pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 4, 2017	January 4, 2017	*See below

SUBJECT

Prior Authorization of Opiate Dependence Treatments - Pharmacy Service

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 requests for prior authorization of prescriptions for Opiate Dependence Treatments for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department of Human Services (DHS) 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 DHS' Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-02	09-17-02	27-17-01	
02-17-01	11-17-01	30-17-02	
03-17-01	14-17-01	31-17-03	
08-17-02	24-17-01	32-17-01	33-17-02

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.pa.gov/provider/healthcaremedicalassistance/index.htm

DISCUSSION:

During the September 26, 2016 meeting, the DUR Board recommended that DHS make a few additions to the existing guidelines to determine medical necessity of Opiate Dependence Treatments. The additions include medical necessity guidelines for a new product, Probuphine (buprenorphine) and a guideline to confirm that the prescribing provider, or a delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for a controlled substance prescription history before prescribing an Opiate Dependence Treatment. 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 DHS. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Opiate Dependence Treatments are included in the attached updated provider handbook pages. The clinical review guidelines serve as a means to ensure quality of care and identity opportunities for care coordination.

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. DHS 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 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

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 a 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: http://www.dhs.pa.gov/provider/pharmacyservices/preferreddruglistinformation/

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://dhs.pa.gov/provider/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 a Buprenorphine Agent.

REMINDER: A prescription for a Narcotic Analgesic requires prior authorization when a recipient has a concurrent prescription for Vivitrol.

B. 5-Day Supply

A pharmacist may dispense a 5-day supply of the prescribed Opiate Dependence Treatment (except a buprenorphine implant (Probuphine)) without prior authorization if, in the professional judgment of the pharmacist, the recipient has an immediate need for the medication, unless the pharmacist determines that taking the medication either alone or along with other medications that the recipient may be taking, would jeopardize the health and safety of

the recipient. The maximum number of 5-day supplies of a prescription for an Oral Buprenorphine Agent (except a buprenorphine implant (Probuphine)) that can be dispensed without prior authorization is one (1) 5-day supply per recipient during a six (6) month period.

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

C. 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:

      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 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 buprenorphine implant (Probuphine), whether the recipient:

a. Has a diagnosis of opioid dependence

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 completion 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. 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. 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

e. Is being prescribed buprenorphine implant 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 must be certified by the Probuphine REMS program, and accepts as payment in full, the amounts paid by the Department plus any copayment required to be paid by a recipient

AND

f. Is not taking a Benzodiazepine

AND

g. Is stable on no more than 8mg per day of oral buprenorphine for at least the last 6 months

AND

h. 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, fentanyl, tramadol and carisoprodol) that is:

    i. Positive for Buprenorphine and Norbuprenorphine

    AND

    ii. Consistent with prescribed controlled substances

AND

i. Will not be receiving supplemental sublingual buprenorphine after implant insertion

AND

j. Will have the buprenorphine implant inserted by a healthcare provider certified by the Probuphine REMS program

3. 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

4. For naltrexone for extended-release injectable suspension (Vivitrol), whether the recipient:

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

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

AND

l. Is being prescribed naltrexone for extended-release injectable suspension (Vivitrol) by a prescriber who is enrolled in the MA Program and accepts as payment in full,

the amounts paid by the Department plus any copayment required to be paid by a recipient

AND

5. For all Opiate Dependence Treatments that require prior authorization, 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 recipient's controlled substance prescription history before prescribing the Opiate Dependence Treatment

OR

6. 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.

7. 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

8. 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

OR

9. 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, fentanyl, tramadol and carisoprodol) 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 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 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 BUPRENORPHINE IMPLANT (PROBUPHINE): The determination of medical necessity of requests for prior authorization of renewals of prescriptions for a buprenorphine implant (Probuphine) that were previously approved, will take into account whether the recipient:

1. Demonstrates compliance with the buprenorphine implant 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:

   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 recommended level of care 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 buprenorphine implant 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 must be certified by the Probuphine REMS program, 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. Is not receiving supplemental sublingual buprenorphine after implant insertion

AND

8. Is having the buprenorphine implant inserted by a healthcare provider certified by the Probuphine REMS program

AND

9. Is not having the implant inserted into a site which was previously used for insertion

OR

10. 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

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, fentanyl, tramadol and carisoprodol) 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

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

AND

9 Is being prescribed naltrexone for extended-release injectable suspension (Vivitrol) by a prescriber who is enrolled in the MA Program and accepts as payment in full, the amounts paid by the Department plus any copayment required to be paid by a recipient

FOR RENEWALS OF PRESCRIPTIONS FOR ALL OPIATE DEPENDNCE TREATMENTS THAT REQURE PRIOR AUTHORIZATION, 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 recipient's controlled substance prescription history before prescribing the Opiate Dependence Treatment

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 Opiate 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 recipient.

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.

E. 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 a buprenorphine implant (Probuphine) will be limited to 1 dose of 4 implants for a period of 6 months.
3. 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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