Ontario Public Drug Programs Division

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

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.

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**.

3. Will patients taking an EAP approved brand drug be required to switch to a generic version?

Yes, beginning November 1, 2016, Ontario Drug Benefit (ODB) recipients with an approval for an EAP brand drug will be required to switch to a generic Off-Formulary Interchangeable (OFI) 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.

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

Similar to an ODB Formulary product, 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.

5. 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 signed by the prescriber.

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

- Clearly note on each 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 drug reaction form.

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

6. Does the new policy apply to biologics?

No, this policy does not apply to biologics.