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MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

2.4 Recommendations for Unwitnessed Induction with Buprenorphine/naloxone

GENERAL CONSIDERATIONS

An unwitnessed induction of buprenorphine/ naloxone, otherwise known as a home induction, is an approach that does not require the patient to take the first dose(s) of buprenorphine under the direct supervision of a pharmacist, approved prescriber, or nurse.

This approach is particularly useful to engage patients in care who are unable to appear for a Conventional Buprenorphine Induction schedule at a pharmacy, or with an approved prescriber, due to a variety of patient characteristics or systemic barriers. The logistics involved with planning a conventional induction may be challenging for both patients and providers. Presenting for induction in moderate withdrawal requires careful planning, as well as some flexibility in the patient and prescriber's availability for assessment and dose titration. This may lead to overall lower utilization of buprenorphine/naloxone despite the superior safety profile.

It is important to note that *unwitnessed induction is not suggested here as an equally evidence-based* alternative to the Conventional Induction described in this manual. 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 to date there are no high-quality randomized controlled trials with adequate power to model the equivalence or noninferiority of the two approaches with respect to infrequent safety events.

Providers must 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, for select patients who face barriers to repeat in-office assessment of withdrawal and witnessed dosing. Some patients may also meet criteria for micro-dosing, as described in Recommendations for Buprenorphine Micro-Dosing Induction.

SPECIFIC CONSIDERATIONS

It is the responsibility of the prescriber to educate a patient being considered for unwitnessed induction about the risks of this approach, including but not limited to precipitated withdrawal.

The prescriber must ensure that the patient can adequately understand these risks and that they know where to seek help if concerns arise. This includes providing afterhours contact number(s) for support.

See the Conventional Buprenorphine Induction chapter for guidance on *Management of Precipitated Withdrawal*, and The Pharmacology of Buprenorphine, Precipitated Withdrawal & Management of Adverse Effects for further details.

Patients Appropriate for Unwitnessed Induction

Unwitnessed induction may be considered in the following patients:

- Patients who have difficulty tolerating moderate withdrawal in the clinic/waiting room environment. (A conventional witnessed induction in the clinic setting requires a patient to be in moderate opioid withdrawal before initiating buprenorphine/naloxone, to avoid precipitated withdrawal. This can take 8-24 hours for short-acting and slow-release opioids, and 48-72 hours for long-acting opioids such as methadone.)
- Patients who have difficulty timing moderate withdrawal with the time of an assigned induction appointment in a clinic.
- Patients with significant psychosocial instability that makes attending a scheduled clinic appointment for induction challenging (examples may include no access to reliable transport, a lack of financial resources for transport, significant mobility limitations, chaotic lifestyle, 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 geographic limitations (distance to pharmacy and/or clinic), especially when dosing multiple times per day during the induction phase.

Good Candidates for Unwitnessed Induction

Patients who may be particularly good candidates for unwitnessed induction 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 (OAT) medications.
- 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 sedative-hypnotics (including over-the-counter medications).
- No polypharmacy, especially multiple prescribed, sedating medications.
- Patients who express willingness to come into 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 (OUD) such as overdose, infectious complications or a mental health crisis.
    - These patients may not be in enough withdrawal for 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 timely care, as long as infrastructure for follow-up OAT care exists. The earliest possible follow-up at a local Rapid Access to Addiction Medicine (RAAM) clinic or an alternative clinic is recommended, ideally within 24-48 hours after discharge from the emergency department.
    - Patients being offered a witnessed or unwitnessed buprenorphine/naloxone 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. (See In Hospital Care, specifically the section EMERGENCY DEPARTMENT/URGENT CARE OF INDIVIDUALS WITH OUD for detailed recommendations).

Contraindications for Unwitnessed Induction

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 include:

- 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 transitioned 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 include:

- Patients with concurrent, heavy, problematic use of alcohol or sedative-hypnotics.
- Prescribed polypharmacy of other sedative/psychoactive medications. (See Managing Polypharmacy, Benzodiazepines, Alcohol, & Polysubstance Use for details.)
- Acute significant medical illness such as pneumonia, sepsis, or recovery from physical injury requiring opioids for analgesia.
- Patients with significant active 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 ability to safely store medication where the patient is staying.

Patient Education & Support

A robust patient education strategy is necessary when preparing for home inductions. A well-documented conversation and written material, reviewed with the patient and their support person (if permitted 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 (see ***Supporting Documents*** below),
- The timing and dosing of buprenorphine/naloxone, and
- The phone numbers or other established processes for patient assistance in the event of patient or support-person questions, concerns, or adverse events. This should include contact information for the prescriber (and/or experienced clinic staff) 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 prescriber group be available for contact 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 & Reassessment

Generally, with conventional induction, buprenorphine/naloxone dose should be dispensed as witnessed doses.

Daily witnessed doses are self-administered under the direct supervision of a pharmacist, approved prescriber, or a nurse, until the patient has demonstrated sufficient clinical stability to be considered for take-home (carry) doses.

