

Executive Officer Notice: Policy for Methadone Maintenance Treatment Reimbursement under the Ontario Drug Benefit Program

July 28, 2022

The *Methadone Maintenance Treatment Reimbursement Policy, 2022* replaces the *Methadone Maintenance Treatment Reimbursement Policy, 2020* to reflect additional methadone 10mg/mL oral concentrate product options that will be listed on the Ontario Drug Benefit Formulary (Formulary).

The *Methadone Maintenance Treatment Reimbursement Policy, 2022* will take effect on **August 31, 2022** and replace the 2020 policy as of that date.

Methadone Maintenance Treatment Reimbursement Policy, 2022

As a precondition to obtaining billing privileges under the *Ontario Drug Benefit Act* (ODBA), all pharmacy operators are required to enter into a Health Network System (HNS) Subscription Agreement with the Executive Officer. Under section 3.2 of this Agreement, pharmacy operators are required to comply with all Applicable Law, Ontario College of Pharmacists Rules, and Ministry Policies.¹

The Executive Officer of the Ontario Public Drug Programs of the Ministry of Health (the “Ministry”) hereby establishes a policy for the reimbursement of methadone for all pharmacy operators in Ontario that supply methadone to Ontario Drug Benefit (ODB) eligible persons requiring methadone maintenance treatment (MMT) for opioid use disorder (hereinafter, referred to as the “**Policy**”). The Policy is comprised of this notice and the accompanying Questions & Answers document.

¹ The terms ‘pharmacy’ and ‘pharmacy operators’ are used in this Policy for consistency and ease of reading, however, all pharmacy requirements refer equally to ‘dispensing physicians’ as well. The term ‘dispensing physician’ refers to a physician who has a valid HNS Subscription Agreement with the ministry and is connected to the HNS.

The Policy is made in accordance with section 5(2) of the ODBA and subsection 20(1) of O. Reg. 201/96 under the ODBA and applies to claims submitted through the HNS for ODB eligible recipients.

Under this Policy the Ministry will reimburse all pharmacy claims for the Formulary listed methadone 10mg/mL oral concentrate products that are dispensed to ODB eligible persons receiving MMT in the manner outlined below.

Table 1: Publicly funded methadone hydrochloride 10mg/mL oral concentrate

Product Name	DIN	Manufacturer	Colour/flavour/sweetener	Interchangeable
Jamp Methadone*	02495783	Jamp Pharma Corporation	Blue/unflavoured/sugar-free, sweetened with sorbitol	Y
Methadose	02394618	Mallinckrodt Canada ULC	Clear/unflavoured/unsweetened	Y
Odan-Methadone*	02495880	Odan Laboratories Ltd.	Clear/unflavoured/unsweetened	Y
Methadose**	02394596	Mallinckrodt Canada ULC	Red/cherry flavour/sucrose	N
Metadol-D**	02244290	Paladin Labs Inc.	Clear/unflavoured/unsweetened	N

*The generic methadone hydrochloride 10mg/mL oral concentrate formulations, Jamp Methadone DIN 02495783 and Odan-methadone DIN 02495880 are interchangeable with Methadose (unflavoured) DIN 02394618

**The Formulary listings of Methadose (cherry flavour) DIN 02394596 and Metadol-D DIN 02244290 are not designated as interchangeable with any drug products.

Payment of Drug Cost

A **transition period** is being provided (**from August 31, 2022 to September 28, 2022**), during which the Ministry will continue to reimburse Methadose (unflavoured) DIN 02394618 at its Formulary Drug Benefit Price (DBP), instead of only paying the Drug Benefit Price of the lowest cost interchangeable product. The lowest cost interchangeable product payment rule will not apply during this transition period. The purpose of this transition period is to allow time for pharmacies to become informed of the changes regarding methadone and allow conversations to occur among stakeholders, including individual discussions with patients and prescribers to ensure appropriate supports are in place for transition.

