

# Appendix III – Criteria for Coverage of Exception Status Drugs

---

Coverage of exception status drugs will be approved according to the following criteria upon review of a prescriber's written request. Included with the Nova Scotia Formulary are forms for Exception Status Drug requests, which may be used to facilitate the approval process.

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 prescriber on the prescription or confirmed by the pharmacist. The use of these codes offers the prescriber 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.

## **ABATACEPT** (*Orencia 250mg/vial Injection*)

- for patients with a diagnosis of active rheumatoid arthritis (RA) who:
  - have not responded or who have had intolerable toxicity to an adequate trial<sup>1</sup> of combination therapy of at least two traditional DMARDs<sup>2</sup> or
  - if combination therapy is not an option, an adequate trial<sup>1</sup> of at least three traditional DMARDs<sup>2</sup> in sequence as monotherapy *and*
  - patients must have had an adequate trial<sup>1</sup> of leflunomide. Exceptions can be considered in cases where leflunomide is contraindicated or not tolerated
- therapy must include methotrexate alone or in combination unless contraindicated or not tolerated
- written request of a rheumatologist or prescriber with a specialty in rheumatology
- coverage will be approved initially for 16 weeks. Can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

---

<sup>1</sup> 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.

<sup>2</sup> Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, penicillamine and cyclosporine.

## **ACAMPROSATE** (*Campral 333mg Tablet*)

- for treatment in patients who have been abstinent from alcohol for at least four days and who have contraindications to naltrexone (i.e., acute hepatitis, liver failure or currently receiving opioids)

## **ADALIMUMAB** (*Humira 40mg/vial Injection*)

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

## **ADEFOVIR DIPIVOXIL** (*Hepsera 10mg Tablet*)

- in combination with lamivudine in patients who:
  - have developed failure to lamivudine (increase in HBV DNA of  $\geq 1 \log_{10}$ iu/mL over the nadir measured on two separate occasions within an interval of at least one month, after the first 3 months of lamivudine therapy) AND
  - when failure to lamivudine is not due to poor adherence to therapy
- coverage approved for 1 year

## **\*ALENDRONATE** (*Fosamax 10mg, 40mg, 70mg Tablet and generic brands*)

- for the treatment of osteoporosis associated with documented fragility fracture
- for the treatment of osteoporosis without documented fracture when the patient is at high 10 year fracture risk (using fracture risk tables)
- as prophylaxis of corticosteroid induced osteoporosis in a patient who will be or has been on systemic corticosteroid therapy for > 3 months
- for the treatment of Paget's disease of bone (6 month limit)
- other requests reviewed on a case by case basis

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

---

**\*ALENDRONATE, VITAMIN D3, (Fosavance 70mg/5600IU)**

- for the treatment of osteoporosis associated with documented fragility fracture
- for the treatment of osteoporosis without documented fracture when the patient is at high 10 year fracture risk (using fracture risk tables)
- as prophylaxis of corticosteroid induced osteoporosis in a patient who will be or has been on systemic corticosteroid therapy for > 3 months

**ALGLUCOSIDASE ALFA (Myozyme 50mg Powder for Injection)**

- for the treatment of infantile onset Pompe disease in patients who have had the onset of symptoms and confirmed cardiomyopathy before the age of 12 months AND
- participation in the long-term evaluation of the efficacy of treatment by periodic medical assessment as outlined in the monitoring of therapy guidelines
- initial approval is for 6 months. Continued coverage will be based on evaluation of the efficacy of treatment by regular medical assessment as outlined in the monitoring and discontinuation of therapy guidelines (available from the Pharmacare Office upon request).

**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 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

*NOTE:* The allergy serum must be dispensed from a pharmacy on prescription from a prescriber. 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<sub>1</sub> - Receptor Agonists**

**\*ALTRETAMINE (Hexalen 50mg Capsule)**

- written request from an oncologist or prescriber with a specialty in oncology
- for the treatment of ovarian carcinoma

**AMBRISENTAN (Volibris 5mg, 10mg Tablet)**

- for the treatment of patients with at least Class III pulmonary arterial hypertension (PAH), either idiopathic or associated with connective tissue disease who have failed therapy with sildenafil or who have contraindications to sildenafil.
- diagnosis must be confirmed by right heart catheterization
- request must be from a PAH specialist

**ANAGRELIDE (Agrylin 0.5mg Capsule and generic brands)**

*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 from 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, Etanercept, Golimumab, Infliximab)**

**Ankylosing Spondylitis (Adalimumab, Etanercept, Golimumab)**

- for the treatment of patients with moderate to severe ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score  $\geq 4$  on 10 point scale) who:
  - have axial symptoms\*\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated OR
  - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at

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

least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD

- must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology
- requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work")

\*\*Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of 2 NSAIDs.

#### **Initial Coverage Duration and Maximum Dosage approved:**

- Adalimumab** - initial period 6 months, maximum dose of 40mg every two weeks and not in combination with other anti-TNF agents
- Etanercept** - initial period 6 months, maximum dose of 50mg per week and not in combination with other anti-TNF agents
- Golimumab** - initial period 16 weeks, maximum dose 50mg per month and not in combination with other anti-TNF agents

#### **Crohn's Disease (Adalimumab)**

- for patients with moderate to severely active Crohn's disease and are:
  - refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy
  - initial reimbursement is restricted to an induction dose of 150mg followed by 80mg
  - clinical response to be assessed twelve weeks after the first induction dose and maintenance therapy approved in responders only at a dose not exceeding 40mg every two weeks

#### **Crohn's Disease (Infliximab)**

- 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 glucocorticoids (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 on a case by case basis
  - in patients with **fistulizing disease** who have actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of appropriate antibiotic therapy (e.g., metronidazole +/-ciprofloxacin for a minimum 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.

#### **Juvenile Rheumatoid Arthritis (Etanercept)**

- 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 DMARDs, and do not have a contraindication to etanercept

#### **Psoriasis (Adalimumab, Etanercept, Infliximab)**

- for patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria:
  - Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region
  - failure to respond to, contraindications to or intolerant of methotrexate and cyclosporine
  - failure to respond to, intolerant of or unable to access phototherapy
- written request of a dermatologist or prescriber with a specialty in dermatology

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

- continued coverage is dependent on evidence of improvement, specifically:
  - $\geq 75\%$  reduction in the Psoriasis Area and Severity Index (PASI) score, or
  - $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in DLQI (Dermatology Life Quality Index), or
  - significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals
- concurrent use of biologics not approved

**Initial duration and maximum dosage approved:**

- Adalimumab** - initial approval for a maximum of 16 weeks  
 - maximum dosage for ongoing coverage is 40mg every two weeks
- Etanercept** - initial approval for a maximum of 12 weeks  
 - maximum dosage approved: 50mg biweekly for the initial 12 weeks then 50mg weekly thereafter
- Infliximab** - initial approval for a maximum of 12 weeks  
 - dosage restricted to infliximab 5mg/kg 0, 2 and 6 weeks then every 8 weeks

**Psoriatic Arthritis (*Adalimumab, Golimumab*)**

- for patients with active psoriatic arthritis who meet all of the following:
  - have at least three active and tender joints
  - have not responded to an adequate trial with two DMARDs or have an intolerance or contraindication to DMARDs
  - not used in combination with other TNF antagonists
- written request of a rheumatologist or prescriber with a specialty in rheumatology
- after initial coverage period, can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

**Initial Coverage Duration and Maximum Dosage approved:**

- Adalimumab** - initial period 3 months, maximum dose of 40mg every two weeks
- Golimumab** - initial period 3 months, maximum dose 50mg per month

