

Effective January 3rd, 2011
Suboxone[®] Sublingual Film becomes Preferred Suboxone[®] Dosage Form

December 28th, 2010

Dear Colleague:

The Drug Utilization Board of the Department of Vermont Health Access (DVHA) voted at the December meeting to designate Suboxone[®] Sublingual Film as the preferred Suboxone[®] dosage form for our beneficiaries. The advantages of the film (compared to the sublingual tablet) include:

- Individually wrapped in compact unit-dose pouches (individually numbered) that are child-resistant and easy to carry
- Faster to dissolve and probably more complete absorption of dose
- Favorable taste rating
- Film cannot be crushed and snorted

While current users of the Suboxone[®] tablet will not be required to switch to the film at this time, all new users will be required to be prescribed the film. A new user will be defined as someone for whom DVHA has not received a paid Suboxone[®] tablet claim in the last 60 days.

DHVA Dosing Limits

- (1) An **absolute dose limit of 16 mg/day** will be adopted for Suboxone[®] Film for new users (see definition above). Patient's buprenorphine needs are unique and a small number of patients may require up to 24 mg/day doses which will require medical justification. Patients currently maintained on doses up to 24 mg/day of Suboxone[®] SL tablet who transition to the film will be permitted to transition on their established dose after PA for the new dosage form is obtained. The manufacturer cautions that because of the potential for greater relative bioavailability of Suboxone[®] Film compared to Suboxone[®] Tablet, patients switching from Suboxone[®] Tablet to Suboxone[®] Film should be monitored for overmedication.
- (2) **Once daily dosing.** Suboxone[®] Film should not be split or cut and is designed to be dosed once per 24 hours. For doses < 8 mg per day or between 8 and 16 mg, a combination of 8 and 2 mg films may be utilized.

Required steps to successfully fill a Suboxone[®] Film prescription:

1. **Prior Authorization Submission:** A new prior authorization request specific for the film must be submitted via fax (copy attached). All requests will be processed within 24 hours. At the time of the approval of the Film PA, any other prior authorizations on file for either Suboxone[®] SL tablets or Subutex[®] will be inactivated and prescriptions for these will no longer process. Please plan your PA submission requests accordingly.
2. **New prescription required:** Suboxone[®] Film and Suboxone[®] Tablet are not legally interchangeable by your pharmacist and therefore a new prescription specific for the film is required.

Patients Reporting Intolerance or Lack of Efficacy with Suboxone[®] Film:

We feel it is important to have information related to treatment failures and adverse events collected and reported to the FDA, particularly on new product releases. Therefore, the DVHA will require you to complete a MedWatch form (copy attached) outlining the therapy failure which we will submit to the FDA.

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