NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

CRITERIA FOR COVERAGE OF EXCEPTION STATUS DRUGS

JULY 2006

Coverage of exception status drugs will be approved according to the following criteria upon review of a physician's written request.

As an alternative to sending a written request to the Pharmacare office, certain exception status drugs have been assigned criteria codes. To allow for on-line payment of these drugs, the criteria code may be provided by the physician either on the prescription or as a verbal order to the pharmacist. The use of these codes offers the physician and the pharmacist access to immediate coverage for patients who clearly meet the exception status criteria. The criteria codes are indicated within the following exception criteria.

Adalimumab (Humira 40mg/vial Injection)

- See ***Anti-Tumor Necrosis Factor (TNF) Agents***

***Alendronate (Fosamax 10mg, 70mg, 40mg Tablet & generic brands)**

- for the treatment of diagnosed osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements
- for the treatment of diagnosed osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area)
- for the treatment of conventional x-ray documented osteopenia/demineralization only in patients without access to BMD measurements. (Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.)
- as prophylaxis of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more
- for the treatment of Paget's disease of bone (6 month limit)
- other requests reviewed on case by case basis
- may be requested by a nurse practitioner for osteoporosis related conditions only (not Paget's Disease)

Allergen Immunotherapy (Allergy Serum, Pollinex-R Injection)

- for immunotherapy with specific, standardized allergenic material, administered in high-dose schedules for carefully selected patients with a diagnosis of:
  - IgE mediated anaphylactic reactions to insect stings or
  - severe, seasonal (lasting two or more years) or perennial IgE dependent allergic rhinoconjunctivitis when optimal drug therapy and allergen avoidance have not been sufficiently effective in controlling symptoms or
  - IgE mediated allergic asthma, specifically those where there is a clear temporal association between exposure and signs and symptoms of asthma and when optimal drug therapy and avoidance measures have not been sufficiently effective in controlling symptoms

The allergy serum must be dispensed from a pharmacy on prescription from a physician. Initial authorization is for two years, and can be continued for up to five years if improvement is noted.

Almotriptan (Axert 6.25mg, 12.5mg Tablet)

- See ***Selective 5HT$_1$ - Receptor Agonists***

***Altretamine (Hexalen 50mg Capsule)**

- written request of an oncologist only
- for the treatment of ovarian carcinoma

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Anagrelide (Agrylin 0.5mg Capsule & generic brand)

Nova Scotia Seniors' Pharmacare Program:

- for the treatment of essential thrombocythemia (ET) in patients who have:
  - failed hydroxyurea therapy (does not provide sufficient platelet reduction) or
  - intolerable side effects to hydroxyurea therapy

Community Services Pharmacare Programs:

- for the treatment of essential thrombocythemia (ET) as an alternative to hydroxyurea

Anti-Tumor Necrosis Factor (TNF) Agents (Adalimumab[4], Etanercept, Infliximab)

- for treatment of Crohn's disease in adults, see ***Infliximab***
- for treatment of juvenile rheumatoid arthritis and psoriatic arthritis, see ***Etanercept***
- for patients with a diagnosis of active rheumatoid arthritis (RA) who
  - have not responded or who have had intolerable toxicity to an adequate trial[1] of combination therapy of at least two traditional DMARDs[2] *or*
  - if combination therapy is not an option, an adequate trial of at least three traditional DMARDs in sequence as monotherapy *and*
  - patients must have had an adequate trial[1] of leflunomide. Exceptions can be considered in cases where leflunomide is contraindicated or not tolerated
- therapy must include methotrexate[3] alone or in combination unless contraindicated or not tolerated
- written request of a rheumatologist only
- coverage will be approved initially for 6 months. Can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%.

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1 An adequate trial is 5 months for IM gold, 6 months for penicillamine, 4 months for hydroxychloroquine and 3 months for all other traditional DMARDs as well as leflunomide, infliximab and etanercept.

2 Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, D-penicillamine and cyclosporine.

3 Unless limited by toxicity, methotrexate dosage should be increased up to 25mg/wk unless response is achieved at a lower dose.

4 Dosage limited to 40mg every 2 weeks.

Artificial Tears, Preservative Free (Celluvisc, Refresh, Refresh Plus, Refresh Tears, Tears Naturale Free Oph Sol)

- for patients with the diagnosis of dry eye requiring frequent daily doses of artificial tears, to prevent sensitivity to preservatives or in patients in whom preservative sensitivity is suspected
- written request from an ophthalmologist or optometrist will be required to initiate the first prescription confirming the diagnosis

***Azithromycin (Zithromax 250mg, 600mg Tablet & generic brands, and P.O.S. 100mg/5mL, 200mg/5mL)**

- for the treatment of pneumonia in clients over 65 years of age **[*Criteria Code 01*]**
- for the treatment of infections requiring a macrolide (including community acquired pneumonia in patients < 65 year of age) when there is documented intolerance to erythromycin **[*Criteria Code 02*]**
- for the treatment of infections when alternatives are not available due to documented patient allergies **[*Criteria Code 03*]**
- for the treatment of infections when alternatives are not available due to serious intolerance to other agents **[*Criteria Code 04*]**
- for the treatment of chlamydia trachomatis as a single dose of 1g (4 capsules) **[*Criteria Code 05*]**
- for the prevention of mycobacterium avium complex (MAC) **[*Criteria Code 06*]**
- for the treatment of infections requiring a macrolide antibiotic when the patient is taking medications that would interact with erythromycin **[*Criteria Code 07*]**
- for the treatment of moderate to severe exacerbations of chronic bronchitis **[*Criteria Code 08*]**
- only *Criteria Codes 01, 02* and *05* may be selected by a nurse practitioner

***Benzydamine HCL (Tantum 0.15% Oral Rinse & generic brands)**

- for oncology patients only
- may be requested by a nurse practitioner

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Betahistine (Serc 16mg, 24mg Tablet)
- for the symptomatic treatment of the recurrent episodes of vertigo associated with Meniere's disease

Bosentan (Tracleer 62.5mg, 125mg Tablet)
- written request of a specialist only
- for the treatment of pulmonary arterial hypertension (PAH) in patients with World Health Organization (WHO) functional class III and IV primary pulmonary hypertension (PPH) who are non-responsive to first line therapy with agents such as calcium channel blockers or who have failed a vasodilator test
- for the treatment of PH secondary to scleroderma who are non-responsive to first line therapy with agents such as calcium channel blockers or who have failed a vasodilator test

Budesonide (Pulmicort Nebuamps 0.125mg/mL, 0.25mg/mL, 0.5mg/mL Susp)
- See ***Wet Nebulization Solutions***

Bumetanide (Burinex 1mg, 2mg, 5mg Tablet)
- for diuresis in patients when treatment with furosemide is deemed inappropriate or ineffective

Bupropion (Wellbutrin SR 100mg, 150mg Tablet)
- for the treatment of depression [***Criteria Code 01***]

NOTE - not insured for smoking cessation

Butorphanol (10mg/mL Nasal Spray, generic brands)
- for the treatment of migraine, upon the request of a neurologist or specialist in pain management, when conventional forms of therapy are ineffective or inappropriate

Cabergoline (Dostinex 0.5mg Tablet)
- for the treatment of micro- or macro-adenoma of the pituitary after failure of bromocriptine (as determined by prolactin levels) or if bromocriptine is not tolerated