**Psoriatic Arthritis (*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 or prescriber with a specialty in rheumatology
- coverage will be approved initially for 3 months. Can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

**Rheumatoid Arthritis (*Adalimumab, Etanercept, Golimumab, Infliximab*)**

- for patients with a diagnosis of active rheumatoid arthritis (RA) who:
  - have not responded or who have had intolerable toxicity to an adequate trial<sup>1</sup> of combination therapy of at least two traditional DMARDs<sup>2</sup> or
  - if combination therapy is not an option, an adequate trial<sup>1</sup> of at least three traditional DMARDs<sup>2</sup> in sequence as monotherapy and
  - patients must have had an adequate trial<sup>1</sup> of leflunomide. Exceptions can be considered in cases where leflunomide is contraindicated or not tolerated
- therapy must include methotrexate alone or in combination unless contraindicated or not tolerated
- written request of a rheumatologist or prescriber with a specialty in rheumatology
- after initial coverage period, can be reassessed for yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%

**Initial Coverage Duration and Maximum Dosage approved:**

- Adalimumab** - initial coverage period 6 months, maximum dose of 40mg every two weeks
- Etanercept** - initial coverage period 6 months
- Golimumab** - initial coverage period 16 weeks, maximum dose 50mg per month
- Infliximab** - initial coverage period 6 months

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

---

<sup>1</sup> 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.

<sup>2</sup> Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, penicillamine and cyclosporine.

\*Please note that the concurrent use of anti-TNF agents will not be approved.

**\*APREPITANT** (*Emend 80mg, 125mg, Tri-Pack Capsules*)

- in combination with a 5-HT<sub>3</sub> antagonist and dexamethasone in adult cancer patients treated with chemotherapy that includes cisplatin as a single day therapy greater than or equal to ( $\geq$ ) 70mg/m<sup>2</sup> to prevent acute and delayed nausea and vomiting.
  - aprepitant will only be used with single day cisplatin-based therapy  $\geq$  70mg/m<sup>2</sup> (and not multiple day cisplatin chemotherapy)
  - aprepitant will not be used in patients receiving moderately emetogenic cancer chemotherapy or radiotherapy
  - the 5-HT<sub>3</sub> antagonist should only be used on the first day of cisplatin therapy with aprepitant continuing on Day 2 and Day 3

**ARIPIRAZOLE** (*Abilify 2mg, 5mg, 10mg, 15mg, 20mg and 30mg Tab*)

- for the treatment of schizophrenia and schizoaffective disorders in patients who have a contraindication to quetiapine and risperidone, or have failed a trial of quetiapine and risperidone due to intolerance or lack of response

**ARTIFICIAL TEARS, PRESERVATIVE FREE** (*Celluvisc, Refresh, Refresh Plus, Refresh Tears, Tears Naturale Free*)

- for patients with a 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 confirming the diagnosis will be required to initiate coverage

**\*AZITHROMYCIN** (*Zithromax POS 100mg/5mL, 200mg/5mL and 250mg, 600mg Tablet and generic brands*)

- for the treatment of pneumonia in clients over 65 years of age [**Criteria Code 65**]
- for the treatment of infections requiring a macrolide (including community acquired pneumonia in patients < 65 years 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 tablets) [**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**]

**\*BENZYLAMINE HCL** (*Tantum 0.15% Oral Rinse and generic brands*)

- for oncology patients only

**BETAHISTINE** (*Serc 16mg, 24mg Tablet and generic brands*)

- for the symptomatic treatment of recurrent episodes of vertigo associated with Meniere's disease

**BETAMETHASONE, CALCIPOTRIOL** (*Xamiol 0.5mg/g/50mcg/g Gel*)

- for the treatment of scalp psoriasis after:
  - failure of a topical steroid
  - the use of a topical steroid and calcipotriol together as single agents

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

---

**BOSENTAN** (*Tracleer 62.5mg, 125mg Tablet*)

- written initial request from a pulmonary arterial hypertension (PAH) specialist only
- diagnosis of PAH should be confirmed by right heart catheterization
- **IPAH (functional class III and IV)**
  - for the treatment of patients with World Health Organization (WHO) functional class III and IV idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB) or are intolerant to CCB
- **PAH secondary to scleroderma, congenital heart disease or HIV (functional class III and IV)**
  - for the treatment of patients with World Health Organization (WHO) functional class III and IV pulmonary arterial hypertension (PAH) associated with scleroderma, congenital heart disease or HIV who do not respond to conventional therapy

**BUDESONIDE** (*Pulmicort Nebuamps 0.125mg/mL, 0.25mg/mL, 0.5mg/mL Suspension*)

- See **Wet Nebulization Solutions**

**BUPRENORPHINE AND NALOXONE** (*Suboxone 2mg/0.5mg, 8mg/2mg Sublingual Tablet*)

- for the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of, or with, QT prolongation, or hypersensitivity to methadone)
- must be prescribed by a physician licensed to prescribe methadone for opioid dependence

**BUTORPHANOL** (*10mg/mL Nasal Spray and generic brands*)

- for the treatment of migraine, upon the request of a neurologist, prescriber with a specialty in neurology or a specialist in pain management, when conventional forms of therapy are ineffective or inappropriate

**CABERGOLINE** (*Dostinex 0.5mg Tablet and generic brands*)

- 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 the treatment of psoriasis when conventional therapies have been ineffective or inappropriate

**\*CALCITONIN, INTRANASAL** (*Miacalcin 200iu Nasal Spray and generic brands*)

- for the treatment of osteoporosis associated with documented fragility fracture when alendronate, risedronate and raloxifene are not tolerated or are contraindicated
- for the treatment of osteoporosis without documented fracture when patient is at high 10 year fracture risk (using fracture risk tables) and alendronate, risedronate and raloxifene are not tolerated or are contraindicated
- for the treatment of pain associated with osteoporotic fragility fractures, bone metastases or pathological fractures (short term up to 3 months)
- other requests reviewed on a case by case basis

**\*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 naive or who have progressed 6 months after completion of adjuvant 5-FU/LV therapy
- for adjuvant treatment of patients with stage III (Dukes' C) colon cancer and ECOG status 0-1 when prescribed by an oncologist
- requests must be from an oncologist or a prescriber with a specialty in oncology, and approval will be granted for three months, to be renewed as required; in stage III colon cancer, coverage approved for 6 months

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

---

**CARVEDILOL** (*Coreg 3.125mg, 6.25mg, 12.5mg, 25mg Tablet and generic brands*)

- for the treatment of stable symptomatic heart failure with systolic dysfunction (i.e., left ventricular ejection fraction (LVEF) less than or equal to 40%)

**CETIRIZINE** (*Reactine 5mg, 10mg Tablet and 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

**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 and generic brands and Ointment*)

- See **Fluoroquinolones, Ophthalmic**

**\*CIPROFLOXACIN, ORAL** (*Cipro 100mg/mL Oral Liquid and 250mg, 500mg, 750mg Tablet and generic brands*)

- See **Fluoroquinolones, Oral**

**\*CIPROFLOXACIN XL, ORAL** (*Cipro XL 1000mg 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 & DEXAMETHASONE, OTIC** (*Ciprodex Otic Suspension*)

- for the treatment of patients with acute otitis media with otorrhea through tympanostomy tubes [**Criteria Code 01**]
- for the treatment of patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane [**Criteria Code 02**]

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

**\*CLARITHROMYCIN** (*Biaxin 250mg, 500mg, XL 500mg Tablet, generic brands and 125mg/5mL, 250mg/5mL Oral Liquid*)

- for the treatment of pneumonia in clients over 65 years of age [**Criteria Code 65**]
- 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 for a one week duration [**Criteria Code 12**]
- 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**]

**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 a GI hemorrhage while on ASA,
  - myocardial infarction (MI) in patients with a documented severe allergy to ASA or who experience a GI hemorrhage while on ASA,
  - peripheral vascular disease (PVD) in patients with a documented severe allergy to ASA or who experience a GI hemorrhage while on ASA,
  - unstable angina in patients with a documented severe allergy to ASA or who experience a GI hemorrhage while on ASA
- in patients with intravascular stent implantation, the coverage period following insertion is:
  - Bare Metal Stent(s) (BMS) - 30 days
  - Drug Eluting Stent(s) (DES) - 12 months

**NOTE:** The [**Criteria Code 30**] may be used for the initial 30 days coverage period for all types of intravascular stent implantation. For coverage beyond the initial 30 day online approval a written request from the prescriber is required.

