College of Pharmacists
of British Columbia

Professional Practice Policy #67

Policy Guide

Injectable Hydromorphone Maintenance Treatment (2018)

Injectable Hydromorphone Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacist supervision of injectable hydromorphone maintenance treatment must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Injectable Hydromorphone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires supervised injection (i.e., 7 days per week, multiple doses per day) the pharmacy hours of service need to accommodate this dosing requirement. Patients may need to have access to injectable hydromorphone up to three times per day with a minimum of three hours between doses.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Only full pharmacists who successfully fulfill the following requirements may be considered 'iOAT trained pharmacists':
- Authorized by the CPBC under the Certification of Practicing Pharmacists for Drug Administration (injection and intranasal route);
- Trained to administer emergency use naloxone as per Principle 1.2.4;
- Holds current certification in cardiopulmonary resuscitation and first aid;
- Is familiar with the information included in the most recent version of British Columbia Centre on Substance Use (BCCSU) *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder*;
- Completed online training through the University of British Columbia Faculty of Medicine, Continuing Professional Development's Provincial Opioid Addiction Treatment Support Program;
- Trained in the use of all equipment required under Principle 1.3.3;
- Knows and applies the principles and guidelines outlined in the CPBC *Injectable Hydromorphone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions; and,
- Records self-declaration of knowledge and training completion in eServices prior to dispensing injectable hydromorphone.

Guideline: Refer to *HPA Bylaws*, Schedule F, Part 4 – Certified Practice – Drug Administration by Injection and Intranasal Standards, Limits and Conditions for more information.

Principle 1.2.2 With respect to pharmacist supervised injectable hydromorphone maintenance treatment, only iOAT trained pharmacists can: accept a prescription for injectable hydromorphone; release a dose of injectable hydromorphone to a patient; conduct a pre- or post-injection patient assessment; or, supervise patients self-administering injectable hydromorphone. These functions cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 1.2.3 Patients must be advised to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, cravings, and/or non-medical opioid use.

Principle 1.2.4 All registrants must be trained to administer emergency use naloxone and hold current certification in cardiopulmonary resuscitation and first aid.

Guideline: It is recommended that all pharmacy staff be trained to administer emergency use naloxone, cardiopulmonary resuscitation and first aid.

Naloxone education and training resources are available through the BC Centre for Disease Control's Towards the Heart Program.

Principle 1.2.5 Registrants must always practice within the scope of their education, training and competence. Where needed, they must obtain appropriate education and training as necessary.

Guideline: Refer to *HPA Bylaws*, Schedule A - Code of Ethics.

1.3 Facility and Equipment

Principle 1.3.1 The pharmacy must have a separate injection room within which the drug is to be self-administered by the patient that is clean, safe, comfortable and appropriately private and furnished for the patient. This room must be equipped with the following at a minimum: stainless steel table, chair, secure container for sharps that is not easily removable, sink, soap, hand sanitizer, antiseptic cleaning wipes and paper-towel in a dispenser.

Principle 1.3.2 The injection room must have the following clean and sterile injection supplies for patient use, including but not limited to: needles for patient self-injection (intravenous, intramuscular and subcutaneous), tourniquets, alcohol swabs, bandages and cotton swabs.

Principle 1.3.3 The injection room must have the following equipment for assessment and overdose management: adequate naloxone and related supplies (e.g., needles, etc.), breathalyzer, pulse oximeter, blood pressure monitor, oxygen, and bag valve mask.

Principle 1.3.4 The injection room surfaces and equipment must be cleaned with appropriate disinfectant at the beginning and end of each day, and between each patient use to prevent the spread of infection.

2.0 Receiving Injectable Hydromorphone Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 Injectable hydromorphone for maintenance prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting prescriptions for injectable hydromorphone maintenance treatment, the iOAT trained pharmacist must ensure that the Controlled Prescription Program form is completed by the prescriber as outlined in the Controlled Prescription Program.

Note: A pharmacist does not have the independent authority to adapt a prescription for injectable hydromorphone maintenance treatment.

