

Provider Educational/Informational Notice on Buprenorphine and Buprenorphine/Naloxone Treatment Authorization Requests

Buprenorphine or buprenorphine/naloxone sublingual formulations, when prescribed by qualified physicians for the treatment of individuals with opioid addiction, are a covered benefit under Medi-Cal fee-for-service (FFS) with an approved *Treatment Authorization Request* (TAR). This article provides instructions for providers on the information required when submitting TARs and background on treatment with buprenorphine, including information about the Drug Addiction Treatment Act of 2000 (DATA 2000).

Buprenorphine and buprenorphine/naloxone:

Medication class: Opioid receptor partial agonist/antagonist; antagonist

FDA-approved uses: Treatment of opioid dependence

Available dosage forms and strengths:

Sublingual tablets (buprenorphine/naloxone): 8 mg/2 mg, 2 mg/0.5 mg

Sublingual tablets (buprenorphine): 8 mg, 2 mg

Sublingual tablets (buprenorphine/naloxone; Orexo US, Inc.): 5.7 mg/1.4 mg*, 1.4 mg/0.36 mg*

Sublingual film (buprenorphine/naloxone): 12 mg/3 mg*, 8 mg/2 mg*, 4 mg/1 mg, 2 mg/0.5 mg

* Not bioequivalent to other formulations

Usual dose:

All doses refer to the amount of active buprenorphine ingredient. Combination buprenorphine/naloxone tablets and films follow the same recommendations except for the buprenorphine/naloxone; Orexo US, Inc. formulation.

Induction:

The recommended initial dose is 2 – 4 mg, which can be repeated in 2 hour intervals up to a maximum of 8 mg on the first day. The dose may be increased as indicated up to 16 mg on day 2, with adjustments on subsequent days by 2 – 4 mg based on clinical response.

Stabilization:

Usual dose is 16 mg – 24 mg daily.

Maintenance:

The target dose is 16 mg as a single daily dose. Usual range is 4 mg – 24 mg daily.

In order to account for the differences in bioavailability of the Orexo US, Inc. sublingual (SL) tablets and other buprenorphine/naloxone SL tablets, when switching between both, comparable doses are as follows:

Buprenorphine/naloxone, Orexo US, Inc. SL tablets	Other combination buprenorphine/naloxone SL tablets
1.4mg/0.36mg	2mg/0.5mg
5.7mg/1.4mg	8mg/2mg

BACKGROUND

The Drug Addiction Treatment Act of 2000 (DATA 2000), Title XXXV, Section 3502 of the Children's Health Act of 2000

DATA 2000 grants qualified physicians a waiver from the special registration requirements defined in the Controlled Substances Act to treat opioid dependence with schedules III-V opioid controlled substances in Office Based Treatment (OBT) settings rather than traditional Opioid Treatment Programs (OTP). The medications used in these settings have to be approved by the Food and Drug Administration (FDA) for use in addiction treatment. Buprenorphine and buprenorphine/naloxone sublingual oral formulations are approved by the FDA for this purpose.

In order to qualify for this waiver, physicians must meet specific requirements such as current state licensure, addiction certification or completion of a training program approved by the Substance Abuse and Mental Health Services Administration (SAMHSA). Once registered, the physician can initially treat up to 30 patients at any one time. After one year, a physician may treat up to 100 patients at any one time. In addition, physicians must attest that they have the capacity to refer addiction treatment patients for appropriate counseling and other non-pharmacologic therapies.

Effective July 25, 2005, physicians are required to include their DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) on prescriptions for opioid addiction treatment medications per Title 21 Code of Federal Regulations (CFR) 1306.05(a).

Buprenorphine Treatment

There are two general approaches to the medication-assisted treatment of opioid addiction: (1) opioid maintenance treatment, and (2) medically supervised withdrawal (detoxification).

Maintenance Treatment with Buprenorphine

Buprenorphine maintenance can be divided into three phrases: induction, stabilization, and maintenance.

