

**NOTE: Important Pharmacy Program Change**  
**Methadone moves to PA Required Effective July 8, 2014**  
**Current Users Grandfathered Until 1/1/2015**  
**Initiation Doses Limited to 30 mg/Day**

June 9<sup>th</sup>, 2014

Dear Prescriber:

The Drug Utilization Review (DUR) Board last year examined methadone utilization in pharmacy claims for beneficiaries of the public programs of the Department of Vermont Health Access (DVHA) and considered the literature and clinical guidelines that addressed the use of methadone for pain. After careful consideration, the Board voted to move methadone from a preferred to prior authorization (PA) required position on the Preferred Drug List (PDL) due to safety concerns which were felt to outweigh methadone's advantage of low cost.

The Vermont Board of Medical Practice adopted an updated Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain in April 2014. While the policy does not prefer one opioid over another," the Medical Board recognizes that principles of high-quality medical practice dictate that the people of the State of Vermont have access to appropriate, safe and effective pain management." To meet these objectives, DVHA is implementing the methadone PDL changes endorsed by the DUR Board.

A 2012 American Society of Interventional Pain Physicians (ASIPP) guideline proposed a more specific recommendation regarding the choice of opioid for chronic pain. They recommend a trial of hydrocodone, oxycodone, hydromorphone, or morphine as first-line therapy of severe pain, with fentanyl as a second-line therapy option. According to the ASIPP guidelines, the use of methadone should be limited to third-line therapy for severe pain after failure of other opioid agents.<sup>1</sup>

The use of methadone for the management of chronic pain has increased in recent years and is associated with a significant rise in methadone-associated deaths in the United States. Methadone is responsible for a disproportionately greater number of fatal overdose cases per prescription dispensed compared to other opioids. It is also more likely to be diverted and abused than either hydrocodone or oxycodone.<sup>2-3</sup> Its pharmacokinetic and pharmacodynamic profiles make it very difficult to dose and titrate. While the half-life of methadone ranges from 8 to 59 hours, its duration of analgesic action is only 4 to 8 hours. Therefore, patients may lose the benefit of pain relief sooner than the other methadone effects, such as its respiratory depressant activity, and if they take additional doses too soon may risk drug accumulation and subsequent toxicity. Furthermore, there is a high inter-patient variability in absorption, metabolism, and relative analgesic potency.<sup>2, 4-6</sup>

The risk of overdose is especially pronounced during the titration phase while the body's steady state has not yet been reached. Therefore, methadone should be started at low doses and titrated slowly by clinicians familiar with its use and risks. Even in opioid-tolerant patients, initiating methadone therapy at a safe but therapeutic dose may be complicated as equianalgesic dose ratios for methadone relative to other opioids vary from person to person. Of note, tolerance for other opioids is not equivalent to tolerance to methadone, so reliance solely on equianalgesic conversion tables may be deceptive.<sup>2, 4-6</sup> **Therefore, DVHA is limiting the starting dose of methadone to 30 mg/day even in patients on high doses of other opioids. This edit will apply to any patient without a methadone claim in the previous 45 days.** In addition, cases of

QT interval prolongation and serious arrhythmia (torsades de pointes) have been observed during treatment with methadone, particularly in patients on high doses. Prescribers may wish to have a universal Cardiac Risk Management Plan for all methadone patients, incorporating electrocardiogram (EKG) monitoring and avoidance of drug interactions.

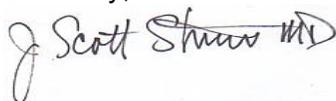
Per our current pharmacy claims activity, you have issued a methadone prescription for at least one DVHA patient in the last 120 days. These patients will be grandfathered until 1/1/2015 at which time a PA for continued use will be required. PAs for long acting narcotics are issued for an initial approval of 3 months with subsequent approvals up to 6 months as the evidence for the effectiveness of long-term opioid therapy in providing pain relief and improving functional outcomes is limited. Patients new to methadone therapy will be required to have had a step-through trial of oral morphine sulfate CR 12hr tablets and the initiation dose may not exceed 30 mg/day.

As a reminder, methadone products, when used for the treatment of opioid addiction in opioid detoxification or maintenance treatment can only be provided in a federally certified opioid (addiction) treatment program (OTP) as stipulated by the Code of Federal Regulations, Title 42, Sec 8.

If you have questions related to this change in benefit coverage, please feel free to contact our on-site Catamaran Clinical Consultant, 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,



J. Scott Strenio, M.D.  
Medical Director

## References

1. Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2. *Pain Physician*. 2012; 15:S67-S116.
2. Center for Substance Abuse Treatment. Emerging issues in the use of methadone. HHS Publication No. (SMA) 09-4368. *Substance Abuse Treatment Advisory*; 2009; 8(1).
3. United States Government Accountability Office (GAO): Methadone-associated overdose deaths-factors contributing to increased deaths and efforts to prevent them. FAO-09-341. Washington, DC: GAO, 2009.
4. Bajwa ZH, Smith HS. Overview of the treatment of chronic pain. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate; 2013 [cited 2013 Jan]. Available from: <http://www.utdol.com/utd/index.do>.
5. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain* 2009; 10:113.
6. Dolophine® [package insert]. Columbus (OH): Roxane Laboratories, Inc.; 2012 Jul.