

Questions and Answers for Pharmacies: Policy for Methadone Maintenance Treatment (MMT) Reimbursement under the Ontario Drug Benefit Program

July 28, 2022

Methadone Maintenance Treatment Reimbursement Policy, 2022

Effective August 31, 2022, the *Methadone Maintenance Treatment Reimbursement Policy, 2022* replaces the *Methadone Maintenance Treatment Reimbursement Policy, 2020*

(hereinafter, referred to as the “**Policy**”). These updated Q&As for pharmacies¹ are part of the Policy.

Updates included in the *Methadone Maintenance Treatment Reimbursement Policy, 2022*

1. What has changed in the *Methadone Maintenance Treatment Reimbursement Policy, 2022* from the previous 2020 Policy?

Two generic formulations of methadone hydrochloride 10mg/mL oral concentrate will be added to the Ontario Drug Benefit Formulary (Formulary) effective August 31, 2022.

With the introduction of these products to the Formulary, pharmacists are encouraged to discuss these changes with patients and prescribers. As such, a transition period is being provided (from August 31, 2022 to September 28, 2022), during which time lowest cost Drug Benefit Price (DBP) interchangeable payment rules will not apply.

Under the Policy, during the transition, for ODB patients, Methadose (unflavoured) DIN 02394618 may be dispensed and will be reimbursed at the Drug Benefit Price (DBP) listed

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.

on the Formulary, pursuant to a valid prescription, without the patient needing to meet medically necessary “no substitution” requirements, as outlined in the Ontario Drug Programs Reference Manual. Under the Policy, this is a temporary exception to the normal interchangeability payment rules and the prescriber is not required to write ‘no sub’ on the prescription written for Methadose in order for the Methadose DBP to be paid to the pharmacy.

Alternatively, prescriptions written for Methadose (unflavoured) DIN 02394618 or methadone can be dispensed as per usual interchangeability rules using either of the newly listed generic formulations that are deemed interchangeable. It is important that pharmacists have discussions with their individual patients and prescribers about appropriate supports being in place to ensure patient safety for transitioning to an interchangeable generic product.

After the transition period (i.e. as of September 29, 2022), the lowest cost interchangeable DBP is paid for a methadone product in an interchangeable category.

2. Why is the ministry allowing a transition period to the standard rule of paying the DBP of the lowest cost interchangeable product?

The ministry has received feedback from stakeholders since generic formulations of methadone were introduced to the Canadian market. In addition, Health Canada posted two “Dear Healthcare Professional Letters” in [March 2020](#) and [July 2020](#) regarding switching of methadone hydrochloride oral concentrate products.

The product monographs for methadone products listed on the Formulary state the following:

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.

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. Patients should be clinically managed and monitored regularly after being switched from any methadone-containing product to another.

3. What are the interchangeable products being added to the Formulary?

Effective with the August 31, 2022 Formulary update, two generic formulations of methadone hydrochloride 10mg/mL oral concentrate from two manufacturers (Jamp Methadone DIN 02495783 and Odan-Methadone DIN 02495880) will be listed as interchangeable, as noted in Table 1, with Methadose (unflavoured) DIN 02394618.

Table 1: Methadone oral concentrate Formulary listings

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

Note: Methadose (cherry flavour) DIN 02394596 and Metadol-D DIN 02244290 are not designated as interchangeable with any products on the Formulary.

4. If my patient is taking Methadose unflavoured, what product should I dispense once the methadone interchangeable listing changes take effect?

Please refer to the standard interchangeability rules in the *Drug Interchangeability and Dispensing Fee Act*.

With respect to ODB payment rules, please refer to the Executive Notice regarding the *Methadone Maintenance Treatment Reimbursement Policy, 2022* available on the [ministry's website](#) for more information about the drug cost paid for dispensing a methadone product in an interchangeable category.

Pharmacists are encouraged to discuss with patients switching from Methadose to a generic formulation in accordance with applicable interchangeability and ODB pricing rules, patients should be monitored as per the precautions noted above.

5. Under what conditions can a pharmacy be paid the Drug Benefit Price of unflavoured Methadose on the Formulary?

Please refer to the Executive Notice regarding the *Methadone Maintenance Treatment Reimbursement Policy, 2022* available on the [ministry's website](#) for more information about the drug cost paid for dispensing a methadone product in an interchangeable category.

Note: The MMT policy information below includes minimal clarifications to questions 16, 17, 19 and 24 from the 2020 Policy. These updates are not affected by the ODB Formulary changes related to the introduction of interchangeable generic methadone formulations.

