

## OPIOID AGONIST TREATMENT UPDATE—Compounded Methadone

January 20, 2020

**IMPORTANT UPDATE:** Compounded methadone 10mg/mL coverage is available, in exceptional circumstances, as a last resort for patients who have not benefited from other forms of oral opioid agonist treatment, including Methadose, Metadol-D, and Sandoz Methadone (Sterinova). See below for information on coverage, which is available only in exceptional circumstances.

### In this Bulletin

1. Overview of Methadone Options in British Columbia
2. Information for Prescribers
3. Information for Pharmacists

### 1. Overview of Methadone Options

There are now 3 methadone options available as regular PharmaCare benefits in BC. Methadose, Metadol-D, and Sandoz Methadone (Sterinova) are covered as regular benefits for those enrolled in PharmaCare Plan C (Income Assistance), Plan G (Psychiatric Medications), and Plan W (First Nations Health Benefits). Methadose was introduced in 2014, replacing 1mg/mL pharmacy compounded methadone. Since this formulation change, many patients who had been stable on compounded methadone 1mg/mL have reported return to illicit opioid use due to inadequate management of withdrawal symptoms.<sup>1-5</sup> As a result, Metadol-D was added as a regular benefit in May 2019. In October 2019, compounded methadone became available as a last-resort option for individuals who had trialed regular benefit formulations without success. A third commercially available option, Sandoz Methadone (Sterinova), is now available as a regular benefit as of December 17, 2019.

*Note: Please see “Opioid Agonist Treatment Update: Methadone Formulation Options and Interchangeability” for further information on each of the methadone formulation options.*

#### Non-benefit, Exceptional, Last-Resort Coverage for Compounded Methadone

- For individuals who have not benefited from documented, reasonable trials of **two** methadone formulations (Metadol-D and **either** Methadose or Sandoz Methadone [Sterinova]), and for whom methadone remains the optimal opioid agonist treatment (OAT) option, compounded methadone 10mg/mL may be considered.
- **Coverage of compounded methadone 10mg/mL is determined on an individual, case-by-case basis. As such, prescribers, patients, and pharmacists should be aware that coverage requires that special procedures be followed, which may delay access compared to the commercial options. It is anticipated that it will take at least 48 hours to acquire stock once a prescription is delivered to the dispensing pharmacy.**
- Currently, all compounded methadone will be provided by the pharmacy at the BC Product Distribution Centre (PDC). Pharmacies are not permitted to compound methadone for OAT, as per

College of Pharmacists of BC policy. One central source has been approved for provision of compounded methadone for this program.

- Compounded methadone 10mg/mL is a clear, colourless, and unflavoured solution. After each dose is measured out from the 10mg/mL solution, it must be diluted to 100mL in a suitable liquid (Crystal Light, Tang, etc.) prior to dispensing to the patient.

## 2. Information for Prescribers

Coverage for compounded methadone will only be considered as a last resort in exceptional circumstances. The patient must have a diagnosis of opioid use disorder and documented trials of **two** regular benefit methadone medications:

1. Metadol-D 10mg/mL unflavoured;  
and one of:
  2. Methadose 10mg/mL cherry-flavoured; or
  3. Sandoz Methadone (Sterinova) 10mg/mL cherry-flavoured.
- **For each trial, document:** Dose, duration, and specific details of response and trial (e.g., if dose not lasting full 24 hours, was BID dosing trialed?); if an intolerance is present, nature and severity of intolerance must be documented along with steps taken to mitigate intolerance.
    - In order to provide the highest likelihood of treatment success on methadone, each commercially available methadone formulation should be trialed at an appropriate dose.<sup>a</sup>

### How to Submit a Compounded Coverage Request

Requests for coverage of compounded methadone will only be considered when PharmaCare benefit options (Metadol-D and either Methadose or Sandoz Methadone [Sterinova]) have been tried without success or are unsuitable for the patient. These exceptional circumstances and the patient's current clinical condition must be clearly articulated on the Compounded Coverage Request Form.

**Special Authority requests for coverage of compounded methadone should be submitted using the [Compounded Coverage Request form](#).** Note: While the [General Special Authority Request form](#) may be used, this path may cause delays and is not recommended.

