

## OPIOID AGONIST TREATMENT UPDATE Methadone Formulation Options and Interchangeability

January 20, 2020

**IMPORTANT UPDATE: As of December 17, 2019, a third methadone option (made by Sterinova and distributed by Sandoz) will be available as a regular PharmaCare benefit in BC. Sandoz Methadone (Sterinova) is cherry-flavoured and uses blue dye, which may be beneficial for patients who have experienced an adverse reaction to the red dye in Methadose. See below for information on each of the methadone formulation options and guidance on formulation selection .**

### 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>1-3</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.

A brief description of each of the 3 commercial methadone formulations and compounded methadone is provided below.

#### Regular Benefit Formulations

##### Methadose (10mg/mL):

- Methadose is a cherry-flavoured 10mg/mL methadone solution (not sugar-free).
- Methadose is eligible for coverage under the income-based Fair PharmaCare plan, and is 100% covered for those enrolled in PharmaCare Plan C, Plan G, and Plan W.

##### Metadol-D (10mg/mL):

- Metadol-D is a clear, colourless, sugar-free, and unflavoured 10mg/mL methadone solution.



- Each dose of Metadol-D must be measured out and diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.), to reduce the risk of diversion, prior to dispensing to the patient (see Dispensing Information for Pharmacists, below). Carries will also require dilution.
- Metadol-D (10mg/mL) is eligible for regular benefit coverage under the income-based Fair PharmaCare plan, and is 100% covered for those enrolled in PharmaCare Plan C, Plan G, and Plan W.

**\*\*NEW\*\* Sandoz Methadone (Sterinova) (10mg/mL):**

- Sandoz Methadone (Sterinova) is a cherry-flavoured, sugar-free, **blue** 10mg/mL methadone solution.
- Sandoz Methadone (Sterinova) is manufactured by Sterinova and distributed by Sandoz.
- Sandoz Methadone (Sterinova) is eligible for coverage under the income-based Fair PharmaCare plan, and is 100% covered for those enrolled in PharmaCare Plan C, Plan G, and Plan W.

*Note: Please see “Deciding on a Formulation” in the Information for Pharmacists section of this bulletin for further details about formulation interchangeability.*

### 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, per College of Pharmacists of BC policy, to compound methadone for OAT. 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

### Starting New Patients on Methadone (Commercial Formulation Options)

- The treating prescriber can discuss all OAT options when initiating opioid agonist treatment.
- When determining which brand of methadone to prescribe, check PharmaNet for an up-to-date dispensing history of methadone and other products.
- For clinical guidance on prescribing methadone for the treatment of individuals with opioid use disorder, please refer to Appendix 1 of the Ministry of Health/BCCSU [Guideline for the Clinical Management of Opioid Use Disorder](#).

### Transitioning Your Patients to Different Commercial Methadone Formulations:

1. Discuss potential risks and benefits of the transition with your patient.
2. If a shared decision is made to switch to a different commercial methadone formulation, document the discussion, decision, and your clinical rationale carefully in the patient's medical record.
3. Call the patient's pharmacy and discuss the switch to ensure the pharmacy is aware of the new transition and able to fill the prescription. This will allow for easier transition for your patient.

### Prescribing Information for Clinicians

- Prescriptions for compounded methadone 10mg/mL must use the **BC Methadone Maintenance Treatment Controlled Prescription Program Form**.

#### To Reduce the Risk of Diversion:

- **All methadone products** for maintenance treatment are daily witnessed ingestion unless and until take-home doses are prescribed.<sup>a</sup>
- Each dose of Metadol-D 10mg/mL must be diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.) prior to dispensing to a patient.
- Each dose of compounded methadone 10mg/mL must be diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.) prior to dispensing to a patient.
- Compounded methadone 10mg/mL will not have a product monograph. For the commercially available products, refer to the relevant product monograph for additional information, below:  
Methadose: [https://pdf.hres.ca/dpd\\_pm/00049876.PDF](https://pdf.hres.ca/dpd_pm/00049876.PDF)  
Metadol-D: [http://www.paladin-labs.com/our\\_products/Metadol-D\\_En.pdf](http://www.paladin-labs.com/our_products/Metadol-D_En.pdf)  
Sandoz Methadone (Sterinova):  
<https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=97248>

*Note: Please see the bulletin **Opioid Agonist Treatment Update: Compounded Methadone** for further information on how to prescribe compounded methadone using a Compounded Coverage Request.*

<sup>a</sup> In the case of take-home doses, the first dose must be daily witnessed ingestion as per College of Pharmacists of BC policies [PPP-66](#) and [PPP-71](#). In exceptional circumstances, the prescriber can notify the pharmacist and they must document the reasoning for the first dose not being daily witnessed ingestion.