- for patients with non-ST-segment elevation acute coronary syndrome (ACS) (i.e., unstable angina or non-ST-segment elevation myocardial infarction), in combination with ASA, for a coverage period of 3 months coverage. Coverage for 12 months is available for high risk patients:
  - with a second ACS within 12 months, or
  - with complex or extensive coronary artery disease (CAD) e.g., diffuse 3 vessel CAD not amenable to revascularization, or
  - who have had a previous stroke, TIA or have symptomatic PVD
- other requests on a case by case basis

**CLOSTRIDIUM BOTULINUM TOXIN TYPE A** (*Botox 100iu/vial Injection*)

- for the treatment of the following Health Canada approved indications:
  - focal spasticity following stroke in adults
  - equinus foot deformity in cerebral palsy patients 2 years of age and older
  - cervical dystonia
  - blepharospasm, hemifacial spasm (VII nerve disorder) and strabismus in patients 12 years of age and older

**CLOSTRIDIUM BOTULINUM TYPE A** (*Xeomin 100u/vial*)

- for the treatment of blepharospasm and cervical dystonia (spasmodic torticollis)

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

**\*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 if they 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 (e.g., post-operative pain)

**CROMOGLYCATE SODIUM** (*pms-Sodium Cromoglycate 1% Nebulizer Solution*)

- See **Wet Nebulization Solutions**

**\*CYANOCOBALAMIN, INJECTION** (*Cyanocobalamin, Vitamin B<sub>12</sub> 100mcg/mL and 1000mcg/mL Injection*)

- for the treatment of documented cyanocobalamin deficiency, when the oral route is inappropriate or contraindicated (criteria applies to all Programs)

**\*CYANOCOBALAMIN, ORAL** (*Vitamin B<sub>12</sub> 500mcg and 1,000mcg Tablet*)

- for the treatment of documented cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program, Family Pharmacare Program and Drug Assistance for Cancer Patients; oral cyanocobalamin is fully insured for Seniors' Pharmacare Program

**\*CYANOCOBALAMIN, ORAL IN COMBINATION** (*Vitamin B<sub>12</sub> 1000mcg SL Tablet with Folic Acid*)

- for the treatment of documented cyanocobalamin deficiency in recipients of the Community Services Pharmacare Program, Family Pharmacare Program and Drug Assistance for Cancer Patients; oral cyanocobalamin is fully insured for Seniors' Pharmacare Program

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

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

**\*DARBEPOETIN** (*Aranesp Syringe Injection*)

- for the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of  $\leq 90\text{g/L}$  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

*NOTE:* Specialized request forms are used to request coverage for darbepoetin.

**DARIFENACIN** (*Enablex 7.5mg, 15mg Tablet*)

- See **Urinary Antispasmodics, Long-Acting**

**\*DASATINIB** (*Sprycel 20mg, 50mg, 70mg Tablet*)

- as a single agent for the treatment of adults with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) and Philadelphia chromosome acute lymphoblastic leukemia (Ph<sup>+</sup> ALL) with resistance or intolerance to prior therapy including imatinib
- coverage approved for 6 months

**DEFERASIROX** (*Exjade 125mg, 250mg, 500mg Tablet for Suspension*)

- for the treatment of patients who require iron chelation and deferoxamine is contraindicated

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

**DENOSUMAB** (*Prolia 60mg/mL pre-filled syringe*)

- for women with postmenopausal osteoporosis for whom bisphosphonates are contraindicated due to hypersensitivity or abnormalities of the esophagus (e.g., esophageal stricture or achalasia) and have at least two of the following:
  - age >75 years
  - a prior fragility fracture
  - a bone mineral density (BMD) T-score  $\leq$  -2.5

**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<sub>3</sub>) Antagonists**  
Recommended dose is 100mg orally 1 hour pre-chemotherapy.

**DONEPEZIL** (*Aricept 5mg, 10mg Tablet*)

- See **Cholinesterase Inhibitors (ChEI)**

**\*DRONABINOL** (*Marinol 2.5mg, 5mg 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

**DULOXETINE** (*Cymbalta 30mg, 60mg Capsule*)

- for the treatment of neuropathic pain in diabetic patients who are unresponsive to adequate courses of two alternative agents, such as tricyclic antidepressants and anticonvulsants
- dose limited to a maximum of 60mg per day

**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 a levodopa and a decarboxylase inhibitor

**ENTECAVIR** (*Baraclude 0.5mg Tablet*)

- for the treatment of chronic hepatitis B infection in patients with:
  - documented cirrhosis on radiologic or histologic grounds AND
  - a HBV DNA concentration above 2000iu/mL

**EPINEPHRINE** (*Epipen 1:1000, Epipen Jr. 1:2000 Injection and Twinject 0.15mg, 0.3mg Auto-Injector*)

- for the emergency treatment of anaphylactic reactions, when out of reach of immediate medical attention

*NOTE* : Regular benefit, but with a quantity limit of two injections per fiscal year. Additional units require an exception status request.

**\*ERLOTINIB** (*Tarceva 100mg, 150mg Tablet*)

- as monotherapy for the treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) after failure of at least one prior chemotherapy regimen and whose EGFR expression status is positive or unknown
- coverage approved for 6 months

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

---

**\*ERYTHROPOIETIN** (*Eprex Multidose Vial and Syringe Injection*)

- for the treatment of transfusion dependent patients with hematologic malignancies who have a baseline anemia of  $\leq 90\text{g/L}$  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)

*NOTE:* Specialized request forms are used to request coverage for erythropoietin.

**\*ESTRADIOL** (*Climara, Estraderm, Estradot Transdermal Patch, Estrogel Topical Gel and generic brands*)

**\*ESTRADIOL/NORETHINDRONE ACETATE** (*Estalis 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 and 50mg/ML Injection*)

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

**\*EVEROLIMUS** (*Afinitor 2.5mg, 5mg, and 10mg Tablet*)

- as a single agent for metastatic renal cell carcinoma (RCC) patients with documented clear cell histology who have a Karnofsky performance status of 70% or higher after progression or intolerance to the multi-targeted tyrosine kinase inhibitors (TKIs), sunitinib **and/or** sorafenib.