#### Information that must be included in the request:

- Confirmed diagnosis of opioid use disorder
- Dose and duration of trial of all regular benefit methadone medications (i.e., Metadol-D, and **either** Methadose or and Sandoz Methadone [Sterinova], including any dose adjustments made and details of response to trials)
- Nature and severity of any intolerance and steps taken to mitigate intolerance
- Any additional clinical rationale


#### Information that DOES NOT need to be included:

- A copy of the costing sheet
- A copy of the actual prescription

<sup>a</sup> Methadone at higher doses (i.e., between 60–120 mg/day or higher) is more effective than lower doses for treatment retention and reducing heroin use during treatment.<sup>4,5</sup>

- Pharmacy information. It is NOT REQUIRED to complete sections marked as N/A (see below) nor to provide a copy of the prescription.

**SECTION 3 - COMPOUND INFORMATION**

<input type="checkbox"/> NEW REQUEST	ACTIVE INGREDIENTS, CONCENTRATION, DOSAGE FORM	DOSAGE AND REGIMEN
<input type="checkbox"/> RENEWAL		
NAME OF COMPOUNDING PHARMACY	PHONE NUMBER	 PharmaCare requires a copy of the compounding pricing and current prescription from this pharmacy before adjudication can be completed.
N/A	N/A	

**Note:** Additional information may be requested by PharmaCare, on a case-by-case basis, in order to adjudicate the request.

The Compounded Coverage Request form can be accessed here:

<https://www2.gov.bc.ca/assets/gov/health/forms/5479fil.pdf>

Compounded Coverage Request forms can be faxed to **1-800-609-4884 (toll free) (preferred)**

OR mailed to PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

#### After the request is submitted

- Compounded Coverage Requests are prioritized by date received and will be classified as “urgent.” Once the request is processed, PharmaCare will notify the prescriber of the decision.
- Prescribers are advised to wait to write the prescription for compounded methadone 10mg/mL until after they have been notified of approval.

#### Estimated turnaround times

Methadone 10mg/mL Compounded Coverage Requests will be processed as urgent requests. The request will be processed within 3 business days.

#### Duration of coverage

- Compounded methadone 10mg/mL coverage is valid from the date that approval is entered into a patient's record on PharmaNet, which links all of the province's community pharmacies and other authorized health care providers.
- The duration of initial coverage for compounded methadone 10mg/mL will be for **6 months**. Renewal will be considered upon submission of a written request indicating the patient's current dose and the specific benefit(s) derived from use of the medication. This renewal will be valid for a period of one year. Subsequent renewals will be indefinite.
- To ensure continuity of coverage, prescribers may wish to schedule an appointment with their patient for re-evaluation several weeks in advance of the expiry date, to ensure that a request for renewal can be submitted at least 2 weeks prior to the expiry date, if required.

#### Level of coverage provided to a patient

An approved request normally grants full coverage of a drug that would otherwise not be covered or be only partially covered.

Note that full coverage differs from actual reimbursement. Actual reimbursement depends on a patient's PharmaCare plan rules, including any annual deductible and co-payment requirements, and is subject to pricing policies such as the [Maximum Pricing Policy](#), the [Low Cost Alternative \(LCA\) Program](#), or the [Reference Drug Program \(RDP\)](#).

## Additional Important Information for Clinicians Prescribing Compounded Methadone

### Transitioning your patients to different methadone formulations:

1. Discuss potential risks and benefits of the transition with your patient.
2. If a shared decision is made to switch methadone products, document the discussion, decision, and your clinical rationale carefully in the patient's medical record.
3. Write a prescription for **the new methadone formulation** using the standard **BC Methadone Maintenance Treatment Controlled Prescription Program Form**.
4. Call the patient's pharmacy and discuss the switch to ensure the pharmacy is aware of the planned transition and will be on alert. This will allow for easier transition for your patient.

### Prescribing information for clinicians

- Given the nature of centralized compounding and delivery, prescribers should consider extending the prescription length by a few days, as it is anticipated to take approximately 48 hours from receipt of prescription to process and deliver the compounded methadone product to the dispensing pharmacy.
- The pharmacy at the PDC will compound and deliver a 7-day supply of patient-specific compounded methadone to the patient's preferred community pharmacy.
- Prescriptions for compounded methadone 10mg/mL must use the **BC Methadone Maintenance Treatment Controlled Prescription Program Form**. An example prescription is provided on the next page.

