Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

   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 policies (e.g., Analgesics, Opioid Long-Acting, Analgesics, Opioid Short-Acting, Anticonvulsants, Anxiolytics, Skeletal Muscle Relaxants, Sedative Hypnotics Policies) 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 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.

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PROBUPHINE (buprenorphine implant) PRIOR AUTHORIZATION FORM

PRIOR AUTHORIZATION INFORMATION		PRESCRIBER INFORMATION	
☐New request ☐Renewal request	total # pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		DATA 2000 waiver DEA number:	
Facility contact/phone:		NPI:	State license #:
BENEFICIARY INFORMATION		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Medication requested: Probuphine 74.2 mg implant	Quantity: ☐1 implant kit (contains 4 implants) ☐other:	
Requested duration: ☐6 months ☐other:	Dx code (*required*):	
Diagnosis *(submit documentation)*:		
1. Is the beneficiary being treated for a diagnosis of opioid use disorder?	☐Yes – *Submit documentation of diagnosis.* ☐No – *Submit medical literature supporting the use of the requested agent for the beneficiary's diagnosis.*	
2. Did the prescriber or prescriber's delegate search the PDMP to review the beneficiary's controlled substance prescription history before issuing this prescription for Probuphine?	☐Yes ☐No	*Submit documentation.*
INITIAL requests		
1. Has the beneficiary achieved and sustained prolonged clinical stability on transmucosal buprenorphine?	☐Yes ☐No	*Submit documentation.*
2. Is the beneficiary stable and on no more than 8 mg per day of oral buprenorphine for at least the last three (3) months without any need for supplemental dosing or adjustments?	☐Yes ☐No	*Submit documentation.*

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Prescriber Signature:	Date:

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OPIOID DEPENDENCE TREATMENTS PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	total # pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		DATA 2000 waiver DEA number:	
Name of facility contact:		NPI:	State license #:
Facility's phone number:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:
Directions:	Quantity:	Requested duration:
Diagnosis *(submit documentation)*:		Dx code *(required)*:
Did the prescriber or prescriber's delegate search the PDMP to review the beneficiary's controlled substance prescription history before issuing this prescription for the requested medication?		☐Yes ☐No *Submit documentation.*

Complete the sections below that are applicable to this request and SUBMIT DOCUMENTATION for each item.

For NON-PREFERRED ORAL buprenorphine products (e.g., films, tablets): Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred oral buprenorphine drugs? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.	☐Yes ☐No *Submit documentation.*
For NON-PREFERRED NON-ORAL buprenorphine products (e.g., injections, implants): Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred non-oral buprenorphine drugs? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.	☐Yes ☐No *Submit documentation.*
For LUCEMYRA: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of clonidine tablet?	☐Yes ☐No *Submit documentation.*

For an ORAL BUPRENORPHINE PRODUCT THAT DOES NOT CONTAIN NALOXONE (i.e., buprenorphine SL tablet): Check all of the following that apply to the beneficiary and submit documentation for each.

- ☐Beneficiary is pregnant
- ☐Beneficiary is breastfeeding
- ☐The requested drug is being used for induction therapy
- ☐Has a contraindication or history of intolerance to naloxone

For an ORAL buprenorphine product ABOVE THE DAILY DOSE LIMIT OF 24 MG of buprenorphine per day: Check all of the following that apply to the beneficiary and submit documentation for each.

- ☐Is prescribed a daily dose consistent with medically accepted prescribing practices and standards of care
- ☐Has an initial or scheduled evaluation to determine the recommended level of care
- ☐Is participating in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program
- ☐Has results of a recent UDS for licit and illicit drugs with abuse potential
- ☐If already established on buprenorphine, has results of a recent UDS demonstrating compliance with oral buprenorphine therapy

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Prescriber Signature:	Date: