Ontario Public Drug Programs, Ministry of Health and Long-Term Care

Regulation Amendments in support of Sustainability and Access for the Ontario Drug Benefit Program

Questions and Answers for Physicians

Responsible management of health care is part of the government's plan to build a better Ontario through its Patients First: Action Plan for Health Care, providing patients with faster access to the right care, better home and community care, the information they need to live healthy and a health care system that's sustainable for generations to come.

The Ministry of Health and Long-Term Care (the "ministry") is making changes to pharmacy payments, fees and program policies under the Ontario Drug Benefit (ODB) program to make the program more efficient, effective and responsive to today's patients.

These initiatives represent a fair and balanced approach to generating savings and will contribute to the Province's efforts to identify short- and longer-term opportunities to ensure continued patient access to drugs. These changes will enable the government to achieve savings of over $200 million annually when fully implemented, as per the 2015 Ontario Budget.

Amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* will come into force of October 1, 2015 to support these ODB program changes. For more information, please visit our website at: http://www.health.gov.on.ca/en/public/programs/drugs/

Any remaining questions can be emailed to the Ontario Public Drug Programs at: PublicDrugPrgrms.moh@ontario.ca

Mark-up Reduction for High-Cost Drugs

1. How will this change affect ODB recipients?

Reducing the mark-up paid to pharmacies for high-cost drugs will not impact ODB recipients as they will continue to pay their usual co-payment (up to $6.11, depending on eligibility) when filling their prescriptions. The mark-up on a drug product is paid to pharmacies by the Government.

For ODB prescriptions, the components of a prescription cost paid to pharmacies include the ODB Drug Benefit Cost plus mark-up plus the ODB dispensing fee minus the recipient co-payment amount.

Dispensing Fee Reduction for Claims for Residents of Long-Term Care Homes

2. How will this change affect residents of Long-Term Care Homes?

Reducing the ODB dispensing fee reimbursed to Long-Term Care Home (LTCH) pharmacy service providers will not be expected to impact LTCH residents who will continue to pay up to

$2.00 towards the cost of their prescriptions through their servicing pharmacy's usual co-payment arrangements.

Please note that ODB dispensing fees may vary depending on whether a pharmacy is located in a rural or urban area. Pharmacies located in rural areas are typically paid a higher ODB dispensing fee.

Maximizing the Quantity Dispensed for Chronic-Use Medications

3. How will this change affect ODB recipients?

By establishing a limit on the number of dispensing fees that can be billed to the Ministry in a year, the government will encourage pharmacists to provide ODB recipients with enough medication for a 3-months' supply for certain chronic-use medications they have been taking for a long time, making it more convenient and less expensive for recipients to fill their prescriptions.

4. What are the 15 classes of chronic-use medications that are affected?

Table 1: Chronic-use medications list

Chronic-Use Drug Category	**ODB Drug Product Examples***
ACE Inhibitors	Enalapril, ramipril, quinapril
Angiotensin II Receptor Blockers	Candesartan, irbesartan, valsartan
Beta-Blockers	Atenolol, metoprolol, sotalol
Calcium Channel Blockers	Amlodipine, diltiazem, nifedipine
Other Drugs Used for Hypertension	Methyldopa, prazosin, terazosin
Other Cardiac Drugs	Amiodarone, digoxin, isosorbide, pentoxifylline
Statin Drugs Used to Lower Cholesterol	Atorvastatin, lovastatin, rosuvastatin
Other Drugs Used to Lower Cholesterol	Bezafibrate, ezetimibe, gemfibrozil
Oral Anti-diabetic Agents	Glyburide, metformin, saxagliptin
Diuretics	Furosemide, hydrochlorothiazide, indapamide
Drugs Used for GI Conditions	Famotidine, misoprostol, omeprazole, sucralfate
Drugs Used to Prevent Gout	Allopurinol
Oral Iron Replacement Therapy	Ferrous fumarate, ferrous gluconate
Drugs Used for Osteoporosis	Alendronate, raloxifene, risedronate
Drugs Used for Prostate Conditions	Dutasteride, silodosin, tamsulosin

*List is not exhaustive

The full list of medications that fall under the 15 categories of chronic-use medications that are subject to the 5 dispensing fees per 365-day period rule is posted on the ministry website at: http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx. This list will be updated on an as-needed basis.

5. What types of ODB recipients are exempt from this change?

ODB recipients who require more frequent dispensing due to an established physical, cognitive or sensory impairment, or because they are on a complex medication regimen where their safety is at risk, can continue to receive their chronic-use medications at more frequent intervals.

Where the dispenser has determined, in his or her professional opinion, that the ODB recipient is incapable of managing his/her medication regimen as a result of physical, cognitive or sensory impairment or a complex medication regimen where the recipient's safety is at risk, the dispenser is required to notify the prescriber with the rationale for the decision.

