Handbook of Limited Use Drug Products

April 2004
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Ontario

The following contains a list of Limited Use drugs and reimbursement criteria. The drugs are listed in therapeutic categories by brand name. Drugs with similar criteria are grouped together. An index is provided at the end of the book which provides page numbers and a cross reference of generic to brand names. For the complete list of products and more information on the Limited Use process, please refer to the Ontario Drug Benefit Formulary/ Comparative Drug Index.

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Alzheimer drugs

Drug(s)	LU code	Clinical criteria
Aricept (donepezil) Exelon (rivastigmine) Reminyl (galantamine)	347	**Initial Trial:** For patients with mild to moderate Alzheimer's Disease (Mini-Mental State Exam [MMSE] 10-26). Patients will be reimbursed for a period of up to 3 months after which continued treatment must be reassessed.
	348	**Continuation:** Further reimbursement will be made available to those patients whose disease has not progressed/deteriorated while on this drug. Patients must continue to have a MMSE score of 10-26.

Drug(s)	LU code	Clinical criteria
Celebrex (celecoxib)	316	**Osteoarthritis** For patients who have failed an adequate trial of acetaminophen (e.g. acetaminophen 1 g QID for several weeks) and have had: History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDS. NOTE: The maximum daily dose of celecoxib which will be reimbursed for the treatment of osteoarthritis is 200 mg.
	317	**Rheumatoid arthritis** For patients who have had: History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDS. NOTE: The maximum daily dose of celecoxib which will be reimbursed for the treatment of rheumatoid arthritis is 400 mg.

Drug(s)	LU code	Clinical criteria
Vioxx (rofecoxib)	318	**Osteoarthritis** For patients who have failed an adequate trial of acetaminophen (e.g. acetaminophen 1 g QID for several weeks) and have had: History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDs. NOTE: The maximum daily dose of rofecoxib which will be reimbursed for the treatment of osteoarthritis is 25 mg.
	377	**Rheumatoid arthritis** For patients who have had: History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDs. NOTE: The maximum daily dose of rofecoxib which will be reimbursed for the treatment of rheumatoid arthritis is 25 mg.
Codeine Contin (codeine) Duragesic Transdermal (fentanyl) Oxycontin (oxycodone)	201	For the treatment of pain in patients who cannot tolerate, or have failed treatment with a listed long-acting opioid.
Demerol (meperidine)	270	Limited to 2 weeks supply for acute pain.

Drug(s)	LU code	Clinical criteria
Arixtra (fondaparinux)	378	For the post-operative prophylaxis of venous thromboembolic events in patients undergoing orthopedic surgery of the lower limbs such as hip fracture, hip replacement or knee surgery. NOTE: Limited to 9 days of reimbursement.
Fragmin (dalteparin) Fraxiparine, Fraxiparine Forte (nadroparin) Innohep (tinzaparin) Lovenox (enoxaparin)	186 187 188 189 323	For acute treatment of deep venous thrombosis (DVT), for a maximum of three weeks; For DVT in pregnant or lactating females; For DVT in patients whom treatment with warfarin is not tolerated, or contraindicated; For DVT in patients who have failed treatment with warfarin. **(For Lovenox and Innohep only):** For acute treatment of pulmonary embolism, maximum of three weeks.

Anticonvulsant drugs

Drug(s)	LU code	Clinical criteria
Frisium (clobazam)	23	As adjunctive therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.
Lamictal (lamotrigine) Neurontin (gabapentin) Sabril (vigabatrin)	136	As adjunctive therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.
Tegretol CR (carbamazepine)	67	For patients who have been tried on conventional carbamazepine with unsatisfactory results due to adverse effects or poor control of symptoms.
Topamax (topiramate)	223	As adjunctive therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.

Drug(s)	LU code	Clinical criteria
Topamax Sprinkle cap (topiramate)	321	In children age 16 and under, as adjunctive therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.

Anti-infective drugs – Antibiotics

Drug(s)	LU code	Clinical criteria
Avelox (moxifloxacin) Levaquin (levofloxacin) Tequin (gatifloxacin)		For the treatment of patients with:
	337	**CAP with co-morbidity:** Community acquired pneumonia with co-morbid illnesses or failure to first-line therapy.
	338	**COPD with risk:** Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) with risk factors[1]; bronchiectasis. [1] Risk factors include: poor pulmonary lung function (FEV1 below 50% predicted level), age over 65 years, co-morbid medical illness (congestive heart failure, diabetes, chronic renal failure, chronic liver disease), chronic corticosteroid use, malnutrition, prolonged duration of disease, or 4 or more exacerbations/year.
	339	**Step-Down:** Step-down therapy after parenteral therapy or hospital/emergency department discharge.
	977	Exceptional cases of allergy or intolerance to all other appropriate therapies.

Drug(s)	LU code	Clinical criteria
Cipro (ciprofloxacin)		For the treatment of patients with:
	332	**SST/BJ (Gram negative bacteria):** Skin/soft tissue and bone/joint infection due to gram negative bacteria; severe diabetic foot infection; severe otitis externa; decubitus ulcers.
	333	**GU Tract:** Urinary tract infection/prostatitis/epididymitis caused by (suspected or documented) Pseudomonas; sexually transmitted diseases.
	334	**COPD with risk:** Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) with risk factors[1]; bronchiectasis; pneumonic illness with cystic fibrosis.
		[1] Risk factors include: poor pulmonary lung function (FEV1 below 50% predicted level), age over 65 years, co-morbid medical illness (congestive heart failure, diabetes, chronic renal failure, chronic liver disease), chronic corticosteroid use, malnutrition, prolonged duration of disease or 4 or more exacerbations per year.