## 3. Information for Pharmacists

PINs and DINs for PharmaCare claims for all oral OAT medications for opioid use disorder can be accessed on the PharmaCare website: <https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/pharmacies/product-identification-numbers/oat-pins-and-dins>

### Dispensing Information for Pharmacists—Compounded Methadone 10mg/mL

- **All compounded methadone will be prepared by the PDC and ordered by the patient's pharmacy.**
- Once a prescription for compounded methadone has been received, the dispensing pharmacy should **complete the Compounded Methadone 10mg/mL Request Form (see last page of this update) and fax the form AND a copy of the current prescription to the PDC**. Each patient prescription requires a separate request form.
- Once the request and copy of the prescription are received by the PDC, the prescribed methadone 10mg/mL will be compounded and delivered to the dispensing pharmacy. Allow a minimum of 48 hours for compounding and delivery of the compounded methadone from the PDC to the dispensing pharmacy. Please see the [PDC website](#) for more information.
- In typical circumstances, a week's supply of the compounded methadone 10mg/mL (patient specific) will be provided with each delivery. There will be no charge to the dispensing pharmacy for the compounded methadone or for the delivery fee.

- The compounded methadone 10mg/mL will be delivered to the dispensing pharmacy in tamperproof boxes and receipt of the compounded methadone 10mg/mL will be signed for at the time of delivery. A confirmation fax will then be required from the dispensing pharmacy to the PDC.
- The PDC will deliver a bulk quantity stock solution for a patient's 7-day supply, from which each dose will need to be measured out as prescribed, diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.), and dispensed by the dispensing pharmacy.
- **The dispensing pharmacy will process the prescription through PharmaNet and follow established methadone record keeping procedures per usual practice requirements.**
- **The drug cost field must be \$0.01 (one cent). This \$0.01 cost is required to trigger payment of the witnessed ingestion fee.**
- **All applicable regulations and best practices regarding the ordering, storage, record keeping, security, and disposal of narcotics such as methadone must be followed for this compounded methadone 10mg/mL preparation.**
- **Compounded methadone 10mg/mL is a clear, colorless and flavourless solution. The dose is to be measured out from the bulk quantity stock solution from the PDC and then diluted to 100mL in a suitable liquid (Crystal Light, Tang, etc.) prior to dispensing to the patient.**
- If a client misses 3 or more days of methadone, the dispensing pharmacy must notify the PDC so that they do not send any further refills.
- *Reminder:* Pharmacists 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 methadone prescription. The automated drug usage evaluation (DUE) built into the PharmaNet system does not include methadone. Pharmacists providing methadone maintenance treatment, including Methadose, Metadol-D, Sandoz Methadone (Sterinova), and compounded methadone 10mg/mL must therefore ensure they maintain their knowledge with respect to potential drug interactions related to methadone.

### PINs for Billing PharmaCare:

**Billing PINs to use for compounded methadone 10mg/mL prescriptions have been updated on the PharmaCare website to include:**

- **67000013: Compounded methadone 10mg/mL - witnessed ingestion**
- **67000014: Compounded methadone 10mg/mL - delivery with witnessed ingestion**
- **67000015: Compounded methadone 10mg/mL - delivery, no witnessed ingestion**
- **67000016: Compounded methadone 10mg/mL - no witnessed ingestion**



## Additional Resources

Example Compounded Methadone Prescription (for prescribers):

BC METHADONE MAINTENANCE TREATMENT CONTROLLED PRESCRIPTION PROGRAM FORM  
Take to pharmacy of choice.  
**PLEASE PRINT**