Calcipotriol (Dovonex 50mcg/g Ointment, Cream and 50mcg/mL Scalp Solution)
- for use in psoriasis therapy when conventional therapies have been inaffective or inappropriate

***Calcitonin, Intranasal (Miacalcin 200iu Nasal Spray & generic brands)**
- for the treatment of diagnosed osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements and alendronate, risedronate and raloxifene are not tolerated or contraindicated
- for the treatment of diagnosed osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area) and alendronate, risedronate and raloxifene are not tolerated or contraindicated
- for the treatment of conventional x-ray documented osteopenia/demineralization only in patients without access to BMD measurements** and alendronate, risedronate and raloxifene are not tolerated or contraindicated
- as prophylaxis of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more and alendronate and risedronate are not tolerated or contraindicated
- for the treatment of pain associated with osteoporotic fragility fractures, bone metastases, pathological fractures (short term up to 3 months)
- other requests reviewed on case by case basis

**Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.

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***Capecitabine (Xeloda 150mg and 500mg Tablet)**

- for treatment of metastatic breast cancer as monotherapy in patients who have failed or cannot tolerate taxane-based therapy and who have an ECOG performance status of 0-2
- as a single agent in patients who have documented evidence of metastatic colorectal cancer, with an ECOG performance status of 0-2, who choose not to receive combination chemotherapy (5-FU/LV/irinotecan) and/or are unable to tolerate first line therapy. This includes patients who are chemotherapy niave or who have progressed 6 months after completion of adjuvant 5-FU/LV therapy.
- requests must be from an oncologist and approval will be granted for three months, to be renewed as required

Carvedilol (Coreg 3.125mg, 6.25mg, 12.5mg, 25mg Tablet & generic brands)

- written request of a cardiologist or internist only
- for the treatment of stable symptomatic congestive heart failure (CHF) in patients with NYHA Class II and III, taking diuretics and angiotensin converting enzyme inhibitors, with or without digoxin

Cetirizine (Reactine 5mg, 10mg Tablet & generic brands)

- for chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with cetirizine
- may be requested by a nurse practitioner

Cholinesterase Inhibitors (ChEI) (Donepezil, Galantamine, Rivastigmine)

- for the treatment of patients with a diagnosis of mild to moderate probable Alzheimer's Disease or possible Alzheimer's Disease with vascular component, with Lewy bodies or other (as specified) who meet the following criteria:

  - Initiation of coverage in a cholinesterase inhibitor (ChEI)-naive patient:
    Coverage is provided for an initial 90 days when all the following criteria are met:
    - a Mini-Mental State Examination (MMSE) score of 10 to 30;
    - a Functional Assessment Staging Test (FAST) score of 4 to 5; and
    - three target symptoms have been established which will be monitored on an ongoing basis to assist in determining clinical meaningfulness.

  - Continuation of coverage for a second 90-day period:
    Coverage can be extended an additional 90 days if:
    - there is demonstrated stabilization or improvement in at least one target symptom after initial 90 days of therapy.

  - Continuation of coverage for 6-month periods:
    Coverage is continued in 6-month increments when:
    - the information provided indicates the patient is in the mild to moderate stage of Alzheimer's Disease
    - a MMSE and FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.

  - Initiation of coverage with a second ChEI for a patient who has previously taken no more than one other ChEI:
    Coverage of a second ChEI can be provided for an initial 90 days if:
    - the reason for discontinuing the first ChEI is indicated; and
    - any changes in target symptoms are indicated.

    Coverage for a second ChEI is provided in the same manner as the first ChEI (i.e. 90-days, second 90-days, then continuation in 6-month periods if criteria are met).

  NOTE - Specialized requests forms, which have been developed for each coverage period, must be submitted for continuation of coverage.

Ciprofloxacin, Ophthalmic (Ciloxan 0.3% Ophthalmic Solution & generic brands and Ointment)

- See ***Fluoroquinolones, Ophthalmic***

***Ciprofloxacin, Oral (Cipro 100mg/mL Oral Liquid and 250mg, 500mg, 750mg Tablet & generic brands)**

- See ***Fluoroquinolones, Oral***

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***Ciprofloxacin XL, Oral (Cipro XL 1,000mg Tablet)**

- for the oral treatment of gram-negative infections in complicated urinary tract infections, for which other oral agents are not effective or available **[*Criteria Code 10*]**
- for the oral treatment of acute uncomplicated pyelonephritis **[*Criteria Code 11*]**

Ciprofloxacin, Otic (Cipro HC Otic Suspension)

- for the treatment of any susceptible ear infection where there is a perforation of the tympanic membrane **[*Criteria Code 01*]**
- for the treatment of otitis externa when traditional agents have failed **[*Criteria Code 02*]**
- for the treatment of chronic otitis media with cholesteatoma with otorrhea **[*Criteria Code 03*]**

***Clarithromycin (Biaxin 250mg, 500mg, XL 500mg Tablet and 125mg/5mL, 250mg/5mL Oral Liquid)**

- for the treatment of pneumonia in clients over 65 years of age **[*Criteria Code 01*]**
- for the treatment of infections requiring a macrolide (including community acquired pneumonia in patients < 65 years of age) when there is a documented intolerance to erythromycin **[*Criteria Code 02*]**
- for the treatment of infections when alternatives are not available due to documented patient allergies **[*Criteria Code 03*]**
- for the treatment of infections when alternatives are not available due to serious intolerance to other agents **[*Criteria Code 04*]**
- for the eradication of Helicobacter pylori infections when used in combination regimens for the treatment of peptic ulcer disease **[*Criteria Code 05*]**
- for the prevention and treatment of mycobacterium avium complex (MAC) **[*Criteria Code 06*]**
- for the treatment of moderate to severe exacerbations of chronic bronchitis **[*Criteria Code 07*]**
- only *Criteria Codes 01, 02, 03* and *05* may be selected by a nurse practitioner

Clopidogrel (Plavix 75mg Tablet)

- for the secondary prevention of the following vascular ischemic events in patients with a history of symptomatic atherosclerotic disease, including:
  - ischemic stroke/ transient ischemic attack (TIA) in patients with a documented severe allergy to ASA or who experience a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA or experience GI hemorrhage while on ASA,
  - myocardial infarction (MI) in patients with a documented severe allergy to ASA or experience GI hemorrhage while on ASA,
  - peripheral artery disease (PAD) in patients with a documented severe allergy to ASA or experience GI hemorrhage while on ASA,
  - unstable angina in patients with a documented severe allergy to ASA or experience GI hemorrhage while on ASA
- in patients with intra coronary stent implantation, the coverage period following insertion is:
  Bare Metal Stents (BMS) - 30 days
  Drug Eluting Stents (DES): Sirolimus (e.g., Cypher®) - 90 days
  Paclitaxel (e.g., Taxus®) - 180 days
  NOTE*:** The ***Criteria Code 02 may be used for the initial 30 days coverage period for all types of intra coronary stent implantation. For coverage beyond the initial 30 day on-line approval a written request from the attending physician is required.
- for patients with non-ST-segment elevation acute coronary syndrome (i.e., unstable angina or non-ST-segment elevation myocardial infarction), in combination with ASA, for a maximum period of 3 months coverage
- other requests on a case by case basis

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Clostridium Botulinum Toxin Type A (Botox 100iu/vial Inj)