**EZETIMIBE** (*Ezetrol 10mg Tablet*)

- 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

**FEBUXOSTAT** (*Uloric 80mg Tablet*)

- for the treatment of symptomatic gout in patients who have documented hypersensitivity to allopurinol

**FENOTEROL** (*Berotec 1mg/mL Solution*)

- See **Wet Nebulization Solutions**

**\*FENTANYL** (*Fentanyl 12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr Transdermal System Generic Brands*)

- for the treatment of malignant or chronic non-malignant pain in adult patients who were previously receiving continuous opioid administration (i.e., not opioid naive), or who are unable to take oral therapy

**FINASTERIDE** (*Proscar 5mg Tablet and generic brands*)

- for the treatment of benign prostatic hypertrophy (BPH) when alpha-antagonists are contraindicated, not tolerated or failed
- for the treatment of benign prostatic hypertrophy (BPH) in combination with an alpha-antagonist when alpha-antagonist therapy has been tried as monotherapy and a partial response has been observed

**\*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

**\*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

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

### **FLUOROQUINOLONES, OPHTHALMIC** (*Ciprofloxacin, Ofloxacin*)

- for the treatment of eye infections upon the order of an ophthalmologist, ophthalmology resident, prescribing optometrist or other prescriber who has a specialty in ophthalmology [**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 multi-resistant, 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**]

### **\*FLUOROQUINOLONES, RESPIRATORY** (*Levofloxacin, Moxifloxacin*)

- for the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB) [**Criteria Code 01**]
- for the treatment of severe pneumonia in nursing home patients [**Criteria Code 02**]
- for the treatment<sup>1</sup> of CAP in patients with comorbidity<sup>2</sup> upon radiographic confirmation of pneumonia, or who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate) [**Criteria Code 03**]
- for the treatment<sup>1</sup> of AECB in complicated patients<sup>3</sup> who have failed treatment with one of the following: amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate [**Criteria Code 04**]

---

<sup>1</sup> If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

<sup>2</sup> Comorbidity includes chronic lung disease, malignancy, diabetes, liver failure, renal failure, 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.

<sup>3</sup> Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea and FEV1 < 50% predicted or FEV1 50% - 65% and one of the following: ≥4 exacerbations per year, ischemic heart disease, chronic oral steroid use or antibiotic use in past 3 months

### **FORMOTEROL** (*Foradil 12ug Capsule For Inhalation and Oxeze 6mcg/Dose, 12mcg/Dose Turbuhaler*)

- See **Long-Acting Beta<sub>2</sub>-Agonists**

### **FORMOTEROL, IN COMBINATION** (*Symbicort 100/6mcg, 200/6mcg Turbuhaler*)

- See **Long-Acting Beta<sub>2</sub>-Agonists/Inhaled Corticosteroids**

### **GALANTAMINE** (*Reminyl Er 8mg, 16mg, 24mg Capsule and generic brands*)

- See **Cholinesterase Inhibitors (ChEI)**

### **GOLIMUMAB** (*Simponi 50mg/0.5ml Autoinjector and Prefilled Syringe*)

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

### **\*GRANISETRON** (*Kytril 1mg Tablet and generic brands*)

- See **Serotonin (5-HT<sub>3</sub>) 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

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

**\*IMATINIB** (*Gleevec 100mg Capsule and 100mg, 400mg Tablet*)

- as a single agent for adult patients with a histological diagnosis of localized primary Gastrointestinal Stromal Tumors (GIST) (KIT (CD-117)-positive) following surgical complete resection and at a high risk or recurrence.
  - risk of recurrence is dependent on location, size and mitotic rate. Specific parameters for considering adjuvant therapy after resection of GIST along the gastrointestinal tract may include but are not limited to:
    - gastric: any tumor >3cm where the mitotic rate is >5/50 high powered fields (HPFs). Adjuvant treatment could be considered where the mitotic rate is <5HPFs and tumor >10cm
    - duodenal, small bowel, peritoneal, colorectal: any tumor where the mitotic rate is >5.
- for the treatment of chronic myelogenous leukemia (CML), as a single agent, in patients who have documented evidence of Philadelphia chromosome positive CML, with an ECOG performance status of 0-2 and who are in blast crisis, accelerated phase, or chronic phase or
- as a secondary treatment 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
- coverage approved for one year

**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
- for the treatment of biopsy-confirmed primary superficial basal cell carcinoma:
  - with a tumor diameter of ≤ 2cm AND
  - located on the trunk, neck or extremities (excluding hands and feet) AND
  - where surgery or eradication therapy is not medically indicated
    - recurrent lesions in previously irradiated area OR
    - multiple lesions, too numerous to irradiate or remove surgically
  - approval period: 6 weeks

*NOTE:* Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions

**INFLIXIMAB** (*Remicade 100mg Powder For Injection*)

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

**INSULIN ASPART** (*Novorapid 100iu/MI Penfill and Vial*)

**INSULIN GLULISINE** (*Apidra 3ml Prefilled Pen, 10ml Vial And Cartridges*)

**INSULIN LISPRO** (*Humalog Insulin, Cartridges and Kwikpen*)

- regular benefit for children 18 years and younger, under Community Services, Family Pharmacare and Diabetes Assistance Programs
- for the management of Type I and Type II diabetes mellitus in patients 19 years of age and older, who are:
  - undergoing intensive therapy, i.e., administering three or more injections of insulin per day including basal insulin, and
  - testing blood glucose levels 4-6 times per day

**\*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

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

**\*IPRATROPIUM BROMIDE** (250mcg/mL Inhaled Solutions - See Formulary Listings For Product Names)

- See **Wet Nebulization Solutions**

**\*IPRATROPIUM BROMIDE, IN COMBINATION** (Combivent Inhaled Solution and generic brands)

- See **Wet Nebulization Solutions**

**\*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 a dermatologist, attending physician or prescriber with a specialty in dermatology

**LACOSAMIDE** (Vimpat 50mg, 100mg, 150mg, 200mg Tablet)

- as adjunctive treatment for patients with refractory partial-onset seizures who meet all of the following criteria:
  - are under the care of a physician experienced in the treatment of epilepsy, and
  - are currently receiving two or more antiepileptic drugs, and
  - in whom all other antiepileptic drugs are ineffective or not appropriate

**\*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

**LANSOPRAZOLE** (Prevacid FasTab 15mg, 30mg Tablet)

- for patients who require the use of a proton pump inhibitor and require administration through a feeding tube.

**LANSOPRAZOLE** (Prevacid 15mg, 30mg Capsule and generic brands)

- See **Proton Pump Inhibitors**

**LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN IN COMBINATION** (HP-Pac)

- helicobacter pylori eradication for a one week duration [**Criteria Code 01**]

**\*LAPATINIB** (Tykerb 250mg Tablet)

- In combination with capecitabine as a treatment option in patients with human epidermal growth factor receptor 2 (HER2) positive advanced or Metastatic Breast Cancer (MBC) with trastuzumab refractory disease (previously treated with trastuzumab alone or in combination with chemotherapy such as taxane and/or vinorelbine) who have an ECOG performance status of 0 to 2 and choose to receive systemic chemotherapy. Patients with previous exposure to capecitabine are not considered eligible

**LEFLUNOMIDE** (Arava 10mg, 20mg Tablet and generic brands)

- written request from a rheumatologist or prescriber with a specialty in rheumatology
- for patients with a diagnosis of active rheumatoid arthritis (RA) who
  - have not responded or who have had intolerable toxicity to an adequate trial<sup>1</sup> of combination therapy of at least two traditional DMARDs<sup>2</sup> 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 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%

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

---

<sup>1</sup> 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.

<sup>2</sup> Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, penicillamine and cyclosporine.

