SUFENTANIL

Prescribed Safer Supply Protocol

CLINICAL SUMMARY

BRITISH COLUMBIA
BRITISH COLUMBIA CENTRE ON SUBSTANCE USE
Networking researchers, educators & care providers
phs COMMUNITY SERVICES SOCIETY

The purpose of this clinical summary is to provide clinicians with an overview of the Provincial Sufentanil Provision (PRN Program) Protocol and serve as a wayfinding document to important information within the protocol.

Outline

1. Evidence Supporting Intervention (pg. 5)

Currently, there is no evidence or established best practices supporting the safety or efficacy of sufentanil for mitigating risk from the unregulated drug supply. There is, however, limited clinical experience demonstrating benefits for those with an opioid use disorder (OUD) that want to reduce their use of unregulated opioids.

2. Program Models (pg. 7)

Sufentanil programs may be offered through regional health authority-operated/funded programs and federally funded programs (e.g., SAFER). This may include adding sufentanil provision to a variety of existing programs and services, including opioid agonist treatment clinics (OAT; both methadone and slow-release oral morphine are acceptable), injectable agonist treatment (iOAT) clinics, and overdose prevention/supervised consumption sites.

Sufentanil is a liquid that can be offered as-needed or *pro re nata* (PRN), and is taken under the tongue sublingually (SL) or administered as an intramuscular (IM) or intravenous (IV) injection.

3. Eligibility (pg. 8)

The following considerations for eligibility should be assessed and documented in the participant's health record:

- Active OUD diagnosis (see note below) **AND**
- Ongoing active unregulated fentanyl use **AND**
    - **For injection program only:** Ongoing injection fentanyl use
- At high risk of overdose, injection-related harms, or other harms related to the use of unregulated opioids via a detailed clinical assessment including overdose history

Note: There may be some individuals who have not been formally diagnosed with an OUD, who use unregulated fentanyl and would benefit from accessing prescribed safer supply. The sufentanil PRN program may be appropriate for these individuals, based on clinical judgment and individual circumstances.

4. Drug–drug Interactions (pg. 12)

Many drugs interact with fentanyl. Prescribers should consult the product monograph and other sources for information on drug–drug interactions for any drug co-administered with fentanyl, including a pharmacist. A detailed list can be found in the Prescribed Safer Supply Protocols.

Special Caution: Antiretroviral Medication

There is a strong interaction between sufentanil and some antiretroviral (ARV) drugs used to treat HIV. Antiretroviral medications containing the "boosters" cobiscisat or ritonavir inhibit CYP3A4, which can lead to significant increases in sufentanil levels. Individuals who are stable on potentially-interacting ARV treatment may be started on sufentanil and should be monitored closely for sedation. Initiating sufentanil for individuals who might stop and restart potentially-interacting ARVs is not recommended. A clinician who specializes in HIV care should be consulted prior to initiating or changing ARVs.

Sufentanil is not bioequivalent to other fentanyl products. Sufentanil has 5–7 times the analgesic potency compared to fentanyl. Do not convert participants on a mcg per mcg basis from other fentanyl products. This includes oral, transdermal, or parenteral formulations of fentanyl.

5. Patient Education Checklist

This checklist can be used to ensure key points have been discussed with the patient prior to the implementation of this program.

✓	KEY POINTS
	Individuals with OUD who engage in active unregulated fentanyl use, and who are at a high risk of overdose or harms are eligible for this program. This program may be appropriate for individuals using unregulated fentanyl who are at high risk of overdose or harms, but may not have an OUD diagnosis.
	Fentanyl poses a significant risk for those who do not have an opioid tolerance, including other adults, children, and pets.
	You may choose the route of administration (under the tongue or injection into muscle or vein) depending on your preferred route of administration before entering the program.
	If you choose the oral route, the medication should be placed under the tongue for at least 2 minutes without swallowing. Food, water, and other medications should not be taken for 3–5 minutes following medication.
	If you attempt to inject in your vein unsuccessfully and decline injecting into a muscle or taking it under the tongue, it will be documented as a missed dose and you may retry (there is no limit to the wait time between a missed attempted dose and a second attempt).
	Use safer injection practices: use sterile supplies for each injection, clean the skin with alcohol, and choose areas of the body that are safer for injection (lower arms, lower legs, and hands).
	Injecting into the jugular vein ("jugging") increases the risk of stroke, infection, and death and is not recommended. Some sites do not allow jugging.
	Post-dose observation of 10 minutes is required when increasing the dose or switching the route of administration (unless switching to under the tongue).
	If there is sedation after the initial test dose, you will not be eligible to continue with this program and must be reassessed by the provider.
	Avoid using downers such as alcohol or benzodiazepines as they may increase risk of overdose.
	Drug–drug interactions exist with HIV medications and may increase the risk of overdose.
	Let your provider know if you experience an overdose.
	Extended absences of 30 days or more will require a re-assessment to re-enter the program.
	Possible side effects: low or high blood pressure, slowed heart rate, muscle rigidity if injected into a vein.