Principle 2.1.2 Injectable hydromorphone for maintenance prescriptions may only be received by facsimile if in accordance with section 7(3) of the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice*. Verbal prescriptions for injectable hydromorphone maintenance treatment may be accepted where permitted under a section 56 exemption to the *Controlled Drugs and Substances Act* in accordance with section 19(6.1) of the bylaws to the *Pharmacy Operations and Drug Scheduling Act*.

3.0 Processing Injectable Hydromorphone Prescriptions

3.1 Assessment of a Prescription

Principle 3.1.1 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of injectable hydromorphone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription.

Guideline: Concurrent use of injectable hydromorphone with other depressants such as benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

Note: Patients on injectable hydromorphone maintenance treatment are routinely co-prescribed other oral opioid agonist drugs. Consulting with prescribers ensures that they are aware that the patient is currently receiving injectable hydromorphone maintenance treatment.

3.2 PharmaNet Records

Principle 3.2.1 The prescribed injectable hydromorphone dose (in both mg and mL) and dose frequency must be entered in the 'sig' field for each patient on PharmaNet. Any injectable hydromorphone dose that has been processed but is not self-administered by the patient on the prescribed day is considered cancelled and must be reflected accurately on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of self-administered injectable hydromorphone doses as other health professionals rely on this information in making treatment decisions.

Example: Patient presents a valid prescription for injectable hydromorphone for supervised injection, stating 125 mg three times daily. Using commercially prepared single use vials of 50mg/mL hydromorphone, each dose corresponds to 2.5mL. Each vial is 1mL. Therefore, 3 X 1mL vials are needed to prepare each dose.

In this example, the sig field should contain something similar to: '125mg (2.5mL) three times daily supervised injection'.

The patient is injecting a total of 7.5mL per day. However, three vials are needed to prepare each dose. So, the total amount dispensed would be 9mL.

At the end of the day, it is expected that the total quantity posted on PharmaNet accurately reflects what was dispensed. If this patient attended and received two doses but missed one, the total amount on PharmaNet at the end of the day should be 6mL.

When viewing patient profiles on PharmaNet, care must be taken to distinguish between dose prescribed and quantity dispensed, as there may be discrepancies between the two due to vial size and wastage from dose preparation.

4.0 Releasing Injectable Hydromorphone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 An iOAT trained pharmacist must release the injectable hydromorphone dose to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

4.2 Pre-Injection Assessment

Principle 4.2.1 Prior to releasing an injectable hydromorphone dose, an iOAT trained pharmacist must complete a pre-injection assessment of the patient to assess for signs of intoxication, including severe agitation, dyskinesia, sedation, slurred speech, or smelling of alcohol. The iOAT trained pharmacist who conducts this assessment must document this by signing a patient/prescription specific log. If the patient is intoxicated, the dose must be postponed or withheld and this must be documented and included with the original prescription. The prescriber must be notified.

Guideline: The sample *Pre-Injection Assessment Checklist* (Appendix 1) can be used for the pre-injection assessment. The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

If the initial assessment results in suspicion of recent use of psychoactive substances, the iOAT trained pharmacist should discuss with the patient if they have consumed illegal or non-medical drugs (including any non-prescribed pharmaceutical drug) or alcohol. Where observation warrants further assessment for alcohol intoxication (e.g., slurred speech, unsteady gait, or smelling of alcohol), the iOAT trained pharmacist may administer breathalyzer testing to check that the patient's blood alcohol level does not exceed 0.05%.

Note: The BCCSU *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder* requires a minimum of three hours between doses.

4.3 Dose Preparation

Principle 4.3.1 If after the pre-injection assessment, the iOAT trained pharmacist deems the patient fit, the injectable hydromorphone dose may be prepared.

Principle 4.3.2 Best practices and established standards for preparing and handling injections must be followed.

Principle 4.3.3 Injectable hydromorphone for maintenance must be dispensed to patients as an approved, commercially available single-use vial formulation.

Principle 4.3.4 Single-use vial formulation allows only one needle puncture per vial. Any unused injectable hydromorphone remaining in the vial must be rendered unusable at the time of dose preparation according to Principle 4.3.6. This principle must be followed unless the preparation is done according to Principle 4.3.5.

Principle 4.3.5 Vials can be used for a maximum of two needle punctures when preparing syringes for the same patient (e.g., patient specific dose), only if the most recent version of NAPRA *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* is followed. Any unused injectable hydromorphone remaining in the vial must be rendered unusable by the end of beyond-use date (BUD) according to Principle 4.3.6.

