

The Newfoundland and Labrador Prescription Drug Program

**CRITERIA FOR THE COVERAGE OF SPECIAL  
AUTHORIZATION DRUGS**

Updated April 2010

Subject to revision

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Coverage of special authorization drugs will be approved according to the following criteria upon receipt of the required clinical information from a health care professional involved in the patient's care, and subject to a medication review by staff of the Pharmaceutical Services Division. A special authorization request form has been prepared at the request of pharmacists and physicians which may be used to facilitate the approval process. Requests can be faxed or mailed and are assessed in the order received. The use of the form, while not mandatory, is encouraged to expedite the approval process.

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**Abatacept (Orencia 250mg vial for injection)**

*Rheumatoid arthritis (RA)*

- For treatment of patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial of an anti-TNF agent.

*Juvenile Idiopathic Arthritis/ Juvenile Rheumatoid Arthritis*

- For children (6-17 years of age) with a diagnosis of juvenile idiopathic arthritis / juvenile rheumatoid arthritis who are intolerant to, or have not had an adequate response from etanercept.
  - Initial treatment should be limited to a maximum of 16 weeks.
  - Retreatment should only be permitted for children who had an adequate initial treatment response and subsequently experience disease flares.

Abatacept not be used in combination with anti-TNF agents.

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_initiation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_continuation\\_request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_continuation_request.pdf)

**Acarbose (Glucobay 50mg and 100mg tablet)**

For patients who are not controlled satisfactorily despite maximum doses of a biguanide and sulfonylurea, or in whom these agents are contraindicated.

## **Acamprosate (Campral 333mg tablet)**

For the maintenance of abstinence from alcohol in patients with a diagnosis of alcohol dependence who:

- have been abstinent from alcohol for at least 4 days.
- maximum treatment duration is 1 year.

## **Adaptalene (Differin)**

For the treatment of acne vulgaris upon failure of or intolerance to benefit topical retinoids.

## **Adalimumab (Humira 40mg/ml)**

*Rheumatoid arthritis (RA)*

For the treatment of Rheumatoid arthritis in patients who:

- have not responded or who have had intolerable toxicity to an adequate trial\* of combination therapy of at least two traditional DMARDs\*\*

**OR**

- if combination therapy is not an option, an adequate trial of at least **three** traditional DMARDs in sequence as monotherapy

**AND**

- patients must have had an adequate trial\* of leflunomide. Exceptions can be considered in cases where leflunomide is ineffective or contraindicated.

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 (ACR) of at least 20%.

\*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.

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

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

Written request of a rheumatologist only

*Ankylosing spondylitis:*

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 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.

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

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- 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")

Approvals will be for a maximum dose of 40mg every two weeks. Adalimumab will not be reimbursed in combination with other anti-TNF agents.

*Psoriatic Arthritis:*

For patients with active psoriatic arthritis who meet all of the following criteria:

- Have at least three active and tender joints
- Failure to respond to non-steroidal anti-inflammatory agents **and**, failure to respond to an adequate trial with two DMARD's (eg sulfasalazine, methotrexate, leflunomide, cyclosporine) or contraindications to, or intolerance of these agents.
- Not used in combination with other TNF antagonists
- Written request from a rheumatologist only
- Dosage restricted to a maximum of 40mg every 2 weeks
- Coverage will be approved initially for 3 months. Can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (*20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria*)

To facilitate this process specific **RA Medication Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_initiation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_continuation\\_request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_continuation_request.pdf)

*Crohn's Disease:*

- For moderately to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy. Eligible patients will be approved for an induction dose of 160mg followed by 80mg two weeks later.

- Clinical response to adalimumab to be assessed four weeks after the first induction dose, using criteria such as a 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.
- Ongoing coverage for adalimumab maintenance therapy will only be provided for responders, as noted above, and for a dose not exceeding 40mg every two weeks.

To facilitate this process a specific **Anti-TNF agents for Crohn's disease Special Authorization Form** has been developed and can be found at:  
[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/crohns\\_meds.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/crohns_meds.pdf)

*Chronic plaque psoriasis:*

For patients with severe, debilitating psoriasis who meet all of the following criteria:

1. Body surface area (BSA) involvement of > 10% and/or significant involvement of the face, hands, feet or genital region;
2. Failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine;
3. Failure to respond to, intolerant to, or unable to access phototherapy.

Response to adalimumab must be assessed after 16 weeks and therapy continued only in patients who have responded to therapy.

Criteria for defining response:

- Achievement of a  $\geq 75\%$  reduction in Psoriasis Area Severity Index (PASI) score, **or**
- A  $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in the Dermatology Life Quality Index (DLQI) **or**
- A significant reduction in BSA involved, with consideration of important regions such as the face, hands, or genital region.

Ongoing coverage for adalimumab maintenance therapy should only be provided for responders, as noted above.

Approved for doses not exceeding 40mg every two weeks.

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:  
[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic\\_Plaque\\_Psoriasis\\_Meds\\_Coverage\\_Request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic_Plaque_Psoriasis_Meds_Coverage_Request.pdf)

**Adefovir Dipivixil (Hepsera 10mg tablets)**

In combination with lamivudine in patients who:

- developed failure to lamivudine, as defined by an increase in HBV DNA of  $\geq 1 \log_{10}$  IU/ml above the nadir, measured on two separate occasions within an interval of at least one month, after the first three months of lamivudine therapy AND
- when failure to lamivudine is not due to poor adherence to therapy.
- Coverage is approved for one year

**Alendronate (Generic 10mg, 70mg tablet/Fosamax 10mg, 70mg tablet)**

- For the treatment of osteoporosis associated with documented fracture
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table)
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months

### **Alendronate (Generic 40mg, Fosamax 40mg tablet)**

For the treatment of Paget's Disease (6 month limit)

### **Alendronate & Cholecalciferol (Fosavance 70/5600)**

- For the treatment of osteoporosis associated with documented fracture
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table)
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months

### **Almotriptan malate (Axert 6.25mg, 12.5mg)**

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

OR

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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

### **Ambrisentan (Volibris 5mg, 10mg tablet)**

For the treatment of idiopathic pulmonary arterial hypertension (PAH) or pulmonary hypertension associated with connective tissue disease in patients with:

- with at least WHO functional class III pulmonary arterial hypertension (either idiopathic or associated with connective tissue disease)
- confirmed by right heart catheterization

- for doses up to 10mg daily

**Amlodipine/atorvastatin (Caduet 5/10mg, 5/20mg, 5/40mg, 5/80mg, 10/10mg, 10/20mg, 10/40mg & 10/80mg)**

For patients who:

- meet the special authorization criteria for amlodipine AND
- have been titrated to a stable combination of the separate components, amlodipine and atorvastatin.

**Anagrelide (Agrylin)**

For the treatment of essential thrombocythemia in patients who have failed or had intolerable side effects to treatment with hydroxyurea.

**Anastrozole (Arimidex 1mg tablet)**

For the first-line treatment of post-menopausal patients with hormone receptor positive metastatic or locally advanced breast cancer.

For the treatment of adjuvant treatment (upfront) (1-5years) of hormone receptor positive early stage breast cancer in post-menopausal patients who:

- have a definite contraindication to tamoxifen OR
- have demonstrated a severe intolerance to tamoxifen

**Aprepitant (Emend 80mg and 125mg tablets)**

In combination with a 5-HT<sub>3</sub> antagonist class of anti-emetics and dexamethasone for the prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy (eg cisplatin  $\geq 70\text{mg}/\text{m}^2$ ) in patients who have experienced emesis despite treatment with a combination of a 5-HT<sub>3</sub> antagonist and dexamethasone in a previous cycle of highly emetogenic chemotherapy.

Please Note: The 5HT<sub>3</sub> antagonist should only be used on the first day of chemotherapy (eg cisplatin  $\geq 70\text{mg}/\text{m}^2$ ) with aprepitant continuing on Day 2 & 3.

**Benzydamine HCL (generics)**

For oncology patients who have failed to respond to benefit lidocaine HCL products.

**Bosentan (Tracleer 62.5mg, 125mg tablets)**

- Written initial request by 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 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 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 (Entocort 3mg capsule, enema 2mg/100ml)**

For the treatment of Crohn's disease or Colitis in patients for whom prednisone is contraindicated or in whom significant side effects have occurred.

### **Budesonide/Formoterol (Symbicort 100ug, 200ug)**

Reversible Obstructive Airway Disease:

For the treatment of reversible obstructive airway disease in patients in whom a combination of an inhaled steroid and long-acting beta agonist is desirable due to the failure of optimal doses of inhaled steroids \*(failure defined as the need for frequent use of inhaled short-acting bronchodilators).

\*Optimal defined as:

- >400mcg/day budesonide
- >250mcg/day HFA- beclomethasone
- >250mcg/day fluticasone

COPD:

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).
- Coverage can be approved without a trial of a short-acting agent if:
  - There is spirometric evidence of at least moderate to severe airflow obstruction, i.e.  $FEV_1 < 60\%$  AND  $FEV_1/FVC$  ratio  $< 0.7$ , and significant symptoms i.e. MRC score 3-5.\*
- Combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist/corticosteroid (i.e. Spiriva plus Advair or Symbicort) will only be considered if:
  - There is spirometric evidence of a least moderate to severe airflow obstruction ( $FEV_1 < 60\%$  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 years (24 consecutive months) 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).

