1000 – 1661 Portage Avenue
Winnipeg, MB R3J 3T7
Tel: (204) 774-4344 Fax: (204) 774-0750
Toll Free (MB only) 1-877-774-4344
www.cpsm.mb.ca

MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

2.3 Recommendations for Buprenorphine Take-home (Carry) Dosing in Opioid Agonist Therapy

GENERAL CONSIDERATIONS

Take-home dosing can help make opioid agonist therapy (OAT) more acceptable to patients by reducing the burden of treatment. It can reduce the time commitment and cost associated with daily pharmacy attendance, enhance patient autonomy, and integrate OAT with other social, employment, and recreational life goals. This, in turn, can have a positive impact on treatment retention and reinforcement of abstinence.

These benefits must be weighed against the patient and public health risks associated with take-home dosing. Diversion of buprenorphine certainly poses a risk to public health. However, buprenorphine/naloxone has a superior safety profile when compared to methadone, slow-release oral morphine (SROM), and other commonly prescribed opioids, and deaths due to buprenorphine/naloxone are very rare. Therefore, the risks associated with take-home dosing of buprenorphine may be considered limited. In contrast, if a patient discontinues OAT due to excessively restrictive take-home dose policies, they will be subject to an increased risk of fatal overdose and the ongoing impacts of untreated opioid use disorder (OUD).

It is the responsibility of the OAT prescriber to determine a patient's eligibility for take-home dosing and to continually reassess the patient's stability/take-home dosing status. Prescribers should consult with treatment team members and other providers involved in the patient's care, including the pharmacy team, to ensure that all relevant safety information is taken into consideration.

It is recommended that patients and providers complete a Take-home (Carry) Dosing Agreement (see **Appendix P**) prior to authorizing carries. A copy of this agreement should be incorporated into with the medical record and a copy should be provided to the patient.

SPECIFIC CONSIDERATIONS

In general, buprenorphine/naloxone doses should be dispensed as daily 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 doses.

INDUCTION: THE FIRST 3 DAYS OF TREATMENT

In most cases, with Conventional Buprenorphine Induction, **the first buprenorphine/naloxone dose given during induction should be witnessed**. **Ideally, all additional doses given during the first 3 days of treatment should also be witnessed.** Conversely, see Recommendations for Unwitnessed Induction with Buprenorphine/naloxone for further guidance on home inductions.

When repeated reassessment after the initial day 1 dose(s) is not feasible due to travel barriers or clinic/pharmacy hours, and continued withdrawal is anticipated, prescribers may consider providing take-home doses during induction.

Specifically, take-home doses of buprenorphine/naloxone may be prescribed in combination with witnessed doses to facilitate induction, **provided that the patient can safely store the medication** in a locked box or a locked cabinet at home. The patient also needs to be provided with detailed instructions and phone number(s) to access support if needed, prior to returning to the clinic or pharmacy for further assessment and witnessed dosing the following day.

For example, the prescriber may prescribe one or two 2 mg tablets (maximum of 4 mg) for the patient to take home to complete the induction, up to a maximum day 1 dose of 12 mg. The patient should be counselled regarding recognition of withdrawal and the appropriate timing of take-home doses (e.g., “2 (two) mg SL q 2h PRN for withdrawal symptoms”). The prescription must have clear instructions as to which doses are to be witnessed, and which doses are to be released as take-home doses.

As above, the **criteria for home inductions** (wherein the first and possibly additional doses of buprenorphine/naloxone are given as take-home doses) are discussed in Recommendations for Unwitnessed Induction. Take-home doses for induction are not recommended unless home induction criteria are met and there are no alternative witnessed dosing options available to engage the patient in care.

TAKE-HOME DOSING AFTER THE FIRST 3 DAYS OF TREATMENT

Recommendations for take-home dosing are discussed under the following categories:

1) Routine recommendations for take-home dosing.

2) Recommendations for take-home dosing for patients who achieve significant, early clinical stability.

3) Recommendations for patients who present with compelling reasons for early take-home doses, who do not achieve significant early stability.

4) Recommendations for patients who should NOT receive take-home dosing.

5) Recommendations for occasional take-home doses in patients who do not otherwise meet criteria for take-home dosing.

1) Routine recommendations for take-home dosing.

All patients treated with buprenorphine/naloxone should receive **daily witnessed dosing for the first two weeks of treatment**. Take-home doses are permitted for pharmacy or clinic closures.

After the first two weeks of treatment, patients may receive **a gradually increasing number of take-home doses** if they meet the following criteria:

- They are on a stable dose of buprenorphine/naloxone.
- Missed doses are an infrequent occurrence (< 2 per month) or are specifically related to access barriers (e.g., transportation, work, or finances) that would be remedied by authorizing take-home doses.
- No evidence of ongoing use of illicit opioids, alcohol, benzodiazepines/Z-drugs, stimulants (e.g., cocaine or methamphetamines), and/or illicit sedating/psychoactive prescription or over-the-counter medications, as evidenced by regular clinical assessment and urine drug testing (UDT) results, collected at the minimum frequency recommended in this manual. (See Recommendations for UDT for further guidance, specifically RECOMMENDATIONS FOR FREQUENCY OF UDT).
- The patient's physical health, mental health, and social situation are sufficiently stable to support the safe consumption and storage of take-home doses in a locked box or a locked cabinet at home.
- The patient is generally compliant with the treatment agreement, including the minimum recommended UDT and pill counting requirements of treatment as outlined in this manual.

