Purpose and Scope

Ensuring uninterrupted access to opioid agonist treatment (OAT) medications for patients during this COVID-19 epidemic is of critical importance to reduce the risk of associated harms. Solutions to challenges are a shared responsibility between the patients, their primary prescriber, and pharmacists. They need to be made in consideration of the balance of the public health risk due to COVID-19 and the public/patient risk of diversion and overdose.

This document provides an interim guideline for the management of OAT with methadone and buprenorphine/naloxone. It addresses office visits, remote visits, carry doses, and frequency of urine drug testing during the COVID-19 Pandemic in light of the need for social distancing, self-isolation, and quarantine.

This document supplements the existing College of Physicians and Surgeons of Newfoundland and Labrador (CPSNL) standards and guidelines and is a resource for practitioners who are clinically proficient in the prescribing of OAT. While this document provides guidance and assistance to prescribers who wish to modify their approach to patient care during this crisis, it is not intended to supersede clinical experience, decision-making skills, prior treatment protocols, or to limit the scope of clinical practice. This document does not address the use of OAT or other narcotics for pain management.

Guidelines within Context of COVID-19 (see Appendix A):

This document applies primarily to patients who are asymptomatic and practicing social distancing as mandated by public health guidance.

Patients who are asymptomatic and under self-isolation: Consult with a pharmacist at the patient’s pharmacy to determine if the pharmacy is able to provide care to the patient under the circumstances; for example, pharmacy delivery of medication or alternate care arrangements.

Patients who are symptomatic and/or quarantined, presumed COVID-19 positive, or confirmed COVID-19 positive: Consult with a pharmacist at the patient’s pharmacy to determine if the pharmacy is able to provide care to the patient under the circumstances; for example, pharmacy delivery of medication or alternate care arrangements. All reasonable measures should be explored to support patients remaining in quarantine, including having a reliable, designated agent (e.g., family member or friend) to pick up or receive the carries. Practice may need to be modified outside the scope of this guideline on an individual basis, applying clinical judgment to weigh risks and benefits to patients and the public in each case.
Terminology:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Carry/carries</td>
<td>Take-home doses of methadone and buprenorphine/naloxone for opioid use disorder treatment</td>
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<tr>
<td>UDS</td>
<td>Urine drug screens</td>
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<tr>
<td>Clear UDS</td>
<td>Urine drug screens that show the absence of illicit substances</td>
</tr>
<tr>
<td>Remote/remotely</td>
<td>Clinical care via telephone, and online platforms</td>
</tr>
<tr>
<td>Bup/nal</td>
<td>Buprenorphine/naloxone</td>
</tr>
</tbody>
</table>

1. GUIDING PRINCIPLES

Purpose of Carries:

- OAT is the gold standard for the treatment of opioid use disorder. It is essential that patients have safe and continued access to treatment during the COVID-19 pandemic.
- During this time of widespread COVID-19 community transmission, exceptional OAT carries can be considered as a way to provide ongoing care that balances the facilitation of physical distancing by reducing pharmacy and clinic visits with considerations of patient and community safety.
- Some patients who might not have been considered eligible for methadone carries under MMTSG may be given carries in light of the COVID-19 pandemic as per the criteria below.
- Given bup/nal safety profile, bup/nal carries are considered differently than methadone. With methadone, there are greater concerns with respiratory depression and overdose. Thus, the risks of community transmission of COVID-19 must be weighed against the known risks of overdose death due to diversion to the community or to overuse of methadone carries by the patient.
- During the COVID-19 pandemic, the role of UDS should be de-emphasized. In most instances, patients may be assessed remotely and may be managed without obtaining a UDS.
- UDS should be performed at the time of a clinical visit when the results can be discussed and are relevant to care, not on a fixed schedule or as a requirement for prescribing and dosing. UDS should be the exception and only be required in the context of a clinical assessment.

Clinical Assessment of Suitability for Carries:

- Assessment of suitability of carries is primarily a clinical assessment that relates to social stability and an individual’s ability to manage carries safely rather than a clear UDS.
- Patients who continue to other use substances, including opioids, can receive carries unless they are at high risk/not suitable based on the criteria below.
- Patients require safe storage for carries (i.e., a locked box) and safe housing.
• Patients not suitable for carries if:
  o Intoxicated or sedated when assessed
  o Unstable behavior in social situations
  o Unstable psychiatric comorbidity (acutely suicidal or psychotic)
  o Lack of secure housing and/or secure medication storage
  o Recent overdose
  o Currently using illicit substances in high-risk ways; particular caution to be exercised with methadone if patients are using alcohol or benzodiazepines in high-risk ways or injecting high-dose intravenous illicit opioids.