- for use in patients with functional impairment originating from spasticity or dystonia (involuntary sustained muscle contraction) resulting from one of the following Health Canada approved indications:
  - the treatment of cervical dystonia (spasmodic torticollis) in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia
  - the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age or older
  - the treatment of dynamic equines foot deformity due to spasticity in pediatric cerebral palsy patients, two years of age or older
  - the management of focal spasticity including the treatment of upper limb spasticity associated with stroke in adults
- requests for other indications, eg., hyperhidrosis, focal limb dystonias, anal fissures, will be considered on a case by case basis

***Codeine, Sustained Release (Codeine Contin 50mg, 100mg, 150mg and 200mg Tablet)**

- for the treatment of mild to moderate chronic pain syndrome, if pain has been controlled by doses less than 200mg q12h
- patients may be considered candidates if they are achieving good pain control from immediate-release plain codeine preparations but prefer the convenience of a long acting preparation or patients who are achieving good pain control from acetaminophen or ASA plus codeine preparations but are limited by the acetaminophen content to no greater than 12 tablets per day
- not insured for the treatment of acute pain (eg., post-operative pain)

Cromoglycate Sodium (1% Nebulizer Solution - see Formulary listings for product names)

- See ***Wet Nebulization Solutions***

***Cyanocobalamin, Injection (Cyanocobalamin, Vitamin B_{12} 100mcg/mL and 1,000mcg/mL Injection)**

- for the treatment of cyanocobalamin deficiency, when the oral route is inappropriate or contraindicated (criteria applies to all Programs)
- may be requested by a nurse practitioner

***Cyanocobalamin, Oral (Vitamin B_{12} 500mcg and 1,000mcg Tab)**

- for the treatment of cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program and Drug Assistance for Cancer Patients. Oral cyanocobalamin is fully insured for Seniors Pharmacare Program
- may be requested by a nurse practitioner

***Cyanocobalamin, Oral in combination (Vitamin B_{12} 1,000mcg SL Tab w Folic Acid)**

- for the treatment of cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program and Drug Assistance for Cancer Patients. Oral cyanocobalamin is fully insured for Seniors Pharmacare Program
- may be requested by a nurse practitioner

Cyclosporine (Neoral 10mg, 25mg, 50mg, 100mg Capsule and 100mg/mL Oral Liquid & generic brands)

- for the treatment of severe psoriasis
- for the treatment of severe rheumatoid arthritis

Desmopressin (DDAVP 0.1mg, 0.2mg Tablet, 100mcg/mL Drops and 10mcg/dose Nasal Spray & generic brands)

- for the management of nocturnal enuresis in children only

Dipyridamole & ASA (Aggrenox 200/25mg Capsule)

- for the secondary prevention of ischemic stroke/transient ischemic attack (TIA) in patients who have experienced a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA

***Dolasetron (Anzemet 50mg, 100mg Tablet)**

- See ***Serotonin (5-HT_3) Antagonists***
  Recommended dose is 100mg orally 1 hour pre-chemotherapy.

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Donepezil (Aricept 5mg, 100mg Tablet)
- See ***Cholinesterase Inhibitors (ChEI)***

Dronabinol (Marinol 2.5mg, 5mg and 10mg Capsule)
- for the treatment of severe nausea and vomiting associated with cancer chemotherapy in patients who have failed a traditional stepwise approach to antiemetic therapy
- for second line treatment of acquired immune deficiency syndrome (AIDS)-related anorexia associated with weight loss

Dutasteride (Avodart 0.5mg Cap)
- for the treatment of Benign Prostatic Hypertrophy when alpha antagonists are contraindicated or not tolerated

Entacapone (Comtan 200mg Tablet)
- for the treatment of Parkinson's disease as adjunctive therapy in patients who are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with levodopa/decarboxylase

Epinephrine (Epipen 1:000 and Epipen Jr. 1:2000 Injection)
- for the emergency treatment of anaphylactic reactions, when out of reach of immediate medical attention
- may be requested by a nurse practitioner

NOTE - Coverage is limited to one unit at a time.
- To allow for replacement of used or expired units, the pharmacist should contact the Pharmacare office and coverage will be provided on the day of the fill. Additional physician requests are not required for replacement units once the initial request has been approved.

***Erlotinib (Tarceva 100mg, 150mg Tablet)**
- as monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen and whose EGFR expression status is positive or unknown

***Erythropoietin (Eprex Multi Dose Vial and Syringe Injection)**
- for the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of $\leq$ 90g/L and whose transfusion requirements are $\geq$ 2 units of packed red blood cells per month over 3 months
- initial approval for 12 weeks with the documentation of dose, hemoglobin and therapeutic outcome (number of transfusions)
- approval of further 12 week cycles are dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly
- if transfusion requirements increase to $\geq$ 2 units/ month (over a 3 month period), one dose increase may be attempted (maximum dose 60,000iu per week)

***Estradiol (Climara, Estrogel Topical Gel and EstradermTransdermal Patch & generic brands)**
***Estradiol/Norethindrone Acetate (Estracomb, Estalis, Estalis-Sequi, Estradot Transdermal Patch)**
- for the treatment of menopausal symptoms in women who cannot tolerate the oral forms of hormone replacement therapy

Etanercept (Enbrel 25mg Powder for Injection)
- See ***Anti-Tumor Necrosis Factor (TNF) Agents*** for criteria for the treatment of adult rheumatoid arthritis
- for the treatment of moderate to severely active, polyarticular juvenile rheumatoid arthritis in children (age 4-17) who have not responded to adequate treatment with one or more DMARDs for at least 3 months or have intolerance to DMARD, and do not have a contraindication to etanercept
- for the treatment of active psoriatic arthritis in patients who have not responded to an adequate trial with two DMARDS or who have an intolerance or contraindication to DMARDS
- written request of a rheumatologist only
- coverage will be approved initially for 6 months. Can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

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Ezetimibe (Ezetrol 10mg Tab)
- for the treatment of hypercholesterolemia, as adjunctive therapy with statins, in patients who have not reached treatment goals on maximum tolerated statin therapy alone
- for the treatment of hypercholesterolemia, as monotherapy, in patients who are intolerant to statins and, when appropriate, fibrates

Fenoterol (Berotec 1mg/mL Solution)
- See ***Wet Nebulization Solutions***

***Fentanyl (Duragesic 25mcg/h, 50mcg/h, 75mcg/h, 100mcg/h Transdermal System)**
- for the treatment of malignant or chronic non-malignant pain in patients who are unresponsive or intolerant to at least two long-acting oral sustained released products, such as morphine and hydromorphone, despite appropriate dose titration and adjunctive therapy including laxatives and antiemetics

Finasteride (Proscar 5mg Tablet)
- for the treatment of Benign Prostatic Hypertrophy (BPH) when alpha-antagonists are contraindicated or not tolerated; *or* alpha-antagonists have failed
- patients successfully treated with combination therapy should be reassessed at 6 months and the alpha-antagonist discontinued. If symptoms return, alpha-antagonist can be restarted.