**\*LENALIDOMIDE** (*Revlimid Cap*)

- in combination with dexamethasone in adult patients with progressive multiple myeloma (MM) after at least one previous treatment, not resistant to dexamethasone, documented measurable disease and an ECOG performance status of 0-2

**LEUKOTRIENE RECEPTOR ANTAGONISTS** (*Montelukast, Zafirlukast*)

- for the treatment of moderate to severe asthma in adults and children who:
  - despite compliance are not adequately controlled with a moderate or high dose inhaled corticosteroid and require additional symptom control (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms) and
  - require increasing amounts of short-acting beta<sub>2</sub>-agonists, indicative of poor control

**LEVETIRACETAM** (*Keppra 250mg, 500mg, 750mg Tablet and generic brands*)

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

**LEVOCARNITINE** (*Carnitor 1g/5mL Injection, 100mg/mL Oral Liquid and 300mg Tablet*)

- for the treatment of primary systemic carnitine deficiency

**LEVODOPA AND CARBIDOPA AND ENTACAPONE** (*Stalevo 50mg, 75mg, 100mg, 125mg, 150mg 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/carbidopa
  - were not well controlled and experienced significant "wearing off" symptoms despite optimal therapy with levodopa/carbidopa and are currently using levodopa/carbidopa and entacapone separately

**\*LEVOFLOXACIN** (*Levaquin 250mg, 500mg Tablet and generic brands*)

- See **Fluoroquinolones, Respiratory**

**LINEZOLID** (*Zyvoxam 600mg Tablet*)

- written request from an infectious disease specialist or prescriber with a specialty in infectious diseases
- 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<sub>2</sub>-AGONISTS** (*Formoterol, Salmeterol*)

**LONG-ACTING BETA<sub>2</sub>-AGONISTS/INHALED CORTICOSTEROIDS** (*Formoterol, In Combination; Salmeterol, In Combination*)

**Asthma**

- 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:
    - >400mcg/day budesonide
    - >250mcg/day beclomethasone dipropionate or
    - >250mcg/day fluticasone propionate **and**
  - require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); **and**
  - require increasing amounts of short-acting beta<sub>2</sub>-agonists, indicative of poor control

---

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

---

### **Chronic Obstructive Pulmonary Disease**

- for the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e., salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day)
- coverage can be provided without a trial of short-acting agent if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction, (i.e., postbronchodilator values  $FEV_1 < 60\%$  and  $FEV_1/FVC$  ratio  $< 0.7$ ), and significant symptoms (i.e., MRC score of 3-5\*)
- combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist/inhaled corticosteroid will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (postbronchodilator values  $FEV_1 < 60\%$  and  $FEV_1/FVC$  ratio  $< 0.7$ ), and significant symptoms (i.e., MRC score of 3-5\*) *and*
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids

**NOTE:** Coverage of combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist (without an inhaled corticosteroid) will not be considered due to insufficient evidence to support substantial benefit.

If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e., MRC scale). Spirometry reports from any point in time will be accepted.

\* Canadian Thoracic Society COPD Classification By Symptom/Disability:

Moderate - (MRC 3-4) Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

Severe - (MRC 5) 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.

MRC= Medical Research Council Dyspnea Scale

### **LORATADINE** (*Claritin 10mg Tablet and 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

### **MAGNESIUM GLUCOHEPTONATE** (*5mg/mL Solution and 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

### \***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, ORAL LIQUID** (*Methadone o/l Compound*)

- 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

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

**METHYLPHENIDATE** (*Biphentin 10mg, 15mg, 20mg 30mg, 40mg, 50mg, 60mg and 80mg Capsule*)

- for patients 6-18 years of age diagnosed with attention deficit hyperactivity disorder (ADHD) who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following:
  - patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning AND
  - prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics, general practitioners or other prescribers with expertise in ADHD AND
  - have been tried on immediate release and slow release methylphenidate with unsatisfactory results

**\*MIDAZOLAM** (*1mg/mL, 5mg/mL Injection and generic brands*)

- for adjunctive therapy of pain management in palliative care patients outside the hospital setting [**Criteria Code 01**]

**MONTELUKAST** (*Singulair 4mg, 5mg Chewtabs, 4mg/pkt Granules and 10mg Tablets*)

- See **Leukotriene Receptor Antagonists**

**\*MOXIFLOXACIN** (*Avelox 400mg Tablet*)

- See **Fluoroquinolones, Respiratory**

**\*NABILONE** (*Cesamet 0.25mg, 0.5mg and 1mg Capsule*)

- For the management of severe nausea and vomiting associated with cancer chemotherapy

**NALTREXONE** (*Revia 50mg Tablet*)

- for the treatment of alcohol dependence, as an adjunct to a comprehensive psychotherapeutic or psychological alcoholism counseling 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, 2.5mg Tablet and generic brands*)

- See **Selective 5HT<sub>1</sub> - Receptor Agonists**

**NILOTINIB** (*Tasigna 200mg Cap*)

- As a single line agent for the treatment of adults with chronic or accelerated phase Chronic Myeloid Leukemia (CML) with resistance or intolerance to prior therapy. This would include:
  - Patients with CML in chronic phase who are intolerant to imatinib or dasatinib or both
  - Patients with CML in chronic phase who are resistant to imatinib 600mg/day
  - Patients with CML that have progressed to accelerated phase while on imatinib
- Sequential use of dasatinib and nilotinib is not permitted except in the circumstance described above (i.e. intolerance)
- Coverage approved for 6 months

**\*NORFLOXACIN** (*400mg Tablet, generic brands*)

- See **Fluoroquinolones, Oral**

**OFLOXACIN, OPHTHALMIC** (*Ocuflox 0.3% Ophthalmic Solution and generic brands*)

- See **Fluoroquinolones, Ophthalmic**

**\*OFLOXACIN, ORAL** (*300mg and 400mg Tablet and generic brands*)

- See **Fluoroquinolones, Oral**

**OLANZAPINE** (*Zyprexa 2.5mg, 5mg, 7.5mg, 10mg, 15mg Tablet and generic brands*)

- 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

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

**OLANZAPINE, ORAL DISINTEGRATING** (*Zyprexa Zydys 5mg, 10mg, 15mg, 20mg Tablet and generic brands*)

- for the use in patients who meet the criteria for treatment with regular release oral olanzapine and who have difficulty swallowing

**OMEPRAZOLE** (*Losec 10mg, 20mg Capsule/Tablet and generic brands*)

- See **Proton Pump Inhibitors**

*NOTE:* Omeprazole is available as a full benefit if the dose does not exceed the standard dose of 20mg per day (maximum of 400 tablets/capsules per year). If the dosage is greater than 20mg per day then the criteria for coverage must be met.

**\*ONDANSETRON** (*Zofran 4mg, 8mg Tablet, 4mg/5mL Oral Liquid and generic brands and ODT Tablet*)

- See **Serotonin (5-HT<sub>3</sub>) 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 is therefore, not insured.

