

OPIOID AGONIST TREATMENT UPDATE—Frequently Asked Questions (FAQs) October 18, 2021

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1. Overview of Methadone Options

Methadose and Metadol-D are commercial methadone formulations available in BC and covered as regular benefits for those enrolled in PharmaCare Plan C (Income Assistance), Plan G (Psychiatric Medications), and Plan W (First Nations Health Benefits). As of October 1, 2021, Sandoz Methadone (Sterinova) is no longer available for distribution in Canada.

For individuals who have not benefited from documented, reasonable trials of **two** methadone formulations (Metadol-D and Methadose), and for whom methadone remains the optimal opioid agonist treatment (OAT) option, compounded methadone 10mg/mL may be considered.

Table 1: Summary of methadone options

Methadose		Metadol-D		Compounded Methadone	
•	Red, cherry-flavoured	Colourless, unflavoured	•	 Colourless, unflavoured 	
•	Contains sugar	Sugar-free		 Sugar-free 	
•	Commercial solution	 Commercial solution 		 Compounded solution 	
•	Regular benefit	Must be diluted (e.g., in		Must be diluted (e.g., in	
		Tang, Crystal Light)		Tang, Crystal Light)	
		 Regular benefit 		 Non-benefit, coverage 	
				considered on a case-	
				by-case basis	

Please see Opioid Agonist Treatment Update—Methadone Formulation Options and Interchangeability for further information about prescribing and dispensing each of these OAT options.











2. What is Interchangeability?

Interchangeability refers to situations in which pharmacists may use their professional judgement to dispense another product if the product being interchanged meets the <u>Health Professions Act definition</u> (section 25.91) of an interchangeable drug:

- Same amount of the same active ingredients
- Comparable pharmacokinetics
- Same clinically significant¹ formulation characteristics
- Administered in the same way as the drug prescribed

A pharmacist may decide to interchange a methadone formulation because of patient preference, cost, or other considerations. Interchanges should be done in consultation with the patient and, when possible, their prescriber. If the pharmacist decides to perform an interchange, they should document both the rationale and circumstances with the original prescription and communicate this decision to the prescriber using standard fax communication.

Methadose and Metadol-D arecommercially available methadone 10mg/mL products that meet the above requirements of an interchangeable drug. While commercial methadone formulations are interchangeable with each other, they cannot be interchanged with compounded methadone, as shown in the table below.

Table 2: Interchangeability

Methadone	Can be interchanged with:				
Product	Methadose	Metadol-D		Compounded Methadone	
Methadose	_	✓		×	
Metadol-D	✓	_		×	
Sandoz Methadone	✓	✓		×	
Compounded Methadone	×	×		_	

¹ See <u>Health Canada Bio-equivalence Standards</u> for more information.



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3. Frequently Asked Questions

For Prescribers

1. How do I decide on a formulation to prescribe to my patient?

Prescribers should consider the needs of their patient when selecting a formulation, for example, whether they would benefit from a sugar-free formulation or have a preference of formulation they would like to try.

2. What if my patient was stable on compounded methadone before the formulation change and wants to go back on it?

Coverage for compounded methadone will only be provided with documented reasonable trials of two regular benefit methadone formulations:

- 1. Metadol-D 10mg/mL unflavoured AND
- 2. Methadose 10mg/mL cherry-flavoured

See the <u>Opioid Agonist Treatment Update—Compounded Methadone</u> bulletin for further information on trialing methadone formulations and prescribing compounded methadone.

3. What would indicate that a different methadone formulation should be trialed rather than a different OAT medication?

While commercial methadone formulations are interchangeable, patients may have success on one formulation but not another. If a patient is not having success on a current methadone formulation, the clinician should re-assess the treatment plan and consider other forms of treatment, in consultation with the patient. The specific treatment to be pursued should be patient-specific and reflect the patient's past experiences with OAT and their treatment goals.

If a patient has experienced some success with their current methadone formulation but still experiences withdrawal, cravings, or side effects, they should be trialed on another methadone formulation. Clinicians should document all methadone formulations that have been trialed, including challenges faced by the patient (e.g., ongoing cravings) and clinical rationale for trialing a different formulation.