***Fluconazole (Diflucan POS 10mg/mL)**
- for the treatment of oropharyngeal candidiasis when nystatin has failed, or for systemic infections when oral tablets are not an option
- may be requested by a nurse practitioner

***Fludarabine (Fludara 10mg Tablet)**
- for the treatment of chronic lymphocytic leukemia (CLL), in patients with an ECOG performance status of 0-2, when
  - the patient has failed to respond or relapsed during or after previous therapy with an alkylating agent, and
  - intravenous administration is not desirable

Fluoroquinolones, Ophthalmic (Ciprofloxacin, Ofloxacin)
- for the treatment of eye infections upon the order of an ophthalmologist or ophthalmology resident **[*Criteria Code 01*]**

***Fluoroquinolones, Oral (Ciprofloxacin, Norfloxacin, Ofloxacin)**
- for the treatment of patients intolerant or allergic (hypersensitivity reaction) to all other effective oral agents **[*Criteria Code 01*]**
- for the treatment of aerobic, gram-negative infections which are resistant to other suitable oral agents **[*Criteria Code 02*]**
- for the oral treatment of multiresistant, aerobic, gram-negative infections traditionally requiring parenteral therapy (e.g., osteomyelitis, complicated urinary tract infections, bacterial pneumonia in cystic fibrosis, prostatitis) for which other oral agents are not effective or available **[*Criteria Code 03*]**
- for infections due to Pseudomonas Aeruginosa (ciprofloxacin is the preferred agent) **[*Criteria Code 04*]**
- for the treatment of necrotizing (malignant) otitis externa **[*Criteria Code 05*]**
- for the prevention of endophthalmitis in patients who have had cataract surgery involving an unplanned vitrectomy (ciprofloxacin) **[*Criteria Code 06*]**
- only *Criteria Code 01* for Ciprofloxacin may be selected by a nurse practitioner

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***Fluoroquinolones, Respiratory (Levofloxacin, Moxifloxacin)**

- for the completion of therapy instituted in the hospital setting for the treatment of nosocomial and community acquired pneumonia **[*Criteria Code 01*]**
- for the treatment of severe pneumonia in nursing home patients **[*Criteria Code 02*]**
- for the treatment[1] of CAP in patients with comorbidity[2] upon radiographic confirmation of pneumonia, *or* who have failed[3] first line therapies (macrolide, doxycycline, amoxicillin-clavulanate) **[*Criteria Code 03*]**
- for the treatment[1] of Group II AECB patients who have failed[3] treatment with one of the following: amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate. Group II AECB patients have an $FEV_1 < 50\%$ predicted or an FEV_1 between 50% and 60% predicted but have significant comorbidity[2] and/or experience ≥ 4 exacerbations per year. **[*Criteria Code 04*]**

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[1] If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

[2] Comorbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.

[3] Defined by clinical deterioration after 72 hours of antibiotic treatment or lack of improvement after completion of antibiotic treatment.

Formoterol (Foradil 12ug Capsule for Inhalation and Oxeze 6mcg/dose, 12mcg/dose Turbuhaler)

- See ***Long-Acting Beta$_2$-Agonists***

Formoterol, in combination (Symbicort 100/6mcg, 200/6mcg Turbuhaler)

- See ***Long-Acting Beta$_2$-Agonists***

Gabapentin (Neurontin 100mg, 300mg, 400mg Capsule and 600mg, 800mg Tablet & generic brands)

- for adjunctive management of epilepsy not satisfactorily controlled by conventional therapy
- for the treatment of neuropathic pain after an adequate trial (minimum 8 weeks) of a tricyclic antidepressant. Therapeutic doses to a maximum of 3,600mg per day will be approved. A traditional anticonvulsant, eg., carbamazepine may be an alternate treatment choice.

Galantamine (Reminyl ER 8mg, 16mg, 24mg Capsule)

- See ***Cholinesterase Inhibitors (ChEI)***

***Granisetron (Kytril 1mg Tablet)**

- See ***Serotonin (5-HT$_3$) Antagonists***

NOTE - Recommended dose is 2mg orally 1 hour pre-chemotherapy *or* 1mg 1 hour pre-chemotherapy and 1mg 12 hours post chemotherapy.

Hydroxyzine (10mg, 25mg, 50mg Capsule, generic brands and Atarax Syrup)

- for chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with hydroxyzine
- may be requested by a nurse practitioner

***Imatinib (Gleevec 100mg Capsule and 100mg, 400mg Tablet)**

- for the treatment of chronic myelogenous leukemia (CML), as a single agent, in patients who have documented evidence of Philadelphia chromosone positive CML, with an ECOG performance status of 0-2, and who are in blast crisis, accelerated phase, or chronic phase, or
- as secondary use in patients who demonstrate a hematologic relapse or cytogenetic progression after interferon-alpha (INF-a) therapy
- requests for other indications will be reviewed on a case by case basis
- written request of an oncologist required

Imiquimod (Aldara 5% Cream)

- for the treatment of external genital and perianal warts and condyloma acuminata in adults
- for the treatment of actinic keratosis on the head and neck in patients who have failed treatment with 5FU and cryotherapy
- request will not be accepted from a nurse practitioner

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Infliximab (Remicade 100mg Powder for Injection)

- for treatment of active rheumatoid arthritis (RA), see ***Anti-Tumor Necrosis Factor (TNF) Agents***
- for treatment of Crohn's disease in adults, when prescribed by a gastroenterologist or physician with a specialty in gastroenterology:
  - in patients with **moderate to severe active disease** refractory to 5-ASA products AND glucocorticosteroids (e.g., prednisone) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)**. Initial approval of infliximab will be for a single infusion of 5mg/kg/dose. A second infusion may be warranted in patients not responding to the first infusion or in patients responding initially but then worsening before maintenance therapy is effective. Request for approval beyond induction therapy will be considered case by case.
  - in patients with **fistulizing disease** who have actively draining perianal or entercutaneous fistula(e) that have recurred or persisted despite a course of appropriate antibiotic therapy (e.g. metronidazole +/-ciprofloxacin for a minumum of 3 weeks) AND immunosuppressive therapy (azathioprine or 6-mercaptopurine or methotrexate)**. Initial approval is for three infusions of infliximab of 5mg/kg/dose at 0,2 and 6 week intervals.

** Patients who are very ill and not candidates for surgery may qualify for infliximab therapy without a trial of AZA, 6-MP or MTX, as they may require a more rapid onset of response.

Insulin Aspart (NovoRapid 100iu/mL Penfill and Vial)

- for the management of Type I and Type II diabetes mellitus in patients undergoing intensive therapy, ie., administering three or more injections of insulin per day including basal insulin and testing blood glucose levels 4-6 times per day
- may be requested by a nurse practitioner

Insulin Lispro (Humalog Insulin and Cartridges)

- for the management of Type I and Type II diabetes mellitus in patients undergoing intensive therapy, ie., administering three or more injections of insulin per day including basal insulin and testing blood glucose levels 4-6 times per day
- may be requested by a nurse practitioner

***Interferon alpha-2a (Roferon-A Injection)**

- written request of an oncologist only
- for hairy cell leukemia
- for AIDS-related Kaposi's sarcoma
- for chronic hepatitis B or C
- for chronic myelogenous leukemia (CML)
- for thrombocytosis associated with CML

***Interferon alpha-2b (Intron-A Injection and Multidose Pen)**

- written request of an oncologist only
- for hairy cell leukemia
- for AIDS-related Kaposi's sarcoma
- for chronic hepatitis B or C
- for chronic myelogenous leukemia (CML)
- for thrombocytosis associated with CML
- for malignant melanoma
- for basal cell carcinoma

Interferon alpha-n1 (Infergen 30mcg/mL Injection)

- for the treatment of hepatitis C upon the written request of a hepatologist or associated internal medicine specialist. Coverage will be for 24 weeks with reassessment at that time.