**OSELTAMIVIR** (*Tamiflu 30mg, 45mg, 75mg Capsule, 12mg/mL Oral Suspension*)

- 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 influenza A or B in long-term care residents where the facility has an outbreak
- a protocol has been developed by Public Health for the treatment of patients in long-term care facilities. The facility must contact the Medical Officer of Health or local Public Health Office, who will notify the Pharmacare office (or dispensing pharmacy after office hours) if coverage is required

**OXCARBAZEPINE** (*Trileptal 60mg/mL Oral Liquid and 150mg, 300mg, 600mg Tablet and generic brands*)

- for the treatment of epileptic seizures in patients who have had an inadequate response to or are intolerant of at least three other formulary agents (prior or current use) including carbamazepine

**OXYBUTYNIN XL** (*Ditropan XL and Uromax 5mg, 10mg Tablet*)

- See **Urinary Antispasmodics, Long-Acting**

**\*OXYCODONE, SUSTAINED RELEASE** (*Oxycontin 5mg, 10mg, 15mg, 20mg, 30mg 40mg, 60mg 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 (e.g., post-operative pain)

**PANTOPRAZOLE MAGNESIUM** (*Tecta 40mg Tablet*)

- See **Proton Pump Inhibitors**

*NOTE:* Pantoprazole magnesium is available as a full benefit if the dose does not exceed the standard dose of 40mg per day (maximum of 400 tablets per year). If the dosage is greater than 40mg per day then the criteria for coverage must be met.

**PANTOPRAZOLE SODIUM** (*Pantoloc 20mg, 40mg Ec Tablet and generic brands*)

- See **Proton Pump Inhibitors**

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

### **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 prescriber with a specialty in hepatitis
- 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)
- for the treatment of HBeAg negative Chronic Hepatitis B (CHB) patients with compensated liver disease, liver inflammation and evidence of viral replication with demonstrated intolerance to or failure of lamivudine therapy, upon written request of a hepatologist or prescriber with a specialty in hepatitis. Maximum duration of coverage is 48 weeks

### **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 prescriber with a specialty in hepatitis
- 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)

### **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 prescriber with a specialty in hepatitis
- 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 and 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 and generic brands*)

- for treatment of Type II diabetes in patients who have:
  - inadequate glycemic control on optimal doses of sulfonylurea and metformin; or
  - demonstrated intolerance or contraindication to metformin and are on optimal doses of sulfonylurea; or
  - demonstrated intolerance or contraindication to sulfonylurea and are on optimal doses of metformin
- patients must have a recent A1C 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 A1C of 0.7 observed to continue coverage)

### **PROTON PUMP INHIBITORS (PPIs)**

#### **Omeprazole, Rabeprazole, and Pantoprazole magnesium (higher than standard daily doses)**

- failed standard daily doses of full benefit PPIs (20mg of omeprazole, 20mg of rabeprazole or 40mg of pantoprazole magnesium)
- coverage duration: 8 week trial, followed by up to one year of coverage. Use beyond the 8 week trial will be considered if step down to standard dose is not successful

*NOTE:* Omeprazole, rabeprazole and pantoprazole magnesium are available as full benefits if the dose does not exceed the standard dose of 20mg per day for omeprazole and rabeprazole and 40mg per day for pantoprazole magnesium (maximum of 400 tablets/capsules per year).

#### **Pantoprazole Sodium and Lansoprazole**

- failure of a trial of all open benefit PPIs (omeprazole, rabeprazole, and pantoprazole magnesium)
- coverage duration: yearly coverage

### **QUINAGOLIDE** (*Norprolac 0.025mg, 0.05mg, 0.075mg, 0.15mg Tablet*)

- for the treatment of hyperprolactinemia (idiopathic or originating from a prolactin secreting micro or macro-adenoma of the pituitary) after failure of bromocriptine (as determined by prolactin levels) or if bromocriptine is not tolerated

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

**RABEPRAZOLE** (*Pariet 10mg, 20mg Tablet and generic brands*)

- See **Proton Pump Inhibitors**

**NOTE:** Rabeprazole is available as a full benefit if the dose does not exceed the standard dose of 20mg per day (maximum of 400 tablets per year). If the dosage is greater than 20mg per day then the criteria for coverage must be met.

**RALOXIFENE** (*Evista 60mg and generic brands*)

- for the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or are contraindicated
- for the treatment of postmenopausal osteoporosis without documented fractures when patient is at high 10 year fracture risk (using fracture risk tables) and bisphosphonates are not tolerated or are contraindicated
- other requests reviewed on a case by case basis

**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, 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 and generic brands*)

- for the treatment of osteoporosis associated with documented fracture
- for the treatment of osteoporosis without documented fracture when patient is at high 10 year fracture risk (using fracture risk tables)
- as prophylaxis of corticosteroid induced osteoporosis in patients who will be, or have been, on systemic corticosteroid therapy for > 3 months
- Paget's disease of bone (2 month limit, one re-treatment course may be considered)
- other requests reviewed on a case by case basis

**RISPERIDONE** (*Risperdal Consta 25mg/mL, 37.5mg/ML, 50mg/2mL Injection*)

- for patients having problems with compliance on an oral antipsychotic or
- for patients who are currently receiving a conventional depot antipsychotic and are experiencing significant side effects (EPS or TD) or lack of efficacy

**RITUXIMAB** (*Rituxan 10mg/mL Injection*)

- for the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent
- cannot be used concomitantly with anti-TNF agents
- written request from a rheumatologist or prescriber with a specialty in rheumatology
- approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose

**RIVAROXABAN** (*Xarelto 10mg Tablet*)

- for the prophylaxis of venous thromboembolism following total knee replacement or total hip replacement, for up to two weeks, as an alternative to low molecular weight heparins
- dose limited to 10mg per day for up to two weeks supply only

**RIVASTIGMINE** (*Exelon 2mg/mL Oral Liquid And 1.5mg, 3mg, 4.5mg, 6mg Capsule and generic brands*)

- See **Cholinesterase Inhibitors (ChEI)**

**RIZATRIPTAN** (*Maxalt 5mg, 10mg Tablets and 5mg, 10mg Wafers*)

- See **Selective 5HT<sub>1</sub> - Receptor Agonists**

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

**\*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 Inhaled Solution And 5mg/mL Inhaled Solution- See Formulary Listings For Product Names*)

- See **Wet Nebulization Solutions**

**\*SALBUTAMOL, IN COMBINATION** (*Combivent Inhaled Solution and generic brands*)

- See **Wet Nebulization Solutions**

**SALMETEROL** (*Serevent 50mcg/dose Diskhaler and 50mcg/dose Diskus*)

- See **Long-Acting Beta<sub>2</sub>-Agonists**

**SALMETEROL IN COMBINATION** (*Advair 50/100mcg, 50/250mcg, 50/500mcg Diskus and HFA 25/125 mcg/dose, HFA 25/250 mcg/dose Inhaler*)

- See **Long-Acting Beta<sub>2</sub>-Agonists/Inhaled Corticosteroids**

**SELECTIVE 5HT<sub>1</sub> - RECEPTOR AGONISTS** (*Almotriptan Tablets, Naratriptan Tablets, Rizatriptan Tablets & Wafers, Sumatriptan Nasal Spray, Zolmitriptan Tablets & Nasal Spray*)

- for the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g., NSAIDs, acetaminophen, DHE spray) are not effective, **AND** patients have not responded to oral sumatriptan.
- for the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when patients have not responded to oral sumatriptan

NOTE: Coverage limited to 18 doses every 3 months<sup>3</sup>.

<sup>1</sup>. As diagnosed based on current Canadian Guidelines

<sup>2</sup> Definitions: Moderate - pain is distracting causing need to slow down and limit activities; Severe - pain affects ability to concentrate and very difficult to continue with daily activities; Ultra severe - unable to speak or think clearly, not able to function, likely lying down or sleeping.

<sup>3</sup>. A quantity limit of 6 doses per month will be instituted for all clients. This will be adjudicated by limiting the quantity payable each quarter (e.g., Jan to Mar) to 18 doses\*. Patients with >3 migraines/month who are on prophylactic therapy may qualify for additional doses, upon written request.

\* Please note: One dose = one tablet, one wafer, one spray or one 0.5mL pre-filled syringe.