Drug(s)	LU code	Clinical criteria
(*continued*) Cipro (ciprofloxacin)	336	**Step-Down:** Step-down therapy after parenteral therapy or hospital/emergency department discharge; febrile neutropenia.
	350	**GI:** Traveller's diarrhea; enteric fever syndromes; Crohn's disease.
	353	For the prophylaxis or treatment of *B. anthracis* exposure.
	977	Exceptional cases of allergy or intolerance to all other appropriate therapies.
Floxin (ofloxacin)		For the treatment of patients with:
	340	**SST/BJ (Gram negative bacteria):** Skin/soft tissue and bone/joint infection due to gram negative bacteria; severe diabetic foot infection.
	341	**GU Tract:** Urinary tract infection/prostatitis/epididymitis; sexually transmitted disease.
	338	**COPD with risk:** Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) with risk factors[i]; bronchiectasis.

Drug(s)	LU code	Clinical criteria
(*continued*) Floxin (ofloxacin)		[1] Risk factors include: poor pulmonary lung function (FEV1 below 50% predicted level), age over 65 years, co-morbid medical illness (congestive heart failure, diabetes, chronic renal failure, chronic liver disease), chronic corticosteroid use, malnutrition, prolonged duration of disease, or 4 or more exacerbations per year.
	335	**GI:** Traveller's diarrhea; enteric fever syndromes.
	339	**Step-Down:** Step-down therapy after parenteral therapy or hospital/emergency department discharge.
	977	Exceptional cases of allergy or intolerance to all other appropriate therapies.

Drug(s)	LU code	Clinical criteria
Fucidin Leo tab (sodium fusidate)	342	As part of combination therapy, for the treatment of serious infections confirmed on culture to be caused by a strain of S. *aureus* or coagulase-negative staphylococci likely susceptible to fusidic acid where standard anti-staphylococcal agents are precluded because of allergy, resistance or treatment failure.
Mycobutin (rifabutin)		For the prevention of **Mycobacterium Avium Intracellular** (MAI) in:
	103	Patients with a CD4+ cell count less than 200/mm^3 with an AIDS defining diagnosis; **or**
	104	Patients with a CD4+ cell count less than 100/mm^3 without an AIDS-defining diagnosis.

Drug(s)	LU code	Clinical criteria
Zyvoxam (linezolid)		For the treatment of patients with:
	362	Methicillin-resistant Staphylococcus species (MRSA, MRSE) infections* in patients who are intolerant or have failed vancomycin therapy, or have contraindications to venous access.
	363	Vancomycin resistant Enterococcus species (VRE) infections* in patients switching from IV linezolid.
	364	Step-down therapy for the treatment of methicillin-resistant Staphylococcus species or vancomycin resistant Enterococcus species (VRE) infections* after parenteral therapy or hospital/ emergency department discharge.
		* Infections must be documented and culture proven. Not approved for colonization (e.g. nares, urine etc). Maximum 28 days supply.

Drug(s)	LU code	Clinical criteria
Diflucan 10mg/mL oral liquid (fluconazole)	274	For the treatment of oral/esophageal candidiasis in immunocompromised patients (e.g. patients with malignancies and transplant patients) who have failed to respond to nystatin or imidazoles and when oral tablets of fluconazole cannot be tolerated. NETWORK NOTE: For oral candidiasis, network will limit supply to 2 weeks. For esophageal candidiasis, network will limit supply to 6 weeks.
	275	For the treatment of patients with disseminated candidiasis when oral tablets of fluconazole cannot be tolerated. NETWORK NOTE: For disseminated candidiasis, network will limit supply to 6 weeks.
	276	For the treatment of patients with cryptococcal meningitis when oral tablets of fluconazole cannot be tolerated. NETWORK NOTE: For cryptococcal meningitis (initial treatment), network will limit supply to 12 weeks.

Drug(s)	LU code	Clinical criteria
(*continued*) Diflucan 10mg/mL oral liquid (fluconazole)	277	For the treatment of patients with vulvovaginal candidiasis when oral tablets of fluconazole cannot be tolerated. NETWORK NOTE: For vulvovaginal candidiasis, network will limit supply to one dose 150 mg (Repeats no more than every 25 days)
Diflucan tab (fluconazole) 50mg, 100mg	202	For the treatment of thrush in immunocompromised patients (i.e. patients with malignancies and transplant recipients) who are unresponsive to nystatin or imidazole preparations.
	203	For the treatment of oroesophageal candidiasis in immunocompromised patients (i.e. patients with malignancies and transplant recipients);
	204	For patients with disseminated candidiasis;
	205	For the treatment of acute cryptococcal meningitis.

Drug(s)	LU code	Clinical criteria
Diflucan-150 cap (fluconazole)	235	For the treatment of vaginal candidiasis. Dose: 150mg orally once daily for 1 day. NOTE: Repeats within a 25 day period will not be reimbursed.