***Ipratropium Bromide (250mcg/mL Inhaler Solutions - see Formulary listings for product names)**

- See ***Wet Nebulization Solutions***

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

***Ipratropium Bromide, in combination (Combivent Inhaler Solution & generic brands)**
- See ***Wet Nebulization Solutions***

Isosorbide Mononitrate (Imdur 60mg Tablet & generic brand)
- for patients requiring nitrate therapy when the short-acting nitrates or nitrate patches are not effective in controlling symptoms or are inappropriate

***Itraconazole (Sporanox 100mg Capsule)**
- for the treatment of severe systemic fungal infections
- for the treatment of severe or resistant fungal infections in immunocompromised patients
- for the treatment of severe onychomycosis caused by dermatophyte fungi as diagnosed by dermatologist or attending physician

***Lactulose (667mg/mL Oral Liquid, generic brands)**
- for portal systemic encephalopathy
- for pneumatosis cystoides intestinalis

Lamivudine (Heptovir 100mg Tablet)
- for the treatment of hepatitis B, upon written request of a specialist
- therapy is approved for one year, with reassessment required at that time

Lamotrigine (Lamictal 5mg Chewable, 25mg, 100mg, 150mg Tablet & generic brands)
- for adjunctive management of epilepsy not satisfactorily controlled by conventional therapy
- for treatment of bipolar disorder in patients who have intolerance or a history of failure to lithium

Lansoprazole (Prevacid 15mg, 30mg Capsule)
- See ***Proton Pump Inhibitors for GERD and PUD***

Lansoprazole, in combination (Hp-PAC)
- See ***Proton Pump Inhibitors for PUD***

Leflunomide (Arava 10mg, 20mg Tablet, generic brands)
- written request of a rheumatologistonly
- for patients with a diagnosis of active rheumatoid arthritis (RA) who
  - have not responded or who have had intolerable toxicity to an adequate trial[1] of combination therapy of at least two traditional DMARDs[2] *or*
  - if combination therapy is not an option, an adequate trial of at least three traditional DMARDs in sequence as monotherapy.
- therapy must include methotrexate[3] alone or in combination unless contraindicated or not tolerated
- coverage will be approved initially for 6 months. Can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%.

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[1] An adequate trial is 5 months for IM gold, 6 months for penicillamine, 4 months for hydroxychloroquine and 3 months for all other traditional DMARDs as well as leflunomide, infliximab and etanercept.

[2] Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, D-penicillamine and cyclosporine.

[3] Unless limited by toxicity, methotrexate dosage should be increased up to 25mg/wk unless response is achieved at a lower dose.

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Leukotriene Receptor Antagonists (Montelukast, Zafirlukast)

- for the treatment of moderate to severe **asthma** in patients who:
  - are compliant with inhaled corticosteroids at a dose of any one of the following:
    - > 500mcg/day CFC-beclomethasone dipropionate
    - > 400mcg/day budesonide
    - > 250mcg/day HFA-beclomethasone dipropionate or
    - > 250mcg/day fluticasone propionate **and**
  - require additional symptom control, e.g., cough, awakening at night, missing activities such as school, work, social activities, because of asthma symptoms; **and**
  - require increasing amounts of short-acting $beta_2$-agonists, indicative of poor control

Levetiracetam (Keppra 250mg, 500mg, 750mg Tablet & generic brands)

- as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy

Levocarnitine (Carnitor1g/5mL Injection, 100mg/mL Oral Liquid and 300mg Tablet)

- for the treatment of primary systemic carnitine deficiency

***Levofloxacin (Levaquin 250mg, 500mg Tablet & generic brands)**

- See ***Fluoroquinolones, Respiratory***

Linezolid (Zyvoxam 600mg Tablet)

- written request of an infectious disease specialist only
- for the treatment of proven vancomycin-resistant *enterococci* (VRE) infections
- for the treatment of proven methicillin-resistant *staphylococcus aureus or epidermidis* (MRSA/MRSE) infections in those patients who are unresponsive to, or intolerant of vancomycin.

Long-Acting $Beta_2$-Agonists (Formoterol, Salmeterol)

- for the treatment of moderate to severe **asthma** in patients who:
  - are compliant with inhaled corticosteroids at a dose of any one of the following:
    - > 500mcg/day CFC-beclomethasone dipropionate
    - > 400mcg/day budesonide
    - > 250mcg/day HFA-beclomethasone dipropionate or
    - > 250mcg/day fluticasone propionate **and**
  - require additional symptom control, e.g., cough, awakening at night, missing activities such as school, work, social activities, because of asthma symptoms; **and**
  - require increasing amounts of short-acting $beta_2$-agonists, indicative of poor control
- for the treatment of moderate** to severe** **chronic obstructive pulmonary disease** (COPD), if a patient continues to be symptomatic after an adequate trial (2-4 months) of ipratropium at a dose of 3 puffs four times daily **and** short-acting $beta_2$-agonists, indicative of poor control
- may be requested by a nurse practitioner

** Canadian Thoracic Society COPD Classification

By Symptom/Disability:

Moderate - shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

Severe - shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

By Lung Function:

Moderate - FEV_1 40-59% predicted, $FEV_1/FVC < 0.7$

Severe - FEV_1 < 40% predicted, $FEV_1/FVC < 0.7$

Loratadine (Claritin 10mg Tablet & generic brands)

- for chronic urticaria, defined as the presence of hives or lesions for longer than six weeks, which has responded to treatment with loratadine
- may be requested by a nurse practitioner

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Magnesium Glucoheptonate (5mg/mL Solution, generic brands)
- for the treatment of hypomagnesemia

Metformin and Rosiglitazone (Avandamet 1/500mg, 2/500mg, 4/500mg, 2/1000mg, 4/1000mg Tablet)
- for the treatment of Type II diabetes in patients currently stabilized on equivalent strengths of metformin and rosiglitazone
- may be requested by a nurse practitioner

***Methadone (Metadol 1mg, 5mg, 10mg, 25mg Tablet)**
- for the management of severe chronic or malignant pain as an alternative to other opiates
- written request of a physician authorized to prescribe methadone

***Methadone, Compounded Oral Liquid (various strengths)**
- for the management of severe chronic or malignant pain as an alternative to other opiates
- for the management of patients undergoing therapy for drug dependence
- written request of a physician authorized to prescribe methadone

***Midazolam (1mg/mL, 5mg/mL Injection, generic brands)**
- for adjunctive therapy of pain management in palliative care patients outside the hospital setting

Midodrine HCL (Amatine 2.5mg, 5mg Tablet)
- for primary neurogenic types of idiopathic orthostatic hypotension, that is in the Bradbury-Eggleston or Shy-Drager Syndromes

Mometasone (Nasonex Nasal Spray)
- for the treatment of seasonal or perennial allergic rhinitis in patients ages 3 - 11 years only. For patients 12 years and older who require nasal steroids, the options for coverage include budesonide and beclomethasone which are fully insured.
- may be requested by a nurse practitioner

Montelukast (Singulair 4mg, 5mg Chewtabs, 4mg/pkt Granules and 10mg Tablets)
- See ***Leukotriene Receptor Antagonists***

***Moxifloxacin (Avelox 400mg Tablet)**
- See ***Fluoroquinolones, Respiratory***

Naltrexone (ReVia 50mgTablet)
- for the treatment of alcohol dependence, as an adjunct to a comprehensive psychotherapeutic or psychological alcoholism counselling program to support abstinence, and reduce the risk of relapse
- eligibility is initially restricted to a three month period with reassessment at that time for further coverage