Effective September 29, 2022, the usual lowest cost interchangeable payment rule will be implemented. In other words, where a methadone 10mg/mL oral concentrate product in an interchangeable category is dispensed, the Ministry will only pay the lowest Drug Benefit Price of the interchangeable products in the category. A patient wishing to receive a higher-priced interchangeable product at their request or pursuant to a “no sub” prescription must pay the difference in price, unless the patient has a “no sub” prescription and has experienced an adverse reaction to at least two of the lower priced interchangeable products, if available, as documented by their prescriber in a Health Canada Side Effect Reporting Form. Please refer to the [Ontario Drug Programs Reference Manual](#) s. 6.2 for requirements and details on how to submit a “no substitution” claim.

For a methadone 10mg/mL oral concentrate product that is not in an interchangeable category (e.g., Methadose (cherry flavour) DIN 02394596 and Metadol-D DIN 02244290), the drug cost paid is the Drug Benefit Price of the product on the Formulary.

Health Canada Safety Information

- Pharmacists are reminded of the two Health Canada “Dear Healthcare Professional” letters posted in [March 2020](#) and [July 2020](#) regarding switching of methadone hydrochloride oral concentrate products.
- Pharmacists are encouraged to discuss switching products with patients and prescribers. The following excerpt is taken from the product monograph of methadone hydrochloride oral concentrate solutions:

General Disorders and Administration Site Conditions: drug ineffective

Isolated reports have been received for drug ineffectiveness following a switch between different methadone products. The current data are insufficient to support an estimate of the incidence or to establish causation. Patients presenting with symptoms of withdrawal following formulation change should be clinically monitored and dose titrated as needed.

- When switching from Methadose to a generic formulation, patients should be monitored as per the precautions noted above.

Ministry requirements for reimbursement of methadone claims under the Policy for Pharmacy Operators:

The Ministry will pay pharmacies, via the HNS, one ODB dispensing fee per daily supply (i.e., the pharmacy's applicable ODB dispensing fee) for dispensing methadone 10mg/mL oral concentrate, as listed on the Formulary, to an ODB eligible person for MMT.

For example, for a prescription written to witness one dose on Monday and dispense 6 carry doses for Tuesday to Sunday, the ministry pays one dispensing fee for one witnessed dose on Monday and one dispensing fee for each daily supply carry dose labelled for Tuesday through Sunday; all 7 prescription claims would be submitted on the Monday, the day of the witnessed dose, and all 7 claims are eligible for a dispensing fee.

Please note:

- persons whose household has not yet reached its quarterly Trillium Drug Program deductible are not eligible for ODB benefits, and as such, their MMT claims do not fall under this Policy.
- the Policy does not apply to the Primary Pharmacy Service Providers (PSP) that dispense MMT to residents of Long-Term Care (LTC) homes as dispensing fees submitted for LTC home residents are included as part of the capitation payment to Primary PSPs effective January 1, 2020. However, the Policy does apply to the dispensing of methadone to a LTC home resident for MMT by a Secondary PSP. Secondary PSPs that dispense to residents of LTC homes on an emergency basis, will follow the protocol outlined under the Policy for Pharmacy Payments under the LTC Home Capitation Funding Model, 2020 that was posted on the ministry's website on December 16, 2019 and can be accessed at this link:
http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx

Payment of mark-up

The Ministry will reimburse the pharmacy for the applicable drug cost in respect of each claim for methadone 10mg/mL oral concentrate plus the applicable % mark-up on that amount. See above section on "Payment of Drug Cost" for more information.

No co-payment

No co-payment may be charged to the ODB eligible person or a private third party with respect to the supply of methadone for maintenance treatment. However, the amount of the co-payment that would apply to the ODB recipient for other drug claims (i.e., \$0, \$2.00 or \$6.11 depending on their class of eligibility) will still be deducted from the dispensing fee paid for the methadone claim.

