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The College of Physicians & Surgeons of Manitoba

Buprenorphine/naloxone Recommended Practice Manual

Take-home (Carry) Dosing Recommendations

GENERAL CONSIDERATIONS

Take-home dosing can contribute to making opioid agonist therapy (OAT) with buprenorphine/naloxone more acceptable to patients by reducing the burden of treatment, reducing the time commitment and cost associated with daily pharmacy attendance, enhancing patient autonomy and allowing integration of OAT within 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/naloxone certainly poses a risk to public health. However, buprenorphine/naloxone has a superior safety profile when compared to methadone, slow-release oral morphine and other commonly prescribed opioids, and deaths due to buprenorphine/naloxone are very rare. Therefore, the risks associated with take-home dosing of buprenorphine/naloxone 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.

It is the responsibility of the buprenorphine/naloxone prescriber to determine an individual's eligibility for take-home dosing and to continually reassess an individual's take-home dosing status. Prescribers should consult with treatment team members and other providers involved in the individual's care as needed to ensure that all relevant safety information is taken into consideration.

It is recommended that patients and providers complete a Take-home Dosing Agreement (see Appendix A for an example) prior to authorizing take-home dosing. A copy of this agreement should be kept on file and a copy should be provided to the patient.

SPECIFIC CONSIDERATIONS

In general, buprenorphine/naloxone doses should be dispensed daily under the supervision of a health care professional until the patient has demonstrated sufficient clinical stability and is able to store take-home doses safely.

Induction: The first 3 days of treatment

In most cases, **the first buprenorphine/naloxone dose given during induction should be witnessed** (further guidance on home inductions to follow). **Ideally, all additional doses given during the first 3 days of treatment should be witnessed.**

If travel considerations or clinic and/or pharmacy hours makes multiple same-day visits impossible or impractical, consideration may be given to providing take-home buprenorphine/naloxone doses during induction. Specifically, take-home doses may be prescribed in combination with witnessed doses to facilitate induction, provided that the patient can safely store the medication in a lock box or a locked cabinet at home. The patient also needs to be provided with detailed instructions and phone number(s) regarding how they may access support if needed.

For example, the patient who is given an initial 4mgs/1mg of buprenorphine/naloxone witnessed in clinic or at the pharmacy may be given an additional dose of buprenorphine/naloxone to take at home in the event of recurrent withdrawal symptoms, prior to returning to the clinic or pharmacy for further assessment and witnessed dosing the following morning.

Please note that criteria for home inductions (wherein the first and possibly additional doses of buprenorphine/naloxone are given as take-home doses) are discussed separately in this manual. Home inductions 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

We will discuss recommendations for take-home dosing under five separate headings:

a) *Routine recommendations for take-home dosing.*
b) *Recommendations for take-home dosing for patients who achieve significant, early clinical stability.*
c) *Recommendations for patients who present with compelling reasons for early take-home doses, who do not achieve significant early stability.*
d) *Recommendations for patients who should NOT receive take-home dosing.*
e) *Recommendations for occasional take home doses in patients who do not otherwise meet criteria for take home dosing.*

a) 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:

1) They are on a stable dose of buprenorphine/naloxone.
2) 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 take-home doses.
3) No evidence of ongoing use of other illicit opioids, alcohol, benzodiazepines or stimulants (such as cocaine or methamphetamines) as evidenced by regular clinical assessments and urine drug test results, collected at the minimum frequency recommended in this manual.
4) 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 lock box or a locked cabinet at home.
5) The patient is generally compliant with the minimum recommended urine drug testing 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 thirteen 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 thirty 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.

b) 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), in the best judgement of the prescriber.

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:

1) The patient's opioid use disorder is not complicated by other significant substance use issues (alcohol, benzodiazepines and stimulants such as cocaine and methamphetamines).
2) The patient has no major unstable physical or mental health conditions.
3) The patient can store take-home doses safely in a lock box or a locked cabinet at home.
4) 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 *a) Routine recommendations for take-home dosing.*

c) 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:

1) 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 far as it is possible and reasonable to do so.
2) Child care or other family responsibilities that makes daily witnessed ingestion impossible or impractical.
3) Physical disability that makes daily witnessed ingestion impossible or impractical.
4) Advanced pregnancy or significant medical complications associated with pregnancy that make daily witnessed ingestion impossible or impractical.
5) The patient lives in a remote community with no reasonable access to daily witnessed ingestion at a clinic or pharmacy.
6) 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 treating clinician, provided the patient can store take-home doses safely in a lock box or a locked cabinet at home.

d) Recommendations for patients who should NOT receive take home dosing

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

1) The patient is unable to store take-home doses safely (homelessness, recurrent history of lost or stolen medication, etc.)
2) Evidence of diversion.
3) Significant, unstable substance use issues (especially involving other opioids, alcohol, stimulants, benzodiazepines and other sedating medications, including over-the-counter).
4) Significant prescribed, sedating polypharmacy 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.
5) Significant, unstable physical or mental health conditions that may impact the patient's ability to manage take-home doses safely and responsibly.
6) Significant cognitive impairment.
7) 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 or patient chart.
8) Abusive, intimidating or harassing behavior directed toward staff or other patients. Behavior expectations need to be explicitly discussed and documented in the treatment agreement or patient chart.
9) It is the patient's preference to attend the pharmacy daily for witnessed ingestion.

Pharmacy closures over weekends and statutory holidays may require occasional take-home doses regardless of the above-mentioned contraindications to take-home dosing. However, the prescriber may elect to withhold take-home doses altogether if the risks to the patient and/or public outweigh the potential benefits.

e) *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 of such circumstances may include:

1) Travel for verified medical appointments.

2) Significant family events such as weddings and funerals.
3) Significant family illness or other responsibilities requiring travel.
4) Other non-specified circumstances deemed reasonable by the treating clinician.

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.

MONITORING FOR CLINICAL INSTABILITY AND DIVERSION OF PRESCRIBED MEDICATION

It is the responsibility of the treating clinician and the treatment team to monitor clinical stability on an ongoing basis. All members of the treatment team need to be vigilant when it comes to detecting diversion of prescribed medication(s). This is especially relevant when it comes to decisions regarding take-home dosing. In practice, monitoring for stability and diversion involves periodic urine drug testing and/or pill counts for patients with take-home doses.

If feasible, random urine drug testing 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 contacts.

Prescribers may consider asking the pharmacist to bubble pack the 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 boxed 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 urine drug testing 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.

Further guidance regarding specific monitoring recommendations will be published in upcoming newsletters and the final guidance document.

Appendix A

TAKE-HOME 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 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 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.

☐ I am aware that I need to always bring my medication to my medical appointments for assessment by clinic staff. If I do not, I may lose access to one or more take-home doses including return to daily witnessed ingestion.

☐ I understand that I must be able to meet the above requirements to receive carry doses. If my situation changes and I can no longer meet these requirements, I may lose access to take-home doses.

Patient Name: _____ Signature: _____

Date: _____

Witness Name: _____ Signature: _____

Date: _____