6. How is a claim for methadone 10mg/mL oral concentrate reimbursed under the Policy?

Methadone 10mg/mL oral concentrate is listed on the Formulary with a Drug Benefit Price (DBP) (or Amount MOH Pays) per mL. Claims for methadone 10mg/mL oral concentrate for methadone maintenance treatment (MMT) follow the same rules as all other ODB claims, except that the co-payment cannot be collected from the ODB recipient and one dispensing fee per daily supply (i.e., one fee for each witnessed or daily supply carry dose) may be submitted to the Health Network System (HNS). See below for instructions on calculating reimbursement:

- Drug cost = DBP x volume (mL)
- + Mark up: applicable %
- + Dispensing Fee: (or applicable rural fee)
- **\$0, \$2 or \$6.11 depending on the eligibility stream of the ODB recipient**

7. How are methadone carry doses reimbursed under the Policy?

Under the Policy, 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.

For example, if you have a prescription for one witnessed dose on Monday and 6 carry doses for Tuesday through 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 submitted on Monday. The claims appear as follows:

- one claim with a dispensing fee is submitted for the Monday witnessed dose;
- one claim with a second dispensing fee is submitted for the Tuesday carry dose;
- one claim is submitted with a third dispensing fee 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 the example above, where 1 witness dose and 6 carry doses are dispensed, a total of 7 dispensing fees are permitted.

In other words, on Monday when all of the doses were dispensed, a total of 7 claims and 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 (ODP) Reference Manual for intervention codes.

All labels must adhere to all Ontario College of Pharmacists policies and guidelines including the dose and date of ingestion on each labelled bottle.

8. What is the dispensing fee under the Policy?

Under the Policy, pharmacies will be paid their applicable ODB dispensing fee (which could be a rural dispensing fee if that applies) for each day’s supply of methadone 10mg/mL liquid that is dispensed, minus the recipient’s co-payment that would apply to other drug claims.

As per the response in Question 7, a dispensing fee is paid for each daily supply of MMT dispensed whether it is a witnessed or a carry dose. All claims submissions for carry doses are submitted on the day the carry doses were dispensed to the patient which is typically on the same day as the witnessed dose.

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 ODP Reference Manual for intervention codes.

Pharmacies are NOT permitted to charge the co-payment to ODB eligible patients or a private third-party when dispensing methadone 10mg/mL oral liquid for MMT. This includes the co-payment of \$0, \$2.00 or \$6.11 depending on the ODB recipient’s eligibility and it includes both witnessed and carry doses of methadone. 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.

9. How do I enter the dose quantity of one of the ODB listed methadone 10mg/mL oral concentrate products into the pharmacy system?

The ministry requires that the prescribed milligram (mg) dose of methadone 10mg/mL oral concentrate be converted to millilitres (mLs) of drug dispensed and entered as a single dose for the submission to the HNS and the Narcotics Monitoring System (NMS). For example, if a physician prescribed 75mg of methadone each day, the claim submission to the HNS and the NMS record must indicate a quantity of 7.5mL of methadone 10mg/mL oral liquid.

10. Our pharmacy system software is not designed with a decimal place for the quantity dispensed. How can I input the correct quantity of 7.5mL for a 75mg dose?

Please contact your pharmacy software vendor to activate the decimal point on your software, if necessary. Software vendors have confirmed that decimal points can be accommodated on software systems.

Decimal Places and Claims Standards

The Health System Network uses CPhA V. 3 Claims standard which supports volumes with one decimal place. For example, a dose of 75mg of methadone would be a volume of 7.5mL.

For some claims, the dose may need to be adjusted. For example, a dose of 2.5mg of methadone would be equal to 0.25mL of 10mg/mL oral concentrate. As a result, the dose may need to be adjusted to 3mg or 2mg. This will require a physician's written authorization.

11. How can I appropriately measure small doses of MMT?

The pharmacist must measure the appropriate dose of methadone 10mg/mL oral concentrate using an appropriate measuring device. All prescribed doses of methadone 10mg/mL oral concentrate can be measured using the appropriate equipment and / or by applying dilution calculations for pediatric dosing.

12. Can I dilute methadone 10mg/mL oral concentrate with drink mix (e.g., Tang®) as was previously done for patients receiving compounded methadone liquid?

Methadone 10mg/mL oral concentrate must be diluted prior to dispensing, as per the requirements under the Ontario College of Pharmacists Policy and Guidelines. The practice of diluting methadone 10mg/mL oral concentrate with any diluent including drink mix (e.g., Tang®) is not considered compounding under the ODB program and is not eligible for reimbursement as an extemporaneous preparation.

