

OPIOID AGONIST TREATMENT UPDATE

Metadol® and Metadol-D® (10mg/mL) available exceptionally via Special Authority request
UPDATE: April 1, 2019

IMPORTANT UPDATE: More supply of Metadol-D® is now available and prescribers may now continue to offer this medication to patients. At this time, patients will need to have a special authority request submitted for Metadol-D® or Metadol® coverage. Metadol® and Metadol-D® are interchangeable products so a patient can use either as available. Prescribers DO NOT need to resubmit a special authority form at this time if one has already been submitted, however, forms can be submitted for NEW patients. Prescribers should be in direct contact with pharmacies that are dispensing Metadol® and Metadol-D® to ensure adequate supplies for current and new patients. Pharmacies should be in contact with PharmaCare Help Desk if experiencing shortages (Vancouver Lower Mainland 604-682-7120, Toll Free 1-800-554-0225).

Background: In 2014, B.C. changed the formulation of benefit methadone covered by PharmaCare from a 1mg/mL pharmacy compounded formulation to Methadose™, a commercially available 10mg/mL cherry-flavoured solution. Since this formulation change, some patients who had previously been stable on the 1mg/mL formulation of methadone have reported inadequate management of withdrawal symptoms and re-initiation of illicit drug use. This is reflected in peer-reviewed research studies referenced at the end of this document.¹⁻³

Methadose™ (10mg/mL):

- Methadose™ is a cherry-flavoured 10mg/mL methadone solution.
- Methadose™ is eligible for coverage under the income-based Fair PharmaCare plan, and is 100% covered for those enrolled in PharmaCare Plan C (Income Assistance), Plan G (Psychiatric Medications), and Plan W (First Nations Health Benefits).

Metadol-D® (10mg/mL):

- Metadol-D® (10mg/mL) is a Health Canada-approved formulation of methadone that is available in B.C. and currently covered by PharmaCare as a limited coverage benefit.
- Stock of Metadol-D® is now available.

Metadol® (10mg/mL):

- Metadol® is a Health Canada approved formulation of methadone for use in the treatment of pain. Metadol® has recently been made available for use in opioid agonist treatment in BC in cases where there has been limited supply of Metadol-D®. Metadol is temporarily covered by PharmaCare on an exceptional basis until supply issues have been fully resolved.
- Metadol® is manufactured by the same company and is the same strength as Metadol-D®.

Both Metadol® and Metadol-D® (are clear, colourless, and unflavoured solutions and are interchangeable. Both solutions must be diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.) to reduce the risk of diversion (see Dispensing Information for Pharmacists).

Transitioning your Patient between methadone products: from Methadose™ to Metadol® OR Metadol-D®; OR from Metadol-D® to Metadol®

1. Discuss all options for opioid agonist treatment (i.e. buprenorphine/naloxone, slow-release oral morphine etc.)
2. Discuss potential risks and benefits of the transition with your patient.
3. 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.
4. Write a new prescription for **Metadol® OR Metadol-D®** (on the same prescription to allow for dispensing of whatever is available at the time) using the standard **BC Methadone Maintenance Treatment Controlled Prescription Program Form**. (See example prescription on p. 4).
5. **Call the patient's pharmacy and discuss the switch to ensure the product is available in adequate quantities.** Advise the pharmacist if Special Authority coverage is approved or pending.
6. Submit a Special Authority request for PharmaCare coverage of Metadol® or Metadol-D®.

How to submit a Special Authority request

Special Authority requests for coverage of Limited Coverage Drugs (like Metadol-D®) are expected to meet the criteria for PharmaCare coverage to be granted. The criteria for Metadol-D can be found here:

<https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/special-authority-criteria-methadone-metadol-d>

Special Authority requests for coverage of Metadol® OR Metadol-D® should be submitted in the following way

The [General Special Authority Request form](#) (with Sections 1, 2 and "Requested drug exemption" portion of Section 3 completed information that must be included in the request:

- Confirmed diagnosis of opioid use disorder;
- Confirmation that the patient was inadequately controlled on or is intolerant to Methadose.

General Special Authority Request form can be accessed here:

<https://www2.gov.bc.ca/assets/gov/health/forms/5328fil.pdf>

Special Authority forms can be faxed to 1-800-609-4884 (toll free) (PREFERRED)

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

After the request is submitted

Special Authority requests are prioritized by date received and by urgency. Once the request is processed, PharmaCare will notify the prescriber of the decision unless the prescriber has indicated on the form that confirmation is not required.

