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MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

3.3 Recommendations for Methadone 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.

As patients build clinical stability, the benefits of methadone take-home doses must be weighed against the associated patient and public health risks. Diversion of methadone poses significant risk of serious harms, including death, to the public. Methadone diversion also contributes to patient instability and often implies ongoing involvement with illicit drugs and related activities. As such, the recommendations for methadone are comparatively more conservative than those for Buprenorphine/naloxone Take-Home Dosing, reflective of buprenorphine's superior safety profile and fewer associated public health risks.

However, if a patient discontinues methadone due to excessively restrictive take-home dose policies, they will be subject to the ongoing harms of untreated opioid use disorder (OUD). Providers must use a balanced approach to managing these risks and benefits, and ensure that patients receive regular education regarding risks as care plans are negotiated and adjusted over time. It is recommended that patients and providers complete a Take-home Dosing (Carry) Agreement (see **Appendix BB**) prior to authorizing carries. This agreement should be incorporated into the medical record and a copy should be provided to the patient.

It is the responsibility of the OAT prescriber to determine a patient's eligibility for take-home dosing and to continually reassess their stability and carry status. Prescribers should consult with 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.

SPECIFIC CONSIDERATIONS

In general, methadone 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 & EARLY STABILIZATION

Daily Witnessed Ingestion

Generally, take-home doses (carries) should not be granted during the first two months of treatment. An exception may be granted for Sunday carries due to pharmacy closures, if the provider determines the benefits of uninterrupted daily dosing outweigh the risks of providing the carry. This may be particularly useful for rural or remote patients with limited pharmacy options and/or where patients must travel longer distances to access a pharmacy or nursing station.

Some OAT programs give weekend carries in similar contexts **when there is no weekend pharmacy access** and the patient demonstrates sufficient early stability, reliable behaviour, and can store the medication safely. However, when patients are deemed unstable and the risks of earlier carry doses are significant, patients may have to forgo one or two doses weekly if no pharmacy access is available on Saturdays and/or Sundays. The prescriber must document their risk assessment and rationale for such decisions.

LATER STABILIZATION & ONGOING CARE

The following criteria should be assessed prior to initiating take-home dosing of methadone and/or adjusting the number of take-home doses permitted:

1) Clinical Stability
2) The Length of Time on Methadone Treatment
3) Ability to Safely Store Methadone

STRONG RECOMMENDATION: INFORM PATIENTS OF THE RISKS TO THE OPIOID NAÏVE

Before initiating carries, OAT prescribers should advise patients of the potential danger to the opioid naïve, particularly children, of consuming methadone and the need to store the carries in a locked box or locked cabinet. Some patients may prefer or need to keep doses cold. Methadone doses stored in the fridge without being locked up is not acceptable. If patients prefer or need to keep methadone doses cold, an icepack can be added to the lockbox, and/or the lockbox stored in the fridge.

1) Clinical Stability

Patients are clinically stable when they demonstrate the social, cognitive, and emotional stability necessary to use methadone as prescribed, and assume responsibility for the care and safeguarding of methadone doses.

Clinical stability has been established when the following is demonstrated:

- The patient is on a stable dose of methadone.
- 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 count/methadone carry bottle count requirements of treatment as outlined in this manual.

2) The Length of Time on Methadone Treatment

As above, carries are not recommended during the first two months of treatment (except for Sundays, as applicable and appropriate). After two months of treatment, if a stable dose of methadone and clinical stability (as above) are established, a patient can receive **one additional take-home dose per month, each month, to a maximum of six carries per week** (i.e., one witnessed dose in the pharmacy, six take-home doses). As per TABLE 1, a clinically stable patient may attend the pharmacy for witnessed dosing once weekly within 6-7 months of starting treatment. Please see exceptions to this schedule further in this chapter.

Patients who have occasional non-problematic drug use while on methadone may be appropriate to receive carries, if the prescriber determines that they are clinically stable and able to store their medication safely. However, the number and progression of carries on their schedule would be reduced. Prescribers should clearly explain these expectations to patients and document these discussions in the medical record. Overall life stability and responsible attitudes are just as important to consider as UDT results.

TABLE 1: METHADONE TAKE-HOME DOSE SCHEDULE FOR CLINICALLY STABLE PATIENTS

TAKE-HOME DOSE CRITERIA	NUMBER OF CARRIES
Meets clinical stability criteria & on methadone for at least **2 months**	**1** (plus Sunday*)
Meets clinical stability criteria & on methadone for the past **3 months**	**2** (plus Sunday*)
Meets clinical stability criteria & on methadone for the past **4 months**	**3** (plus Sunday*)
Meets clinical stability criteria & on methadone for the past **5 months**	**4** (plus Sunday*)
Meets clinical stability criteria & on methadone for the past **6 months**	**5** (plus Sunday*)

*As applicable to the patient circumstances.