Additional Requirements

- A separate claim must be submitted on-line for each day's supply of methadone for ODB eligible persons receiving MMT (i.e., one claim for each day's supply) using the appropriate Drug Identification Number (DIN) and the quantity of methadone 10mg/mL oral concentrate dispensed.
- The quantity must reflect only the amount of methadone 10mg/mL oral concentrate dispensed, and must not include any amount of drink mix (e.g., Tang®) also included in the bottle dispensed.
 - one claim is submitted for each witness dose and one claim is submitted for **each** daily supply carry dose that is provided to the ODB recipient
 - claims for witness doses and individual carry doses must be submitted on the date that the witness dose and/or carry doses are dispensed
 - a maximum of one dispensing fee may be claimed per ODB recipient per daily dose
- For example, if you have a prescription for one witnessed dose on Monday and 6 carry doses for Tuesday through Sunday, on Monday the claims appear as follows:
 - one claim is submitted for the Monday witnessed dose
 - one claim is submitted for the Tuesday carry dose
 - one claim is submitted for the Wednesday carry dose; and so on for Thursday, Friday, Saturday and Sunday
 - each claim for the carry doses is submitted on the day that the carry doses were dispensed (i.e., Monday in this example)
- In other words, on Monday when all of the doses were dispensed, a total of 7 claims with 7 dispensing fees would have been submitted to the Ministry for payment through the HNS.
 - When more than one claim is submitted for the same DIN on the same day for the same patient, the HNS will reject the second (and subsequent) claim(s) with response code "A3" – identical claim processed which can be overridden with an appropriate intervention code. Please refer to the Ontario Drug Programs Reference Manual for intervention codes.
 - If replacement claims are required because of dose changes after carry doses have already been dispensed, the replacement claims are not eligible for additional dispensing fees as this would exceed the maximum number of dispensing fees allowed. Similarly, additional doses to supplement the carry doses already dispensed are not eligible for additional dispensing fees.
- All labels must adhere to all Ontario College of Pharmacists policies and guidelines including the dose and date of ingestion on each labelled bottle.
- No co-payment amount may be collected from ODB eligible persons or a private third party for ODB eligible persons receiving methadone for MMT. However, additional charges such as ODB deductible amounts and out-of-pocket charges for patients who

request a higher priced interchangeable product but do not meet the medically necessary “no substitution” requirements are eligible to be collected.

- No compounding time or charge is permitted for the dispensing of methadone 10mg/mL oral liquid. For example, when methadone 10mg/mL oral concentrate is diluted prior to dispensing, this practice is not considered compounding.
- No other ingredient costs may be added to the amount billed to the ministry (i.e., cost of distilled water or drink mix (e.g., Tang®) may not be billed to the ministry in addition to the cost of methadone amount already being reimbursed).
- If an ODB recipient’s dose is changed by their prescriber after the ODB recipient’s carry doses have already been dispensed (i.e., the dispensing fee from that day’s dose has already been billed with the original carries), the replacement claim must not include a dispensing fee.
- The quantity of methadone 10mg/mL oral concentrate used in dispensing the final prescribed methadone dose must be entered as milliliters (mLs) of drug dispensed. The milligrams of methadone prescribed must be converted to mLs of methadone 10mg/mL oral concentrate dispensed and entered as a single dose for the submission to the HNS and the Narcotics Monitoring System (NMS). For example, if the physician prescribed methadone 100 mg each day, the claim submission to the HNS and the NMS record must indicate a quantity of 10 mLs of methadone 10mg/mL oral concentrate.
- The pharmacy-generated prescription label must comply with the appropriate Ontario College of Pharmacists policies and guidelines.
- The drug cost, plus the applicable % mark-up and the applicable dispensing fee are to be submitted on-line via the HNS. The prescription receipt must indicate a zero co-payment amount.
- Methadone used for the treatment of chronic pain is not eligible for reimbursement under this Policy. An application for funding consideration must be submitted by an authorized prescriber to the Exceptional Access Program for any ODB eligible patient who is prescribed methadone for chronic pain.

Use of extemporaneous compounded methadone liquid:

- Effective September 1, 2014, the extemporaneously compounded methadone solution prepared using methadone powder is no longer funded under the ODB program for MMT.
- However, compounded methadone (using methadone powder) under the Policy may only be dispensed to patients who have had an allergic reaction to all manufactured methadone products listed on the Formulary. Exceptional Access Program approval is required.

Amendments and Updates

The Ministry may make changes to this Policy at any time upon giving at least 30 days' notice to Ontario pharmacy operators.

Prior EO Notices

- Executive Officer Notice: Policy for Methadone Maintenance Treatment Reimbursement under the Ontario Drug Benefit Program, 2014, effective June 26, 2014.
- Executive Officer Notice: Policy for Methadone Maintenance Treatment Reimbursement under the Ontario Drug Benefit Program 2020, effective April 1, 2020.

Additional Information:**For pharmacy inquiries and billing:**

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.