

OPIOID AGONIST TREATMENT UPDATE

Metadol-D[®] (10mg/mL) available exceptionally via Special Authority request
UPDATE: January 3rd, 2019

IMPORTANT UPDATE: There is currently a limited supply of Metadol-D[®]. At this time only patients that have already been approved through the special authority request process are able to continue on this medication due to limited supply. Prescribers should be in direct contact with pharmacies that are dispensing Metadol-D[®] to ensure adequate supplies for current 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).
- Note: A clear, unflavoured formulation of 10mg/mL Methadose[™] is also commercially available, and some patients have been provided with PharmaCare coverage for this product on an exceptional basis. These patients will continue to receive coverage for unflavoured Methadose[™] and renewals to this coverage on request, however, as of June 13, 2018, this formulation will no longer be provided as an exceptional option for new patients who cannot take the cherry-flavoured Methadose[™] 10mg/mL solution. While there is limited supply of Metadol-D, this medication will be an option in the interim and provided on an exceptional basis.
- PharmaCare is now providing exceptional coverage for the Metadol-D[®] product as an alternative for patients who cannot take or are not benefiting from the cherry-flavoured Methadose[™] 10mg/mL solution (see below).

Metadol-D[®] (10mg/mL):

- Metadol-D[®] (10mg/mL) is a Health Canada-approved formulation of methadone that is available in B.C. but is only covered by PharmaCare on an exceptional basis.
- It is clear, colourless, and unflavoured, but must be diluted to 100mL in a suitable beverage (Crystal Light, Tang, etc.) to reduce the risk of diversion (see **Dispensing Information for Pharmacists**).
- When stock becomes available, clinicians can consider transitioning patients who are not benefiting from treatment with or who have a significant adverse reaction to Methadose[™]. It is important to discuss any changes in treatment with patients and make a collaborative decision.

In the interim, please follow regular treatment guidelines for the other products at this time.

- Clinicians can apply for coverage of this non-benefit drug for their patients by submitting a written Special Authority request or letter to PharmaCare's Special Authority department (see ***Transitioning your Patient from Methadose™ to Metadol-D®*** below). **Please hold off on sending these through while supply is limited.**

Transitioning your Patient from Methadose™ to Metadol-D®

1. Discuss current issues around limited drug supply and 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 to Metadol-D®, document the discussion, decision, and your clinical rationale carefully in the patient's medical record.
4. Write a new prescription for Metadol-D® 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 Metadol-D® 10mg/mL (DIN 2244290) 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-D®.

How to submit a Special Authority request

Special Authority requests for coverage of Non-Benefit drugs (like Metadol-D®) will be only considered on an exceptional basis, generally when all available PharmaCare benefit options 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 Special Authority Request Form.

Special Authority requests for coverage of Metadol-D® can be submitted in two ways:

1. The [General Special Authority Request form](#) (with Sections 1, 2 and "Requested drug exemption" portion of Section 3 completed); **OR**
2. A signed letter from the prescriber.

Information that must be included in the request or letter:

- Confirmed diagnosis of opioid use disorder;
- Dose and duration of trial of benefit Methadose™ 10mg/mL cherry-flavoured solution;
- Details of response to trial of benefit Methadose™ 10mg/mL;
- Detailed rationale that a trial of Metadol-D® is required; and
- Any additional pertinent information.

General Special Authority Request form can be accessed here:

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

Once the supply issue has been resolved, 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.
- The duration of coverage for Metadol-D[®] will be for **one year**. Renewal will be available upon submission of a written request indicating the patient's current dose and the specific benefit(s) derived from use of the medication.
- 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 so that if a request for renewal is required, it can be submitted at least 2 weeks before the expiry date.

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[®] 10mg/mL formulation of methadone 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[®] 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-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[®] prescriptions
- The Metadol-D[®] product DIN is 2244290 for ordering purposes
- 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



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.