Communications:

• Verify current contact information (e.g., phone numbers and email addresses) for all patients.
• Provide increased support to patients via telephone or video calls.
• Prescribers should provide their contact information to pharmacy colleagues to troubleshoot clinical scenarios as they arise.
• Collaborate with the pharmacy team to inform them of the patient’s current health status as it relates to COVID-19 (e.g., asymptomatic, isolating, quarantined), assess for patients’ clinical stability, make modifications to the current carry schedule and rationale, and ensure access to medication.
• Inform patients that the clinical decision is based on this protocol. Explain the need to avoid in-person visits to the clinic or pharmacies unless absolutely necessary.

Safety and Documentation:

• **Document in the patient’s medical record the rationale for any treatment plan changes due to COVID-19.**
• Methadone carry safety, including safe storage, should be assessed and documented, as per MMTSG.
• Clinicians should consider possible misuse or diversion and overdose risk.
• Advise patients that exceptional carries are being given due to the current health emergency, and MMTSG standards will reapply once it is over.
• Discuss and document issues related to safe storage and risks of carries, including overdose and death, as per MMTSG.
• Prescribers should continue their normal practice with respect to bup/nal storage safety.
• Patients should be directed to obtain naloxone overdose kits and educated in the use of naloxone. Visit the Health and Community Services Naloxone webpage for more information.
• A carry agreement should be either signed or agreed to remotely and documented in the chart.
• Lost or diverted methadone carries should be managed as per MMTSG. Lost or diverted bup/nal carries should be managed according to the usual standard of care.
• Vomiting will be treated as indicated in MMTSG. Prescriber and Pharmacist has to ensure the rules for vomiting expressed in the MMTSG before giving carries. It should be done written and verbal where ever possible.
2.0 CLINICAL PRACTICE

Frequency of remote assessments:

- Whenever possible, remote assessments should be emphasized to support physical distancing and reduce overall risks.
- Assessments are important when clinical decisions are being made, e.g., when doses and carries are being adjusted.
- Assessments can be an important source of support to patients who no longer have access to meetings, groups, or counselling.
- When a UDS is not required for carries, consider using technology to allow patients to connect with their provider without coming to the clinic.
- Clinical judgment should apply when determining the frequency of clinic visits.

Bup/nal:

- Perform clinical assessment of suitability for carries.
- Clear UDS is not required for carries.
- Doses of bup/nal do not need to be witnessed, unless to address some specific clinical issue. This will minimize time spent in pharmacy, reducing the risk to both patients and pharmacy staff.
- Up to four weeks of bup/nal carry doses may be prescribed, regardless of how long patient has been on bup/nal; prescriber to use clinical judgment to determine whether to be progressive with carries (e.g., advancing from one to four weeks).
- Very stable patients on bup/nal may be assessed less frequently (e.g., every six to twelve weeks).

Methadone:

- Perform clinical assessment of suitability for carries. If suitable, refer to the table below.
- The Pre-COVID-19 “Carry Level” guides the transition to the “Carry Ladder”, which will apply during COVID-19 community transmission (Table Methadone Carries).
- Once on the “Carry Ladder”, patients may move up the steps on a weekly basis if they remain suitable for carries, and if the prescriber judges this to be clinically appropriate considering risks and benefits. They may also move down the ladder as a result of safety considerations.
- Non-consecutive carries are a way of reducing the frequency of pharmacy visits while reducing the risks of misuse/diversion of larger amounts of methadone. At their observed doses, patients are seen by a pharmacist and assessed for sedation/intoxication.
- Starting with non-consecutive carries and progressing as per the table below can assist with developing patient and provider comfort around carry safety.
### Table 1: Methadone Carries

<table>
<thead>
<tr>
<th>Pre-COVID-19 “Carry Level”</th>
<th>“Carry Ladder” during COVID-19 community transmission</th>
<th>Nomenclature</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 and unsuitable for carries</td>
<td>No carries</td>
<td>COV-0</td>
</tr>
<tr>
<td>0 and suitable for carries</td>
<td>To be determined by clinical stability</td>
<td>COV-3</td>
</tr>
<tr>
<td>1</td>
<td>To be determined by clinical stability</td>
<td>COV-4</td>
</tr>
<tr>
<td>2</td>
<td>To be determined by clinical stability</td>
<td>COV-5</td>
</tr>
<tr>
<td>3</td>
<td>To be determined by clinical stability</td>
<td>COV-6</td>
</tr>
<tr>
<td>4</td>
<td>Up to 1 to 2 weeks***</td>
<td>COV-13</td>
</tr>
<tr>
<td>5 or 6</td>
<td>Up to 1 to 2 weeks***</td>
<td>COV-27**</td>
</tr>
</tbody>
</table>

**Notes:**

* No clear UDS required.