After an **initial two weeks of daily witnessed dosing**, patients who continuously meet the above criteria may receive **one weekly take-home dose for every two weeks of demonstrated stability**. After twelve weeks, a clinically stable patient will thereby attend the pharmacy for witnessed dosing once weekly (i.e., a maximum of six take-home doses).

If a patient with six regular take-home doses demonstrates a **further three months of clinical stability**, they may transition to witnessed dosing once every two weeks (i.e., a maximum of 13 take-home doses).

After **one year of documented clinical stability**, a patient may transition to witnessed dosing once per month, receiving the rest of the month's medication supply as take-home doses (i.e., a maximum of 29 take-home doses).

If a period of instability occurs, the prescriber should determine if the frequency of take-home doses needs to be reduced while treatment is intensified. If treatment intensification results in improved stability, the prescriber, in consultation with other members of the treatment team, may elect to reinstate take-home dosing more rapidly than outlined above.

2) Recommendations for take-home dosing for patients who achieve significant, early stability.

In some cases (see more detailed criteria below), sufficient clinical stability could be evident shortly after buprenorphine/naloxone induction (as early as 1-3 days), according to the prescriber's best judgement.

After the first 1-3 days of treatment, early take-home dosing (i.e., take-home dosing for up to 6 days per week) may be considered in patients who meet the following criteria:

- The patient's OUD is not complicated by other significant substance use issues (alcohol, benzodiazepines/Z-drugs, stimulants such as cocaine or methamphetamines, and/or illicit sedating/psychoactive prescription or over-the-counter medications).
- The patient has no major unstable physical or mental health conditions.
- The patient can store take-home doses safely in a locked box or locked cabinet at home.
- The patient rapidly achieves satisfactory physical and emotional stability during the induction phase, including a stable dose of buprenorphine/naloxone that eliminates significant opioid withdrawal and the need for illicit opioid use.

Once a patient with 6 weekly take-home doses demonstrates a **further 3 months of clinical stability**, providers may follow the same recommendations for take home doses as outlined above under *[1)] Routine recommendations for take-home dosing.*

LOCKED BOXES & NIHB

For patients whose medications are covered by Non-Insured Health Benefits (NIHB), the cost of a lockbox may be covered once per patient, per lifetime (up to $35), for the safe storage of take-home doses of OAT. If indicated, this coverage extends to safe storage of other high-risk medications, including other opioids, benzodiazepines, stimulants, or sedating/psychoactive drugs, where a lockbox can improve safety for NIHB clients and communities.

3) Recommendations for patients who present with compelling reasons for early take-home doses, who do not achieve significant early stability.

Patients who do not meet the above criteria for early clinical stability and take-home dosing may nonetheless present with other compelling reasons to consider early take-home dosing. These reasons may include:

- Meaningful work opportunities that make daily attendance at a clinic or pharmacy for witnessed ingestion impossible or impractical. Such work opportunities should be verified by clinic staff, as is possible and reasonable.
- Childcare or other family responsibilities that make daily witnessed ingestion impossible or impractical.
- Physical disability that makes daily witnessed ingestion impossible or impractical.
- Advanced pregnancy or significant medical complications associated with pregnancy that make daily witnessed ingestion impossible or impractical.
- The patient lives in a remote community with no reasonable access to daily witnessed ingestion at a clinic or pharmacy.
- The patient is unable to start treatment due to an immediate lack of funding or coverage for daily witnessed ingestion and the associated travel.

In such cases, early take-home doses for up to 6 days per week may be considered at the discretion of the OAT prescriber, provided the patient can store take-home doses safely in a locked box or a locked cabinet at home.

4) Recommendations for patients who should NOT receive take-home dosing.

Take-home doses *should not* be given under the following circumstances:

- The patient is unable to store take-home doses safely (e.g., unstable housing, no fixed address, recurrent history of lost or stolen medication, etc.)
- Evidence of diversion.
- Significant, unstable substance use issues (especially other opioids, alcohol, stimulants, benzodiazepines/Z-drugs, and other sedating medications, including over-the-counters).
- Significant prescribed polypharmacy involving sedating/psychoactive medications where there is notable risk of accidental or intentional overdose. In these cases, polypharmacy needs to be carefully addressed prior to considering take-home dosing. See Managing Polypharmacy, Benzodiazepines, Alcohol & Polysubstance Use for discussion of these issues, specifically AN APPROACH TO POLYPHARMACY IN THE CONTEXT OF OAT.