4. How long should I trial my patient on a given methadone formulation before considering a switch?

Clinicians should assess patients initiating methadone at least weekly to monitor treatment response. As it can take several days at a stable dose for a given methadone formulation to reach its maximum therapeutic effect, clinicians should consider the patient's response to treatment over one to two weeks at each dose.











If the patient does not stabilize at a safe therapeutic dose, the clinician should consider switching to another methadone formulation. Refer to the BCCSU/Ministry of Health Guideline for the Clinical Management of Opioid Use Disorder for induction and dosing guidelines for methadone.

5. What if I do not indicate a specific formulation on the methadone prescription?

The pharmacist filling the prescription will choose a methadone formulation based on the patient's needs and preferences. They will then document which formulation was chosen and fax this information to the prescriber using the Pharmacist-Prescriber Communication Form. Any documentation from the pharmacist indicating a chosen formulation or an interchange should be included in the patient's medical record. These communications do not require the prescriber to send a confirmation to the pharmacist.

For Pharmacists

Do I need to communicate methadone formulation interchanges with the prescriber?

The pharmacist must notify the prescriber using the Pharmacist-Prescriber Communication Form and document the notification when a methadone formulation is chosen or interchanged by the pharmacist. This is standard fax communication and best practice. A confirmation from the prescriber is not required for communications indicating a chosen formulation or an interchange.

2. What if the methadone formulation is not specified on a renewed prescription (i.e., for a stable patient)?

Pharmacists should review the patient's profile on PharmaNet and dispense the same product that is on file. If the patient wants to use a different formulation, the pharmacist may perform an interchange after discussing options with the patient.

In these instances, a new prescription is not required, but the prescriber should be notified using standard fax communication. The pharmacist should document both the rationale behind the decision and the communication with the prescriber with the original prescription.

3. What if the methadone formulation is not specified on an initial methadone prescription (aka methadone "start" or "restart")?

The pharmacist should discuss the methadone formulation options with the patient and choose a formulation based on their needs and preferences. Additional factors such as availability of specific methadone formulations should also be considered. A new prescription is not required but the prescriber should be notified using standard fax communication. The pharmacist should document both the rationale behind the decision and the communication with the prescriber with the original prescription.











4. What if the patient wants to switch to a methadone formulation that is different from what is written on the prescription?

The pharmacist should attempt to contact the prescriber to discuss the patient's desire to switch methadone formulations. In the meantime, the pharmacist can dispense the formulation written on the prescription until the prescriber can be reached for confirmation. If the decision is then made to switch the patient's formulation, the pharmacist can perform an interchange and should document both the decision and communication with the prescriber with the original prescription.

If the prescriber cannot be reached to discuss the patient's desire to switch, the pharmacist can still interchange the formulation after discussion with the patient. Pharmacists should review the patient's profile on PharmaNet to ensure that a reasonable trial of the current formulation has been documented.

In the case of an interchange, a new prescription is not required, but the prescriber should be notified using standard fax communication. The pharmacist should document the rationale behind the decision and the communication with the prescriber with the original prescription.

5. What if the pharmacy does not have all of the commercial methadone formulations in stock?

If the patient is stable, the pharmacist should not interchange based solely on what is in stock, unless there is a clear rationale for interchanging (e.g., a shortage or recall of a particular formulation). The pharmacist may choose to direct the patient to another pharmacy or log the prescription and transfer it to another pharmacy that has the required formulation in stock. If an order is due to arrive at the pharmacy shortly, the pharmacy may buy a small amount of the required formulation from another pharmacy until their own stock is replenished. With the patient's approval, the pharmacist can also perform an interchange and dispense an alternative formulation until the original requested formulation is in stock.

If an interchange is made, the prescriber should be notified using standard fax communication. The pharmacist should document both the rationale behind the decision and the communication with the prescriber with the original prescription.

6. Can a commercial methadone formulation be interchanged for compounded methadone?

Compounded methadone is not interchangeable with commercial methadone formulations (Methadose and Metadol-D). If a patient expresses interest in compounded methadone, they must have appropriately trialed both Metadol-D and Methadose without success in order to be eligible for exceptional, last-resort coverage. See the Opioid Agonist Treatment Update—Compounded Methadone bulletin for more information on requesting compounded methadone from the BC Product Distribution Centre (PDC).







