1000 – 1661 Portage Avenue, Winnipeg Manitoba R3J 3Y7

Tel: (204) 774-4344 Fax: (204) 774-0750

Website: www.cpsm.mb.ca

The College of Physicians & Surgeons of Manitoba

Buprenorphine/naloxone Recommended Practice Manual

Recommendations Regarding Unwitnessed Induction with Buprenorphine/naloxone

Introduction

An unwitnessed induction, otherwise known as a 'home induction' with buprenorphine/naloxone is an approach that does not require the patient to take the first dose(s) of buprenorphine/naloxone under the direct supervision of a pharmacist, approved prescriber or nurse. This approach is particularly useful in engaging patients in care who are unable to appear for a traditional witnessed induction schedule at a pharmacy, or with an approved prescriber due to a variety of patient characteristics or systemic barriers.

A limited number of studies that compare unobserved versus observed induction protocols have not shown differing rates of adverse or serious adverse events. These events include precipitated or protracted opioid withdrawal, pediatric exposure or diversion-related emergency department visits. However, it is important to note that there are no high quality randomized controlled trials to date with adequate power to model the equivalence or noninferiority of the two approaches with respect to infrequent safety events.

Providers need to weigh the benefits and risks of witnessed versus unwitnessed induction in each case based on individual circumstances. Only experienced prescribers who are competent and comfortable with witnessed buprenorphine/naloxone inductions should consider or utilize an unwitnessed induction approach.

General Recommendations:

Individuals for whom you may consider an unwitnessed induction onto buprenorphine/ naloxone:

- Patients who have difficulty tolerating moderate withdrawal in the clinic/waiting room environment. (Evidence of withdrawal is required to begin a witnessed induction in clinic).
- Patients who have difficulty timing moderate withdrawal with the time of an assigned induction appointment in a clinic.
- Patients with significant social instability that makes attending a scheduled clinic appointment for induction challenging (examples may include no access to reliable transport or a lack of financial resources for transport, chaotic life style, lack of social supports etc.)
- Work, school or child/family care commitments that make attending a clinic appointment difficult or impossible.
- Patients who do not have reasonable access to a pharmacy for witnessed induction due to geography (distance to pharmacy and/or clinic), especially when dosing multiple times per day during the induction phase.

Patients who may be particularly good candidates for home inductions include:

- Patients who have previously completed a successful witnessed induction with buprenorphine/naloxone.
- Patients who have previously demonstrated responsible use of prescribed medications, including previous opioid agonist therapy.
- Patients who can adequately understand the risks of unwitnessed inductions, including but not limited to precipitated withdrawal.
- No regular or heavy use of alcohol, benzodiazepines or other sedatives (including OTC medications).
- No polypharmacy, especially multiple prescribed, sedating medications.
- Patients who express willingness to come in to the office or attend an emergency department if problems arise during the induction process.
- Patients with stable housing.
- Patients with stable and supportive friends or family (as defined by the patient) who may assist in supporting and monitoring the home induction process.

- Individuals who present to the emergency department or other episodic care facilities with serious complications of opioid use disorder such as overdose, infectious complications or a mental health crisis. These patients may not be in enough withdrawal to facilitate a buprenorphine/naloxone induction in the emergency department. Discharging these individuals with a limited medication supply and home induction instructions may be an effective way to engage this high-risk population in care, if infrastructure for follow-up care exists. Earliest possible follow-up at RAAM or an alternative clinic, ideally within 24-48 hours after discharge from the emergency department, is recommended. Patients being offered a witnessed or unwitnessed induction in the emergency department must be provided with written information on where they can reasonably access follow-up care as part of the induction plan.

Some patients are more likely to experience adverse effects during unwitnessed induction. In general, it is not recommended for the following patient populations:

Relative contraindications

- Patients who are being switched from methadone to buprenorphine/naloxone. This is a much more difficult induction process. Protracted opioid withdrawal persisting over several days after buprenorphine/naloxone induction is much more likely in patients being switched from methadone.
- Patients who express significant fear of opioid withdrawal. These patients may be more likely to start buprenorphine/naloxone too early and cause precipitated withdrawal.
- Patients who have experienced precipitated withdrawal in the past and who express reluctance to risk such an outcome again.