- Significant, unstable physical or mental health conditions that may impact the patient's ability to manage take-home doses safely and responsibly.
- Significant cognitive impairment.
- The patient is not attending the minimum acceptable number of clinic appointments required by the treatment team to provide care safely. These expectations need to be explicitly discussed and documented in the treatment agreement and/or patient chart.
- Abusive, intimidating, or harassing behavior directed toward staff, including pharmacy staff, or other patients in the clinic and pharmacy. Behavior expectations need to be explicitly discussed and documented in the treatment agreement and/or patient chart.
- The patient's preference is to attend the pharmacy daily or more frequently for witnessed ingestion.

Pharmacy closures over weekends and statutory holidays may require occasional take-home doses regardless of the above-mentioned contraindications. However, the prescriber may elect to withhold take-home doses altogether if the risks to the patient and/or public outweigh the potential benefits, and there is no other pharmacy available to access on these days.

5) Recommendations for occasional take-home doses in patients who do not otherwise meet criteria for take-home dosing.

Occasional take-home doses may be appropriate under certain circumstances for patients who do not otherwise meet criteria for take-home doses. Examples may include:

- Travel for verified medical appointments.
- Significant family events such as weddings and funerals.
- Significant family illness or other responsibilities requiring travel.
- Other non-specified circumstances deemed reasonable by the OAT provider.

Before authorizing take-home doses for travel purposes, clinicians should consider whether guest dosing at a pharmacy near the patient's travel destination may more appropriate.

Authorization of Take-home Doses & Communication with Pharmacy

Additions, changes, and exceptions to the take-home dosing schedule must be clearly documented in the medical record, and clearly communicated with the pharmacy.

The schedule of take-home doses can be communicated to the pharmacy by either writing the instructions for witnessed and take-home doses directly on the prescription, or by sending it to the pharmacy as a separate note or letter (see Relationship with Pharmacy for an example).

The latter is especially useful when the current prescription is still valid and the treatment team wishes to authorize changes to take-home doses, such as a new permanent carry or one-time carries for travel or another reason.

Take-home doses must be authorized by the prescriber or a member of the clinical team. The pharmacist cannot authorize take-home doses, and the prescriber/clinic staff should clearly explain this to the patient to avoid misunderstanding. Pharmacists can often provide valuable input on the appropriateness of take-home doses. Discussion is encouraged, especially when the prescriber/clinic staff are questioning the safety of providing carries in certain situations.

MONITORING FOR CLINICAL INSTABILITY & DIVERSION OF PRESCRIBED MEDICATION

It is the responsibility of the OAT prescriber and the treatment team to monitor clinical stability on an ongoing basis. All members of the treatment team must be vigilant when it comes to detecting diversion of prescribed medication. This is especially relevant when it comes to decisions regarding take-home dosing. See Discontinuing Treatment for guidance on managing potential diversion and considerations for involuntary withdrawal of treatment.

UDT & Medication Monitoring

In practice, monitoring for stability and diversion involves periodic UDT and/or pill counts for patients with take-home doses. If feasible, random UDT and/or random pill counts are an effective method for detecting diversion and illicit substance use. Due to the inherent logistical challenges associated with *random* testing and pill counts, it is recognized that most clinicians perform *periodic* testing and pill counts at scheduled patient visits.

Prescribers may consider asking the pharmacist to bubble pack take home doses to improve compliance and facilitate monitoring (pill counts). Bubble packed medications are not child proof and therefore may not be a safe option in some patient settings. Patients must secure bubble packs in a locked box or cabinet.

It should be noted that at this time the only reliable method of detecting buprenorphine in urine is by using point-of-care UDT kits that include a buprenorphine detection strip. The current street urine drug screen does not detect buprenorphine and the comprehensive urine drug screen only detects buprenorphine at supratherapeutic levels (as well as two metabolites).

See the Use of UDT in the Management of OUD chapter for a general approach to drug testing, including the recommended frequency and important issues to consider when interpreting results. Determination of clinical stability is never based on UDT results alone. Clinicians should rely on patient history, collateral information, and direct observation/clinical examination, which is augmented by UDT results, to formulate treatment plans in partnership with the patient. The chapters on Ongoing Care and Managing Polypharmacy, Benzodiazepines, Alcohol & Polysubstance Use also provide further guidance on assessing clinical stability.

Appendix P

TAKE-HOME (CARRY) DOSING AGREEMENT

I, _____, agree to the following conditions to receive take-home (or "carry") doses of my medication.

☐ I am aware that the ingestion of even a small amount of my medication by a child or other person who is not accustomed to opioids could result in overdose or death.

☐ I will store my medication in a safe, locked box, or locked cabinet that cannot be accessed by other people or by pets.

☐ I will not sell or share my medication with another person. I understand that doing so is dangerous and may lead to loss of access to take-home doses or removal from the program.

☐ I will assume responsibility for my take-home doses, and I understand that take-home doses cannot be replaced if they are lost, stolen, spilled, or vomited.

☐ I will provide a urine sample when asked to do so by program staff. If I do not provide a sample as requested, or non-prescribed drugs are found in my sample, I may lose access to one or more take-home doses.

☐ I will bring my medication to my clinic or pharmacy if asked to do so. If I do not, I may lose access to one or more take-home doses including return to daily witnessed ingestion.

Patient Name: _____ Date: _____

Signature: _____

Witness Name: _____ Date: _____

Signature: _____