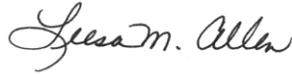


<b>ISSUE DATE</b> July 13, 2015	<b>EFFECTIVE DATE</b> July 13, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b> Prior Authorization of Opiate Dependence Treatments – Pharmacy Service		<b>BY</b>  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of naltrexone for extended-release injectable suspension (Vivitrol)
2. Issue handbook pages that include instructions on how to request prior authorization of Opiate Dependence Treatments, including the type of medical information needed to evaluate requests for medical necessity.

**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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

The Department’s Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department’s Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-11	09-15-10	27-15-09	
02-15-09	11-15-09	30-15-09	
03-15-09	14-15-09	31-15-10	
08-15-11	24-15-09	32-15-09	33-15-10

**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 Web site at  
<http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

During the March 18, 2015 meeting, the DUR Board recommended that the Department require prior authorization of naltrexone for extended-release injectable suspension (Vivitrol), and proposed guidelines to determine medical necessity. The proposed guidelines to determine medical necessity address health and safety concerns associated with naltrexone for extended-release injectable suspension (Vivitrol) and appropriate patient selection and drug utilization. The requirement for prior authorization and the guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of naltrexone for extended-release injectable suspension (Vivitrol) are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Opiate 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 chapters related to Opiate 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  
Opiate Dependence Treatments

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**I. Requirements for Prior Authorization of Opiate Dependence Treatments**

A. Prescriptions That Require Prior Authorization

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

1. A prescription for an Oral Buprenorphine Agent, regardless of the quantity prescribed
2. A prescription for a non-preferred Opiate Dependence Treatment. See the Preferred Drug List (PDL) for the list of preferred and non-preferred Opiate Dependence Treatments at:  
[www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
3. A prescription for an Opiate Dependence Treatment with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:  
<http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>
4. A prescription for naltrexone for extended-release injectable suspension (Vivitrol)

REMINDER: A prescription for a Benzodiazepine, Narcotic Analgesic, or Skeletal Muscle Relaxant requires prior authorization when a recipient has a concurrent prescription for an Oral Buprenorphine Agent.

B. Review of Documentation for Medical Necessity

In evaluating an initial request for prior authorization of a prescription for an Opiate Dependence Treatment, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For an Oral Buprenorphine Agent, whether the recipient:
  - a. Has a diagnosis of opioid dependence as documented by the following:

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- i. A history consistent with the most current Diagnostic and Statistical Manual of Mental Disorder (DSM) criteria

**AND**

- ii. An initial urine drug screen (includes testing for substances of abuse) that is consistent with the diagnosis of opioid dependence

**OR**

- iii. A history of opioid dependence and active withdrawal as documented by a Clinical Opiate Withdrawal Scale (COWS) score greater than or equal to 9 at the time of treatment initiation

**OR**

- iv. A history of opioid dependence with cravings

**AND**

- b. Has documentation of a signed consent form authorizing the certified physician to release the recipient's medical information in the patient record for the purposes of referral to substance abuse or behavioral health treatment

**AND**

- c. Has documentation of an initial evaluation by a licensed Drug & Alcohol (D&A) provider or a Single County Authority (SCA) to determine the recommended level of care; additional evaluations may be required when the recipient has a history of previous treatment for opioid dependence with treatment failures

**AND**

- d. Has documentation of a referral to or participation in a substance abuse or behavioral health

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treatment program, or behavioral health counseling. Treatment programs and counseling must be conducted by a licensed Drug & Alcohol (D&A) provider and must be consistent with the recommended level of care determined in the evaluation by the D&A provider or the SCA.

**AND**

- e. Has documentation of a mental health screening and, if diagnosed with a co-occurring mental health disorder, has been referred for, or is receiving, treatment for that condition

**AND**

- f. Is being prescribed an Oral Buprenorphine Agent by a prescriber who is enrolled in the MA Program, has been issued a unique identification number by the Drug Enforcement Agency (DEA) certifying prescribing authority for Buprenorphine Agents, and accepts as payment in full, the amounts paid by the Department plus any copayment required to be paid by a recipient

**AND**

- g. Is not taking a Benzodiazepine

**AND**

- h. Has documentation of a clinical assessment of effectiveness and dosage if the recipient has been receiving treatment with an Oral Buprenorphine Agent for more than 12 months

**AND**

- 2. For a non-preferred Opiate Dependence Treatment, whether the recipient has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Opiate Dependence Treatments
- 3. For naltrexone for extended-release injectable suspension (Vivitrol), whether the recipient:

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- a. Is being prescribed the medication by, or in consultation with, a behavioral health or licensed Drug & Alcohol (D&A) provider

**AND**

- b. Has a diagnosis of opioid use disorder that is documented by a history consistent with the most current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria

**OR**

- c. Has a diagnosis of alcohol dependence that is documented by a history consistent with the most current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria

**AND**

- d. Has documentation of an initial evaluation by a licensed Drug & Alcohol (D&A) provider or a Single County Authority (SCA) to determine the recommended level of care; additional evaluations may be required when the recipient has a history of previous treatment failures

**AND**

- e. Has documentation of a referral to or participation in a substance abuse or behavioral health treatment program, or behavioral health counseling. Treatment programs and counseling must be conducted by a licensed Drug & Alcohol (D&A) provider and must be consistent with the recommended level of care determined in the evaluation by the D&A provider or the SCA.

