Universal Influenza Immunization Program *(see Section 6.15)*

Policy for Pharmacy Payments under the Long-Term Care Home Capitation Funding Model *(see Section 6.16)*

Valved Holding Chambers *(See Section 6.17)*

6.1 Extemporaneous Preparations

This policy effective on January 1, 2020 replaces the previous extemporaneous preparation policy.

Section 17 of the *Ontario Drug Benefit Act* (ODBA) gives the Executive Officer of the Ontario public drug programs (the "Executive Officer") the authority to:

a) determine the conditions which must be met before a pharmaceutical product, including an extemporaneous preparation, is designated as a designated pharmaceutical product (DPP) and therefore eligible for reimbursement under the Ontario Drug Benefit (ODB) Program; and

b) determine the drug benefit price of a DPP including a formula by which the drug benefit price may be calculated.

Extemporaneous Preparations

An extemporaneous preparation is defined in section 1(1) of O. Reg 201/96 made under the ODBA as a "drug or combination of drugs prepared or compounded in a pharmacy according to a prescription".

In this policy "ODB benefit" refers to any of the following:

- A General Benefit on the Formulary;
- A General Benefit with Therapeutic Notes on the Formulary, where the Therapeutic Note requirements are satisfied by the patient or prescriber, as applicable;
- A Limited Use Benefit on the Formulary, where the Limited Use criteria are satisfied by the patient and the required Reason for Use code appears on the prescription for the patient;
- A drug product approved for the patient under the Exceptional Access Program[1]

[1]It is the responsibility of the dispenser to refer to the list of drugs requiring authorization of funding through the Exceptional Access Program. A searchable list is provided on the Ministry website at the following URL: https://www.ontario.ca/page/check-medication-coverage/

The ODB benefit utilized in an extemporaneous mixture must meet all other reimbursement conditions for that product under the ODB program (e.g., Limited Use Criteria, generic substitution regulations and policies, Medically Necessary "No Substitution" claims, Cost-to-Operator claims).

Only the cost of the quantity of each ingredient used in the preparation of a DPP is eligible for reimbursement. Drug costs for unused or wasted portions of any ingredient are not eligible for reimbursement.

An extemporaneous preparation that meets the general guidelines of compounding activities as described in the Regulatory Framework section of the *Guidance Document for Pharmacy Compounding of Non-Sterile Preparations* published by the National Association of Pharmacy Regulatory Authorities will be deemed by the Executive Officer to be a DPP and therefore eligible for reimbursement under the ODB Program, in the circumstances set out in paragraphs 1 to 4 below, provided that the preparation does not meet any of the exclusion criteria in paragraph 5:

1. The preparation is compounded into a liquid or capsule for internal oral consumption and contains a single ODB benefit that is a solid oral dosage form and no other medicinally active substance. For example, compounded lozenges, lollipops, or other solid or semi-solid formulations are not eligible for funding.

2. The preparation is for dermatological/topical use and:

    a) Contains a single ODB benefit approved by Health Canada for dermatological/topical use and no other medicinally active substances other than one or more of the following: camphor, compound benzoin tincture, hydrocortisone powder, liquor carbonis detergens, menthol, salicylic acid, sulfur or tar distillate; or

    b) is a dermatological/topical nitrogen mustard preparation; or

    c) is a dermatological/topical preparation consisting of liquor carbonis detergens, salicylic acid, sulfur and/or tar distillate, but no other medicinally active substances, and is compounded in petrolatum jelly or lanolin.

    Note: In this section the term "dermatological/topical" refers to a formulation intended for use on the surface of the skin and does not include suppositories or formulations

intended for other routes of administration (e.g., intrathecal, intranasal, rectal, intravaginal).

The combining of two or more ODB benefits (e.g., combining two or more topical ODB benefits approved by Health Canada for dermatological/topical use) is not eligible for reimbursement as a DPP.

3. The preparation is for ophthalmic administration and contains either:

   a) Amikacin, cefazolin or vancomycin; or
   b) Gentamicin or tobramycin in a concentration greater than three milligrams per millilitre.