Again, the decision to give take-home doses must take into consideration both patient safety and public safety. If a period of instability recurs the prescriber must reassess the number and progression of carries (see *Reassessment & Reduction of Take-home Doses* and *Managing Relapse* below).

Some providers may choose to adopt a slower and more cautious rate of awarding carries. However, this should be balanced with managing the burden of treatment for patients, for treatment retention and re-engagement with meaningful life activities.

3) Ability to Safely Store Methadone

The patient must be instructed to store methadone take-home doses in a locked box and or locked cabinet. A pharmacist is required to observe and document evidence of a locked box or cabinet prior to releasing methadone take-home doses for the first time. A photograph of the patient with same would be sufficient proof in most circumstances. Additionally, evidence of this can be shown to the prescriber when carries are initiated. It is *not recommended* to ask patients to regularly carry locked boxes in and out of the clinic/pharmacy, as they may be targeted for theft.

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.

The use of a locked box should be specified in the treatment agreement. The safe storage of medications should be assessed periodically by the OAT provider and pharmacist. Patients with unstable living arrangements, where medications cannot be safely stored, are not candidates for take-home doses, as below.

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, residing in shelters without locked storage, recurrent history of lost or stolen medication, or living with individuals with unstable mental health or substance use disorders).
- 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 or other patients. Behavior expectations need to be explicitly discussed and documented in the treatment agreement and/or patient chart. This expectation also extends to the pharmacy and pharmacy staff.
- 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.

Occasional Take-home Doses for Exceptional Circumstances

Occasional take-home doses may be appropriate under certain circumstances for patients who do not otherwise meet criteria for regular carries. 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**. It may, for instance, be appropriate to provide one carry for the day of travel, arrange for guest dosing during the stay away from home, and then request the guest dosing pharmacy provide a travel carry to the patient for the return trip home.

When prescribers provide a new prescription for guest dosing temporarily at a different pharmacy, it must be remembered that *any new prescription cancels the old prescription* (see Relationship with Pharmacy & Prescriptions chapter). Accordingly, **the old prescription at the previous/regular pharmacy must be canceled**. It is important for the OAT prescriber/clinic team to coordinate with the regular pharmacy that the patient will attend upon return from travel, to inform them of the arrangements and to provide a new prescription for when the patient returns. This could mean proactively sending another prescription to the previous/regular pharmacy to be initiated upon return from travel, and/or requiring the patient to contact the prescriber/clinic team after returning from travel to arrange a new prescription.

Extended Take-home Doses for Work or Travel

Patients who are eligible and have earned five to six methadone carries per week (thereby attending the pharmacy once or twice weekly), may be temporarily granted an increased number of carries for reasons such as travel and employment. Patients may be asked to provide the clinic with verification of their travel plans (e.g., plane ticket, letter from work).

Again, clinicians should consider whether guest dosing at a pharmacy near the patient's travel destination may be more appropriate. A ***maximum of two to four weeks*** of take-home dosing is recommended, if deemed appropriate in clinically stable patients. See the Continuity of Care chapter for further guidance regarding longer-term travel and guest dosing.

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 the Relationship with Pharmacy chapter appendix 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 other reasons.

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 or carry bottle counts for patients with take-home doses. Patients may be asked to routinely return labelled empty methadone bottles to the pharmacy, or they may be periodically asked to show unused carry bottles to the prescriber.

If feasible, random UDT and/or random pill/bottle counts are an effective method for detecting diversion and illicit substance use. Due to the inherent logistical challenges associated with *random* testing and counts, it is recognized that most clinicians perform *periodic* testing and pill/bottle counts at scheduled patient visits.

Prescribers may consider asking the pharmacist to bubble pack the patient's other medications 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 be able to secure bubble packs in a locked box or cabinet.

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.

Reassessment & Reduction of 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. This could include instability in reliable or safe housing, mental health issues, relationship breakdown, and/or relapse to substance use. Patients who consume methadone carries early, report lost or stolen carries, or frequently vomit carries, should also have their number of take-home doses reduced, with possible return to daily witnessed ingestion (see *Complete Forfeit of Take-home Doses* below).

If treatment intensification results in improved stability, the prescriber, in consultation with the treatment team, may elect to reinstate take-home dosing more rapidly than outlined above.

