

Informed Consent & Sublocade: Resources for Opioid Agonist Therapy Providers

With the availability of Sublocade for the treatment of Opioid Use Disorder in Manitoba, Opioid Agonist Therapy (OAT) providers are faced with new considerations while incorporating this treatment option into practice. One of these considerations is informed consent to treatment with Sublocade, especially in women of reproductive age.

BACKGROUND

Sublocade (buprenorphine extended-release injection) is a partial opioid agonist for the management of moderate to severe opioid use disorder that must be administered by subcutaneous injection in the abdominal region by a trained healthcare professional. For effective treatment, Sublocade is administered once per month.

It is important to note that thus far in clinical trials Sublocade has only been evaluated for clinical effectiveness in the treatment of Opioid Use Disorder against placebo. The effectiveness of Sublocade has yet to be compared to sublingual buprenorphine/naloxone. In short, we do not have results from a true non-inferiority study available yet. Thus, the intent of this article is **not** to promote Sublocade use over daily sublingual buprenorphine/naloxone treatment.

However, Sublocade it is an option to consider for patients who do not have practical pharmacy access, or for whom daily or even weekly pharmacy visits are not practical or acceptable for some reason. The monthly administration of Sublocade can offer these patients more flexibility with treatment, even when clinical stability does not warrant take-home dosing of sublingual buprenorphine/naloxone.

OPASKWAYAK HEALTH AUTHORITY OAT PROGRAM

The OHA OAT Program is a northern remote program serving individuals with Opioid Use Disorder from Opaskwayak Cree Nation, The Pas, Moose Lake, Easterville, Grand Rapids and surrounding areas. Many of them do not have pharmacy access in their home communities, making daily witnessed ingestion of methadone or buprenorphine/naloxone especially challenging.

WANT MORE INFO ABOUT SUBLOCADE?

More information on Sublocade use and administration is available for prescribers and pharmacists here:

<https://cpsm.mb.ca/assets/PrescribingPracticesProgram/Sublocade-Administration-Joint-Document%20Final.pdf>

Please note that physicians must hold a current, active buprenorphine/naloxone prescribing approval from CPSM to prescribe Sublocade. Approved physicians wanting to prescribe and administer Sublocade must complete the non-accredited certification program, which can be found at www.sublocadecertification.ca.

This is a Health Canada requirement.

The availability of Sublocade has thus created treatment access for patients who previously did not have practical access to OAT. The OHA OAT program's clinical experience with Sublocade has highlighted key aspects of patient care and consent that require careful navigation.

SPECIAL CONSIDERATIONS IN PATIENT CONSENT

When starting any OAT medication, prescribers must counsel patients about the benefits and risks of treatment to obtain informed consent. Starting Sublocade is no different. Unique considerations with Sublocade include discussion about pregnancy and reliable contraception. **Presently, it is *not known if Sublocade is safe in pregnancy***. Prescribers must therefore ensure that female patients of reproductive age are counselled to use a reliable form of birth control (such as an IUD or Depo Provera) prior to receiving a Sublocade injection, and for the duration of treatment with Sublocade. Two forms of less reliable birth control (such as an oral contraceptive pill combined with a barrier method) may be an alternative. Due diligence is also needed to ensure patients understand the potential implications of not using reliable birth control. While we are not aware of any teratogenicity with Sublocade use in pregnant women to date, it is not yet known if Sublocade is safe in pregnancy.

If a female patient, who understands this information, indicates that she does not require birth control for some reason, or indicates that she finds the use of birth control unacceptable, OAT providers are to use good clinical judgement. The potential benefits of treatment with Sublocade (including treatment access and retention) must be weighed against the risks of an unplanned pregnancy while on Sublocade. This conversation should be carefully documented in the patient record.

Regardless of the patient's choice around the use of reliable birth control, if the provider and patient agree to proceed with Sublocade treatment, the use of a written consent form (example linked below) is strongly recommended to facilitate further documentation of the patient's informed consent to treatment with Sublocade.

Another important aspect of informed consent is ensuring that patients understand the implications of missing their monthly Sublocade injection. If patients are more than two weeks late for a scheduled administration, this will likely necessitate restarting on daily witnessed buprenorphine/naloxone at a pharmacy, for a period, before transitioning to Sublocade again. Additionally, this may require in-person assessment and can delay restarting buprenorphine/naloxone, considering prescriber and patient availability, as well as travel and transportation issues. Missed monthly administration can have substantial negative impacts on patients' lives and responsibilities, and carries a risk of relapse.

INFORMED CONSENT TEMPLATES

The OHA OAT Program has developed consent forms to manage these special considerations in clinic and offered to share their forms as a resource for other programs. These templates can be accessed at the links below and modified for specific program needs. Please contact tcarter@cpsm.mb.ca if you require forms in a more modifiable format.

The forms are available along with published chapters of the [Manitoba Buprenorphine/Naloxone Recommended Practice Manual](#) under the Prescribing Practices Program:

- Consent Form to Participate in Treatment with Sublocade [General Version](#)
- Consent Form to Participate in Treatment with Sublocade [Reproductive Age Version](#)

Respectfully, please retain the footnote acknowledgment that this work is the intellectual property of the OHA OAT program staff when adapting them for your clinical use.

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