Note: NAPRA "Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations" requires that preparation be done in a primary engineering control (PEC) (e.g., laminar airflow workbench or compounding aseptic isolator) that maintains ISO Class 5 air quality. Once the single-use vial is punctured in the PEC, the BUD of the drug remaining in the vial is ***6 hours***.

In addition to equipment, facility and BUD requirements noted above, it is important to note that there are numerous requirements outlined in the NAPRA "Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations" (i.e., labelling, personnel, policy and procedure requirements, etc.) which must be met to prepare the dose under Principle 4.3.5 to ensure patient safety. Otherwise, Principle 4.3.4 must be followed.

Principle 4.3.6 Prior to being rendered unusable as per Principles 4.3.4 or 4.3.5, any unused drug in vials from dose preparation must be documented in the patient/prescription specific log. A pharmacist and one other health professional must sign off on this drug destruction. This documentation must be kept in accordance with CPBC filing retention requirements. Empty vials must be disposed of in a secure container for sharps.

Guideline: The goal is to alter or denature the drug to such an extent that consumption has been rendered impossible or improbable. It should be readily apparent that the resulting product has been safely rendered unusable.

The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

4.4 Prior to Releasing the Dose

Principle 4.4.1 Prior to releasing the injectable hydromorphone dose, the iOAT trained pharmacist must confirm the patient's identity against the original prescription and verify that the correct quantity of the dose has been prepared in the syringe.

Principle 4.4.2 The patient and iOAT trained pharmacist must acknowledge receipt by signing a patient/prescription specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. Every part-fill dispensed must be reviewable as a complete history on one document.

Guideline: The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for this purpose. Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

4.5 Supervised Injection

Principle 4.5.1 An iOAT trained pharmacist must supervise the patient self-administering the prepared dose of injectable hydromorphone, to address patient safety and potential drug diversion issues. An iOAT trained pharmacist must be physically present in the injection room and directly monitor the patient for the full duration of the self-administered injection. The patient must never be left unattended in the injection room.

Guideline: Patients may inject intravenously, intramuscularly, or subcutaneously. For safety reasons, it is recommended that intravenous injection only be allowed in the upper extremities (hands or arms, no jugular use is permitted), while intramuscular injections can be allowed in the deltoid, thighs, and gluteal muscles.

Under no circumstances may a registrant administer the dose of injectable hydromorphone to a patient.

Assisting a patient to self-administer an injection (for example, by steadying a patient's hand) may place a health professional at high risk of a needle-stick injury. Part of the ongoing assessment of the patient is ensuring their continued ability to safely self-administer an injection, and notifying the prescriber if the patient can no longer do so.

Principle 4.5.2 If for any reason the patient does not self-administer a full dose, the remaining drug in the syringe must be rendered unusable. A pharmacist and one other health professional must sign off on this drug destruction. This documentation must be kept in accordance with CPBC filing retention requirements. The iOAT trained pharmacist must estimate the amount of drug injected and note this on the patient/prescription specific log. The prescriber must also be notified.

Guideline: The goal is to alter or denature the drug to such an extent that consumption has been rendered impossible or improbable. It should be readily apparent that the resulting product has been safely rendered unusable.

The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used to document the amount of drug injected in the patient/prescription specific log.

Principle 4.5.3 An iOAT trained pharmacist must only supervise one patient self-administering a dose of hydromorphone at a time (i.e., a 1:1 pharmacist to patient) ratio. The 1:1 ratio is needed to better ensure effective overdose response and emergency management.

Guideline: Staffing needs of the pharmacy should be considered when providing injectable hydromorphone treatment. While an iOAT trained pharmacist is required to monitor patients self-administering the dose of hydromorphone, appropriate supervision of the pharmacy premise is also needed, in compliance with legislative requirements.

Principle 4.5.4 Any empty used syringes and needles must be immediately disposed of in a secure container for sharps in the injection room.