6. Visit Assessment and Assessment of Benefit (initial and ongoing pg. 36, pre- and post-dose assessment pg.22)

- An initial assessment should be performed and documented prior to starting the program
- Ongoing assessments should be done at least every 2 months, depending on clinical and participant context and capacity, including:
    - An assessment of benefit that includes subjective and objective indicators (e.g., how the participant is doing, general appearance)
- Pre-dose assessments should include a subjective assessment (i.e., last dose tolerated, any concerns) and an objective assessment (SAFER Sedation Scale [SSS])
- Post-dose assessments should include dose and time of medication administration, SSS post-dose, next dose, and follow up or referral to other services

7. Routes of Administration (pg.19)

The participant must choose the route of administration when starting (i.e., IV/IM or SL), and the prescriber will specify the route of administration on the prescription. Participants may only choose injection if they have previously injected. Participants have the option to switch routes of administration and may switch multiple times on the same day. Participants on SL or IM administration who would like to switch to IV must have one post-dose observation period of 10 minutes at the same dose to ensure tolerance to IV.

Note: Post-dose observation is only required when increasing dose or switching route of administration (unless switching to SL).

8. Initiation (pg.18)

The participant will receive an initial test dosage of 50mcg via chosen route (i.e., IV/IM or SL), followed by a 10-minute post-dose observation period.

a) If there is sedation after the first dose (i.e., SSS >2; see Appendix 4), the participant is not eligible for this program and must see a prescriber (see Sedation and Post-Dose Observation in protocol). The prescriber should reassess the individual's drug use history and urine drug test (UDT) result and create a new clinical plan. Consider recent prescribed or unregulated substance use when considering tolerance in these situations.

b) If there is no sedation (i.e., SSS score ≤2) after 10 minutes of receiving the first dose, the participant can access an additional dose of 50mcg, if desired, followed by another 10-minute post-dose observation. The participant may continue on 50mcg Q1H PRN dosing or increase to 100mcg, depending on their reaction. The prescriber can review and write an ongoing prescription.

8.1 Titration (pg. 18)

If the participant experiences withdrawal or cravings at 50mcg or 100mcg, they can continue to increase by 50mcg each subsequent dose to a **maximum of 250mcg**, as long as they have received a dose within the past 7 days.

Each dose increase requires a 10-minute post-dose observation period. If the participant's SSS score is >2 after 10 minutes, they are ineligible to increase doses further. **The doses are not required to be consecutive to continue titration.**

Once cravings and withdrawal symptoms are managed (or other individual goals are achieved), that dose will be considered their maintenance dose unless a decision is subsequently made to undergo further titration.

Once a participant has been titrated to a dose that is comfortable for them or has achieved the maximum dose of 250mcg, the prescriber should review and write an ongoing prescription for the participant's set dose. Once the participant is on a set dose, they cannot increase the dose without a new order, even if it is below the maximum dose of 250mcg.

9. Missed Doses (pg. 20)

The following procedures apply to both titration and maintenance doses. The table below summarizes the procedures to follow for missed doses.

Table 1. Summary of Actions for Missed Doses

Consecutive Days of Doses Missed	Action
7–29 **with** ongoing unregulated opioid use	Assess participant for recent substance use. Administer the last dose given with 10-minute post-dose observation.
7–10 **without** ongoing unregulated opioid use	Assess participant for recent substance use. Administer the last dose given with 10-minute post-dose observation.
11-29 **without** ongoing unregulated opioid use	Re-assess participant including their treatment goals and program engagement.
30+	Conduct re-assessment (vitals, weight, point-of-care UDT, use of unregulated opioids): • If no unregulated opioid use present (i.e., due to detox, incarceration, or other events/factors): restart program at initiation • If unregulated opioid use present: restart program with test dose + 10-minute post-dose observation Pharmacy receives order from prescriber to re-start prescription.

9.1 Missed Attempted Dose

If a participant has attempted to inject IV unsuccessfully and declines IM or SL, or if the syringe is clogged, the dose is considered a missed attempted dose. Participants can return to retry their dose as there is no limit to the wait time between missed attempted dose and a second attempt.

The only time doses are wasted and redrawn is if it is clearly witnessed by staff that none of the medication was injected or there was a crack in the barrel or mechanical error with the participant accidentally depressing the plunger before injecting.

10. Documentation (pg. 23)

10.1 Integrated Interdisciplinary Model of Opioid Agonist Treatment (IIMOAT)

For programs that have implemented IIMOAT, health care professionals or delegates are to document any changes made to pharmacy-prepared patient-specific medication—such as increased doses, decreased doses, or missed doses—on PharmaNet using the transaction medication update (TMU). In cases where the patient requires a dose and the pharmacy is unable to prepare, it can be prepared by nursing and provided through clinic stock. The exceptional reason must be documented and entered in PharmaNet by using the TMU.

10.2 Safer Alternative Documentation

Prescribers are asked to add "SA" to all prescribed safer supply prescriptions to improve data collection for safer supply programs and identify unintended risks or harms. If required, pharmacists should add "SA" to prescriptions at transmission to PharmaNet.

11. Feedback and Support

As the use of sufentanil is not an evidence-based approach, the BCCSU welcomes clinicians to share observations, comments, or issues based on clinical experience. Please email BCCSU Education: **bccsu_education@bccsu.ubc.ca**

Clinicians can also call the 24/7 Addiction Medicine Clinician Support Line at **(778) 945-7619** for clinical advice about substance use care and treatment.

More information on the sufentanil program can be found on the BCCSU website.