** Irrespective of diluent (i.e., Tang, apple juice, Crystal Light or Kool-Aid), microbial growth is likely to occur after two weeks of storage at room temperature. There should be refrigeration of carries if more than two weeks are provided.

*** Stable patients where pharmacist and prescriber deem in special circumstances a longer course is required 28 days or four weeks would be maximum.

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**COV-0 to COV-5 (i.e., up to 5 carries per week; max. 3 consecutive doses):**

- Represents an area of unstable patient. The term unstable is defined by the individual prescriber, often with pharmacy conversation.
- The prescriber in consultation with pharmacist may extend to 5 carries per week, max of three consecutive days as determined by clinical stability.
- A positive UDS or change in stability would warrant closer inspection of carries and possible reduction.
- The prescriber should move forward with caution. The max guidelines set cannot be interpreted as the normal practice.
- Do not require clear UDS.
- If assessed remotely, the patient does not need to provide a UDS.
- Positive UDS should always be a discussion point regarding safety, stability, and harm reduction. In most circumstances, the level of take-home doses should not be reduced if the patient remains suitable for carries. Carries may still be increased as per the “Ladder” up to COV-5.
- The prescriber may adjust the number of carries upwards or downwards on the “Carry Ladder” as per their clinical judgment around safety.

**COV-6 to COV-27:**

- Patients should generally provide a UDS when each prescription ends; clear UDS are generally expected given the safety issues associated with 6 or more carries.
- Positive UDS should prompt discussion regarding safety, stability, and harm reduction. Carries do not need to be reduced in light of a “slip” or isolated non-problematic use as long as the other parameters of stability remain intact. If the patient is less stable, carries can be reduced to COV-5 or less.
- For some patients with long-term stability (including long-term clear UDS), it may be appropriate to prescribe up to 6 or more carries on an ongoing basis, with remote assessments without UDS.
**Appendix A - Scope:**

- Prescribers must have appropriate education, training, and experience to competently assess and manage patients with opioid use disorder.
- Variables that may impact the application of these guidelines include individual patient variables, local COVID-19 issues, prescriber or patient ability to leave the home, distance and means of travel, access to medications, prescriber and pharmacy availability, and other unforeseen issues.
- In individual cases, clinicians may need to assess risks and benefits and provide carries to selected patients more liberally or more restrictively than outlined.
- For methadone, on matters not covered by this document, MMTSG continues to apply.
- For bup/nal, on matters not covered by this document, previous standards of care apply.
- While this document provides guidance and assistance to prescribers who wish to modify their approach to patient care during this crisis, it does not necessitate any specific actions; prescribers may choose to make appropriate clinical decisions based on their prior treatment protocols.

**Appendix B - Special Considerations:**

- **New methadone Starts:** Methadone should be initiated in methadone-naive patients only after a comprehensive assessment (virtual or in person), including a UDS.Prescribers should keep in mind that there is an increased risk of overdose in the first two weeks of taking methadone. This warrants more frequent clinical assessments, whether in-person or remotely. Consider waiting one month before initiating carries.
- **Methadone Restarts:** Complete a virtual or in-person assessment and offer bup/nal as a preferred treatment option. If a patient wishes to restart methadone and a UDS cannot be performed, prescribers should consider using a lower starting dose of methadone.
- **Patients who have had missed doses (i.e., up to 7 missed doses of methadone, or 14 missed doses of bup/nal):** Restart after an assessment (virtual), without a mandatory UDS.

**Appendix C - Guidelines for Extended Remote Care:**

- Consider using the telephone or online platforms to provide care.
- Review each patient’s case individually, taking into account the fundamental concerns of stability, safety, storage, overdose risk, diversion risk, lapse or relapse, the new dangers associated with COVID-19, and current public health advice around physical distancing.
- The use of this guideline assumes open, ongoing communication with the patient. This means that the patient is to stay in touch with the clinic, i.e., respond to calls from the clinic, calls the clinic for any changes, accesses the clinic website for information (if such a medium is used). If open, ongoing remote communication is not possible, it may be more appropriate to continue in-person care using standard carry parameters.
“You don’t have to do this, or you can do it differently, depending on your judgment.”

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This document was adapted (with permission) from the COVID-19 Opioid Agonist Treatment Guidelines (March 22, 2020) developed by CAMH, META: PHI, and OMA. This document will be reviewed and updated as the COVID-19 pandemic evolves.

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