

Methadose and the Policy for Methadone Maintenance Treatment Reimbursement under the Ontario Drug Benefit Program

Frequently Asked Questions for Pharmacists

Methadose[®] (methadone hydrochloride oral concentrate 10mg/mL) will be listed on the Ontario Drug Benefit (ODB) Formulary (Formulary) as a General Benefit on June 26th, 2014. Methadose is indicated for substitution treatment in opioid drug dependence.

As of August 1st, 2014, after a one-month transition, the ODB program will only cover Methadose 10mg/mL for ODB-eligible recipients receiving Methadone Maintenance Therapy (MMT). Effective August 1st, 2014, claims for extemporaneously compounded methadone solution (PIN 09850619) prepared using methadone powder will no longer be eligible for payment under the ODB program.

Recognizing the importance of clinician communication and patient education with respect to changes in MMT program delivery, the ministry is allowing the transition period to identify any outstanding concerns that might occur and to allow pharmacies time to deplete their stock of methadone powder.

All Ontario pharmacies are required to comply with the *Methadone Maintenance Treatment Reimbursement Policy, 2014* effective June 26th, 2014.

Why is the ministry introducing changes to the reimbursement of methadone for MMT?

This decision was recommended by the ministry's expert advisory group, the Committee to Evaluate Drugs and was made in consultation with ministry officials, other Canadian jurisdictions that reimburse Methadose for MMT, and external stakeholders. The change may reduce the risks associated with manual compounding.

When can I start dispensing Methadose for MMT?

As of June 26th, 2014, pharmacists may begin dispensing Methadose to eligible ODB patients receiving MMT.

What happens to my existing Methadone (MMT) Capitation Agreement between the pharmacy and the Ministry?

Pharmacies that hold the MMT Capitation Agreement with the Ministry (i.e., the Executive Officer) are notified that their respective agreement will end on June 25th, 2014, one day prior to the effective date of the *Methadone Maintenance Treatment Reimbursement Policy, 2014*.

What has changed in regards to submitting a claim under ODB for MMT using Methadose?

Under the new *Methadone Maintenance Treatment Reimbursement Policy, 2014*, the ministry will pay pharmacies that dispense MMT one ODB dispensing fee per day (minus the applicable co-payment) for dispensing Methadose solution for an ODB recipient. This is payable only in respect of those days for which a daily supply of the drug is provided to the patient and for which a claim is submitted through

the ODB Health Network System. As per standard reimbursement, payment includes the drug cost as indicated by the Drug Benefit Price (DBP) in the ODB Formulary and the 8% markup on that cost. No compounding fees are allowed for Methadose solution.

What is the dispensing fee for MMT if the pharmacy is classified with an approved “rural dispensing fee”?

The ministry will pay pharmacies that dispense MMT their respective ODB dispensing fee, minus the applicable patient co-payment. Under the *Methadone Maintenance Treatment Reimbursement Policy, 2014*, pharmacies must adjust their claims submissions to reflect that no co-payment is charged to the ODB eligible patient.

How do I enter the dose quantity of Methadose solution into the pharmacy system?

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

What is the required information on the prescription label?

The pharmacy-generated prescription label must comply with the OCP *Methadone Maintenance Treatment and Dispensing Policy* and indicate the methadone dose and the date of ingestion.

Can the pharmacy charge the ODB recipient a co-payment for Methadose?

No. Under the *Methadone Maintenance Treatment Reimbursement Policy, 2014* effective June 26th, 2014 pharmacists are not allowed to charge a co-payment to ODB eligible patients when dispensing Methadose solution.

Will compounded methadone solution dispensed on or after July 31st be reimbursed under the ODB program?

Effective August 1st, 2014, claims for extemporaneously compounded methadone solution (PIN 09850619) prepared using methadone powder will no longer be eligible for payment under the ODB program. Claims submitted on July 31st, 2014 for extemporaneously compounded methadone solution are still eligible.

For certain exceptional circumstances for patients who have experienced a true allergy to both formulations of Methadose, the patient’s physician may submit a request for consideration of funding for compounded methadone under the ODB Exceptional Access Program. The request must be accompanied by a completed Health Canada adverse drug reaction form (Canada Vigilance Adverse Reaction Reporting Form) and include a detailed description of the allergic reaction to each Methadose product, a description of the circumstances in which the reactions occurred and demonstration that the allergy is unlikely related to any diluent in which Methadose was mixed but rather that it was caused by the excipients within the Methadose formulation.