Induction

The goal of the induction is to find the patient's ideal daily dose of buprenorphine. The ideal daily dose minimizes both side effects and drug craving. Induction usually takes approximately 1 week to complete. The initial induction doses are usually administered as observed treatment (for example, in the office). Patient may be given a prescription afterwards for additional doses.

Stabilization

Stabilization occurs in the 1 to 2 months following induction. This period begins when the patient is no longer experiencing withdrawal symptoms or intense cravings. The main goal of stabilization is to eliminate opioid use as verifiable by the absence of illicit opioids in toxicological samples. Dosage adjustments may be necessary during early stabilization, and frequent visits with the physician increase the likelihood of compliance. Once a stable dose is attained and toxicological samples are free of illicit drugs, physician visits become less frequent.

Maintenance

The longest period that a patient is on buprenorphine is the maintenance phase. This period can be relatively short-term (for example, less than 12 months) or indefinite. Long-term maintenance is recommended due to high relapse rates. During this phase, the patient is maintained at a comfortable dose and reports minimal craving or side effects. The psychosocial and family issues that have been identified during the course of treatment must be addressed.

Medically supervised withdrawal (detoxification)

Buprenorphine can be used for the medically supervised withdrawal of patients from both self-administered opioids and from opioid agonist treatment with methadone.

Medically supervised withdrawal with buprenorphine consists of two phases: an induction phase and a dose-reduction phase.

Medically supervised withdrawal is aimed at providing a smooth transition from a physically dependent to a physically nondependent state. Prior to the initiation of buprenorphine induction, patients should have stopped all use of illicit opioids and are showing the early symptoms of withdrawal.

The dose-reduction phase begins after a patient has completely stopped use of illicit opioids.

It is recommended that withdrawal treatment be followed by long-term drug-free or naltrexone (an opioid antagonist) treatment in order to minimize the chance of relapse to opioid abuse.

Instructions for Providers:

Providers are instructed to provide the following information when applying for TAR for buprenorphine or buprenorphine/naloxone sublingual formulations in order to expedite the process:

1. Documentation of the patient's age. The patient must be 16 years of age or older.
2. A diagnosis related to ICD-9-CM code 304.00 (opioid dependence) – for example, the treatment of opioid addiction treatment.
3. Evidence that the prescriber has met the qualifications for a waiver under the Drug Addiction Treatment Act of 2000 (DATA) and has an X-DEA number. This X-DEA number and prescriber's regular DEA number must be documented on the TAR form.
4. Provider to indicate the treatment phase (induction, stabilization or maintenance) and anticipated dosing plan. The quantity of medication requested and duration of treatment should be reflective of the treatment phase.
5. If treatment is at induction, stabilization or maintenance phases, provider can request percent (%) variance of quantity based on the phase of treatment for dosing flexibility.

The percentage of variation on authorized quantity allows the provider to dispense varied quantities without submitting a new TAR. For example, a TAR quantity of 60 tablets with an approved percent (%) variance of 50% will permit the dispensing of up to 50% above or below the authorized quantity. The provider can dispense up to 90 tablets (50% above 60 tablets) or as low as 30 tablets (50% below the 60 tablets) without requiring a new TAR.

6. Provider to document the proposed length of treatment (including maintenance plan) if known.
7. Provider to document plan for patient follow-up with the prescriber, that is, frequency of physician visits (weekly, bi-weekly, monthly, etc.) whenever possible.
8. TAR reauthorization request to include any revised plan for treatment and dosing.
9. Providers to note that combination with sedative-hypnotics (benzodiazepines, barbiturates, etc.) amphetamines, tramadol, carisoprodol, alcohol, naltrexone or opioids, may be basis for TAR delay, deferral or denial. Prescriber's justification must be provided for continued treatment with buprenorphine or buprenorphine/naloxone in this case.
10. Submission of TARs electronically using eTAR enables the Pharmacy Sections of the TAR field offices to quickly search for a TAR that has already been submitted. Submission of paper TARs take additional time for processing and adjudication.

SAMHSA's Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction are available here:

<http://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/TOC.pdf>