13. Will the pharmacy be reimbursed for the cost of drink mix (e.g., Tang®) and distilled water that is used to prepare the methadone dose for the patient?

No. The Ministry will reimburse the pharmacy only for the Drug Benefit Price as listed on the Formulary (see Amount MOH Pays) in respect of each claim for methadone 10mg/mL oral concentrate plus a % mark-up on that amount.

14. When we bill the methadone 10mg/mL oral concentrate, do we submit the claim as a regular drug product, or should we bill it as a compound?

Methadone 10mg/mL oral concentrate must be diluted prior to dispensing, as per the requirements under the Ontario College of Pharmacists applicable Policy and Guidelines. The practice of diluting methadone 10mg/mL oral concentrate with any diluent including drink mix (e.g., Tang®) is not compounding and is not eligible for reimbursement as an extemporaneous preparation. The claim should be submitted for the drug product in accordance with the Policy.

15. Can the pharmacy charge the ODB recipient or a private third party a co-payment for MMT?

No. Under the Policy, pharmacists are not allowed to charge a co-payment to ODB eligible patients or other private third party when dispensing methadone liquid for MMT, even though the dispensing fee paid is reduced by \$0, \$2 or \$6.11 based on the recipient's co-payment for other drug claims.

16. Can the pharmacy charge any other costs to an ODB recipient related to the dispensing of MMT?

Yes. Pharmacists may charge ODB recipients costs towards their annual ODB deductible fees if applicable. In addition, patients who choose a higher priced brand product but fail to meet the medically necessary "no substitution" requirements, as outlined in the Ontario

Drug Programs Reference Manual, may be charged the cost difference between a lower cost interchangeable drug and the brand.

17. Will the Health Network System (HNS) be transmitting a patient pays value = \$0.00 back to the pharmacy OR will it transmit a value of \$2.00 or \$6.11?

Since the claim is being processed in the same manner as other ODB claims, the HNS does not transmit a \$0.00 patient co-payment value. Pharmacists must ensure the patient co-payment value of either \$2.00 or \$6.11 on the patient prescription receipt is changed to a zero value and patients are not charged the co-payment.

18. How are split or supplemental doses reimbursed under the Policy?

According to the Policy, “One fee is paid for each daily supply that is provided to an eligible person...”

If there are split or supplemental doses, the pharmacy must submit only one fee for each day’s total supply. For example, 30mg methadone twice daily, dispensed as two prescriptions, means that for the first claim the fee must be included but for the second claim on that day, no fee can be submitted (i.e., only drug cost and mark-up). Additional fees are not eligible for reimbursement.

19. What is the required information on the prescription label?

The pharmacy-generated prescription label must comply with the usual methadone maintenance treatment prescription label requirements as outlined by Ontario College of Pharmacists’ [Policy](#) and include the methadone dose and the date of ingestion.

20. For patients working towards their Trillium deductible, will all fees/costs be applied towards their deductible? What happens when the Trillium deductible has been met?

Yes, all eligible fees and costs for prescriptions, including methadone can be applied towards a patient’s Trillium deductible provided the costs were paid out of pocket by the patient. When the deductible has been met, claims may be submitted for ODB recipients as per the terms of the Policy.

21. Will compounded methadone solution be reimbursed under the ODB program?

Effective September 1st, 2014 claims for extemporaneously compounded methadone solution are not eligible for payment under the ODB program.

However, compounded methadone (using methadone powder) under the Policy may 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.

22. Are prescriptions for methadone oral concentrate for chronic pain reimbursed under the ODB Program?

An application for funding consideration must be submitted by an authorized prescriber to the Exceptional Access Program for any ODB eligible patients who are prescribed methadone for chronic pain.

The Policy does not apply to methadone for chronic pain.

23. How are replacement claims billed if there is a dose change after carries have been dispensed?

If the prescribed dose is changed after carry doses for an ODB recipient have already been dispensed, (i.e., the pharmacy has already billed a dispensing fee for that ODB recipient for that day's dose with the original claim), the replacement claim(s) must not include a dispensing fee. A maximum of one dispensing fee is eligible for payment per ODB recipient per daily dose. 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.

24. I work at a pharmacy that dispenses to residents of a long-term care (LTC) home, does the Policy apply to the dispensing fees for these patients if they are prescribed MMT?

The Policy does not apply to 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 payments to Primary PSPs. 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 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

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.