

Effective October 25th, 2010
Important Changes to Suboxone[®]/Subutex[®] (Buprenorphine) Program

September 22nd, 2010

Dear Colleague:

The Department of Vermont Health Access (DVHA) remains committed to providing medication-assisted opioid-dependence treatment in an office-based setting for appropriately selected beneficiaries. The Drug Utilization Review (DUR) Board of the DVHA made significant changes to the prior authorization requirements for Suboxone[®] and Subutex[®] that became effective in December 2007 with further changes in August 2008. After a thorough review of our claims data and prior authorization requests, and meeting with the Department of Corrections regarding reports of diversion and abuse (of both Subutex[®] and Suboxone[®]), the DUR Board voted May 18, 2010 to implement further changes to ensure access while limiting the risk of diversion.

Diagnosis: Suboxone[®] and Subutex[®] have received FDA approval only for the treatment of opioid addiction. Vermont Medicaid policy is consistent with these approved indications. DVHA will continue to grant prior authorization only for patients who have a diagnosis of opioid dependency. Prior authorization will not be granted for buprenorphine prescribed for pain control.

Who May Prescribe: The Drug Addiction Treatment Act of 2000 (DATA 2000) enables *qualifying physicians* to receive a *waiver* from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid addiction therapy. Physician assistants and nurse practitioners may not prescribe buprenorphine for opioid addiction treatment as these practitioners are not included in the definition of “*qualifying physicians*”. Prior authorization will only be granted to patients whose requesting prescriber has a DATA 2000 waiver ID number.

Subutex[®]: Due to reports of Subutex[®] (buprenorphine “mono” tablet) diversion and abuse by injection or intranasal use (to a greater extent than Suboxone[®]), prior authorization will only be granted for Subutex[®] for pregnant women and women breastfeeding methadone dependent babies. The buprenorphine prescriber must provide documentation from the OB provider or pediatrician/neonatologist with the prior authorization request. All other requests for Subutex[®] must be discussed on a case-by-case basis with the DVHA Medical Director.

Prior Authorization Submission: To process your prior authorization request in the most expeditious manner, all PA requests must be submitted via fax to ensure that requests are not delayed for incomplete information. DVHA requests additional information on the revised PA form (copy attached). All requests will be processed within 24 hours.

Dosing: Correct dosing contributes to the success of your patients’ treatment. Due to the “ceiling effect” of buprenorphine (see below), higher dosing offers little extra benefit and increases the potential for diversion, while low dosing may result in cravings and withdrawal symptoms causing the patient to drop out of treatment.¹ As the average buprenorphine dose prescribed to DVHA beneficiaries has increased, the following review is being provided.

¹ Medical Advisory & Best-Practices Update, Reckitt Benckiser Pharmaceuticals Inc. 11/06

Mechanism of Action

Buprenorphine binds tightly to the mu-opioid receptor and is not easily displaced by other opioid agonists and, therefore, it blocks the effects of subsequently administered opioids in a dose-dependent manner. There is considerable evidence that the generally effective daily Suboxone[®] dose is approximately 16 mg/day¹. At 16 mg/day, mu-opioid receptor availability is decreased by 85% to 92%. While the mean mu-opiate receptor binding potential values for 32 mg/day doses are higher than 16 mg/day, they do not significantly differ². This degree of blockade (at 16 mg/day) appears to minimize withdrawal symptoms, promotes attendance at counseling sessions, and prevents euphoria from other ingested opioids.

Maintenance Dosages

Following successful induction, a clinically effective maintenance dose should be established. The dosage should be progressively adjusted in increments/decrements of 2 mg or 4 mg to a level that maintains the patient in treatment and suppresses opioid withdrawal effects. While the target dose is 16 mg/day, expected doses can range from 4 mg – 16 mg/day and should be effective for at least 24 hours. The provider should assess other psychosocial and medical/psychiatric co-morbidity issues that may contribute to a patient's perception that the current dose is not adequate.¹

Dosing Instructions

The provider must educate their patients on the proper administration of buprenorphine (i.e., sublingual, not oral, administration).¹ Buprenorphine has low **oral** bioavailability relative to **sublingual** bioavailability. Sublingual buprenorphine takes at least 5 minutes and up to 12 minutes for a dose to adequately dissolve and completely absorb sublingually. Not allowing time for complete absorption may result in the perception that the dose is not sufficient. A patient instruction sheet with helpful tips to photocopy and to provide to your patients is included below.

The FDA has recently approved a new dosage formulation of Suboxone[®] (a sublingual film). The DUR Board will evaluate both the clinical and cost implications of this new dosage form in the coming months and determine the Medicaid policy for this product.