**AND**

- f. Does not have a contraindication to Naltrexone For Extended-Release Injectable Suspension

**AND**

- g. Has evidence of tolerability to oral naltrexone

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**AND**

- h. Does not have acute hepatitis or liver failure as documented by liver function tests

**AND**

- i. Was screened for symptoms of depression and suicidality

**AND**

- j. For a recipient with symptoms of depression and suicidality, was referred for treatment with a behavioral health provider

**AND**

- k. Has documentation of being opioid-free for a minimum of 7-10 days before starting treatment

**OR**

- 4. The request does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.
- 5. In addition, if a prescription for an Opiate Dependence Treatment is in 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**

- 6. If the prescription for an Oral Buprenorphine Agent is in a quantity that exceeds the quantity limit, whether the prescribed quantity is:
  - a. Consistent with medically accepted prescribing practices and standards of care

**AND**

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- b. Supported by peer-reviewed literature or national treatment guidelines that corroborate that the quantity of medication being prescribed improved treatment outcomes as evidenced by improvements in urine drug screen results

**OR**

- 7. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR AN ORAL BUPRENORPHINE AGENT: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for an Oral Buprenorphine Agent that were previously approved, will take into account whether the recipient:

- 1. Demonstrates compliance with the Oral Buprenorphine Agent 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 and fentanyl) that is:
  - a. Positive for Buprenorphine and Norbuprenorphine

**AND**

- b. Consistent with prescribed controlled substances.

**AND**

- 2. Has a documented history in the medical record of abstinence from alcohol

**AND**

- 3. Has documentation of:
  - a. Participation with a licensed drug and alcohol (D&A) or behavioral health provider at the

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recommended level until successful completion of  
the program

**AND**

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

**AND**

- 4. Is being prescribed an Oral Buprenorphine Agent by a prescriber who is enrolled in the MA Program, has been issued a unique identification number by the Drug Enforcement Agency (DEA) certifying prescribing authority for Buprenorphine Agents, and accepts as payment in full, the amounts paid by the Department plus any copayment required to be paid by a recipient

**AND**

- 5. Is not taking a Benzodiazepine

**AND**

- 6. If diagnosed with a co-occurring mental health disorder, continues to receive treatment for that condition

**AND**

- 7. Has documentation of a clinical assessment of effectiveness and dosage if the recipient has been receiving treatment with an Oral Buprenorphine Agent for more than 12 months

**OR**

- 8. Does not meet the clinical review guidelines for a renewal listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient
- 9. In addition, if a prescription for an Opiate 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**

10. If the prescription for an Oral Buprenorphine Agent is in a quantity that exceeds the quantity limit, whether the prescribed quantity is:
  - a. Consistent with medically accepted prescribing practices and standards of care

**AND**

- b. Supported by peer-reviewed literature or national treatment guidelines that corroborate that the quantity of medication being prescribed improved treatment outcomes as evidenced by improvements in urine drug screen results

**FOR RENEWALS OF PRESCRIPTIONS FOR NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION (VIVITROL):**

The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Vivitrol, that were previously approved, will take into account whether the recipient:

1. Has a diagnosis of opioid dependence and demonstrates compliance with treatment 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 and fentanyl) that is consistent with prescribed controlled substances

**OR**

2. Has a diagnosis of alcohol dependence and demonstrates compliance with treatment documented by history in the medical record of abstinence from alcohol and recent testing for alcohol use

**AND**

3. Has documentation of participation with a licensed drug and alcohol (D&A) or behavioral health provider at the recommended level until successful completion of the program

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**AND**

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

**AND**

5. Does not have a contraindication to Naltrexone For Extended-Release Injectable Suspension

**AND**

6. Does not have acute hepatitis or liver failure as documented by liver function tests performed within the last 6-12 months

**AND**

7. Was screened for symptoms of depression and suicidality

**AND**

8. For a recipient with symptoms of depression and suicidality, was referred for treatment with a behavioral health provider

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 the request for a prescription for an Opiate 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 recipient.

When an Oral Buprenorphine Agent is being prescribed and is therapeutically equivalent to other Oral Buprenorphine Agents, the

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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.

D. Dose and Duration of Therapy

1. Requests for prior authorization of Oral Buprenorphine Agents will be approved for a period of up to three (3) months.
2. Requests for prior authorization of naltrexone for extended-release injectable suspension (Vivitrol) will be approved for a period of up to three (3) months.

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