

Extemporaneous Preparations

An extemporaneous preparation is defined in section 1(1) of O.Reg 201/96 made under the *Ontario Drug Benefit Act* as a “drug or combination of drugs prepared or compounded in a pharmacy according to a prescription”.

Section 17 of the *Ontario Drug Benefit Act* gives the Executive Officer of Ontario Public Drug Programs (the “Executive Officer”) the authority to:

- (a) determine the conditions which must be met before an extemporaneous preparation is designated as a designated pharmaceutical product (“DPP”) and therefore deemed 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.

Effective October 1, 2006, an extemporaneous preparation that is not equivalent to a manufactured drug product will be deemed by the Executive Officer to be a DPP and therefore eligible for reimbursement under the ODB Program, if:

- a) the preparation is for internal consumption and contains a solid oral dosage form of a listed drug product and no other active substance;
- b) the preparation is for injection and is prepared by or under the direct supervision of a pharmacist (i.e. a person holding a certificate of registration from the Ontario College of Pharmacists in accordance with the *Pharmacy Act, 1991* and the *Regulated Health Professions Act, 1991*) (see restrictions below);
- c) the preparation is for dermatological use and contains a listed drug product used for dermatological purposes and no other 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;
- d) the preparation is for a topical nitrogen mustard preparation;
- e) the preparation is for a topical preparation consisting of liquor carbonis detergens, salicylic acid, sulfur or tar distillate, but no other active substances, compounded in petrolatum jelly or lanolin;
- f) the preparation is for an ophthalmic solution containing amikacin, cefazolin or vancomycin, or
- g) the preparation is for an ophthalmic solution containing gentamicin or tobramycin in a concentration greater than three milligrams per millilitre.

Restrictions Regarding Extemporaneous Injectables:

- 1) Compounded injectable products which contain one or more of the drug products noted below are not eligible for reimbursement as DPPs under the ODB Program unless approved by the Executive Officer under the Individual Clinical Review (ICR) mechanism.

alprostadil
amphotericin B lipid complex
ancestim
azithromycin
baclofen
calcitriol
cefotaxime
cephalothin
clodronate
daclizumab
danaparoid
darbepoietin

deferoxamine
desmopressin
dolasetron
epoetin alfa
epoprostenol
estradiol dienanthate/estradiol benzoate/testosterone enanthate benzilic
acid hydrazone
etanercept
filgrastim
fludarabine
fondaparinux
glatiramer acetate
hepatitis A vaccine
hepatitis B vaccine
infliximab
Interferon alfa-2b/ribavirin
interferon beta-1a
interferon beta-1b
iron dextran
iron sucrose
ketorolac
levofloxacin
mycophenolate mofetil
nandrolone decanoate
pamidronate disodium
peginterferon alfa-2b
somatrem
somatropin
sumatriptan
verteporfin
zoledronic acid

- 2) Any injectable drug product which received a Notice of Compliance from Health Canada on or after September 4, 2003 is ineligible for reimbursement as a DPP under the ODB Program unless approved by the Executive Officer under the Individual Clinical Review (ICR) mechanism.
- 3) Any injectable drug product that is listed in Part III-A of the Formulary as a Limited Use benefit is ineligible for reimbursement as a DPP under the ODB Program unless the patient meets the clinical criteria outlined in Part III-A of the Formulary. Claims for these products in respect of patients who do not meet the defined Limited Use criteria may be considered by the Executive Officer for reimbursement under the Individual Clinical Review (ICR) mechanism.

Please refer to Section 6.1 of the Ontario Drug Programs Reference Manual for requirements regarding claims for extemporaneous preparations.

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.