PERSONAL HEALTH NO. 123456789		PRESCRIBING DATE 16 12 04 YEAR MONTH DAY	
PATIENT NAME FIRST: James INITIAL: X LAST: Smith	STREET 123 45th Street		
ADDRESS CITY: Anytown PROVINCE: BC	DATE OF BIRTH 76 02 26 YEAR MONTH DAY		
Rx: DRUG NAME AND STRENGTH <b>METHADONE 10 mg/ml</b>	DUE TO THE PATIENT'S IMMOBILITY, I CONFIRM DELIVERY IS REQUIRED. PRESCRIBER'S SIGNATURE		
QUANTITY NUMERIC: 420 mg ALPHA: four hundred twenty mg	START DAY: 2016 12 04 LAST DAY: 2016 12 10 YYYY MM DD		
DIRECTIONS FOR USE <b>METHADONE 60 mg/day</b> CIRCLE ONE: <input checked="" type="checkbox"/> DWI <input type="checkbox"/> CARRIES	SPECIFY NUMBER OF DAYS PER WEEK OF WITNESSED INGESTION IN PHARMACY NUMERIC: ALPHA:		
SPECIAL INSTRUCTIONS Compounded methadone	PRESCRIBER'S SIGNATURE <i>W. Osler</i>		
PRESCRIBER'S INFORMATION DR. WENDY OSLER 543 21st AVE ANYTOWN BC V2K 2B6	CPSID 12345 67 12345678 FOLIO		
<b>PHARMACY USE ONLY</b>			
RECEIVED BY: PATIENT OR AGENT SIGNATURE		SIGNATURE OF DISPENSING PHARMACIST	

PHARMACY COPY - COPYING OR DUPLICATING THIS FORM IN ANY WAY CONSTITUTES AN OFFENSE  
**PRESS HARD**  
**YOU ARE MAKING 2 COPIES**  
PRINTED IN BRITISH COLUMBIA

### Example Prescription:

- Use designated Methadone Prescription Pad and fill out as per usual procedure
- No adjustment to daily dose (mg/day) is required for patients who are being transitioned to compounded methadone.
- Write "**Compounded methadone**" in Special Instructions field

Compounded Methadone Request Form (for pharmacists -see following page):



# Compounded Methadone 10mg/mL Request Form to Product Distribution Centre Pharmacy (PDC)

To order a patient's supply of compounded methadone 10mg/mL, the dispensing pharmacy must complete the following and fax to 604-941-0532. The dispensing pharmacy may need to add a "1" if there is a need to dial long distance. For your reference, PDC's phone number is: 604-927-2620

Dispensing Pharmacy name: \_\_\_\_\_ Pharmacy code: \_\_\_\_\_

Pharmacy address for delivery:

\_\_\_\_\_

Pharmacy fax #: \_\_\_\_\_ Pharmacy phone #: \_\_\_\_\_

Requesting pharmacist (print): \_\_\_\_\_

Requesting pharmacist's license number: \_\_\_\_\_

Patient's name: \_\_\_\_\_

PHN: \_\_\_\_\_

## To Pharmacy - Product Distribution Centre:

Please provide compounded methadone 10mg/mL for the above patient as per the attached prescription.

Notes:

Affix Compounded Methadone  
Prescription form here

## References

1. McNeil R, Kerr T, Anderson S, et al. Negotiating structural vulnerability following regulatory changes to a provincial methadone program in vancouver, canada: A qualitative study. *Social Science & Medicine*. 2015; 133:168-176. 10.1016/j.socscimed.2015.04.008
2. Greer AM, Hu S, Amlani A, Moreheart S, Sampson O, Buxton JA. Patient perspectives of methadone formulation change in british columbia, canada: Outcomes of a provincial survey. *Substance abuse treatment, prevention, and policy*. 2016; 11:3-3. 10.1186/s13011-016-0048-3
3. Socias ME, Wood E, McNeil R, et al. Unintended impacts of regulatory changes to british columbia methadone maintenance program on addiction and hiv-related outcomes: An interrupted time series analysis. *Int J Drug Policy*. 2017; 45:1-8. 10.1016/j.drugpo.2017.03.008
4. Faggiano F, Vigna-Taglianti F, Versino E, Lemma P. Methadone maintenance at different dosages for opioid dependence. *The Cochrane database of systematic reviews*. 2003; (3):CD002208. 10.1002/14651858.CD002208
5. Nosyk B, MacNab YC, Sun H, et al. Proportional hazards frailty models for recurrent methadone maintenance treatment. *American journal of epidemiology*. 2009; 170(6):783-792. 10.1093/aje/kwp186