PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

(buprenorphine sublingual tablets)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 780-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated.*

FDA-APPROVED INDICATIONS

Buprenorphine sublingual tablets are indicated for the treatment of opioid dependence and are preferred for induction. Buprenorphine sublingual tablets should be used as part of a complete treatment plan to include counseling and psychosocial support.

Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being used as part of a complete program for the treatment of opioid dependence
  [Note: Complete treatment programs may include the following: A) Behavioral therapies (e.g., individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, motivational incentives), B) Medical history, physical exam, and screening laboratory tests as needed (e.g., HIV and hepatitis C screening), C) Diversion control protocols such as observed dosing, pill counts, testing for buprenorphine's metabolite (nor-buprenorphine), D) Random testing for heroin and other drugs of abuse, E) Use of the Prescription Drug Monitoring Program (PDMP) if available in state.]
  AND
  - The patient is pregnant or breastfeeding **AND**
  - The requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment
    OR
  - The requested drug is being prescribed for INDUCTION THERAPY for transition from opioid use to opioid dependence treatment

Quantity limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Buprenorphine sublingual tablets are indicated for the treatment of opioid dependence and is preferred for induction. Buprenorphine sublingual tablets should be used as part of a complete treatment plan to include counseling and psychosocial support. Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.[1-3]

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Ideal candidates for opioid addiction treatment with buprenorphine are individuals who have been objectively diagnosed with opioid addiction, are willing to follow safety precautions for treatment, can be expected to comply with treatment, have no contraindications to buprenorphine therapy, and who agree to buprenorphine treatment after a review of treatment options.[4] Physicians who use buprenorphine to treat opioid addiction must consider the entire process of treatment. The Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction - A Treatment Improvement Protocol guideline (TIP 40) indicates the importance of educating patients about substance use, associated problems, and prevention of relapse. The guidelines further recommend that progress be reassessed periodically.[5] In some situations, the short-term use of opioid analgesia for pain management may be appropriate (e.g., surgeries).

According to the American Society of Addiction Medicine (ASAM) National Practice Guidelines, patients on buprenorphine containing opioid agonist therapy should receive a comprehensive assessment including physical examination and screening for hepatitis and HIV prior to beginning medication treatment. Diversion control protocols should be used such as observed dosing, recall visits with pill counts, random drug testing for illicit drugs such as heroin, and testing for buprenorphine and its metabolite (nor-buprenorphine). Accessing Prescription Drug Monitoring Program (PDMP) data is advisable to check for other medications that the patient may be receiving.[7]

To improve outcomes, buprenorphine therapy is recommended to be combined with behavioral therapies. Research shows that when treating opioid dependence, a combination of medication and behavioral therapies is the most effective. Behavioral therapies help patients engage in the treatment process, modify their attitudes and behaviors related to drug and alcohol abuse, and increase healthy life skills. These treatments can also enhance the effectiveness of medications and help people stay in treatment longer. Treatment programs that combine pharmacological and behavioral therapy services increase the likelihood of cessation relative to programs without these services. There are a number of treatment strategies that can be used in combination with medications to successfully address opioid dependence. These include individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, and motivational incentives.[8]

There are three phases of treatment with buprenorphine for opioid addiction: Induction (usual duration is approximately one week or less), Stabilization (usual duration approximately one to two months), and Maintenance. Maintenance is the longest period that a patient is on buprenorphine. Maintenance can be relatively short-term (less than twelve months) or a lifetime process. Data suggest that a longer duration of medication treatment is associated with less illicit drug use and fewer complications.[5]

For non-pregnant patients, induction may be carried out using either buprenorphine/naloxone or buprenorphine depending on the prescribing physician's judgment.[4,5] When the buprenorphine monotherapy formulation is used for induction, it is recommended that it be used for no more than 2 days before switching to the buprenorphine/naloxone combination formulation. Buprenorphine/naloxone is the preferred medication for maintenance treatment due to the presence of naloxone in the formulation, which is intended to deter intravenous drug abuse by persons dependent on other opiates.[5]

According to the TIP 40 guidelines, multiple previous attempts at detoxification which were followed by relapse to opioid use are not a contraindication to maintenance with buprenorphine. Rather, such a history is a strong indication for maintenance treatment with pharmacotherapy.[5] In addition, the Centers for Substance Abuse Treatment (CSAT) TIP 43 guidelines recommend for patients who were unsuccessful at attempted medication tapering should be counseled that a return to medication maintenance is more appropriate for some patients and does not represent treatment failure.[6] For induction, the dosage of buprenorphine should be individualized based on the type and degree of opioid dependence and the timing of last use. For maintenance, the typical dosing range of buprenorphine is 4 to 24 mg once daily. Doses higher than this have not been demonstrated to provide any clinical advantage.[1-3] Buprenorphine sublingual tablets are available in 2 mg and 8 mg strengths, therefore non-pregnant patients undergoing induction will be approved for 21 tablets every 3 months to allow for a maximum of 24 mg per day at the highest available strength. Typical induction lasts 1 to 3 days and rarely over 7 days. This quantity and duration of approval will allow the patient to have 7 days of induction therapy every 3 months. If there is further need for induction, a buprenorphine combination product may be used. Setting a limit regarding the number of reauthorizations is beyond the scope of this program, and the decision to request reauthorization will be left at the discretion of prescribers.