Naratriptan (Amerge 1mg, 2mg Tablet)
- See ***Selective 5HT$_1$ - Receptor Agonists***

***Norfloxacin (400mg Tablet, generic brands)**
- See ***Fluoroquinolones, Oral***

Ofloxacin, Ophthalmic (Ocuflox 0.3% Ophthalmic Solution & generic brands)
- See ***Fluoroquinolones, Ophthalmic***

***Ofloxacin, Oral (Floxin 300mg, 400mg Tablet & generic brands)**
- See ***Fluoroquinolones, Oral***

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Olanzapine (Zyprexa 2.5mg, 5mg, 7.5mg, 10mg, 15mg and Zyprexa Zydis 5mg, 10mg, 15mg Tablet)
- for the treatment of schizophrenia and related psychotic disorders upon the written request of a psychiatrist, either first line or upon failure of other antipsychotic agents
- for the acute treatment of manic or mixed episodes in bipolar I disorder in patients with intolerance or a history of failure to one other atypical antipsychotic
- for maintenance therapy in patients with bipolar disease who are currently stabilized on olanzapine

Omeprazole (20mg Capsule, generic brand and Losec10mg, 20mg Tablet)
- See ***Proton Pump Inhibitors for GERD and PUD***

***Ondansetron (Zofran 4mg, 8mg Tablet and 4mg/5mL Oral Liquid)**
- See ***Serotonin (5-HT$_3$) Antagonists***

NOTE - Only requests for the oral dosage forms are eligible for consideration. Although the dose may vary, usually a single oral 8mg dose pre-chemotherapy is sufficient to control symptoms. As well, some patients may require additional therapy up to 48 hours after the last dose of chemotherapy or last radiation treatment. Benefit beyond 48 hours has not been established and, therefore, not insured.

Oseltamivir (Tamiflu 75mg Capsule)
- for the treatment of long-term care residents with clinically suspected or lab confirmed influenza A or B. A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community.
- for the prophylaxis of long term care residents where the facility has an influenza A or B outbreak

Treatment of individual cases in LTC facilities will be covered by Pharmacare, but not individual cases in the community, because treating LTC cases has the potential to prevent an outbreak.

Oxcarbazepine (Trileptal 60mg/mL Oral Liquid and 150mg, 300mg, 600mg Tablet)
- for the treatment of epileptic seizures in patients who have had an inadequate response or are intolerant to at least three other formulary agents (prior or current use) including carbamazepine

Oxybutynin XL (Ditropan XL 5mg, 10mg Tablet)
- for the treatment of over-active bladder (not stress incontinence) after a reasonable trial of oxybutynin immediate-release (IR) is not tolerated
- a three month trial will be approved initially with assessment of the effectiveness of this therapy required if further coverage is considered

***Oxycodone, Sustained Release (OxyContin 5mg, 10mg, 20mg, 40mg and 80mg Tablet)**
- for the treatment of moderate to severe chronic pain syndromes, as an alternative to morphine or hydromorphone
- not insured for the treatment of acute pain (eg., post-operative pain)

Pantoprazole (Pantoloc 20mg, 40mg EC Tablet)
- See ***Proton Pump Inhibitors for GERD and PUD***

Peginterferon alfa-2a (Pegasys 180mcg Injection)
- for the treatment of hepatitis C in patients who are treatment naive, upon the written request of a hepatologist, or other specialist in this area
- a 24 week period will be initially approved at which time a further request will be required documenting the patient's response. If a positive response occurs, coverage can be continued for an additional 24 weeks (48 weeks total)

Peginterferon alfa-2a and Ribavirin (Pegasys RBV Injection/Tablet)
- for the treatment of hepatitis C in patients who are treatment naive, upon the written request of a hepatologist, or other specialist in this area
- a 24 week period will initially be approved at which time a further request will be required documenting the patient's response. If a positive response occurs, coverage can be continued for an additional 24 weeks (48 weeks total).

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Peginterferon alfa-2b and Ribavirin (Pegetron and Pegetron Redipen Injection/Capsule)
- for the treatment of hepatitis C in patients who are treatment naive, upon the written request of a hepatologist, or other specialist in this area
- a 24 week period will initially be approved at which time a further request will be required documenting the patient's response. If a positive response occurs, coverage can be continued for an additional 24 weeks (48 weeks total).

Pentoxifylline (Trental 400mg Tablet & generic brands)
- for the treatment of patients with ulcers due to ischemia of critical limbs

Pilocarpine, Oral (Salagen 5mg Tablet)
- for oncology patients only
- for the treatment of the symptoms of xerostomia due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck

Pioglitazone (Actos 15mg, 30mg, 45mg Tablet)
- See ***Thiazolidinediones***

Proton Pump Inhibitors for Gastroesophageal Reflux Disease (GERD)
(Lansoprazole, Omeprazole, Pantoprazole and Rabeprazole)

Moderate Symptoms of GERD and/or Mild to Moderate Esophagitis
- for the treatment of GERD that is refractory to lifestyle adjustments, antacids and 8 weeks of prescription strength H_2RA (eg., ranitidine 150mg bid)
  Initial Coverage Duration: 8 weeks
- longer term coverage can be provided for patients who discontinue PPI therapy after initial 8 weeks of coverage, and a retrial (2nd trial) of H_2RA is not successful
  Coverage Duration: 1 year, with reassessment

Severe Symptoms of GERD
- for the treatment of severe symptoms of GERD, which may include daily attacks of reflux pain or GERD causing nighttime wakening (with or without trial of H_2RA)
  Initial Coverage Duration: 8 weeks
- longer term coverage can be provided for patients who discontinue PPI therapy and a trial of H_2RA is not successful
  Coverage Duration: 1 year with reassessment

Severe Esophagitis, Barrett's Esophagus
- for the treatment of endoscopically proven severe esophagitis or Barrett's esophagitis. A copy of endoscopy report or specialist consultation is required.
  Coverage Duration: long-term

Other reflux-associated indications on the basis of specialist recommendation
(eg., laryngeal reflux, asthma-related GERD, non-cardiac chest pain)
- consultation report is required
  Initial Coverage Duration: 8 weeks
- longer term coverage can be considered, on a case by case basis, in patients who have had a successful trial of PPI therapy and step down to H_2RA therapy is not considered an option
  Coverage Duration: 1 year with reassessment

NOTE - Patients who are starting new therapy for GERD related symptoms must have a 4-8 weeks trial of both omeprazole and rabeprazole before coverage for another PPI can be considered. Two 10mg Pariet tablets can be used to provide the usual daily dose of 20mg; in some patients a maintenance dose of 10mg has been sufficient.