Drug(s)	LU code	Clinical criteria
Cytovene injection (ganciclovir sodium)	12	For the treatment of CMV retinitis secondary to AIDS and other immunosuppressive syndromes.
Famvir (famciclovir)	147	Herpes zoster in patients 50 years of age or older, up to 72 hours* after appearance of lesions. Dose: 500mg 3 times/day for 7 days. * The patient must begin treatment within the time frame specified for the product to be reimbursed. There is no benefit from the therapy begun after this time frame. NETWORK NOTE: Network will limit supply to 7 days and 21 tablets.

Drug(s)	LU code	Clinical criteria
Tamiflu (oseltamivir phosphate)	371	For the prophylaxis (max: 75mg daily) of institutionalized individuals during confirmed* outbreaks of Influenza A or Influenza B. NOTE: Network will limit supply to 6 weeks.
	372	For the treatment (max: 75 mg twice a day) of institutionalized individuals during confirmed* outbreaks due to: Influenza B or, Influenza A (as an alternative to amantadine) or, Influenza A where new cases have developed despite amantadine prophylaxis. NOTE: Network will limit supply to 5 days. * The outbreak must be confirmed by Public Health.
Valcyte (valganciclovir)	374	For the treatment of CMV retinitis in patients with AIDS.

Drug(s)	LU code	Clinical criteria
Valtrex (valacyclovir)	159	Herpes zoster in patients 50 years of age or older, up to 72 hours* after appearance of lesions. Dose: 1 gram 3 times/day for 7 days. * The patient must begin treatment within the time frame specified for the product to be reimbursed. There is no benefit for the therapy begun after this time frame. NETWORK NOTE: Network will limit supply to 7 days and 42 capsules.

Drug(s)	LU code	Clinical criteria
Zovirax 800mg tab (acyclovir)		Where specified, treatment must begin within the time frames indicated for the product to be reimbursed. There is no benefit from the therapy begun after these time frames.
	95	Herpes zoster in immunocompetent patients 50 years of age or older, up to 72 hours after appearance of lesions: Dose: 800mg 5 times/day for 7 days.
	96	Herpes zoster ophthalmicus regardless of age, up to 72 hours after appearance of lesions: Dose: 800mg 5 times/day for 7 days.
	97	Herpes zoster in immunocompromised patients regardless of age and time elapsed from onset: Dose: 800mg 5 times/day for 7 days.
	314	Varicella zoster in immunocompetent patients greater than or equal to 12 years of age, up to 24 hours after appearance of lesions: Dose: 20mg/kg/dose (max. 800mg) 4 times/day for 5 days. NETWORK NOTE: Network will limit supply up to 7 days and up to 35 tablets.

Drug(s)	LU code	Clinical criteria
Zovirax injection (acyclovir)		In immunocompromised patients who are not responding to oral acyclovir, famciclovir or valacyclovir, and in whom there is concern about the absorption of oral acyclovir, famciclovir or valacyclovir for the treatment of:
	166	**Herpes simplex** infection, or
	167	**Herpes zoster** infection.
		In immunocompromised patients who are unable to take oral acyclovir, famciclovir or valacyclovir, for the treatment of:
	168	**Herpes simplex** infection, or
	169	**Herpes zoster** infection.

Antineoplastic and other Cancer-related drugs

Drug(s)	LU code	Clinical criteria
Arimidex (anastrozole) Femara (letrozole)	365	For the treatment of metastatic breast cancer in hormone receptor positive post-menopausal women.
Aromasin (exemestane)	180	For the hormonal treatment of metastatic breast cancer in hormone receptor positive post-menopausal women who have disease progression following tamoxifen therapy.
Fludara (fludarabine)	379	For second line therapy of patients with chronic lymphocytic leukemia (CLL) who have failed or are intolerant to chlorambucil.
Temodal (temozolomide)	320	For patients with recurrent or progressive glioblastoma multiforme or anaplastic astrocytoma.
Thyrogen (thyrotropin alfa)	368	For use in the monitoring of patients with well-differentiated thyroid cancer.

Drug(s)	LU code	Clinical criteria
Xeloda (capecitabine)	346	For the first-line treatment of patients with metastatic colorectal cancer in whom combination chemotherapy is not recommended. NOTE: Not to be used in patients who have failed 5-fluorouracil.
	360	For the treatment of metastatic breast cancer in combination with docetaxel in women who experience disease progression on or after an anthracycline.
Bonefos, Ostac (clodronate)	280	For the control and prophylaxis of hypercalcemia of malignancy.
	358	For the treatment of bony metastases in patients with breast cancer.
	359	For the prevention and treatment of osteolytic lesions in patients with multiple myeloma.
Didronel (etidronate)	237	For the treatment of hypercalcemia of malignancy.

Drug(s)	LU code	Clinical criteria
Intron-A (interferon alfa-2B) Roferon-A (interferon alfa-2A)	28 29	For hairy cell leukemia. For Kaposi's Sarcoma.
Leustatin (cladribine)	99	For hairy cell leukemia, as a single 7-day treatment course.
Anzemet (dolasetron)	229 230 231	For the treatment of emesis in cancer patients receiving highly emetogenic chemotherapy. For patients receiving intravenous chemotherapy who have not experienced adequate control with other available anti-emetics. For patients receiving intravenous chemotherapy who experience intolerable side effects with other anti-emetics. NOTE: The therapeutic value of Anzemet more than **24 hours** after the last dose of chemotherapy is unproven.

