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| <b>ISSUE DATE</b><br><br>April 10, 2018   | <b>EFFECTIVE DATE</b><br><br>April 10, 2018  | <b>NUMBER</b><br><br>*See below |
| <b>SUBJECT</b><br><br>Prior Authorization of Opioid Dependence Treatments – Pharmacy Services | <b>BY</b><br><br><br>Sally A. Kozak, Acting Deputy Secretary<br>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: [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include changes to the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Opioid Dependence Treatments and medication assisted treatment (MAT) submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to Opioid Dependence Treatments and MAT to the appropriate managed care organization.

**BACKGROUND:**

As part of the ongoing effort to address the opioid crisis in the Commonwealth, the Wolf

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| *01-18-06 | 09-18-07 | 27-18-06 | 33-18-07 |
| 02-18-04  | 11-18-04 | 30-18-04 |          |
| 03-18-04  | 14-18-05 | 31-18-07 |          |
| 08-18-07  | 24-18-04 | 32-18-04 |          |

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| <p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at<br/> <a href="http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm">http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</a></p> |
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Administration recently announced plans to implement new policies in the MA program intended to facilitate access to MAT and support comprehensive treatment for dependency.

**DISCUSSION:**

The Department of Human Services (Department) revised the guidelines as follows:

- The thresholds for prior authorizations were revised to reflect that:
  - A covered buprenorphine/naloxone combination product designated as preferred on the Preferred Drug List will not require prior authorization.
  - Vivitrol (naltrexone) will not require prior authorization
- The guidelines to determine medical necessity of the following prescriptions were revised to be consistent with the modification to the thresholds for prior authorization of Opioid Dependence Treatments:
  - Buprenorphine without naloxone
  - Buprenorphine for beneficiaries also taking benzodiazepines or other central nervous system depressants
  - Prescribed quantities that exceed the quantity limits

The proposed revisions were shared with the Medical Assistance Advisory Committee and were subject to public review and comment.

**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

SECTION II  
Opioid Dependence Treatments

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**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. A prescription for an oral buprenorphine agent without naloxone
2. A prescription for an oral buprenorphine agent when used in combination with a benzodiazepine or Central Nervous System (CNS) depressant
3. A prescription for a non-oral buprenorphine agent
4. A prescription for a non-preferred Opioid Dependence Treatment. See the Preferred Drug List (PDL) for the list of preferred and non-preferred Opioid Dependence Treatments at:  
<http://www.dhs.pa.gov/provider/pharmacyservices/preferreddruglistinformation/>
5. A prescription for an Opioid Dependence Treatment with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:  
<http://dhs.pa.gov/provider/pharmacyservices/quantitylimit/slist/index.htm>

REMINDER: A prescription for a Benzodiazepine, Opioid Analgesic, Sedative Hypnotic or Skeletal Muscle Relaxant requires prior authorization when a beneficiary has a concurrent prescription for a buprenorphine agent.

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

B. 5-Day Supply

A pharmacist may dispense a 5-day supply of the prescribed oral Opioid Dependence Treatment without prior authorization if, in the professional judgment of the pharmacist, the beneficiary has an

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immediate need for the medication, unless the 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 Opioid Dependence Treatment that can be dispensed without prior authorization is one (1) 5-day supply per beneficiary during a six (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.

C. 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 the following:

1. Whether the beneficiary has a diagnosis of opioid use disorder

2. For an oral buprenorphine agent without naloxone, whether the beneficiary:

a. Is prescribed the agent for induction therapy

**OR**

b. Is pregnant

**OR**

c. Is breastfeeding

3. For an oral buprenorphine agent when used in combination with a benzodiazepine or CNS depressant, whether the beneficiary has documentation of the following:

a. Being educated about the serious risks of combined use

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**AND**

- b. A tapering plan for the benzodiazepine or CNS depressant

**OR**

- c. If the beneficiary is receiving benzodiazepines or other CNS depressants for anxiety or insomnia, the prescriber verified the diagnosis and considered other treatment options for these conditions

**AND**

- d. Concomitant use is medically necessary

**AND**

- e. Urine or blood drug screening
- 4. For a non-oral buprenorphine agent, whether the beneficiary is prescribed the agent for treatment of a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication and consistent with package labeling
  - 5. For a non-preferred Opioid Dependence Treatment, whether the beneficiary has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Opioid Dependence Treatments

**AND**

- 6. Whether the prescribing provider confirms that he/she, or the prescribing provider's delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history before prescribing the Opioid Dependence Treatment
- 7. In addition, if a prescription for an Opioid Dependence Treatment is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically

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necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**AND**

8. If the prescription for an oral buprenorphine agent is in a quantity that exceeds the quantity limit, whether the beneficiary:
  - a. Is prescribed a quantity consistent with medically accepted prescribing practices and standards of care

**AND**

- b. Has documentation of an evaluation by a licensed Drug & Alcohol (D&A) provider or a Single County Authority (SCA) to determine the recommended level of care

**AND**

- c. Has documentation of:
        - i. Participation with a licensed drug and alcohol (D&A) or behavioral health provider at the recommended level of care until successful completion of the program

**AND**

- ii. Upon successful completion of the program, participation in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program

**AND**

- d. Demonstrates compliance with oral buprenorphine therapy as documented by a recent urine drug screen (including testing for licit and illicit drugs with the potential for abuse; must include specific testing for oxycodone, fentanyl, tramadol and carisoprodol) that is:

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- i. Positive for buprenorphine and norbuprenorphine

**AND**

- ii. Consistent with prescribed controlled substances

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.

**D. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines above, to assess the medical necessity of the request for a prescription for an Opioid Dependence Treatment. If the guidelines 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.

When an oral buprenorphine agent is being prescribed and is therapeutically equivalent to other oral buprenorphine agents, the reviewer will take into account the cost of the drug, including the Federal Drug Rebate Program rebate and any supplemental rebate. The reviewer will prior authorize a prescription for the least costly therapeutically equivalent oral buprenorphine agent. If the prescriber does not agree to the therapeutically equivalent oral buprenorphine agent authorized by the reviewer, the prior authorization request will be referred to a physician reviewer for a medical necessity determination.

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