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Proton Pump Inhibitors for Peptic Ulcer Disease (PUD)
(Lansoprazole, Omeprazole, Pantoprazole and Rabeprazole)

Complicated Peptic Ulcer
- for the treatment of peptic ulcers in patients who have procedurally confirmed ulcer complications (ie., perforation, obstruction, large ulcers, or GI bleed) or patients with suspected ulcer with alarm symptoms (eg., GI bleeding, unexplained vomiting or weight loss, etc.)
  Coverage Duration: up to 8-12 weeks

NSAID induced Ulcers
- for the treatment of NSAID induced complicated peptic ulcer (bleeding ulcer, perforation, etc.) when the NSAID is discontinued
  Coverage Duration: up to 8-12 weeks
- for the treatment and prophylaxis of NSAID induced complications in patients who have had previous NSAID related ulcer or ulcer complications and NSAID therapy cannot be discontinued
  Coverage Duration: while on NSAID or a maximum of 1 year with reassessment
- for the prophylaxis of NSAID induced complications in patients who are at high risk (i.e., NSAID therapy plus two other risk factors including advanced age, concomitant anticoagulant or oral corticosteroid therapy)
  Coverage Duration: while on NSAID or a maximum of 1 year with reassessment

Gastric or Duodenal Ulcers - Helicobacter pylori positive
- combination therapy with antibiotics for 1 week duration **[*Criteria Code 01*]**
- up to one month of PPI may be covered, if included in eradication regimen to heal active ulcer. Further coverage will require a written request.
- may be requested by a nurse practitioner for the H.pylori positive (eradication) indication only

Uncomplicated ulcer, not related to H. pylori or NSAID
- for the treatment of uncomplicated ulcer (H. pylori negative, not due to NSAIDs) when 8-12 weeks of H_2RA therapy has failed
  Coverage Duration: up to 8 weeks

Zollinger-Ellison Syndrome
Coverage Duration: long term

Other requests individually assessed upon written physician request.

NOTE - Patients who are starting therapy for peptic ulcer disease must have a trial of both omeprazole and rabeprazole before coverage of another PPI can be considered. Two 10mg Pariet tablets can be used to provide the usual daily dose of 20mg. However, all PPIs can be insured for H.pylori eradication and for NSAID induced ulcer treatment and prophylaxis, as per criteria.

Rabeprazole (Pariet 10mg Tablet)
- See ***Proton Pump Inhibitors for GERD and PUD***

Raloxifene (Evista 60mg Tablet)
- for the treatment of diagnosed post-menopausal osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements
- for the treatment of diagnosed post-menopausal osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area)
- for the treatment of conventional x-ray documented osteopenia/demineralization only in women without access to BMD measurements. (Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.)
- other requests reviewed on case by case basis

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Riluzole (Rilutek 50mg Tablet)

- for the treatment of amyotrophic lateral sclerosis (ALS) or Lou Gehrig's Disease, when initiated by a neurologist with expertise in the management of ALS and authorized to prescribe riluzole (is a member of the Canadian ALS Consortium), and when the patient has:
  - Probable or definite diagnosis of ALS
  - ALS symptoms for less than five years
  - FVC >60% predicted upon initiation of therapy
  - No tracheostomy for invasive ventilation
- coverage to be reviewed every six months
- coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation

***Risedronate (Actonel 5mg, 30mg, 35mg Tablet)**

- for the treatment of diagnosed osteoporosis associated with documented fragility fracture (with low impact) even in the absence of bone mineral density (BMD) measurements
- for the treatment of diagnosed osteoporosis without documented fractures when patients have BMD measurements of -2.5 or lower at the spine (L2-L4) or at the hip (excluding Ward's area)
- for the treatment of conventional x-ray documented osteopenia/demineralization only in patients without access to BMD measurements. (Ideally, radiologist's comment of osteopenia or demineralization on any x-ray report warrants further assessment with BMD measurement. However, since there is evidence to show that once osteopenia is visible on conventional x-ray that bone is usually decidedly osteoporotic (BMD of -2.5 or lower), conventional x-ray can be used to recommend treatment if BMD is not accessible.)
- as prophylaxis of corticosteroid induced osteoporosis in patients expected to receive oral corticosteroid therapy for 3 months or more
- Paget's disease of bone (2 month limit, one re-treatment course may be considered)
- other requests reviewed on case by case basis
- may be requested by a nurse practitioner for osteoporosis related conditions only (not Paget's Disease)

Risperidone (Risperdal Consta 25mg/mL, 37.5mg/mL, 50mg/2mL Injection)

- for patients with a history of non-adherence *and* inadequate control or significant side-effects from two or more oral antipsychotic medications *and* inadequate control or significant side-effects from at least **one** typical depot antipsychotic agent

Rivastigmine (Exelon 1.5mg, 3mg, 4.5mg, 6mg Capsule and 2mg/mL Oral Liquid)

- See ***Cholinesterase Inhibitors (ChEI)***

Rizatriptan (Maxalt 5mg, 10mg Tablets and 5mg, 10mg Wafers)

- See ***Selective 5HT$_1$ - Receptor Agonists***

Rosiglitazone (Avandia 2mg, 4mg, 8mg Tablet)

- See ***Thiazolidinediones***

***Saccharated Iron Oxide (Venofer 20mg/mL Injection)**

- for patients in whom parenteral iron is indicated and who have had a hypersensitivity or anaphylactic reaction to IV iron dextran

***Salbutamol (0.5mg/mL, 1mg/mL, 2mg/mL Unit Dose Inhaler Solution and 5mg/mL Inhaler Solution - see Formulary listings for product names)**

- See ***Wet Nebulization Solutions***

***Salbutamol, in combination (Combivent Inhaler Solution & generic brands)**

- See ***Wet Nebulization Solutions***

Salmeterol (Serevent 50mcg/dose Diskhaler, 50mcg/dose Diskus and 25mcg/dose Inhaler)

- See ***Long-Acting Beta$_2$-Agonists***

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Salmeterol, in combination (Advair 50/100mcg, 50/250mcg, 50/500mcg Diskus and HFA 25/125mcg/dose, HFA 25/250mcg dose Inhaler)

- See ***Long-Acting Beta$_2$-Agonists***

Selective 5HT$_1$ - Receptor Agonists (Almotriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan)

- for the treatment of migraine attacks when a diagnosis of migraine headache has been determined according to the guidelines (Canadian Medical Association J 1997;156(9)) and
  - the patient is experiencing moderate migraine headaches and other therapies (e.g., NSAIDS, DHE spray) have not been effective, or
  - the patient is experiencing severe or ultra severe migraine attacks
- naratriptan, rizatriptan, sumatriptan and zolmitriptan may be requested by a nurse practitioner

***Serotonin (5-HT$_3$) Antagonists (Dolasetron, Granisetron, Ondansetron)**

- for the treatment of emesis in patients who are:
  - receiving moderately or severely emetogenic chemotherapy [***Criteria Code 01***] or
  - receiving intravenous chemotherapy or radiotherapy and who have not experienced adequate control with other available antiemetics [***Criteria Code 02***] or
  - experiencing intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents [***Criteria Code 03***]

Sevelamer (Renagel 800mg Tablet)

- upon the written request of a nephrologist within the Provincial Dialysis Program
- for the treatment of hyperphosphatemia (>1.8 mmol/L) and calciphylaxis (calcific arteriolopathy) or hypercalcemia after failure on a magnesium-based binder

NOTE - The initial coverage will be for a three-month period. Renewals will be in six month intervals when there has been a significant reduction in phosphate levels (a decrease of more than 0.7 mmol of phosphate)

Somatropin (Humatrope, Nutropin, Nutropin AQ, Saizen Injections)

- for treatment of growth hormone deficiency in patients with Turner's Syndrome, upon the request of an endocrinologist

Spacer Devices (AeroChamber, AeroChamber Max Only)

- for patients who require a spacer device to optimize existing MDI therapy and the pharmacy has not billed an spacer device to the Nova Scotia Pharmacare Programs for this patient within the last 12 months [***Criteria Code 01***]
- for patients who require a spacer device to switch from wet nebulization to MDI therapy and the pharmacy has not billed an spacer device to the Nova Scotia Pharmacare Programs for this patient within the last 12 months [***Criteria Code 02***]

AeroChambers may be prescribed by a physician, nurse practitioner or pharmacist. The code can be selected by the pharmacist based on the patient's medication history. Since the average usage lifetime of AeroChamber® devices is one year, Pharmacare recipients are eligible for approval of a maximum of one spacer per 12 month period.