Drug(s)	LU code	Clinical criteria
Kytril (granisetron)	91	For the treatment of emesis in cancer patients receiving highly emetogenic chemotherapy.
	92	For patients receiving intravenous chemotherapy or radiation therapy who have not experienced adequate control with other available anti-emetics.
	93	For patients receiving intravenous chemotherapy or radiation therapy who experience intolerable side effects with other anti-emetics.
	326	For the treatment of emesis in patients receiving radiation therapy which consists of single fraction treatment to the abdominal cavity, hemi-body irradiation and total body irradiation. NOTE: The therapeutic value of Kytril more than 24 hours after the last dose of chemotherapy is unproven.

Drug(s)	LU code	Clinical criteria
Zofran (ondansetron)	215	For the treatment of emesis in cancer patients receiving highly emetogenic chemotherapy.
	216	For patients receiving intravenous chemotherapy or radiation therapy who have not experienced adequate control with other available anti-emetics.
	217	For patients receiving intravenous chemotherapy or radiation therapy who experience intolerable side effects with other anti-emetics.
	218	For the treatment of emesis in patients receiving radiation therapy which consists of single fraction treatment to the abdominal cavity, hemi-body irradiation and total body irradiation. NOTE: The therapeutic value of Zofran more than 24 hours after the last dose of chemotherapy is unproven.

Drug(s)	LU code	Clinical criteria
Marinol (delta-9-tetrahydro-cannabinol)	40	For the treatment of emesis associated with cancer chemotherapy in patients who are unresponsive to conventional antiemetic therapy.
Imodium (loperamide) Lomotil (diphenoxylate/ atropine)	113	For the treatment of diarrhea associated with cancer, including chemotherapy or radiation therapy.
Tantum (benzydamine)	240	For the symptomatic relief of treatment induced mucositis in cancer patients.

Benign Prostatic Hypertrophy (BPH) drugs

Drug(s)	LU code	Clinical criteria
Flomax (tamsulosin) Xatral (alfuzosin)	351	For the management of benign prostatic hyperplasia where six weeks of treatment with other formulary alpha blockers (e.g., doxazosin, terazosin) have been ineffective.
	352	For the management of benign prostatic hyperplasia where other formulary alpha blockers have produced intolerable side effects.

Benign Prostatic Hypertrophy (BPH) drugs

Drug(s)	LU code	Clinical criteria
(NEW) Proscar (finasteride)	384	For use in combination with an alpha blocker for the treatment of men with symptomatic* Benign Prostatic Hyperplasia.
	385	For monotherapy, as a second line agent in patients with symptomatic* Benign Prostatic Hyperplasia following treatment failure or intolerance to an alpha blocker.
		*Symptomatic is defined as having moderate (about half the time) to severe (almost always) symptoms related to the prostate in at least 4 of the following domains: 1. feeling of incomplete emptying of the bladder after voiding 2. needing to urinate again less than 2 hours after previous void 3. stopping and starting urine several times while voiding 4. difficulty postponing urination 5. weak urinary stream 6. pushing or straining to begin voiding 7. the need to get up to void at least 3 times in the night.

Cardiovascular drugs

Drug(s)	LU code	Clinical criteria
Aggrenox (dipyridamole/ ASA)	349	For the secondary prevention of stroke.
Amatine (midodrine)	01	For the treatment of patients disabled by moderate to severe neurogenic orthostatic hypotension (i.e. drop in systolic BP ≤20mm Hg from supine to standing position), in whom conventional nonpharmacologic and pharmacologic (i.e., fludrocortisone) therapies have proven ineffective or are poorly tolerated.

Drug(s)	LU code	Clinical criteria
Coreg (carvedilol)	183	For patients with: a) NYHA Class II or III Congestive Heart Failure (CHF); **and** b) Currently being treated with an angiotensin converting enzyme (ACE inhibitor, diuretics with or without digoxin, or previously treated, and failed these agents; **and** c) An ejection fraction ≤35%; **and** d) At least one episode of symptomatic CHF within a 12 month period while receiving optimal management.

Drug(s)	LU code	Clinical criteria
(381 revised) Ezetrol (ezetimibe)	380	For use in combination with a HMG-CoA reductase inhibitor ('statin') in patients with hypercholesterolemia who have not reached target LDL levels despite the use of maximally tolerated doses.
	381	For use as monotherapy in the management of hypercholesterolemia in patients who are intolerant to HMG-CoA reductase inhibitors or where HMG-CoA reductase inhibitors are contraindicated.
Lasix Special 500mg tab (furosemide)	33	For patients with severely impaired renal function refractory to conventional dosages of the drug.

Drug(s)	LU code	Clinical criteria
Plavix (clopidogrel)	375	For patients immediately post-hospitalization* for non-ST segment elevation acute coronary syndrome (ACS)**; NOTE: approval for 12 months
	376	For patients immediately pre- or post- percutaneous coronary intervention (PCI)***. NOTE: approval for 12 months

* The first prescription must be written by a physician at the hospital where the patient was hospitalized.

** ACS, as defined by the CURE study, includes hospitalized patients with unstable angina or non-ST segment elevation myocardial infarctions.

*** Therapy may be initiated up to 10 days prior to PCI.

Drug(s)	LU code	Clinical criteria
Ticlid (ticlopidine)		Ticlopidine is restricted to patients with transient cerebral ischemia. Ticlopidine will be reimbursed for patients:
	219	Who are known to be, or become, intolerant of ASA;
	220	Where ASA is contraindicated;
	221	Who continue to have TIA or stroke symptoms while being treated with ASA.
Trental (pentoxifylline)	76	For the treatment of patients with critical limb ischemia (with arterial ulcers, gangrene and/or rest pain) and documented arterial vascular disease. NOTE: Limited use form must specify if arterial ulcers, gangrene and/or rest pain are present.

