Ontario Public Drug Programs Division

Application of Generic Substitution to the Exceptional Access Program - Frequently Asked Questions for Pharmacists

October 7, 2016

1. Why is the ministry applying a Generic Substitution policy to the Exceptional Access Program (EAP)?

Currently where there are generic Off-Formulary Interchangeable (OFI) drug products available for a brand name drug, the ministry's EAP approval allows for the dispensing of the brand name drug or the generic drug. The ministry is now applying a Generic Substitution policy to the EAP in order to increase the use of safe and effective generic alternatives to brand name products. Under the policy, the ministry will only approve the funding of the generic product, unless the Ontario Drug Benefit recipient has a prescription directing the dispensing of the brand product with "no substitution" and the recipient has a documented adverse reaction to at least two (2) generic versions of the drug.

Generic drugs approved for use by Health Canada are as safe and effective as their brand name counterparts. Increasing the use of generic drug products offers cost savings for our healthcare system to allow for the funding of new innovative drug therapies.

Ontario is the only province in Canada that does not have a generic substitution requirement for drugs that require special authorization.

2. When does the new policy become effective?

The new policy will become effective on **November 1, 2016**. Changes will be made in the Health Network System (HNS) to enforce this policy starting November 1, 2016.

3. What are the changes to the ODB electronic Formulary (e-Formulary)?

To support this policy, the e-Formulary will have several enhancements as of October 11, 2016.

- OFI drug products will be displayed as such and their unit costs will be displayed as well. Currently this information is only available in the Edition 42 Formulary pdf document.

- OFI drug products that are reimbursed through the EAP will have the notation of "Exceptional Access Program Product" and there will be an "Amount MOHLTC Pays" displayed, informing the pharmacist the reimbursement amount for a particular drug from the ministry. For brand name products with OFI generics reimbursed through the EAP, the "Amount MOHLTC Pays" will be the unit cost of the highest-priced OFI generic in the interchangeable category. For all OFI generics that are reimbursed through the EAP, the "Unit Cost" and the "Amount MOHLTC Pays" values will be the same.

- For brand name products of OFI generics that are discontinued, both the "Unit Cost" and the "Amount MOHLTC Pays" will be displayed as "N/A." This is also the case with brand name products of OFI generics reimbursed through the EAP that do not have product listing agreements with the ministry. For brand name products funded under the EAP that do not have product listing agreements, although the unit cost information is not displayed, the brand product claims in the HNS will still be reimbursed according to this new generic substitution policy.

Another enhancement to the e-Formulary will be the addition of the notation "Chronic-Use Medication" to applicable drugs.

4. What price will I be reimbursed when billing for generic OFI products?

Pharmacists will be reimbursed the unit cost of the generic drug that is dispensed, as published in the ODB e-Formulary.

Pharmacists are encouraged to visit the e-Formulary at: https://www.formulary.health.gov.on.ca/formulary/ to familiarize themselves with these enhancements made to the e-Formulary on October 11, 2016.

5. How will this change affect Ontario Drug Benefit (ODB) recipients?

Beginning November 1, 2016, ODB recipients with either an existing or a new approval for an EAP brand name drug will be required to switch to a generic alternative, where available. Patients will be required to try two (2) or more generic alternatives before a "no substitution" prescription for a brand name drug will be reimbursed under the ODB program.

6. **How will a "no substitution" prescription be reimbursed where only one generic version is available?**

Where only one generic product is available, the ministry will reimburse the brand higher-cost brand product, provided the ODB recipient has tried the one generic version and has experienced an adverse reaction. Prescribers will still be required to indicate "no substitution" or "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 Side Effect Reporting Form

If pharmacies have any questions or concerns related to this policy or billing issues, please contact the Ontario Drug Benefit (ODB) Help Desk 1-800-668-6641.

7. **What if an ODB recipient wishes to either start or continue taking a brand name product rather switching to a generic alternative?**

If ODB recipients choose to exercise their personal preference for the brand therapy without trying one or more 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. The same will apply if the ODB recipient's prescriber does not provide the appropriate Side Effect Reporting Form(s) to the pharmacy.

Pharmacists are encouraged to discuss alternative lower-cost treatment options, where available, with these patients and their prescribers.

8. **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 Side Effect Reporting Form for **each** interchangeable drug product trialed, and will continue to be required to write "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 be signed by the prescriber.

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

- Clearly note on the Side Effect Reporting 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. Note: Copies must be kept for two (2) years past the last claim that relied on the adverse reaction form.

Health Canada Side Effect Reporting Forms do not have an expiry date and serve as a permanent record.

The pharmacist will continue to be required to mail or fax the completed form(s), where it has not been submitted by the prescriber, to:

> Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Address locator 0701E, Ottawa, Ontario, K1A 0K9 Fax: 1-866-678-6789

If ODB recipients choose to exercise their personal preference for the brand therapy without trying one or more 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. The same will apply if the ODB recipient's prescriber does not provide the appropriate Side Effect Reporting Form(s) to the pharmacy.

Please note that it is the responsibility of the pharmacist to ensure that the patient qualifies for the use of brand name product in accordance with the No Substitution rules and the proper documentation is readily retrievable upon request. Overpayments due to inappropriate use of "No Substitution" are subject to inspection by the ministry and recovery through post-payment verification.

9. Does the new policy apply to biologics?

No, this policy does not apply to biologics.

It is important to note that this policy, along with its associated rules in the HNS, come into force on November 1, 2016. The changes to the e-Formulary are made in October to allow pharmacists time to familiarize themselves with the changes and provide advanced notices to their patients.

If pharmacies have any questions or concerns related to this policy or billing issues, please contact the Ontario Drug Benefit (ODB) Help Desk 1-800-668-6641.