Will prescriptions for compounded methadone solution for chronic pain continue to be reimbursed under the ODB Exceptional Access Program?

As per the drug manufacturer's product monograph, Methadose is only indicated for substitution treatment in opioid drug dependence and as such, it is only funded under the ODB program for MMT. ODB patients receiving methadone for the treatment of chronic pain will continue to receive the methadone product that has been prescribed for them and if applicable approved for funding under the Exceptional Access Program.

An application is required to be submitted to the Exceptional Access Program for any new ODB eligible patients who are prescribed methadone for chronic pain.

Will new PINs be introduced to bill for Methadose in the Health Network System (HNS)?

No. Claims submission for Methadose solution will be transmitted using the drug identification number (DIN). Please refer to the ODB Formulary listing and the *Methadone Maintenance Treatment Reimbursement Policy, 2014* for more information.

How can I appropriately measure small doses of Methadose?

The pharmacist must measure the appropriate dose of Methadose using a measuring device as outlined in the OCP *Methadone Maintenance Treatment and Dispensing Policy*. All prescribed doses of Methadose can be measured using the appropriate equipment and / or by applying dilution calculations for pediatric dosing.

Can I dilute Methadose with Tang® as was previously done for patients receiving compounded methadone solution?

Methadose 10mg/mL oral solution is funded under the ODB Formulary as either a cherry flavoured solution or an un-flavoured, sugar-free, dye-free solution.

Methadose 10mg/mL oral solution must be diluted prior to dispensing, as per the requirements under the OCP *Methadone Maintenance Treatment and Dispensing Policy*. The practice of diluting Methadose with any diluent including Tang is not considered compounding under the ODB program and is not eligible for reimbursement as an extemporaneous compound.

How will the change affect patients?

Given that pharmacists will continue to dilute methadone doses to 100 mL using a vehicle that does not lend itself to injection (e.g. Tang), most patients will not observe any changes compared to the previous methadone solution. However, for some patients it is possible they may note differences in the dispensing of Methadose versus compounded methadone solution, including:

Colour change: Methadose is available as a colourless (flavourless) or red colour (cherry) formulation. Depending on the formulation of Methadose that is dispensed, there may or may not be a change in the colour of the final dose dispensed to the patient.

Different taste: Methadose is available as flavourless or cherry-flavoured formulations. Depending on the formulation dispensed, the final methadone dose may or may not have a different flavour.

Volume: Pharmacists are required to dilute Methadose oral solution prior to dispensing as per the OCP *Methadone Maintenance Treatment and Dispensing Policy*. Therefore the final volume dispensed should remain the same.

Viscosity: Methadose may impact the viscosity or consistency of the final product dispensed to patients. Patients may perceive this change as being slightly thicker or “stickier”.

Pharmacists are reminded that monitoring of adverse events may be necessary during the transition period of compounded methadone solution to Methadose solution.

Due to the differences in formulations it is important for physicians and pharmacists to communicate these changes to patients. The new strength of methadone used to prepare the methadone dose may also pose a public safety risk during this time of transition, therefore careful management and communication between physicians and pharmacy staff involved in the preparation of doses is encouraged.

How can I appropriately educate my patient about this change?

Physicians who write prescriptions for methadone for any indication are held accountable for educating their patients on safety concerns related to their treatment regimen. This may include advising patients on the transition to Methadose for MMT and the differences between the old and new formulations (including change to the base solution, colour change, different taste etc.).

Pharmacists are also required to provide patient counselling and supplemental education and in turn meet the requirements of the OCP *Methadone Maintenance Treatment and Dispensing Policy*.

Pharmacists may also direct patients to resources posted on the Ministry of Health and Long-Term Care’s website, which include a patient Frequently Asked Questions (FAQ) document /patient Fact Sheet.

For more information

For additional information including patient and physician frequently asked questions and the *Methadone Maintenance Treatment Reimbursement Policy, 2014*, please visit the Ministry website at: <http://www.health.gov.on.ca/en/public/programs/drugs/>

You may also email your questions to: PublicDrugPrgrms.moh@ontario.ca