Drug(s)	LU code	Clinical criteria
Dovonex (calcipotriol)	191	For the treatment of psoriasis in patients who have failed topical corticosteroids alone, or are intolerant to topical corticosteroids.
Elidel (pimecrolimus) Protopic (tacrolimus)	383	For use in combination with moisturizers or oral antihistamines in patients with atopic dermatitis who have failed or are intolerant to an 8 week trial of an intermediate potency topical steroid. Therapy should be reassessed at 6 months.
Neoral (cyclosporine)	177	For the treatment of psoriasis in patients who have failed, or are intolerant to, other systemic therapies, including methotrexate, acitretin or PUVA.
Nix 5% dermal cream (permethrin)	311	For the treatment of patients who have failed on a less costly listed alternative.
Stieva-A Vitamin A acid (tretinoin)	269	For the treatment of acne vulgaris.

Diabetes drugs

Drug(s)	LU code	Clinical criteria
Humalog (insulin lispro) Humalog Mix25 (insulin lispro/insulin lispro protamine) NovoRapid (insulin aspart)	226 227	For insulin requiring diabetics using multiple doses of regular insulin (greater or equal to 3 injections per day) and experiencing recurrent hypoglycemia or poor glycemic control. **(Humalog and NovoRapid only):** For insulin requiring diabetics using an insulin pump.
Prandase (acarbose)	175 176	In patients who cannot tolerate or have failed treatment with other oral hypoglycemic agents or in whom other oral hypoglycemic agents are contraindicated; In patients who require combination therapy with more than one oral hypoglycemic agent to control their serum glucose concentrations.

Drug(s)	LU code	Clinical criteria
Losec (omeprazole) Pantoloc (pantoprazole) Prevacid (lansoprazole)	291	**Complicated GERD or Upper GI Malignancy-Procedurally Confirmed** For the first-line treatment of procedurally confirmed complicated esophagitis (i.e. severe erosive esophagitis, Barrett's esophagitis, ulcerative esophagitis, esophagitis with bleeding or stricture) or upper GI malignancy. Maximum duration: unlimited
	292	**Severe GERD.** For the first-line treatment of severe GERD. Maximum duration: 6 months Any one of the following may characterize severe GERD: i Daily attacks of reflux pain; ii Symptoms that wake the patient at night; iii Severe symptoms. Patients should be reassessed within 6 months after initial treatment with a PPI. The reassessment could include confirmation with endoscopy or step-down therapy. Patients stepping down should be tried on at least a two-week trial of H_2-receptor antagonist therapy. NETWORK NOTE: Network will limit supply to 6 months.

Drug(s)	LU code	Clinical criteria
(*continued*) Losec (omeprazole) Pantoloc (pantoprazole) Prevacid (lansoprazole)	293	**Mild to Moderate GERD** For the second-line treatment of mild to moderate GERD in patients who have not responded to at least a 4-week course of an H_2-receptor antagonist. Maximum duration: 6 months For initial treatment, the treatment period with a proton pump inhibitor may extend for no longer than 6 months, after which the need for continued treatment should be reassessed. Reassessment could include a repeat of a course of an H_2-receptor antagonist, or a procedural assessment of the condition. NETWORK NOTE: Network will verify previous H_2-receptor antagonist use in past year.
	294	**GERD Recurrence** For the treatment of recurrence, once GERD has been procedurally confirmed or the patient has undergone step-down therapy. Maximum duration: unlimited

Drug(s)	LU code	Clinical criteria
(*continued*) Losec (omeprazole) Pantoloc (pantoprazole) Prevacid (lansoprazole)	295 296	***H. pylori*** **– Positive Peptic Ulcers:** a) For the treatment of H. pylori-positive peptic ulcers where H. pylori is documented, by serology, breath test or endoscopy, for a one-week course in combination with antimicrobial therapy. Maximum duration: 7 days b) For the **retreatment** of H. pylori-positive peptic ulcers where H. pylori recurrence or persistence is documented, by breath test or endoscopy, for a one-week course in combination with antimicrobial therapy. Maximum duration: 7 days (after a four-week period has elapsed since the end of the previous treatment) Retreatment decisions should be based upon positive symptoms and positive endoscopy or positive urea breath test. Retreatment should **not be based on a positive serology test**, as serology tests may remain positive indefinitely. An alternative antibiotic regimen is recommended when initial therapy fails due to concerns of antimicrobial resistance.