4. The preparation is for injectable administration and contains:

   a) An ODB benefit that is approved by Health Canada for injectable administration; or

   b) Ingredients used in the preparation of a DPP which is an extemporaneous Total Parenteral Nutrition (TPN) solution; or

   c) An injectable drug product which received a Notice of Compliance from Health Canada on or prior to September 3, 2003 or which is listed by Health Canada with an original market date on or prior to September 3, 2003, except:

      - Injectable vitamins, minerals, amino acids, lipids, botanicals and other natural health products (NHPs)
      - Vaccines
      - Alprostadil injection
      - Ketorolac injection
      - Injectable products funded under the Ministry's Special Drugs Program, Visudyne Program, Inherited Metabolic Disease Program, Respiratory Syncytial Virus (RSV) Program, or the New Drugs Funding Program

5. Restrictions Regarding the Reimbursement of Extemporaneous Preparations:

   Note that the following are ineligible for reimbursement:

a) An extemporaneous preparation that is equivalent to a commercially manufactured product.

b) Transferring a manufacturer prepared drug solution to another vessel.

c) Transferring an ODB benefit into a new dosage delivery format (e.g., pre-filling insulin syringes).

d) Insertion of an infusion set into a manufacturer prepared preparation.

e) Products prepared from medicinally active bulk drug substances that are not an ODB benefit. These may include medicinally active substances in dry powder or solution that are used to prepare a sterile or non-sterile medicinally active drug product used to treat patients by any route of administration.

f) Reconstitution of an ODB benefit provided by a manufacturer in a dry powder format that is to be used for any route of administration (for example, oral, injectable, rectal, intrathecal, intravaginal)

g) Cutting or crushing of tablets, opening capsules, or otherwise altering any solid oral dosage form, including transferring the altered dosage form into an empty capsule or other vessel without added excipients.

h) Filling a capsule or other vessel with non-medicinal ingredients.

Pharmacists are reminded that claims reimbursed under the *Ontario Drug Benefit Act* are subject to post-payment verification.

Questions can be directed to the Ministry's ODB Health Network System (HNS) Help Desk at 1-800-668-6641.

Extemporaneous Preparations Claim Requirements

Aside from the fields indicated in *Section 5.1*, there are additional fields required (or certain exceptions applicable to specific fields) when submitting claims for extemporaneous preparations (DPPs), namely:

Fields	Required (Y/N)	Explanation
DIN/GP#/PIN	Y	Enter the DIN or Ministry-assigned PIN of the listed drug product with the highest cost for a Formulary benefit, OR Enter the specific compounding PIN (*see Appendix A, Extemporaneous Preparation Table.)* (if applicable)
Quantity	Y	Enter total volume or weight of compound dispensed unless otherwise indicated. (e.g., if using seven tablets to compound 100mL, enter 100; if compounding injection into one 50mL cassette/bag/vial, enter 1)
Unlisted Compound*	Y	If a DIN (not a Ministry-assigned extemporaneous PIN) is entered for a Formulary benefit product (or EAP approved product), enter the appropriate Compound Type Code (see below) in the Unlisted Compound field Ministry-assigned extemporaneous PIN's require the Unlisted Compound field to be blank. 0 = compounded topical cream (category 4) 1 = compounded topical ointment (category 4) 2 = compounded external lotion (category 4) 3 = compounded internal use liquid (category 2) 5 = compounded internal powder (category 2) 6 = compounded injection or infusion (category 3) 7 = compounded ear/eye drop (category 7 & 8) (*See Appendix A, Extemporaneous Preparation Table*.)
Drug Cost/Product Value	Y	Enter the total cost of all ingredients used, based on the following: For Formulary products, use the Drug Benefit Price (DBP). For non-Formulary products, such as products granted approval of reimbursement by the Exceptional Access Program, refer to the Ministry website for Drug Benefit Price at

Fields	Required (Y/N)	Explanation
		http://www.health.gov.on.ca/en/pro/programs/drugs/odbf/odbf_except_access.aspx If the DBP of a product used in the preparation of a DPP is not listed on the Ministry website or on the e-Formulary, use the actual or net Acquisition Cost (equal to manufacturer's or wholesaler's invoice amount minus discounts). Do not include mark-ups and/or HST in this field. *(Refer to Acquisition Cost in Section 6.7).*
Cost Mark-up	Y	Enter the mark-up amount, 8% when the total drug cost is less than $1,000.00 or 6% when the total drug cost is greater than or equal to $1,000.00.
Compounding Charge*	Y	Enter the total amount billed for compounding the prescription (equal to Compounding Rate x Compounding Time)
Compounding Time*	Y	Enter the actual time required to mix the ingredients. This does not include weighing, measuring, and other dispensing activities.

The asterisk (*) indicates additional fields.

6.2 Medically Necessary "No Substitution" Claims

The Ministry will provide reimbursement of a higher-cost interchangeable product in medically necessary circumstances where a patient has experienced a significant adverse reaction with two (2) lower-cost interchangeable drug products, where available. When a prescriber identifies a patient for which it is medically necessary that a higher cost interchangeable product be provided, the prescriber must:

- Complete, sign and forward to the pharmacist a copy of the Health Canada side effect reporting form for each lower-cost interchangeable drug product trialed (Side Effect Reporting Form(s)); and

- Write "No Substitution" or "No Sub" on a written prescription or indicate "No Substitution" to the pharmacist in the case of a verbal prescription.