Estimated turnaround times

If a response for coverage is required urgently then please indicate "**urgent**" on the request so that it is processed as a top priority over all other Special Authority requests. If not urgent, the request will be processed within 10 business days.

Duration of coverage

- Special Authority coverage is valid from the date that approval is entered into a patient's record on PharmaNet, B.C.'s electronic network that links all of the province's community pharmacies and other authorized health care providers.
- If coverage is approved, it will be granted for both Metadol® and Metadol-D®. The duration of coverage for Metadol® is two months and the coverage of Metadol-D® is indefinite.

Level of coverage provided to a patient

An approved Special Authority request normally grants full coverage to 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 \(RDP\)](#).

Prescribing Information for Clinicians

- Prescriptions for the Metadol-D® and Metadol® 10mg/mL products must use the **BC Methadone Maintenance Treatment Controlled Prescription Program Forms**. An example prescription is provided on the next page.
- For clinical guidance on prescribing Metadol-D® and Metadol® for the treatment of individuals with opioid use disorder, please refer to Appendix 1 of the [MoH/BCCSU Guideline for the Clinical Management of Opioid Use Disorder](#).

Dispensing Information for Pharmacists

- **Pharmacists can contact the PharmaCare Help Desk if experiencing shortages of Metadol® or Metadol-D® (Vancouver Lower Mainland 604-682-7120, Toll Free 1-800-554-0225).**
- Prescribing clinicians should use the **BC Methadone Maintenance Treatment Controlled Prescription Program Forms** for Metadol-D® and Metadol® prescriptions.
- The Metadol-D® product DIN is 2244290 for ordering purposes only. Pharmacists must use the appropriate PseudoDIN (PIN) when processing prescriptions for Metadol-D.
- The Metadol® product DIN is 2241377 for ordering purposes only. Pharmacists must use the appropriate PseudoDIN (PIN) when processing prescriptions for Metadol.
- *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 Metadol® and Metadol-D®, must therefore ensure they maintain their knowledge with respect to potential drug interactions related to methadone.

PINs and DINs for PharmaCare claims for opioid agonist treatment (OAT) 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>

To reduce the risk of diversion for BOTH Metadol-D® and Metadol®

- The unflavoured 10mg/mL solution must be diluted to 100mL with a suitable beverage (Crystal Light, Tang, etc.) prior to dispensing to a patient.
- Refer to the product monograph for additional information, available here:
[Metadol-D® http://www.paladin-labs.com/our_products/Metadol-D_En.pdf](http://www.paladin-labs.com/our_products/Metadol-D_En.pdf)
[Metadol® https://pdf.hres.ca/dpd_pm/00046900.PDF](https://pdf.hres.ca/dpd_pm/00046900.PDF)

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 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 METHADONE 10 mg/ml	DUE TO THE PATIENT'S INABILITY, 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 METHADONE 60 mg/day CIRCLE ONE DWI → CARRIES → SPECIFY NUMBER OF DAYS PER WEEK OF WITNESSED INGESTION IN PHARMACY	PRESCRIBER'S SIGNATURE <i>W. Osler</i>		
SPECIAL INSTRUCTIONS Metadol-D or Metadol	CPSID 12345 67 12345678 FOLIO		
PRESCRIBER'S INFORMATION DR. WENDY OSLER 543 21st AVE ANYTOWN BC V2K 2B6	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**
PRINTED IN BRITISH COLUMBIA

Example Prescription:

- Patient on stable dose of 60mg/day methadone transitioning from Methadose™ to Metadol® or Metadol-D® (7-day supply)
- Use designated Methadone Prescription Pad and fill out as per usual procedure
- No adjustment to daily dose (mg/day) is required, i.e., 60mg/day Methadose™ = 60mg/day Metadol® or Metadol-D®
- Write **“Metadol-D OR Metadol”** in Special Instructions field
- For **new prescriptions**, it is recommended to **call the patient’s pharmacy first:**
 - Ensure that Metadol-D® (DIN 2244290) or Metadol® (DIN 2241377) is in stock and available
 - Advise if Special Authority coverage is **approved** or **pending**

References:

1. Greer et al. Patient perspectives of methadone formulation change in British Columbia, Canada: outcomes of a provincial survey. *Subst Abuse Treat Prev Policy*. 2016; 11:3.
2. McNeil et al. Negotiating structural vulnerability following regulatory changes to a provincial methadone program in Vancouver, Canada: a qualitative study. *Soc Sci Med*. 2015; 133:168-176.
3. Socias 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.