Drug(s)	LU code	Clinical criteria
(*continued*) Losec (omeprazole) Pantoloc (pantoprazole)		NETWORK NOTE: Network will supply to 7 days. Network will verify that retreatments are reimbursed only after a four-week period has elapsed since the end of the previous treatment.
Prevacid (lansoprazole)	297	**Complicated Peptic Ulcers:** For the treatment of peptic ulcers in patients that have procedurally confirmed ulcer complications (i.e. perforation, obstruction, large ulcers or GI bleed). Maximum duration: unlimited.
	298	**NSAID induced Ulcers:** a) For the treatment of NSAID induced ulcers where the NSAID must be continued. Maximum duration: unlimited while on NSAID therapy.
	299	b) For the prophylaxis of NSAID induced ulcers in patients who have ulcer complications (i.e. perforation or recurrent GI bleed) or are at high-risk for complications (i.e. cardio-vascular disease, current or previous peptic ulcer disease, or coagulopathies). Maximum duration: unlimited

Drug(s)	LU code	Clinical criteria
(*continued*) Losec (omeprazole) Pantoloc (pantoprazole) Prevacid (lansoprazole)	300	**Other Criteria** For the treatment of procedurally confirmed pathological hypersecretory conditions (e.g. Zollinger-Ellison syndrome).
	301	For patients with a known allergy to or intolerance of H_2 –receptor antagonist.
	302	For patients with gastroduodenal Crohn's disease.
	303	For patients with short-gut syndrome.
	304	For patients with scleroderma.
	305	For patients with pancreatitis.
		Maximum duration: unlimited

Drug(s)	LU code	Clinical criteria
Hp-PAC (lansoprazole/ clarithromycin/ amoxicillin)	306	a) For the treatment of *H. pylori*-positive peptic ulcers where *H. Pylori* is documented, by serology, breath test or endoscopy, for a one-week course. Maximum duration: 7 days
	307	b) For the **retreatment** of *H. pylori*-positive peptic ulcers where *H. Pylori* recurrence or persistence is documented, by breath test or endoscopy, for a one-week course. Maximum duration: 7 days (after a four-week period has elapsed since the end of the previous treatment) Retreatment decisions should be based upon positive symptoms and positive endoscopy or positive urea breath test. Retreatment should **not be based on a positive serology test**, as serology tests may remain positive indefinitely. An alternative antibiotic regimen is recommended when initial therapy fails due to concerns of antimicrobial resistance. NETWORK NOTE: Network will limit supply to 7 days. Network will verify that retreatments are reimbursed only after a four-week period has elapsed since the end of the previous treatment.

Drug(s)	LU code	Clinical criteria
Cotazym Cotazym ECS 4 Cotazym ECS 8 Cotazym ECS 20 Creon 5 Creon 10 Creon 20 Creon 25 Pancrease Pancrease MT4 Viokase Viokase 16 (pancrelipase)	124 125 126 225	Replacement therapy for pancreatic insufficiency secondary to pancreatic surgery (resection); Replacement therapy for pancreatic insufficiency due to chronic pancreatitis; Replacement therapy for pancreatic insufficiency due to carcinoma of the pancreas; (**Cotazym and Creon products only**): Replacement therapy for pancreatic insufficiency due to cystic fibrosis.

Drug(s)	LU code	Clinical criteria
Imodium (loperamide) Lomotil (diphenoxylate/ atropine)		For the treatment of diarrhea associated with:
	110	An ileostomy or a colostomy;
	111	Bowel resection, including short bowel syndrome;
	112	Inflammatory Bowel Diseases, i.e. Crohn's disease and Ulcerative Colitis;
	113	Cancer, including chemotherapy or radiation therapy;
	114	HIV/AIDS;
	115	Acute diarrhea in patients in congregated housing, i.e. Long Term Care Facilities (LTCF), or for patients receiving Home Care;
	224	Fecal incontinence.
Urso, Urso DS (ursodiol)	273	For the treatment of primary biliary cirrhosis.

Drug(s)	LU code	Clinical criteria
Climara 50 Climara 100 Estraderm Estradot Oesclim Vivelle (estradiol 17-B)	17	For patients in whom an oral estrogen product is contraindicated.
	18	For patients in whom an oral estrogen product has been tried and caused an adverse effect.
Estalis-Sequi 140/50, 250/50 (estradiol 17-B & norethindrone acetate + estradiol 17-B) Estalis Transdermal Pad 140/50 mcg 250/50 mcg (norethindrone acetate & estradiol 17-B) Estracomb (estraderm 50 & estragest)	138	For patients in whom a combination of a less costly listed oral estrogen product and oral progestin is contraindicated.
	139	For patients in whom a combination of a less costly listed oral estrogen product and oral progestin has been tried and caused an adverse effect.

Drug(s)	LU code	Clinical criteria
Estrogel (estradiol 17-B)	308	For patients in whom an oral estrogen product is contraindicated.
	288	For patients in whom an oral estrogen product has been tried and caused an adverse effect. NETWORK NOTE: Network will limit supply to one pump per month.

Drug(s)	LU code	Clinical criteria
Alphagan (brimonidine tartrate) Azopt (brinzolamide) Lumigan (bimatoprost) Trusopt (dorzolamide) Travatan (travoprost) Xalatan (latanoprost)	171 172	As first line treatment of elevated intraocular pressure in patients who cannot tolerate an ophthalmic beta-blocking agent or where beta- blocking agents are contraindicated; As adjunctive therapy of elevated intraocular pressure in patients who cannot tolerate oral carbonic anhydrase therapy, or topical pilocarpine therapy, or topical beta-blocker therapy, or in whom these therapies have been ineffective.
Cosopt (dorzolamide/ timolol maleate)	 309 310	For the treatment of patients with elevated intraocular pressure in whom: First-line agents were not tolerated or are contraindicated (i.e. oral carbonic anhydrase therapy or topical pilocarpine therapy). First-line agents were ineffective (i.e. oral carbonic anhydrase therapy, topical pilocarpine therapy, or topical beta-blocker therapy alone).

