College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Slow Release Oral Morphine (SROM) Maintenance Treatment (2018)

Slow Release Oral Morphine (SROM) Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to SROM maintenance treatment must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Slow Release Oral Morphine (SROM) 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 daily witness ingestion or daily dispense (i.e., 7 days per week) the pharmacy hours of service need to accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for SROM maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Provide patient education on how to properly take SROM.

Note: See Principle 4.1.4 for detailed administration requirements.

Principle 1.2.2 Advise patients to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, craving, and/or non-medical opioid use.

Principle 1.2.3 Refer colleagues, prescribers, and clinical staff who are unfamiliar with the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*. Recommend completion of online training through the University of British Columbia Faculty of Medicine Continuing Professional Development's Provincial Opioid Addiction Treatment Support Program.

2.0 Receiving SROM Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 SROM prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting SROM prescriptions, the pharmacist must ensure that the Controlled Prescription Program Form is completed by the prescriber as outlined in the Controlled Prescription Program.

3.0 Processing (Dispensing) SROM Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 SROM for maintenance must be dispensed in approved, commercially available strengths and formulations. Capsule contents cannot be split.

Principle 3.1.2 **Guideline:** Only the once-daily, 24-hour formulation of SROM has been studied in clinical trials for the treatment of opioid use disorder. Other formulations of oral morphine, such as twice-daily, 12-hour sustained- or extended-release formulations, have not been empirically studied in this context and are not recommended. Pharmacists and pharmacy technicians (working within their scope) must review the prescription to ensure that the specific needs of the patient can be accommodated by the pharmacy.

Guideline: Each prescription should be reviewed in detail in consultation with the patient, to ensure that the patient's specific needs can be accommodated. For example:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a day when the patient will not be able to see a prescriber for a new prescription (e.g., weekends and holidays).
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.

3.2 Assessment of a Prescription

Principle 3.2.1 Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'Opioid Agonist Treatment (OAT)' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Guideline: Effective June 5, 2017, PharmaCare established PINs for the use of Kadian® SROM as OAT. These PINs are to be used when submitting claims for the various dosing strengths through PharmaNet. Similar to methadone, DINs will be used by pharmacists exclusively for claims for analgesia, and the PINs will be used for claims for OAT.

Prescriptions for Kadian® should specify whether it is designated for analgesia or OAT (i.e., "for OAT" or "for opioid agonist treatment" is to be indicated on the prescription). If there is a question as to whether the prescription is for OAT (i.e., indicated by the dose strength, directions to "open and sprinkle" capsules for daily witnessed ingestion, or other

elements of the prescription), but the prescription lacks the explicit indication "for OAT", the pharmacist should contact the prescriber to confirm the intended use prior to dispensing the medication and properly document any alteration of the prescription.

The claim entered into PharmaNet should match the prescription written by the prescriber. If a claim marked "for OAT" has been entered under the DIN rather than under the PIN for Kadian® for OAT, it must be reversed, following the full standard procedure for reversing a claim entered under the wrong DIN or PIN. Only after a claim has been reversed can it then be re-entered with the correct PIN.

Principle 3.2.2 As with all medications a pharmacist must review each individual PharmaNet patient record, as stated in *HPA Bylaws* (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any SROM prescription. This step is particularly critical for SROM for OAT prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system **does not include SROM for OAT**.

Pharmacists providing SROM for OAT maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to SROM.

Guideline: A PharmaNet patient record review should be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3 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 SROM 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. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the SROM maintenance program.

Guideline: Mood altering drugs, including benzodiazepines and opioids, should not be prescribed to patients on the SROM maintenance program. Co-ingestion of SROM with alcohol or benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

4.0 Releasing SROM for OAT Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present to release the SROM prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a SROM prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and include it with the original prescription.

Guideline: Assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's usual behaviour in order to be able to detect significant deviations.

Principle 4.1.3 Prior to releasing a SROM prescription, the patient and 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. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

Guideline: The sample *SROM Part-Fill Accountability Log* (Appendix 1) can be used for this purpose.

Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

Principle 4.1.4 With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guideline: SROM has a high risk of diversion, even when administered as witnessed doses (e.g., intact capsules can be 'cheeked' or 'palmed').

To reduce the risk of diversion, daily witnessed ingestion doses should be prepared by opening the capsule(s) and sprinkling the enclosed pellets for immediate ingestion. The patient should be instructed that pellets must not be chewed or crushed.

Pellets may be sprinkled into a 30 mL medicine cup or small cup followed by at least 30 mL of water to ensure that all pellets have been swallowed.

Immediately following observing the patient's ingestion of the medication, the pharmacist should ensure that the entire dose has been swallowed. This may include: engaging the patient in short conversation, asking the patient if there are pellets remaining in their teeth or gums, offering additional water for rinsing, or inspecting the inside of the patient's mouth.

Important Safety Notice: SROM pellets must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.

Principle 4.1.5 If take home doses (carries) are prescribed, the first dose must be a witnessed ingestion. The subsequent take-home doses must be dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.

Guideline: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.
Note that the majority of prescriptions for SROM will be for daily witnessed ingestion (DWI). In exceptional cases, patients may be transitioned to take-home dosing schedules. If a patient's prescription indicates transition to a

take-home dosing schedule for SROM, it is best practice to call and confirm with the prescriber.

Compliance packaging (e.g., blister packaging, pouch packs) may be ordered by the prescriber to discourage diversion and allow for better monitoring during medication call-backs. In these cases, the pharmacy still needs to ensure that the medications are provided in child-resistant packaging.

Patients should be reminded that SROM should be stored out of the reach of children, preferably in a locked cupboard or small lock box.

5.0 Responding to SROM Dosing Issues

5.1 Missed Doses

Principle 5.1.1 Any SROM prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed 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 consumed and picked-up SROM doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.1.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.1.3 The pharmacist must notify the prescriber of any missed doses before the next scheduled release of medication. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for this purpose.

Principle 5.1.4 If a patient misses 2 or more consecutive doses, the prescription must be cancelled.

Guideline: The pharmacist should advise the patient to see the prescriber for a new prescription, as dose adjustment and re-stabilization may be required.

For more information, refer to the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 3: Induction and Dosing Guidelines for Slow Release Oral Morphine.

5.2 Partial Consumption of Doses

Principle 5.2.1 If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. All patient documentation including the patient-prescription specific log and PharmaNet record must accurately reflect the actual dose consumed by the patient.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the documentation and communication.

The *SROM Part-Fill Accountability Log* (Appendix 1) can be used for the Part-Fill Accountability Log.

5.3 Vomited Doses

Principle 5.3.1 If a patient reports that they vomited their dose, a replacement dose cannot be provided. The pharmacist must notify the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.4 Lost or Stolen Doses

Principle 5.4.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided. The pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.5 Tapering

Principle 5.5.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the purpose of notifying the prescriber.

Appendix 1

SROM Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Appendix 2

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 slow release oral morphine dose on _____(date).
- ❑ This patient did not take their full daily dose today _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.
- ❑ This patient's dose has been held due to _____ (reason and date).
- ❑ This patient lost or had their dose(s) stolen _____(dates).
- ❑ This patient's prescription has been cancelled due to _____(number of missed doses).

Additional Information

You May Attach Controlled Prescription Program Form.

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