Documentation must include the reason for this opinion, the dispenser's notification to the prescriber, as well as a record of the authorization received from the ODB recipient (or person presenting the prescription) for dispensing in reduced quantities. The nature of the physical, cognitive or sensory impairment or complex medication regimen must be clearly documented, including clinical or safety risks to the patient if larger quantities were dispensed.

These authorizations are valid for a period of 365 days and are required to be updated annually, and maintained as part of the ODB recipient's permanent pharmacy health record.

ODB recipients who are deemed to require more frequent dispensing will need to be assessed regularly to verify an ongoing need for more frequent dispensing. For example, a patient on a complex medication regimen may require assistance for a short period of time, in order to learn to manage their medications as directed, but once stabilized, may be capable of managing 100 day supplies.

The conditions for payment of a dispensing fee for chronic-use medications do not apply to Ontario Works (OW) recipients, LTCH residents and residents of publicly-funded residential care facilities listed on the ministry's website (i.e. Homes for Special Care). All extemporaneous preparations of chronic-use medications are also exempt from this change.

6. What can physicians do to support this change?

Where appropriate, physicians are encouraged to prescribe the maximum quantity (i.e. 100 days) for the 15 categories of chronic-use medications affected by this change.

Physicians are also encouraged to discuss this change with their patients, and help to identify ODB recipients who may require more frequent dispensing by documenting an appropriate clinical reason on the recipient's prescription that reflects the established exemption criteria.

Reimbursement of Medically Necessary "No Substitution" Claims

7. Why is the ministry changing the current "no substitution" policy?

The ministry is changing the "no substitution" policy in order to increase the use of safe and effective generic alternatives to brand name products.

Generic drugs approved for use by Health Canada are as safe and effective as their brand name counterparts, but cost significantly less. Increasing the use of generic drug products offers enormous cost saving potential for our health care system.

8. How will this change affect ODB recipients?

A "no substitution" prescription allows ODB recipients to receive a higher-cost brand name drug when they have had an adverse drug reaction to a generic equivalent and now require the brand name drug product for safety reasons.

Effective October 1, 2015, the government will require ODB recipients to try two lower-cost generic drug products (where available) before a "no substitution" prescription for a brand name drug will be reimbursed under the ODB program. This will maximize the use of safe and effective generic alternatives and provide better value to taxpayers.

9. How will a "no substitution" prescription be reimbursed where two or more lower-cost interchangeable drug products are not available?

Where only one lower-cost interchangeable generic product is listed as a benefit, the ministry will reimburse the higher-cost brand product, provided the ODB recipient has tried the one lower-cost generic and has experienced a significant adverse reaction. Prescribers will still be required to indicate "no sub" (either hand written in the case of a written prescription or verbally in the case of a verbal prescription) and complete a copy of the Health Canada's Canada Vigilance Adverse Reaction Reporting Form.

10. What additional documentation am I required to supply in support of this change?

Prescribers are required to complete, sign and forward to the pharmacist a copy of the Health Canada Canada Vigilance Adverse Reaction Reporting Form for **each** lower-cost interchangeable drug product trialed, and will continue to be required to write a "no substitution" or "no sub" on a written prescription or indicate "no substitution" to the pharmacist in the case of a verbal prescription. The form(s) must be completely filled out noting the details of the adverse reaction(s) and signed by the prescriber.

Upon receipt of a "no substitution" prescription, the pharmacist will continue to:

- Clearly note on each adverse drug reaction form(s) - "**ODB NO SUBSTITUTION**"; and
- Fax or mail the completed and signed form(s) to Health Canada's Canada Vigilance Program if not already submitted by the prescriber; and

- Retain copies of the completed and signed adverse drug reaction form(s) in a readily retrievable format at the pharmacy.

Health Canada adverse drug reaction forms do not have an expiry date and serve as a permanent record.

11. How will this change affect my patients with an existing “no substitution” prescription?

ODB recipients with a valid “no substitution” prescription that was filled **prior** to October 1, 2015 will be permitted to renew and refill their brand therapy as directed, as long as the appropriate documentation remains on file.

If an ODB recipient chooses to exercise their personal preference for the brand therapy without trying one or more lower-cost generic drug products, pharmacists may continue to provide them with their choice and it will be the responsibility of the recipient to pay for any cost difference as per the usual process.

In light of the changes, physicians and pharmacists are encouraged to discuss alternative lower-cost treatment options, where available, with their patients.

12. Where can I find more information on generic drugs?

If you would like more information on the interchangeability of brand and generic drugs, please visit:

http://www.rxfiles.ca/rxfiles/uploads/documents/Bioequivalency-QandA-Links.pdf

https://www.cadth.ca/sites/default/files/pdf/similarities_differences_brandname_generic_drugs_e.pdf