**\*SEROTONIN (5-HT<sub>3</sub>) 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
- receiving intravenous chemotherapy or radiotherapy and who are experiencing intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents [**Criteria Code 03**]

NOTE: Use of criteria codes is limited to appropriate doses pre and post chemotherapy or radiation. Criteria codes must not be used for claims related to other causes of nausea and vomiting or for long term, daily management of nausea and vomiting.

**SEVELAMER** (*Renagel 800mg Tablet*)

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

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

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

**SILDENAFIL** (*Revatio 20mg Tablet and generic brands*)

- written request from a pulmonary arterial hypertension (PAH) specialist only
- diagnosis of PAH should be confirmed by right heart catheterization
- dose of sildenafil will be limited to 20mg tid
- **IPAH (functional class III)**
  - for the treatment of patients with World Health Organization (WHO) functional class III idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing, or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB), or are intolerant to CCB
- **PAH secondary to connective tissue disease (functional class III)**
  - for the treatment of patients with World Health Organization (WHO) functional class III pulmonary hypertension associated with connective tissue disease who do not respond to conventional therapy

**SITAGLIPTIN** (*Januvia 100mg Tablet*)

- for treatment of Type II diabetes in patients who have:
  - inadequate glycemic control on optimal doses of sulfonylurea and metformin; or
  - demonstrated intolerance or contraindication to metformin and are on optimal doses of sulfonylurea; or
  - demonstrated intolerance or contraindication to sulfonylurea and are on optimal doses of metformin;
  - patients must have a recent A1C 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 A1C of 0.7 observed to continue coverage)

**SITAGLIPTIN AND METFORMIN** (*Janumet 50/500mg, 50/850mg, and 50/1000mg Tablet*)

- for combination treatment of type 2 diabetes mellitus for patients already stabilized on combination treatment with the individual components of metformin and sitagliptin

**SOLIFENACIN** (*Vesicare 5mg, 10mg Tablet*)

- See **Urinary Antispasmodics, Long-Acting**

**SOMATROPIN** (*Humatrope, Nutropin, Nutropin Aq, Saizen Injection*)

- for treatment of growth hormone deficiency in patients with Turner Syndrome, upon the request of an endocrinologist or prescriber with a specialty in endocrinology

*NOTE:* The larger 8.8mg/vial format can be approved when suitable for dosing requirements, if it does not result in drug wastage.

**\*SORAFENIB** (*Nexavar 200mg Tablet*)

- as a single agent first line systemic therapy option in adult patients with a diagnosis of hepatocellular carcinoma (HCC) with Child-Pugh Class A liver dysfunction (mild hepatic impairment) with ECOG performance status 0-1; and who have either progression of disease, or who are not candidates for curative intent treatments (transplantation, hepatic resection), or other well established palliative interventions (ablation, transcatheter arterial chemo-embolization (TACE), internal radiation)
- as a single agent for second line treatment of patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma, considered to be intermediate or low risk (according to Memorial Sloan-Kettering (MSKCC) prognostic score), have an ECOG performance status of 0 or 1 and progressed after prior cytokine therapy (or intolerance) within the previous 8 months. In any one patient all of the following conditions must be met:
  - Sorafenib may be a second line option only after cytokine therapy
  - Sorafenib may not be used after another tyrosine kinase inhibitor (i.e., sunitinib) as sequential therapy
  - In the event of severe toxicity within the first 8 weeks of therapy, a switch to another tyrosine kinase inhibitor (i.e., sunitinib) may be allowed
- coverage approved for 5 months with reassessment

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

### **SUMATRIPTAN** (*Imitrex 50mg, 100mg Tablet and generic brands*)

- for the treatment of migraine<sup>1</sup> headache when:
  - migraines are moderate<sup>2</sup> in severity and other therapies (e.g., NSAIDs, acetaminophen, DHE spray) are not effective, or
  - migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

NOTE: Coverage limited to 18 doses every 3 months<sup>3</sup>.

<sup>1</sup>. As diagnosed based on current Canadian Guidelines

<sup>2</sup>. Definitions: Moderate - pain is distracting causing need to slow down and limit activities; Severe - pain affects ability to concentrate and very difficult to continue with daily activities; Ultra severe - unable to speak or think clearly, not able to function, likely lying down or sleeping.

<sup>3</sup>. A quantity limit of 6 doses per month will be instituted for all clients. This will be adjudicated by limiting the quantity payable each quarter (e.g., Jan to Mar) to 18 doses\*. Patients with >3 migraines/month who are on prophylactic therapy may qualify for additional doses, upon written request.

\* Please note: One dose = one tablet, one wafer, one spray or one 0.5mL pre-filled syringe.

### **SUMATRIPTAN** (*Imitrex 6mg/Syringe Injection*)

- for the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g., NSAIDs, acetaminophen, DHE spray) are not effective, AND oral and nasal triptans are not appropriate
- for the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when oral and nasal triptans are not appropriate

NOTE: Coverage limited to 18 doses every 3 months<sup>3</sup>.

<sup>1</sup>. As diagnosed based on current Canadian Guidelines

<sup>2</sup>. Definitions: Moderate - pain is distracting causing need to slow down and limit activities; Severe - pain affects ability to concentrate and very difficult to continue with daily activities; Ultra severe - unable to speak or think clearly, not able to function, likely lying down or sleeping.

<sup>3</sup>. A quantity limit of 6 doses per month will be instituted for all clients. This will be adjudicated by limiting the quantity payable each quarter (e.g., Jan to Mar) to 18 doses\*. Patients with >3 migraines/month who are on prophylactic therapy may qualify for additional doses, upon written request.

\* Please note: One dose = one tablet, one wafer, one spray or one 0.5mL pre-filled syringe.

### **\*SUNITINIB** (*Sutent 12.5mg, 25mg, 50mg Capsule*)

- as a single agent first line treatment in patients with documented evidence of histologically confirmed advanced or metastatic clear cell renal cell carcinoma who have an ECOG performance status of 0 or 1. In any one patient all of the following conditions must be met:
  - Sunitinib may be a first line option
  - Sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib) as sequential therapy.
  - In the event of severe toxicity within the first 8 weeks of therapy, a switch to another tyrosine kinase inhibitor (i.e., sorafenib) may be allowed
- as a single agent for the treatment of advanced gastrointestinal stromal tumor (GIST) patients after failure of imatinib due to intolerance or resistance
- coverage approved for 9 months with reassessment

### **TACROLIMUS** (*Protopic 0.03%, 0.1% Ointment*)

- for children greater than 2 years of age with refractory atopic dermatitis. Coverage will be renewed yearly
- for the intermittent use for moderate to severe atopic dermatitis in adults who have:
  - failed or are intolerant to a site appropriate strength of corticosteroid therapy (i.e., low potency on face versus intermediate to high potency for trunk and extremities)

### **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 Drug Assistance for Cancer Patients are indicated by an asterisk (\*).