Methadone is currently the standard of care in the United States for the treatment of opioid addiction in pregnant women. Pregnant women presenting for treatment of opioid addiction should be referred to specialized services in methadone maintenance treatment programs. If such specialized services are refused by a patient or are unavailable in the community, maintenance treatment with the buprenorphine monotherapy formulation may be considered as an alternative. Despite the fact that naloxone is classified by the FDA as a Pregnancy Category B drug (buprenorphine has been classified by the FDA as a Pregnancy Category C drug), it should be used with caution in pregnant women who are addicted to opioids. Because both mother and fetus will be dependent on the opioids used by the mother, administration of naloxone could precipitate withdrawal in both. Thus, if it is determined that buprenorphine is the only acceptable option for the treatment of a pregnant woman, and she understands the issues and risks, then she should be treated with buprenorphine monotherapy so as not to risk fetal exposure to naloxone.[5]

The American Society of Addiction Medicine (ASAM) Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use state that a buprenorphine-only product is one of the treatment options available for breastfeeding mothers receiving treatment for an opioid use disorder. Mothers receiving the buprenorphine monotherapy formulation for the treatment of opioid use disorders should be encouraged to breastfeed.[7] In a study of buprenorphine and breastfeeding, it was shown that the amount of buprenorphine metabolites secreted in breast milk are so low that they pose little risk to breastfeeding infants.[1-3] The American Academy of Pediatrics recommends exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant.[9] Buprenorphine sublingual tablets will be approved for a duration of 12 months when being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment for pregnant and breastfeeding patients.

Buprenorphine sublingual tablets are available in 2 mg and 8 mg strengths, therefore the post limit quantity will allow pregnant and breastfeeding patients 90 buprenorphine tablets per month when being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment to allow for a maximum of 24 mg per day at the highest available strength.

A 7-day emergency supply is permitted for members requiring an immediate start of therapy for treatment of opioid dependence while a prior authorization is being worked. The reject message displays "PA req call XXXXXXXXXX. For Emerg. Fill CALL 8009665772". When calling for an emergency fill, the Customer Care representative is instructed to ask if the buprenorphine is being used for treatment of opioid dependence. If so, the representative will enter a onetime 7-day supply override in the system to allow the patient to get the medication while a prior authorization is being worked. The representative will also explain that doctor must initiate the Prior Authorization process. Emergency supplies will be allowed with a PA reject once every 90 days in the event of a relapse.

REFERENCES

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CRITERIA FOR APPROVAL

1	Is the requested drug being used as part of a complete program for the treatment of opioid dependence? [Note: Complete treatment programs may include the following: A) Behavioral therapies (e.g., individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, motivational incentives), B) Medical history, physical exam, and screening laboratory tests as needed (e.g., HIV and hepatitis C screening), C) Diversion control protocols such as observed dosing, pill counts, testing for buprenorphine's metabolite (nor-buprenorphine), D) Random testing for heroin and other drugs of abuse, E) Use of the Prescription Drug Monitoring Program (PDMP) if available in state.]	Yes	No
2	Is the patient pregnant or breastfeeding? [If no, then skip to question 5.]	Yes	No
3	Is the requested drug being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment?	Yes	No
4	Does the patient require use of MORE than the plan allowance of 90 tablets per month? [No further questions.] [Tech Note: If yes, then deny and enter a partial approval for 90 tablets per month of buprenorphine.]	Yes	No
5	Is the requested drug being prescribed for INDUCTION THERAPY for transition from opioid use to opioid dependence treatment?	Yes	No
6	Does the patient require use of MORE than the plan allowance of 21 tablets? [Tech Note: If yes, then deny and enter a partial approval for 21 tablets per 75 days of buprenorphine.]	Yes	No

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Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	Your plan covers this drug when it is being used as part of a program for the treatment of opioid dependence. Your use of this drug does not meet the requirement. This is based on the information we have.
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	Your plan covers this drug when you meet all of these conditions: - You are pregnant or breastfeeding - You are using buprenorphine to start and/or keep up with addiction treatment Your use of this drug does not meet the requirements. This is based on the information we have.
4.	Deny	Approve, 12 months 90 tablets per 25 days* 270 tablets per 75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 90 tablets per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers. Your request for additional quantities of the requested drug and strength has been denied.
5.	Go to 6	Deny	Your plan covers this drug when you are using buprenorphine to start addiction treatment. Your use of this drug does not meet the requirement. This is based on the information we have.
6.	Deny	Approve, 3 months 21 tablets per 75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 21 tablets of the requested drug and strength. You have been approved for the maximum quantity that your plan covers. Your request for additional quantities of the requested drug and strength has been denied.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.