Managing Relapse

A relapse is defined as a return to sustained problematic drug use, along with loss of clinical stability, and as such, the frequency of methadone carries should be reduced. Meanwhile, the frequency of clinical assessment and monitoring (UDT, pill/bottle counts) should increase until stability is re-established.

Prescribers may elect to *not* reduce the number of carries following a single episode of drug use (i.e., a slip or lapse), if the episode was short-lived and the patient does not demonstrate other signs of instability. The patient may instead be asked to present for one or more additional UDTs (7-10 days apart) and/or for additional clinical assessments with a member of the treatment team, to establish that the slip was indeed short-lived.

The following is recommended during a relapse for patients on methadone:

- Patients who demonstrate continued sustained substance use and/or clinical instability should have all take-home doses removed and return to daily witnessed ingestion.
- If the patient remains otherwise clinically stable, remove one carry dose per week for each positive urine sample (typically tested once per week).
- If the patient is otherwise stable and again meets take-home dosing criteria, carries can be gradually reinstated, but no faster than one carry per week for each negative urine sample (typically tested once per week).

Complete Forfeit of Take-home Doses

All take-home doses should be removed for the following reasons, if confirmed by sufficient collateral/evidence, and discussed collaboratively with the patient:

- Evidence of diverted methadone.

- Evidence of tampering with urine samples.
- Evidence of repeated failure to ingest dispensed methadone doses.
- Take-home doses are ingested early, and the patient runs out of methadone.

If the patient was not consuming their full dose or if they were skipping or diverting one or more doses, it may be necessary to reduce the methadone dose to 50% of the original dose (similar to recommendations for missed doses, as outline in the Ongoing Care chapter). Such a **dose reduction is intended to protect against overdose** when take-home doses are converted to witnessed doses and/or when the patient resumes consuming their full witnessed dose on a daily basis. Observing the patient for a period after dosing (i.e., in clinic or in collaboration with pharmacy) may be warranted to monitor for sedation/opioid toxicity.

If the methadone dose is reduced, the patient should also be assessed for signs and symptoms of opioid withdrawal, and appropriate dose increases should then be made to restabilize the patient, if the plan is to continue OAT.

Conversely, **if diversion is confirmed**, this constitutes sufficient grounds for an involuntary taper to zero or immediate cessation of OAT. See Discontinuing Treatment for guidance on the involuntary withdrawal process. Alternatively, increased supervision and strict witnessed dosing seven days per week, with no option for take-home doses (for any reason) may be considered, if deemed appropriate by the treatment team. If the latter option is chosen but the behavior continues, methadone must be discontinued. Evidence of methadone diversion is typically considered a much greater safety risk to the public, and thus results in involuntary withdrawal of treatment more often (compared to buprenorphine/naloxone).

Methadone Carries & Benzodiazepines/Z-Drugs

Patients are at greater risk of methadone toxicity if they are taking prescribed or illicitly acquired benzodiazepines/Z-drugs. See Managing Polypharmacy in OAT, specifically MANAGING PRESCRIBED AND ILLICIT BENZODIAZEPINES & Z-DRUG USE for detailed guidance.

Patients using *illicitly* acquired benzodiazepines/Z-drugs are typically not candidates for take-home dosing. Patients who are *prescribed* benzodiazepines/Z-drugs and methadone may earn take-home doses if the following conditions are met, up to a **maximum of five carries a week**:

- The patient meets criteria for clinical stability.
- The prescribing physician has made a specific medical diagnosis that warrants the ongoing use of the benzodiazepines/Z-drug. This condition should be regularly reassessed.
- The dispensing interval of prescribed benzodiazepines/Z-drugs should mirror the OAT dispensing schedule, in most cases. **Communication and collaboration with any other prescribers and the pharmacy about this expectation is essential for patient safety**.

- Early refills should not be granted and lost stolen medication should generally not be replaced.
- If not medically essential, a taper of the benzodiazepine/Z-drug should periodically be attempted. Again, see Managing Polypharmacy for detailed guidance around tapering and managing problematic use of benzodiazepines/Z-drugs.

IMPORTANT NOTE: BENZODIAZEPINES/Z-DRUGS & CARRIES

In patients prescribed benzodiazepines/Z-drugs in the context of agonist therapy with methadone, the **maximum number of carries permitted per week is five**. If not medically essential, the patient should be encouraged to slowly taper off benzodiazepines over time. Once a taper to zero is complete, they may be awarded a sixth and final carry dose per week.

In the context of agonist therapy with buprenorphine and prescribed benzodiazepines/Z-drugs, the approach to carries is identical to the recommendations outlined in the Buprenorphine/naloxone Take-home (Carry) Dosing Recommendations section of this manual.

