

Executive Officer Notice: Clarification on Restrictions to the Extemporaneous Preparations Policy

Effective January 8, 2024

This Executive Officer (EO) Notice clarifies certain terms and conditions regarding submitting claims for payment for dispensing extemporaneous preparations under Section 6.1 of the [Ontario Drug Programs Reference Manual](#) (the “Manual”). This document is a Ministry of Health (“ministry”) policy that pharmacy operators must comply with under section 3.2 of the Health Network System (“HNS”) Subscription Agreement for Pharmacy Operators.

This EO Notice is an addendum to the Extemporaneous Preparations Policy in Section 6.1 of the Manual (the “Policy”).

Background:

According to the restrictions regarding the reimbursement of extemporaneous preparations, the Policy stipulates that “*an extemporaneous preparation that is equivalent to a commercially manufactured product*” is ineligible for reimbursement. This would include marketed products that are currently on back-order.

Overview of Change:

Due to the ongoing shortages of necessary drug therapies in Canada, the ministry is updating the Policy to allow for a liquid or capsule for internal oral consumption to be compounded when there is an actual drug shortage of the marketed product OR when the product is listed as ‘dormant’ on Health Canada’s website and where no reasonable alternatives exist (see points below).

Point #5a under the Policy - Restrictions Regarding the Reimbursement of Extemporaneous Preparations has been amended to read:

Note that the following are ineligible for reimbursement:

- a. An extemporaneous preparation that is equivalent to a commercially manufactured product *unless the product is for oral administration and is not commercially available, meaning it has a dormant status on Health Canada’s Drug Product Database or there is a documented shortage of the product either by being listed on Canada’s Drug*

Shortage website or the manufacturer has confirmed the shortage in writing.

For clarity:

- *ODB products with a documented shortage on Canada's Drug Shortages website can be compounded during the period if: (i) the drug is listed on that website (or the shortage period stated in the written communication from the manufacturer), (ii) the preparation is being prepared using a single ODB benefit that is a solid oral dosage form and contains no other medicinally active substance, and (iii) there is no Temporary Benefit option that the ministry has provided as an alternative to the drug that is on shortage.*
- *ODB products with a 'dormant' status on Health Canada's Drug Product Database can be compounded if the preparation is being prepared using a single ODB benefit that is a solid oral dosage form and contains no other medicinally active substance.*

Pharmacies must adhere to the following requirements for an extemporaneous preparation for **oral administration** to be reimbursed under the Policy:

- At the time of claim submission for the extemporaneous preparation, the orally administered product and its interchangeable alternatives must be verified as having a dormant status on Health Canada's Drug Product Database or as an actual drug shortage(s) (i.e., not an anticipated shortage) either listed on Canada's [Drug Shortages website](#) or in written communication from the manufacturer stating that their product is not available.
- There must be no alternative commercially available products funded under the Ontario Drug Benefit ("ODB") Program (e.g., different brand, different strength/format, etc.), including any Health Canada approved product imported to mitigate a shortage (e.g., Temporary Benefits), or alternatives not reimbursed under the ODB Program.
- There is a significant medical need and/or the extemporaneous preparation is the best available treatment option.
- All other criteria under the Policy must be met (e.g., products prepared from medicinally active bulk drug substances [i.e., active pharmaceutical ingredients (APIs)] that are not an ODB benefit are not allowed).
- The product used for compounding must be an ODB benefit that is a solid oral dosage form (i.e., listed on the ODB Formulary or approved for funding through the EAP for the specific patient).
- The pharmacy must maintain proper documentation (e.g., print out of Drug Shortage Report(s), print out of dormant status on Health Canada's Drug Product Database website) demonstrating that the orally administered product and its interchangeable alternatives were commercially unavailable (i.e., on back-order or in dormant status) at the time of dispensing/compounding. The documentation must be provided to the ministry upon request for the purposes of post-payment verification of applicable claims and be kept on file at the pharmacy for the Retention Period¹.
- Documentation of all medicinal and non-medicinal agents added to the

¹ A period of at least 10 years from the last recorded pharmacy service provided to the ODB recipient, or 10 years after the day on which the ODB recipient reached or would have reached the age of 18 years, whichever is longer.

extemporaneous preparation must be on file with the prescription.

- The compounding must meet with NAPRA and/or provincial regulatory guidelines with respect to evidence for stability, efficacy, safety, beyond use dates and requirements for non-sterile compounding as applicable.

An extemporaneous preparation for oral administration does **NOT** qualify for reimbursement:

- If the orally administered product or its interchangeable alternatives are commercially available, but not currently in a pharmacy's inventory.
- If it is equivalent to a product that is commercially manufactured that is not an ODB benefit.

The clarifications to the Policy set out in this EO Notice will be reflected in a future revised version of the Manual.

For additional questions, you may contact one of the following:

For pharmacies:

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