Absolute contraindications

- Patients with concurrent, heavy, alcohol or sedative use or misuse.
- Prescribed, sedating polypharmacy.
- Acute, significant medical illness such as pneumonia, sepsis or recovery from physical injury requiring opioids for analgesia.
- Patients with active, significant mental health concerns in the absence of a reliable support person at home who can assist in monitoring the home induction process.
- Patients with acute psychosis.
- Patients with active suicidal ideation or recent suicide attempts.
- Severe respiratory disease requiring careful monitoring during induction.
- Elderly, frail individuals, especially if they have multiple medical comorbidities.

- Significant cognitive impairment in the absence of a reliable support person at home who can assist in monitoring the home induction process.
- No safe place to stay during the induction
- No safe medication storage where the patient is staying.

Specific Recommendations Regarding Home Inductions:

Patient Education and Support

- A robust patient education strategy is necessary when preparing for home inductions. A well-documented conversation as well as written material that is reviewed with the patient and their support person (if so desired by the patient) should be used to support this process.
- Patients should be provided with written instructions regarding:
    - The subjective and objective assessment of opioid withdrawal,
    - The timing and dosing of buprenorphine and
    - The phone numbers or other established processes for patient assistance in the event of questions from the patient (or support person) or adverse events. This should include contact information for the prescriber (and/or experienced clinic staff person) and the pharmacy involved.
    - Simply advising the patient to "go to the nearest emergency department" is not an adequate support strategy. If a patient does not have access to a phone, or clinic hours do not permit in-person assessment after hours, attending an emergency department may be used as an additional strategy to support patients during the unwitnessed induction process. It is important that the prescriber or representative of a group of prescribers is available to be contacted by the pharmacy or emergency room staff to discuss issues that may arise during the induction process.
- Patients must receive clear instructions on safe storage of buprenorphine (ideally in locked box or cabinet) as well as what to do with any unused medication (e.g. return to pharmacy for disposal at next pharmacy visit).

Witnessed dosing requirements

- **In most cases, buprenorphine/naloxone doses should be witnessed at the pharmacy starting on day 2.** Should an evening top-up dose be required on day 2, this dose may be given as a take-home dose.

- Under exceptional circumstances (e. g. geographic isolation from pharmacy, with phone support and reassessment from prescriber or experienced clinic staff) patients may be given more than a one-day supply of medication for home induction. The rationale for this approach must be clearly documented.

Reassessment

- The patient should be reassessed by the prescriber or experienced clinic staff, in person, no later than day 3 after initiating buprenorphine/naloxone at home. If this is not possible for any reason, a phone assessment must be completed with in-person follow-up as soon as possible after that.
- All interactions with clinic staff (by phone or in person) during the home induction should be documented in the patient's medical record.

Pharmacy communication

- Clear communication with the pharmacy is essential to facilitate a smooth unwitnessed induction process. Even if a patient is provided with a medication starter pack from clinic stock, the pharmacy that the patient attends for further treatment should be aware of the plan since the patient may seeks support from the pharmacy at any time during the induction process.
- In addition to the M3P prescription, the pharmacy should be provided with the following

  information (see appendix B for suggested template):

  - A copy of the unwitnessed induction protocol/schedule provided to the patient
  - The induction start date
  - When the patient is expected to attend the pharmacy for witnessed dosing
  - Clinic information
  - After-hours prescriber contact information

Supporting Documents

- An example of an unwitnessed induction protocol for individuals with moderate to high dose opioid use is included as Appendix C. For patients with lower dose opioid use or other risk factors for oversedation or toxicity, lower induction doses will need to be used (see the section on dosing during the induction phase). This induction protocol, or a similar customized protocol, should be provided to the patient along with a copy of the SOWS (Subjective Opiate Withdrawal Scale) or COWS (Clinical Opiate Withdrawal Scale)

score sheet. SOWS is a useful tool for a support person to utilize when assisting the patient in managing a home induction.

- The patient may also be provided with an unwitnessed induction wallet card. This is especially important when a patient is given an unwitnessed induction medication starter pack from the emergency department or clinic stock. **Buprenorphine/naloxone provided from clinic stock or the emergency department is not entered into the DPIN system.** The wallet card thus serves as a notification to EMS/ER staff that the patient was prescribed an unwitnessed induction protocol. See Appendix D for a template of what such a wallet card may look like.