Comparatively, the following is recommended unwitnessed inductions:

- In most cases, buprenorphine/naloxone doses should be witnessed at the pharmacy starting **no later than 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 the 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 and communicated to the pharmacy.
- 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 thereafter.

All interactions with clinic staff (by phone or in person) during the home induction should be documented in the patient's medical record.

Criteria for the provision of take-home doses are discussed elsewhere in this manual. See Take-home (Carry) Dosing Recommendations and Managing Polypharmacy, Benzodiazepines, Alcohol, & Polysubstance Use in OAT for take-home guidance, and Ongoing Care for a detailed review of other issues often encountered during the maintenance phase of treatment.

Pharmacy Communication

Clear communication with the pharmacy is essential to facilitate a smooth home induction process. Even if the patient is provided with a medication starter pack from clinic or hospital stock, the community pharmacy that the patient attends for continued treatment must be contacted and made aware of the plan, as the patient may seek support from the pharmacy at any time during the unwitnessed induction process.

If possible, the induction doses should be dispensed by the pharmacy, and not given as a starter pack from clinic or hospital stock, to ensure that the medication is entered into the patient's medication record (DPIN).

In addition to the M3P prescription, the community pharmacy must also be provided with the following information (see **Appendix Q** for suggested template):

- A copy of the unwitnessed induction protocol/instructions provided to the patient (see **Appendix R** for an example).
- The induction start date.
- When the patient is expected to attend the pharmacy to commence witnessed dosing.
- Clinic contact information.
- After-hours prescriber contact information.

Supporting Documents

An example of an unwitnessed induction protocol for patients with moderate- to high-dose opioid use is included as **Appendix R**. These induction instructions, or a similar customized protocol, should be provided to the patient and the pharmacy.

This induction protocol, or a similar customized protocol, should be provided to the patient along with a copy of the Subjective Opiate Withdrawal Scale (SOWS) or the Clinical Opiate Withdrawal Scale (COWS) score sheet. SOWS is a useful tool for a support person to utilize when assisting the patient in managing a home induction.

For patients with low-dose opioid use, or other risk factors for over-sedation or toxicity, lower overall induction doses will need to be used. See the Conventional Buprenorphine Induction chapter for further induction and titration dosing guidance, and the Ongoing Care chapter for recommendations around overall dosing stability.

The patient must also be provided with an **unwitnessed induction wallet card**. This is especially important when a patient is given an unwitnessed induction starter pack from hospital or clinic stock and the medication has not been entered into the DPIN system. The wallet card serves as a notification to EMS/ER staff that the patient was prescribed an unwitnessed induction protocol. See **Appendix S** for an unwitnessed induction wallet card template.

Appendix Q

PHARMACY UNWITNESSED INDUCTION NOTIFICATION

Date:	
Pharmacy:	
Phone:	
Fax:	

Dear Pharmacist,

RE:		
DOB:		
PHIN:		
Clinic Phone:	Fax:	

I have assessed the above-named patient and they are a candidate for unwitnessed induction of buprenorphine/naloxone. I have provided instructions to the patient regarding their unwitnessed induction. A copy of the induction protocol is included. **Please note the following**:

☐ The patient has been provided with a **starter pack of buprenorphine/naloxone from clinic/hospital stock** to start home induction. They 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 (home) induction medication supply.

The patient will present to pharmacy again on _____ (DATE) to commence witnessed dosing.

Please notify my clinic at _____ (PHONE NUMBER) of any missed doses, in case the induction schedule needs to be adjusted. I have advised my patient as follows regarding missed doses at home: _____.

After hours I can be reached at _____ (PHONE NUMBER) or call _____ to speak to our on-call prescriber.

Sincerely,

_____

Prescriber Name, signature, & credentials

Appendix R

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.**

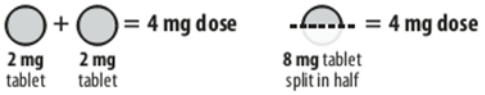
Prescriber Name: _____

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 an example only. Prescribers should adjust dosages to reflect factors such as low opioid tolerance.

Appendix S

SAMPLE WALLET UNWITNESSED INDUCTION NOTIFICATION CARD

FRONT

UNWITNESSED INDUCTION NOTIFICATION CARD
For buprenorphine/naloxone (Suboxone®)

I, _____ (NAME)
and _____ (DOB) am undergoing an unwitnessed (home) induction with Suboxone®

Pharmacy Name: _____

Pharmacy Address: _____

Pharmacy Phone: _____

Start date: _____

BACK

PRESCRIBER/HOSPITAL INFORMATION
(**could be copy of business card**)

Suboxone® starter pack provided?

☐ **Yes** ☐ **No**

Provided by: _____

(Prescriber/Hospital Name)

Address: _____

Phone: _____

After Hours Ph: _____