DHVA Dosing Limits

Patient buprenorphine needs are unique and a small number of patients may require up to 24 mg/day doses. The possibility for diversion of part or all of a dose must always be considered. **For either drug, caution should be used when prescribing doses higher than 16 mg per day.** Effective 10/25/2010, an absolute dose limit of 16 mg/day will be adopted for Subutex[®] and 24 mg/day for Suboxone[®]. Patient specific information is attached to this letter for all your patients who currently have claims exceeding these limits. Authorization for continuation of dosing at levels above these limits will require that additional clinical information justifying this need be provided. To prevent any disruption in medication therapy, please call DVHA at 879-5955 to discuss the patients prior to 10/15/2010.

Pharmacy Home: In order to assist patients in their recovery from opiate addiction, DVHA will be requiring all beneficiaries prescribed buprenorphine to identify a "pharmacy home" where **all** of their prescriptions will be filled. Please discuss this requirement with the patient and document their pharmacy choice on the PA form. Prescriptions may not be filled at other pharmacies and prior authorization requests for buprenorphine for patients without a pharmacy home will be returned as incomplete. In an urgent situation when a beneficiary cannot obtain a prescription at their chosen Pharmacy Home, DVHA may be contacted to arrange approval to obtain it at a different pharmacy.

Prescription Days Supply: In some circumstances, excess medication may tempt an individual to divert some of their medication to provide income or to share medication with others.¹ Beginning October 25, 2010, the maximum allowable days supply will be 14 days. This will limit quantities on hand in the community and also reduce medication waste from patients who do not tolerate or choose to discontinue therapy.

² Greenwald MK, Johanson CE, Moody DE, Woods JH, Kilbourn MR, Koeppe RA *et al* (2003). Effects of buprenorphine maintenance dose on mu-opioid receptor availability, plasma concentrations, and antagonist blockade in heroin-dependent volunteers. *Neuropsychopharmacology* **28**: 2000–2009.

Vermont Prescription Monitoring Program (VPMS): As a provider of opioid addiction treatment, DVHA strongly recommends that all prescribers register for and use the VPMS. The VPMS was established to provide prescribers with as much information as possible about their patients' prescription medication history. This is particularly important if you are not the primary care physician for a patient obtaining Schedule II – IV medications from other prescribers in addition to buprenorphine. Please query the VPMS to review the patient's scheduled II-IV medication history before requesting prior authorization for buprenorphine and at regular intervals after that time and if there is a change in patient status.

Registration and designation instructions and forms may be found at <http://healthvermont.gov/adap/VPMS.aspx#HealthCareProvider> or you may contact Meika Zilberberg MS, Program Coordinator, at (802) 652-4147.

Diversion and Non-Compliance: DVHA is committed to providing the correct medication in the correct dose for appropriately selected patients. Some behaviors that may suggest non-adherence with treatment include offers to pay “out of pocket” for the mono-product or repeated requests for increased dosing. For patients discharged from your practice due to non-adherence with your medication-assisted opioid-dependence program, please contact the Clinical Call Center at 1-800-918-7549 to inactivate the prior authorization requested by you on file for that patient.

Drug Interactions/Safety Concerns: Buprenorphine exhibits a “ceiling effect” with regard to respiratory depression, making a lethal overdose unlikely. This ceiling effect and its potential safety margin are eliminated when combining buprenorphine with alcohol or other sedative drugs, including benzodiazepines (particularly when administered intravenously). Although the combination of buprenorphine and benzodiazepines is not absolutely contraindicated, buprenorphine should be prescribed with caution to patients taking benzodiazepines or other sedative drugs including tramadol. Additionally, the administration of opiates to patients receiving buprenorphine is discouraged since their effect may be blocked by buprenorphine and either the buprenorphine or the opiate may be subject to diversion.

There have been reports of disastrous consequences when small children are exposed even briefly to buprenorphine as the “ceiling effect” does not appear to hold for this population. Please educate your patients about the need for safe storage of buprenorphine along with all other medications³.

Methadone vs Buprenorphine: Some patients may be better candidates for treatment with methadone in a clinic setting rather than with buprenorphine in an office based setting. The buprenorphine prior authorization form now includes a question asking if you would have referred your opioid dependent patient to a methadone clinic if this option was conveniently located and available. Please indicate your optimal choice each time you submit a buprenorphine prior authorization form.

Vermont Buprenorphine Practice Guidelines: Pharmacotherapy is only one aspect of opiate addiction treatment. The *Vermont Buprenorphine Practice Guidelines* provide Vermont practitioners with a consolidated set of recommendations and best practices for the management of opioid dependence in an office-based setting. Our full guidelines may be accessed at <http://dvha.vermont.gov/for-providers>.

If you have questions related to this change in benefit coverage, please feel free to contact our on-site MedMetrics' Clinical Account Manager, Diane Neal, R.Ph, at 1-802-879-5605. Thank you for your continued support of the State of Vermont's clinical pharmacy programs.

Sincerely,



Michael Farber, M.D.
Medical Director

³ Boyer EW, McCance-Katz E, Marcus, S., Methadone and Buprenorphine Toxicity in Children *The American Journal on Addictions*, 19: 89–95, 2009