Medical Conditions Limiting Pharmacy Access

When a medical condition significantly interferes with the ability to attend the pharmacy, a prescriber may decide to initiate or increase take-home doses for a patient who otherwise would not qualify for carries, in collaboration with the treatment team.

Of note, the medical condition that necessitates take-home dosing may involve pain and/or other symptoms that could destabilize the patient and/or trigger relapse to substance use. A risk-benefit assessment that balances safety with treatment retention should be discussed and documented in the medical record.

For medical conditions of a temporary nature, the requirement for take-home doses should be reassessed once the patient's ability to attend the pharmacy is re-established.

Delivery of methadone to the patient's address is rarely indicated and should only be requested in exceptional medical/social circumstances. This would require collaboration with the pharmacist to evaluate a viable plan, dependent on the ability of the pharmacy to arrange for the delivery of methadone in an acceptable manner.

A witnessed self-administered dose can only be observed by a pharmacist, approved prescriber, or nurse in Manitoba. As such, delivered doses would be considered unwitnessed take-home doses (i.e., that the patient would self-administer in their own home) unless ingestion is actually witnessed by the pharmacist, and this is typically not feasible or realistic. **The prescriber should make it clear to the pharmacist that these delivered doses are intended to be unwitnessed, or take-home doses, in these circumstances**.

Arrangements to go without witnessed doses cannot be ongoing. Please refer to the Advice for OAT Take-home Dosing in the context of COVID-19 for specific pandemic-related guidance.

CARE OF PATIENTS ON METHADONE WITH EXTENDED CLINICAL STABILITY

Some patients on long-term OAT may demonstrate extended clinical stability, including sustained remission of their OUD and successfully rehabilitated lives. This long-term stability may permit more flexibility with take-home dosing for quality-of-life reasons and to further decrease the burden of treatment.

The recommendations for Buprenorphine/naloxone Take-Home Dosing permit more flexibility for patients with long-term clinical stability. Patients on OAT with buprenorphine with one year of documented clinical stability may transition to witnessed dosing of buprenorphine once per month, receiving the rest of the month's medication supply as take-home doses.

Some patients on methadone with long-term clinical stability may similarly benefit from bi-weekly or eventually monthly witnessed dosing *if specific criteria are met*. This could also include temporary extended carries for personal or work-related travel.

To be considered for extended take-home dosing, patients must meet the following three criteria:

1) **Two consecutive years of documented clinical stability on OAT**, including:
    - Employment or other socially productive activity (e.g., school, parenting, volunteering/community involvement),
    - Absence of criminality or illicit activity, and
    - Sustained remission from problematic drug and alcohol use.
2) Reliability and honesty in keeping appointments and interaction with the OAT provider, treatment team, and pharmacy staff.
3) Ongoing ability to safely store medication.

As outlined in the Ongoing Care chapter, for stable patients with no significant changes in treatment, follow-up appointments every three months are appropriate. Clinical judgement should be applied to the frequency of appointments. Typically, at each visit, UDT should be completed, and the methadone prescription would be written for 3 months. If the above criteria are met, methadone may be dispensed every two weeks or, at the prescriber's discretion, monthly, with a witnessed dose at the time of dispensing (i.e., 13 take-home doses bi-weekly, or up to a maximum of 29 take-home doses for monthly dispensing). Tablets may be considered as an alternative to liquid methadone, especially for international travel purposes.

However, it is important to advise the patient that tablets are typically not covered for OUD. Providers must also document their risk-benefit assessment in this regard, as both diversion and injection use may be facilitated by prescribing tablets.

If *any* concern about stability arises, then the frequency of clinic visits and UDT should be increased, and the carry status should be reassessed. Any demonstrated instability should see the patient returned to *at most* weekly dispensing, and care should align with the recommendations for earlier treatment phases.

Signs of instability may include:

- Unexpected (confirmed) UDT results.
- Significant decompensation in mental or physical health.
- Loss of employment or other socially productive activity.
- Difficulty attending appointments or pharmacy.
- Signs of aberrant behaviour (e.g., criminal/illicit activity, concerns about diversion).

As outlined in the Discontinuing Treatment chapter, specifically VOLUNTARY TAPERING, some patients with long-term stability may choose to attempt a methadone taper. Voluntary tapering can be suspended at any time and patients who relapse to opioid use or who decompensate psychosocially or functionally should be encouraged to titrate back up to a stable dose. If these patients re-stabilize, they may be considered candidates for extended take-home dosing again after a further six months of sustained clinical stability.

Appendix BB

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: _____