### 3. Information for Pharmacists

Sandoz Methadone (Sterinova): DIN 02481979 is available as a regular benefit as of December 17, 2019. Billing PINs for this formulation have been updated on the PharmaCare website to include:

- PIN 67000017: Methadone (Sandoz) 10mg/mL - witnessed ingestion
- PIN 67000018: Methadone (Sandoz) 10mg/mL - delivery with witnessed ingestion
- PIN 67000019: Methadone (Sandoz) 10mg/mL - delivery no witnessed ingestion
- PIN 67000020: Methadone (Sandoz) 10mg/mL - no witnessed ingestion

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>

#### Deciding on a Formulation

Methadose, Metadol-D, and Sandoz Methadone (Sterinova) are all commercially available methadone 10mg/mL products that meet the [Health Professions Act definition \(section 25.91\)](#) of an interchangeable drug:

- Same amount of the same active ingredients,
- Comparable pharmacokinetics,
- Same clinically significant<sup>b</sup> formulation characteristics, and
- Administered in the same way as the drug prescribed.

For individuals who are stable on a given formulation, changes should only be made in exceptional circumstances in consultation with the patient and their prescriber. If the prescriber has indicated a specific product or has indicated no substitutions, the formulation should not be interchanged. Any decision to interchange methadone formulations should consider the following:

- **Cost:** Pharmacists should not interchange the formulation for one that exceeds the price of the prescribed drug.
- **Patient preference:** Patients may prefer one commercially available product over another. Members of the care team should ask about patient preference and take this into account when considering a change.
- **Adequate trials:** 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>c</sup> If a client has not benefited from reasonable trials of two of the available methadone formulations (Metadol-D and *either* Methadose or Sandoz Methadone [Sterinova]) at an adequate dose, an application may be made for exceptional, last-resort coverage of compounded methadone. Documentation of trials, including length and dose on each commercially available methadone formulation is required for compounded methadone eligibility.
- **Availability:** A pharmacy may have a particular formulation in stock at the time of filling a patient's prescription.

<sup>b</sup> See [Health Canada Standards for bio-equivalence of oral agents](#) for more information.

<sup>c</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>



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: John MIDDLE: 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 MOBILITY, I CONFIRM DELIVERY IS REQUIRED: _____ PRESCRIBER'S SIGNATURE		
QUANTITY 420 mg	ALPHA four hundred twenty mg		
DIRECTIONS FOR USE <b>METHADONE 60 mg/day</b> CIRCLE ONE (DWI) CARRIES * SPECIFY NUMBER OF DAYS PER WEEK OF WITNESSED INGESTION IN PHARMACY			
SPECIAL INSTRUCTIONS Metadol-D	PRESCRIBER'S SIGNATURE <i>[Signature]</i>		
PRESCRIBER'S INFORMATION DR. WENDY OSLER 543 21st AVE ANYTOWN BC V2K 2B6		CPSID 12345 67 12345678 FOLIO	
PHARMACY USE ONLY			
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**  
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### Example Prescription:

- Patient on stable dose of 60mg/day methadone transitioning from Methadose to Metadol-D (7-day supply)
- Use designated Methadone Prescription Pad and fill out per usual procedure
- No adjustment to daily dose (mg/day) is required, i.e., 60mg/day Methadose = 60mg/day Metadol-D
- Write "**Metadol-D**" in Special Instructions field\*
- For new prescriptions, it is recommended to **call the patient's pharmacy first** to ensure that Metadol-D (DIN 2244290) is in stock and available

*Note: If patient preference or clinical judgment indicate a specific formulation is warranted, it must be specified in the "Special Instructions" field.*

### References

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