4.6 Post-Injection Assessment

Principle 4.6.1 Post-injection, the patient must stay in the pharmacy for a minimum of 15 minutes, and within view of an iOAT trained pharmacist. Any refusal must be documented and the prescriber must be notified. After 15 minutes has elapsed, the iOAT trained pharmacist must conduct a post-injection assessment, observing any signs of intoxication including dyskinesia, sedation, slurred speech, agitation, or decreased respiration rate. If adverse events are observed, the pharmacist must notify the prescriber. The iOAT trained pharmacist who conducts this assessment must document this by signing a patient/prescription specific log.

Guideline: The sample *Post-Injection Assessment Checklist* (Appendix 3) can be used for the post-injection assessment. The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

While awaiting the post-injection period to elapse, the patient must remain within the view of an iOAT trained pharmacist. This may be in the separate

injection room, a reception area or elsewhere within 25 feet from the perimeter of the dispensary.

If the patient seems to be intoxicated, a pulse oximeter and/or a vital sign assessment should be completed and documented. If at any time during the post-injection assessment the iOAT trained pharmacist determines that the patient requires medical attention, they should immediately call 911.

Principle 4.6.2 If after the post-injection assessment, the iOAT trained pharmacist deems the patient fit to leave the premises, then the patient may do so.

5.0 Security and Reconciliation

Principle 5.1.1 At the end of each day the secure container(s) for sharps must be kept in a locked area, such as a locked cage or cabinet that only registrants have access to.

Principle 5.1.2 At the end of each day, a count and reconciliation for injectable hydromorphone must be conducted and signed off on by a pharmacist and one other regulated health professional. This documentation must be kept in accordance with CPBC filing retention requirements.

Principle 5.1.3 The pharmacy must have a security camera in the injection room.

Guideline: Patients must be informed of the security camera, see *Professional Practice Policy 74 – Community Pharmacy Security* for more guidance.

6.0 Responding to Dosing Issues

6.1 Missed Doses

Principle 6.1.1 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 6.1.2 The prescriber must be notified of any missed doses before the next supervised injection. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 4) can be used for this purpose.

Principle 6.1.3 If a patient misses 9 consecutive sessions or 3 days (whichever is first), the prescription must be cancelled, and the prescriber notified of the cancellation. A new prescription is required for the next dose.

Appendix 1

Pre-Injection Assessment Checklist

Patient Name:	Assessment Date and Time:

Yes	No	Unknown	
☐	☐	☐	Severely anxious or agitated
☐	☐	☐	Dyskinetic
☐	☐	☐	Overly sedated
☐	☐	☐	Slurred speech
☐	☐	☐	Smells of alcohol

Baseline respiration rate: _____ breaths/minute

Pasero Opioid-induced Sedation Scale (POSS) level: _____

Breathalyzer required: ☐ Yes ☐ No

If yes, breathalyzer reading: _____

Notes:

Appendix 2

Injectable Hydromorphone Part-Fill Accountability Log

Patient Name:_____

Prescription Number:_____

Date	Time	Transaction Number	Prescribed Dose (mg and mL)	Total Volume Used to Prepare Dose (mL)	Wastage after Dose Preparation (mL)	Drug Destruction (Health Professional's Signatures)	Pre-Injection Assessment (Pharmacist's Initials)	Patient's Signature	Supervision (Pharmacist's Initials)	Post-Injection Assessment (Pharmacist's Initials)	Notes

Appendix 3

Post-Injection Assessment Checklist

Name:	Assessment Date and Time:

Yes	No	Unknown	
☐	☐	☐	Severely anxious or agitated
☐	☐	☐	Dyskinetic
☐	☐	☐	Overly sedated
☐	☐	☐	Slurred speech
☐	☐	☐	Smells of alcohol
☐	☐	☐	Decreased respiration rate

Respiration rate: _____

Pasero Opioid-induced Sedation Scale (POSS) level: _____

Notes:

Appendix 4

Pharmacist-Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

❑ This patient missed their injectable hydromorphone dose(s) _____ (dates).

❑ This patient did not take their full AM dose(s) today _____ (date) and consumed only ____ mg/mL of the ____ mg/mL prescribed dose.

❑ This patient did not take their full PM dose(s) today _____ (date) and consumed only ____ mg/mL of the ____ mg/mL prescribed dose.

Additional Information/Other

You May Attach Controlled Prescription Form.

Notes: