If the member 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 member, 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 member.

D. Approval Duration:

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.

All other agents: 12 months

E. 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 al 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](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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Per direction from DHS, removing criteria for an oral buprenorphine Opioid Dependence Treatment when used in combination with a benzodiazepine or CNS depressant	01/13/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021