Appendix B

Date

Name of Clinic and Address (IF NOT ON CLINIC LETTERHEAD)

Pharmacy Name
Address

RE: UNWITNESSED INDUCTION NOTIFICATION

Dear (Pharmacist Name)

This letter is regarding patient _____NAME_____ DOB: _____

I have assessed _____PATIENT NAME_____ and they are a candidate for a buprenorphine/ naloxone unwitnessed induction.

I have provided instructions to the patient regarding their unwitnessed induction. A copy of the induction protocol is included.

Note the following:

☐ Patient has been provided with a starter pack of buprenorphine/naloxone from clinic stock to start home induction and will present to pharmacy on (DATE) to commence witnessed dosing. An M3P prescription is included.

OR

☐ An M3P prescription is included and the patient will present to pharmacy on (DATE) to obtain the unwitnessed induction medication supply. The Patient will present to pharmacy for witnessed dosing on _____DATE_____.

Please notify my clinic at _____Phone Number_____ of any missed doses, in case the induction schedule needs to be adjusted.

After hours I can be reached at _____Phone Number_____ or call _____Phone Number_____ to speak to our on-call prescriber.

Sincerely

Physician Name

Starting buprenorphine/naloxone (Suboxone®) at home

Before starting buprenorphine/naloxone (Suboxone®) at home, you need to wait until you feel very sick from withdrawal ("dope sick").

Your prescriber will tell you how long you should wait after using opioids before following these steps.

Use the SOWS withdrawal scale on the next page before you start the medication. **When your SOWS score is 17 or higher, you are ready to begin.**

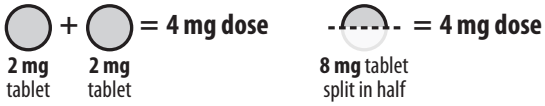
Prescriber Name: _____

Prescriber Phone: _____

Next Appointment: _____

Pharmacy Name: _____

Pharmacy Phone: _____



DAY 1 — 8-12 mg of buprenorphine

4 mg

STEP 1: Take your first 4 mg dose when your SOWS score is 17 or higher.

- Keep the medication under your tongue until it has dissolved completely (15 minutes).
- Do NOT eat, drink or swallow while it's dissolving, or it will not work.
- If you feel a lot worse, STOP and contact your provider or pharmacy. This can happen if you start the medication before your withdrawal symptoms are bad enough.

Wait 1 hour

4 mg

STEP 2 (after 1 hour): If you still feel sick, take a second 4 mg dose.

- Many people feel better after two doses (8 mg total).

Wait 6 hours

4 mg

STEP 3 (after 6 hours): If you still feel sick, take a third 4 mg dose.

- STOP after this dose. Don't take more than 12 mg total on Day 1.

DAY 2 — 12-16 mg of buprenorphine

12 mg

STEP 1: Take your Day 2 morning dose (usually 12 mg).

- Your morning dose will usually be taken at your pharmacy. You'll also receive a dose to take home for later.

Wait 6 hours

4 mg

STEP 2 (after 6 hours): If you still feel sick, take an additional 4 mg dose.

- Don't take more than 16 mg total on Day 2.

DAY 3 — 16 mg of buprenorphine

16 mg

STEP 1: Take your Day 3 morning dose (usually 16 mg).

- This dose will usually be taken at your pharmacy.
- Repeat this dose each day until you see your provider in clinic (usually by Day 3).

This induction protocol is provided as an example only. Prescribers should adjust dosages to reflect factors such as low opioid tolerance.

Appendix D

Sample Wallet Induction Notification Card

FRONT

UNWITNESSED INDUCTION NOTIFICATION CARD
(buprenorphine/naloxone)

I, _____(NAME_____
____DOB_____ am undergoing an unwitnessed (home) induction with buprenorphine/naloxone.

Pharmacy Name _____

Pharmacy Address _____

Pharmacy Phone No _____

Start date _____

BACK

PRESCRIBER/HOSPITAL INFORMATION
(Could be copy of business card)

Starter pack provided? Yes No ☐

By who? ____ (Prescriber/Hospital Name) _____

_____

Address _____

Phone No. _____

After Hours Contact No._____