Drug(s)	LU code	Clinical criteria
Botox (botulinum toxin type A)	10	For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age or older.
Duolube, Lacri-Lube (petrolatum/ mineral oil) Hypotears, Liquifilm Tears (polyvinyl alcohol) Isopto Tears 0.5%, 1%, Murocel 1% (methylcellulose) Tears Naturale (dextran 70 & hydroxypropyl methylcellulose) Tears Naturale II (dextran 70 & hydroxypropyl methylcellulose & polyquad)	49	For patients with objective evidence of keratoconjunctivitis sicca as confirmed by filamentary keratopathy on slit lamp examination or biopsy.

Drug(s)	LU code	Clinical criteria
Tears Plus (polyvinyl alcohol & polyvinylpyrrolidone)	49	For patients with objective evidence of keratoconjunctivitis sicca as confirmed by filamentary keratopathy on slit lamp examination or biopsy.
Ocuflox 0.3% (ofloxacin)	170	For the treatment of conjunctivitis caused by susceptible strain(s) of **Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae** and **Hemophilus influenzae** which is/are resistant or unresponsive to listed alternative agents.

Osteoporosis drugs

Drug(s)	LU code	Clinical criteria
Actonel (risedronate) 5mg, 35mg Fosamax (alendronate) 10mg,70mg	369 370	For the treatment of osteoporosis in patients who have: Two out of the following three criteria: BMD at least 3.0 standard deviations below the young adult mean, age of 75 or greater, prior osteoporosis-related fracture; **or** Failed* **or**, experienced intractable side effects, **or** have a contra-indication to, cyclical etidronate (Didrocal) therapy. * Failure is defined as: continued loss of bone mineral density (loss of more than 3%) after two years of therapy, **or** a new osteoporosis related fracture after one year of therapy.
Evista (raloxifene)	373	For the treatment of osteoporosis in postmenopausal women who have: Failed* **or**, experienced intractable side effects, **or** have a contraindication to, alendronate **OR** risedronate. * Failure is defined as continued loss of bone mineral density (loss of more than 3%) after two years of therapy, **or** a new osteoporosis related fracture after one year of therapy.

Drug(s)	LU code	Clinical criteria
Comtan (entacapone)	367	For the treatment of patients with Parkinson's disease with 25% of the waking day in the off state despite maximally tolerated doses of levodopa.

Drug(s)	LU code	Clinical criteria
Sinemet CR (levodopa/ carbidopa)	64	For patients with Parkinson's disease who have been treated with conventional therapy (Prolopa or conventional Sinemet), and experienced adverse effects related to drug level fluctuations, such as ON/OFF or wearing off phenomena.
	65	For patients presently requiring anti-parkinsonian drug administration (levodopa/carbidopa) more than three times daily.

Drug(s)	LU code	Clinical criteria
Alupent Inh soln* (orciprenaline) Atrovent Inh soln* (ipratropium) Berotec Inh soln* (fenoterol) Combivent Inh soln* (ipratropium/ salbutamol) Vaponefrin Inh soln* (racemic epinephrine) Ventolin Inh soln* (salbutamol)	256 257 258 259	Patients who have a tracheostomy; Patients with cystic fibrosis in whom nebulizer therapy is indicated; Patients with severe mental or physical disabilities; Patients who have previously used nebulizer therapy within the last 12 month period.

Drug(s)	LU code	Clinical criteria
Isuprel Inh soln* (isoproterenol) Pulmicort Nebuamp (budesonide)*	260 261 262 263 264	Children aged 6 years or less; Patients who have a tracheostomy; Patients with cystic fibrosis in whom nebulizer therapy is indicated; Patients with severe mental or physical disabilities; Patients who have previously used nebulizer therapy within the last 12 month period.

Drug(s)	LU code	Clinical criteria
Atrovent Inh soln UDV* (ipratropium) Ventolin Nebules* (salbutamol)	265	Individuals must have a known hypersensitivity to the preservative in the bulk solution, and have a tracheostomy;
	266	Individuals must have a known hypersensitivity to the preservative in the bulk solution, and be patients with cystic fibrosis in whom nebulizer therapy is indicated;
	267	Individuals must have a known hypersensitivity to the preservative in the bulk solution, and have severe mental or physical disabilities;
	268	Patients who have previously used nebulizer therapy within the last 12 month period.
		* **NOTE (For nebulizer solution products):** For the vast majority of patients, a metered dose inhaler is the preferred therapy. Nebulizer therapy will be reimbursed for patients who are unable to use a metered dose inhaler, including an inhaler with a spacer attachment, or a turbuhaler.

Drug(s)	LU code	Clinical criteria
Berotec Inh Pdr (fenoterol)	08	For patients who have not responded to other less expensive inhaled beta-2 adrenergic agonists.
Advair, Advair Diskus (salmeterol xinafoate & fluticasone propionate) Symbicort Turbuhaler (budesonide & formoterol fumarate dihydrate)	330	For the treatment of asthma in patients who are using optimum anti-inflammatory treatment and are still experiencing breakthrough symptoms.
Foradil (formoterol fumarate) Oxeze (formoterol fumarate dihydrate) Serevent, Serevent Diskus, Serevent Diskhaler Disks (salmeterol xinafoate)	132	For the treatment of asthma in patients who are using optimum anti-inflammatory treatment and are still experiencing breakthrough symptoms. NOTE: This drug is not for relief of acute symptoms.