**\*TEMOZOLOMIDE** (*Temodal 5mg, 20mg, 100mg, 200mg Capsule*)

- in combination with radiotherapy (concomitant therapy) and as adjuvant therapy (post radiation for 6 cycles) for newly diagnosed high grade glioma patients with a good performance status (PS) (Karnofsky  $\geq$  60) and who choose to receive first line systemic chemotherapy
- use as a single agent may be considered for patients with recurrent high grade glioma and a good PS (Karnofsky  $\geq$  60) who have not previously been treated with first line combination (temozolomide and radiation) therapy
- use as a single agent may be considered for patients with high grade glioma who have recurrent disease occurring during their initial adjuvant therapy. Other systemic treatment options such as etoposide, nitrosourea based therapy or a clinical trial should be considered for patients who recur immediately following temozolomide therapy. Rechallenge with temozolomide could be considered for patients with a temozolomide free interval of six months

**TENOFOVIR DISOPROXIL** (*Viread 300mg Tablet*)

- for the treatment of chronic hepatitis B infection in patients with:
  - documented cirrhosis on radiologic or histologic grounds AND
  - a HBV DNA concentration above 2000iu/mL

**TERBINAFINE** (*Lamisil 250mg Tablet and generic brands*)

- for the treatment of severe onychomycosis caused by dermatophyte fungi as diagnosed by a dermatologist, attending prescriber with a specialty in dermatology

**TESTOSTERONE, TOPICAL** (*Androderm Patch, Androgel Gel Packet & Testim Gel*)

- for the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:
  - Primary: cryptorchidism, Klinefelter's, orchidectomy, and other established causes
  - Secondary: pituitary-hypothalamic injury due to tumors, trauma, radiation
  - deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any therapy

**NOTE:** Maximum dose approved is 5g per day or a 5mg patch per day.

This will be adjudicated by limiting the quantity payable each quarter (e.g. Jan-Mar) to:

- 120 Androderm Patches (2.5mg or 5mg Patch);
- 300g of Androgel 2.5g gel (packet);
- 600g of Androgel 5g gel (packet); or
- 600g of Testim Gel.

Please be reminded that topical gels are to be billed per gram (not per packet).

**\*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 withdrawal
  - 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 withdrawal resulting in a documented life-threatening event
- as a single agent for the preparation of radioiodine remnant ablation in patients with papillary or follicular thyroid cancer who have undergone thyroidectomy as treatment for thyroid cancer
  - thyrotropin is a reasonable alternate to thyroid hormone withdrawal in patients who are unable to tolerate the prolonged hypothyroid state or who cannot achieve satisfactory elevation of endogenous TSH
  - thyrotropin may be used in new patients or patients with previously incomplete remnant ablation or who have a recurrence of thyroid cancer and require therapeutic remnant ablation

**TICLOPIDINE** (*Ticlid 250mg Tablet and generic brands*)

- for the secondary prevention of ischemic stroke or 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 **[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

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

### **TIOTROPIUM BROMIDE** (*Spiriva 18mcg Cap For Inhalation*)

- for the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e., salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day)
- coverage can be provided without a trial of short-acting agent if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction, (i.e., postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e., MRC score of 3-5\*\*)
- combination therapy with tiotropium and a long-acting beta2 agonist/inhaled corticosteroid will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e., MRC score of 3-5\*\*) and
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids

**NOTE:** Coverage of combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist (without an inhaled corticosteroid) will not be considered due to insufficient evidence to support substantial benefit.

If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e., MRC scale). Spirometry reports from any point in time will be accepted.

---

\*\* *Canadian Thoracic Society COPD Classification By Symptom/Disability:*

*Moderate* - (MRC 3-4) Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

*Severe* - (MRC 5) 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.

MRC= Medical Research Council Dyspnea Scale

### **TIZANIDINE** (*Zanaflex 4mg Tablet and generic brands*)

- for the treatment of spasticity resulting from traumatic brain injury, multiple sclerosis (MS), spinal cord injury (SCI) or cerebral vascular accident (CVA) in patients for whom baclofen is not indicated, ineffective or not tolerated

### **TOCLIZUMAB** (*Actemra 80mg/4mL, 200mg/10mL, 400mg/20mL Injection*)

- for patients with a diagnosis of moderate-to-severely active RA who have failed to respond to an adequate trial of both disease-modifying antirheumatic drugs (DMARDs) and a tumour necrosis factor (TNF)-alpha inhibitor
- therapy must include methotrexate unless contraindicated or not tolerated
- written request of rheumatologist or prescriber with a specialty in rheumatology
- initial coverage for 16 weeks at dose of 4mg/kg, yearly coverage dependent on patient achieving an improvement in symptoms of at least 20%
- maximum dose: 800 mg every 4 weeks

### **TOLTERODINE** (*Detrol 1mg, 2mg and Detrol LA 2mg, 4mg Tablet*)

- See **Urinary Antispasmodics, Long-Acting**

### **TOPIRAMATE** (*Topamax 25mg, 100mg, 200mg Tablet and 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 for beneficiaries 30 years and under
- for treatment of actinic keratosis in beneficiaries over the age of 30

### **TROSPIUM** (*Trosec 20mg Tablet*)

- See **Urinary Antispasmodics, Long-Acting**

---

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

**TRYPTOPHAN** (*Tryptan 500mg Capsule and 500mg, 750mg, 1g Tablet and generic brands*)

- as an adjunct for the treatment of depression in the management of patients suffering from bipolar affective disorders

**URINARY ANTISPASMODICS, LONG-ACTING** (*Darifenacin, Oxybutynin XL, Tolterodine, Trospium, Solifenacin*)

- 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

**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

**USTEKINUMAB** (*Stelara 45mg/0.5mL Injection*)

- for patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria:
  - Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals
  - failure to respond to, contraindication to or intolerant of methotrexate and cyclosporine
  - failure to respond to, intolerant of or unable to access phototherapy
- written request of a dermatologist or prescriber with a specialty in dermatology
- continued coverage is dependent on evidence of improvement, specifically:
  - $\geq 75\%$  reduction in the Psoriasis Area and Severity Index (PASI) score, *or*
  - $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in DLQI (Dermatology Life Quality Index), *or*
  - significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals
- concurrent use of biologics not approved
- initial approval for a maximum of 16 weeks
- dosage restricted to 45mg at 0, 4 and 16 weeks, response must be assessed prior to fourth dose
- maintenance dosing every 12 weeks

**VALGANCICLOVIR** (*Valcyte 450mg Tablet*)

- for the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist or prescriber with a specialty in infectious disease
- 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 maximum 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<sub>12</sub>, INJECTION**

- See *Cyanocobalamin, Injection*

**VITAMIN B<sub>12</sub>, ORAL**

- See *Cyanocobalamin, Oral*

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

**VORICONAZOLE** (*Vfend 50mg, 200mg Tablet*)

- for the treatment of patients with invasive aspergillosis
- for the treatment of invasive candidiasis (proven on culture) with documented resistance to fluconazole

**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**

**ZANAMIVIR** (*Relenza 5mg Powder For Inhalation*)

- for the treatment of long-term care residents with clinically suspected or lab confirmed influenza A or B, when there is documented resistance to oseltamivir or when oseltamivir is contraindicated. 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 influenza A or B in long term care residents where the facility has an outbreak, when there is documented resistance to oseltamivir or when oseltamivir is contraindicated.
- a protocol has been developed by Public Health for the treatment of patients in long-term care facilities. The facility must contact the Medical Officer of Health or local Public Health Office, who will notify the Pharmacare office (or dispensing pharmacy after office hours) if coverage is required

**ZIPRASIDONE** (*Zeldox 20mg, 40mg, 60mg, 80mg Capsule*)

- for the treatment of schizophrenia and schizoaffective disorder

**ZOLEDRONIC ACID** (*Aclasta 5mg/100ml Injection*)

- for the treatment of Paget's disease

**ZOLMITRIPTAN** (*Zomig, Zomig Rapimelt 2.5mg Tablet*)

- See **Selective 5HT<sub>1</sub> - Receptor Agonists**

---

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