Sumatriptan (Imitrex 25mg, 50mg, 100mg Tablet & generic brands, Imitrex 6mg/syringe Injection and 5mg, 20mg Nasal Spray)

- See ***Selective 5HT$_1$ - Receptor Agonists***

Tacrolimus (Protopic 0.03% Ointment)

- for children greater than 2 years of age with refractory atopic dermatitis. Coverage will be renewed yearly.

Tazarotene (Tazorac 0.05%, 0.1% Gel)

- for use in psoriasis therapy when conventional therapies have been ineffective or inappropriate

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Terbinafine (Lamisil 250mg Tablet & generic brands)

- for the treatment of severe onychomycosis caused by dermatophyte fungi as diagnosed by dermatologist or attending physician

Thiazolidinediones (Pioglitazone, Rosiglitazone)

- for treatment of Type II diabetes in patients who have:
  - inadequate glycemic control[1] on optimal doses[2] of sulfonylurea and metformin; *or*
  - demonstrated intolerance or contraindication to metformin[3] and are on optimal doses[2] of sulfonylurea; *or*
  - demonstrated intolerance or contraindication to sulfonylurea[4] and are on optimal doses[2] of metformin; *or*
  - inadequate glycemic control[1] on optimal doses[2] of metformin and a BMI $\geq$27. (A glitazone is recommended over a sulfonylurea (second line to metformin).)
- patients must have a recent A_{1C} of < 10% unless insulin therapy is inappropriate for the patient. Duration of initial approval will be 6 months; further coverage will require demonstrated evidence of efficacy (a reduction of A_{1C} of 0.7 observed to continue converage).
- may be requested by a nurse practitioner

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[1] A_{1C} >7% and <10%

[2] Maximum doses: metformin 2000mg/day, glyburide 10mg bid

[3] Metformin: Intolerance-GI adverse effects; Contraindications renal impairment or hepatic failure (cautious repaglinide use preferred to rosiglitazone in hepatic failure patients), acute or chronic metabolic acidosis.

[4] Sulfonylureas: Intolerance - hypoglycemia; Contraindications - sulfa allergy, severe renal insufficiency

***Thyrotropin (Thyrogen 0.9mg/mL Injection)**

- to monitor for recurrence and metastatic disease, in patients who have documented evidence of thyroid cancer and who have undergone appropriate surgical and/or medical management. This includes:
  - primary use in patients with inability to raise an endogenous TSH level ($\geq$25 mu/L) with thyroid hormone withdrawl,
  - primary use in cases of documented morbidity in patients for whom severe hypothyroidism could be life-threatening,
  - secondary use in patients with previous thyroid hormone withdrawl resulting in a documented life-threatening event

Ticlopidine (Ticlid 250mg Tablet & generic brands)

- for the secondary prevention of ischemic stroke or transient ischemic attack (TIA) in patients with a documented severe allergy to ASA <u>*or*</u> who experience a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA [***Criteria Code 01***]
- for the prevention of thrombosis in patients post intracoronary stent implantation for a period of up to 30 days following insertion [***Criteria Code 02***]
- other requests on a case by case basis

Tiotropium Bromide (Spiriva 18mcg Cap for Inhalation)

- for the treatment of moderate** to severe** chronic obstructive pulmonary disease (COPD), if a patient continues to be symptomatic after an adequate trial (2-4 months) of ipratropium at a dose of 12 puffs daily
- may be requested by a nurse practitioner

** Canadian Thoracic Society COPD Classification

By Symptom/Disability:

<u>Moderate</u> - shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

<u>Severe</u> - shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

By Lung Function:

<u>Moderate</u> - FEV_1 40-59% predicted, FEV_1/FVC <0.7

<u>Severe</u> - FEV_1 <40% predicted, FEV_1/FVC <0.7

NOTE: Exception status drugs for the Drug Assistance for Cancer Patients are indicated by an asterisk (*).

Tizanidine (Zanaflex 4mg Tablet & generic brand)
- for the treatment of spasticity resulting from traumatic brain injury, multiple sclerosis (MS), spinal cord injury (SCI) or cerebral vascular accident (CVA) **and** the patient is intolerant to or has had a lack of efficacy from baclofen and/or diazepam

Tolterodine (Detrol 1mg, 2mg and Detrol LA 2mg, 4mg Tablet)
- for the treatment of over-active bladder (not stress incontinence) after a reasonable trial of oxybutynin immediate-release (IR) is not tolerated
- three months trial will be approved with reassessment of the effectiveness of this therapy required if further coverage is to be considered

Topiramate (Topamax 25mg, 100mg, 200mg Tablet & generic brands and Topamax 15mg, 25mg Sprinkle Capsule)
- for adjunctive management of epilepsy not satisfactorily controlled by conventional therapy

Tretinoin (Vitamin A Acid Topical Preparations)
- regular benefit under Community Services Pharmacare Programs
- exception status drug under Seniors' Pharmacare Program, for treatment of actinic keratoses

Tryptophan (Tryptan 500mg Capsule and 500mg, 750mg, 1g Tablet & generic brands)
- as an adjunct for the treatment of depression in the management of patients suffering from bipolar affective disorders

Ursodiol (Urso 250mg, DS 500mg Tablet)
- for dissolution of radiolucent, noncalcified gallstones of less than 20mm size for patients who cannot undergo a cholecystectomy
- for management of cholestatic liver disease such as primary biliary cirrhosis

Valganciclovir (Valcyte 450mg Tablet)
- for the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist only
- for the prevention of CMV disease post kidney, heart, liver or kidney-pancreas transplantation in patients at high-risk (D+ / R-) (i.e., donor positive/recipient negative). Coverage will be for a maxiumum of 90 days.

Vancomycin (Vancocin 125mg, 250mg Capsule)
- for the treatment of pseudomembranous colitis (PMC) when patients have not responded to initial therapy with metronidazole, or for initial treatment of severe PMC, or when drug interactions or intolerance prevent the use of metronidazole [***Criteria Code 01***]

Verteporfin (Visudyne 15mg/vial Injection)
- for the treatment of wet age-related macular degeneration (AMD) as prescribed by an authorized ophthalmologist [***Criteria Code 01***]

Vigabatrin (Sabril 0.5g Sachet and 500mg Tablet)
- for adjunctive management of epilepsy not satisfactorily controlled by conventional therapy

Vitamin B_{12}, Injection
- See ***Cyanocobalamin, Injection***

Vitamin B_{12}, Oral
- See ***Cyanocobalamin, Oral***

Voriconazole (Vfend 50mg, 200mg Tablet)
- for the treatment of patients with confirmed invasive aspergillus

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Wet Nebulization Solutions (Budesonide, Cromoglycate Sodium, Fenoterol, Ipratropium Bromide, Salbutamol)

- for adult patients with a vital capacity of 900mL or less
- for adult patients with a respiratory rate greater than 25 breaths/minute
- for patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it
- other requests reviewed on a case by case basis

Zafirlukast (Accolate 20mg Tablet)

- See ***Leukotriene Receptor Antagonists***

Zolmitriptan (Zomig, Zomig Rapimelt 2.5mg Tablet)

- See ***Selective 5HT$_1$ - Receptor Agonists***

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