Drug(s)	LU code	Clinical criteria
Atrovent nasal spray (ipratropium bromide)	03	For the treatment of non-allergic vasomotor rhinitis.
Tilade Inh (nedocromil sodium)	72	As second line therapy for asthmatics who are intolerant of sodium cromoglycate.
Singulair 4mg (montelukast)	382	For the treatment of asthma in patients aged 2-5 years old.

Rheumatoid Arthritis drugs

Drug(s)	LU code	Clinical criteria
Arava (leflunomide)	331	For the treatment of rheumatoid arthritis in patients who have failed, or are intolerant to, one **or** more of the listed Disease-Modifying Anti-Rheumatic Drugs (DMARDS).
Celebrex (celecoxib)	317	History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDS. NOTE: The maximum daily dose of celecoxib which will be reimbursed for the treatment of rheumatoid arthritis is 400mg.
Neoral (cyclosporine)	178	For the treatment of rheumatoid arthritis in patients who have failed, or are intolerant to, other systemic therapies, including Disease-Modifying Anti Rheumatic Drugs (DMARDs).
Vioxx (rofecoxib)	377	Rheumatoid arthritis: For patients who have had: History of a documented, clinically significant ulcer or GI bleed; **or** Failure or intolerance to at least three listed NSAIDs. NOTE: The maximum daily dose of rofecoxib which will be reimbursed for the treatment of rheumatoid arthritis is 25mg.

Drug(s)	LU code	Clinical criteria
Cellcept (mycophenolate)	190	For the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.
Prograf (tacrolimus)	173	For solid organ transplant and bone marrow transplant.

Miscellaneous Drugs

Drug(s)	LU code	Clinical criteria
Actonel (risedronate) 30mg tab	319	For the treatment of Paget's disease.
Botox 100u/vial (botulinum toxin type A)	10	For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age or older.
	130	To reduce the subjective symptoms and objective signs of cervical dystonia (spasmodic torticollis) in adults.
Detrol, Unidet (tolterodine)	290	For patients with urinary frequency, urgency or urge incontinence who have: • Failed to respond to behavioral techniques AND • An adequate trial of oxybutynin with gradual dose escalation has been shown to be either ineffective or resulted in unacceptable side effects. NOTE: If after a trial of 2 weeks, patients continue to experience similar side effects and no greater efficacy than oxybutynin, continued therapy with this more costly agent should be reassessed.

Drug(s)	LU code	Clinical criteria
Didronel (etidronate)	236	For the treatment of Paget's disease.
	237	For the management of hypercalcemia of malignancy.
Fluotic (sodium fluoride)	20	For the treatment of otosclerosis
	21	For the treatment of otospongiosis.
Lactaid (lactase enzyme) tab, 6.5mL oral liquid package, 15.5mL oral liquid package	31	For the management of lactose intolerance which has been confirmed by history or by lactose tolerance test.
Marinol (delta-9-tetrahyrdo-cannabinol)	40	For the treatment of emesis associated with cancer chemotherapy in patients who are unresponsive to conventional antiemetic therapy.
	345	For the treatment of AIDS-related anorexia associated with weight loss and prescription is from a prescriber approved for the Facilitated Access mechanism (see Part VI of the Formulary/ CDI binder).

Drug(s)	LU code	Clinical criteria
Nimotop (nimodipine)	42	As adjunctive therapy to improve the neurologic outcome following subarachnoid haemorrhage during the acute management period (within 4 days of haemorrhage).
	43	As prophylaxis of ischemia if surgery is delayed.
Sibelium (flunarizine HCl)	60	For patients with migraine headaches who have not responded to propranolol.
	61	For patients who have tried propranolol and experienced significant adverse effects.
	62	For patients in whom propranolol is contraindicated.
		CAUTIONS: Contraindicated in patients with clinical depression and in patients with extrapyramidal disorders.
Wellbutrin SR (bupropion)	315	For the treatment of depression.

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This handbook is also available at the Ministry of Health and Long-Term Care website:
http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html

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For more information, contact the Drug Programs Branch:
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www.health.gov.on.ca

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Ontario

Benign Prostatic Hypertrophy (BPH) drugs

Drug(s)	LU code	Clinical criteria
(NEW) Proscar (finasteride)	384	For use in combination with an alpha blocker for the treatment of men with symptomatic* Benign Prostatic Hyperplasia.
	385	For monotherapy, as a second line agent in patients with symptomatic* Benign Prostatic Hyperplasia following treatment failure or intolerance to an alpha blocker.
		*Symptomatic is defined as having moderate (about half the time) to severe (almost always) symptoms related to the prostate in at least 4 of the following domains: 1. feeling of incomplete emptying of the bladder after voiding 2. needing to urinate again less than 2 hours after previous void 3. stopping and starting urine several times while voiding 4. difficulty postponing urination 5. weak urinary stream 6. pushing or straining to begin voiding 7. the need to get up to void at least 3 times in the night.

Drug(s)	LU code	Clinical criteria
(381 revised) Ezetrol (ezetimibe)	380	For use in combination with a HMG-CoA reductase inhibitor ('statin') in patients with hypercholesterolemia who have not reached target LDL levels despite the use of maximally tolerated doses.
	381	For use as monotherapy in the management of hypercholesterolemia in patients who are intolerant to HMG-CoA reductase inhibitors or where HMG-CoA reductase inhibitors are contraindicated.
Lasix Special 500mg tab (furosemide)	33	For patients with severely impaired renal function refractory to conventional dosages of the drug.