#### **\*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 walking 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.*

**Bupropion HCL (Wellbutrin SR 100mg and 150mg and generics, Wellbutrin XL 150mg, 300mg)**

- For the treatment of depression in patients for whom other treatments have failed or resulted in intolerance.

**Please Note:** not insured for smoking cessation

**Butorphanol (Stadol NS 10mg/ml nasal spray)**

For the treatment of migraine, following assessment by a neurologist or specialist in pain management and where conventional forms of therapy are ineffective or clinically unsuitable.

**Cabergoline (Dostinex 0.5mg tablet & generics)**

For the treatment of hyperprolactinemic disorders in patients who have failed to respond or are intolerant to treatment with bromocriptine.

**Calcipotriol (Dovonex 50mcg/g scalp solution)**

For patients unresponsive to high-potency corticosteroid scalp solutions or in whom such products are medically contraindicated.

**Calcipotriol/betamethasone (Xamiol scalp gel)**

For the treatment of scalp psoriasis in patients:

- Who have failed a trial with a topical steroid alone **AND**
- Who have failed a trial with a topical steroid AND calcipotriol together

**Calcitonin, synthetic (generic Calcitonin Nasal, Miacalcin)**

- For the treatment of osteoporosis associated with documented fracture when alendronate, risedronate and raloxifene are contraindicated or not tolerated
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk ((based on age, sex and T-score, see Appendix 1 below for fracture risk table) and alendronate, risedronate and raloxifene are contraindicated or not tolerated
- Pain associated with osteoporotic fragility fractures, bone metastases, pathological fractures (short-term up to 3 months)

**Capecitabine (Xeloda 150mg, 500mg)**

Breast Cancer:

- For treatment of metastatic breast cancer where patients have progressed after prior chemotherapy. Requests must be made from an oncologist and approval will be granted for six months, to be renewed as required.

### Colorectal Cancer:

- As monotherapy in patients with advanced or metastatic colorectal cancer (MRCRC), with an ECOG performance status of 0-2 as an alternative to treatment with combination therapy (5-FU/LV/irinotecan) and/or are unable to tolerate first line therapy. Requests must be made from an oncologist and approval will be granted for six months, to be renewed upon request.
- As part of the CAPOX regimen for the first-line and second-line treatment of metastatic colorectal cancer (mCRC). Requests must be made from an oncologist and approval will be granted for six months, to be renewed upon request.

### Carbamazepine (Tegretol 20mg/ml suspension)

For patients who are fed via gastric tube

### Carvedilol (Coreg and Generic 3.125mg, 6.25mg, 12.5mg, 25mg tablet)

- For the treatment of stable symptomatic congestive heart failure (CHF) in patients receiving combination therapy with an ace inhibitor and a diuretic, with or without digoxin.
- For the treatment of stable symptomatic heart failure with left ventricular ejection fraction (LVEF) less than or equal to 40%.

### Celecoxib (Celebrex 100mg, 200mg capsules):

For the treatment of osteoarthritis\* in patients who have one or more of the following risk factors:

- 65 years of age or older
- concurrent oral steroids
- documented history of PUD
- concurrent warfarin therapy
- persistent dyspeptic symptoms despite trials of at least 3 NSAIDS, including an enteric coated formulation

**\* maximum daily dose approved in OA is 200mg**

For the treatment of rheumatoid arthritis\*\* in patients who have one or more of the following factors:

- 65 years of age or older
- concurrent oral steroids
- documented history of PUD
- concurrent warfarin therapy
- persistent dyspeptic symptoms despite trials of at least 3 NSAIDS, including an enteric coated formulation

**\*\* maximum daily dose approved is 400mg**

### Cholinesterase Inhibitors (ChEI's) (donepezil, galantamine, rivastigmine & generics)

For the treatment of patients with a diagnosis of mild to moderate 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)- New Request:**

Patients who meet all of the following reimbursement criteria will be approved for an initial 180 days of therapy.

Coverage is provided for an initial 180 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
- 3 target symptoms that have been established in each of three domains (chosen from the four domains of cognition, function, behaviour and social/leisure). These will be monitored on an ongoing basis to assist in determining clinical meaningfulness.

**Request for Continuation of Cholinesterase Inhibitor- Renewal Request**

Patients who meet the following monitoring criteria will be approved for a second 180 days of therapy:

- o A MMSE score of 10 to 30;
- o A FAST score of 4 to 5; and
- o Stabilization or improvement in at least one target symptom.

Patients who meet the following monitoring criteria will be approved for 12 months of therapy at a time:

- o A MMSE score of 10 to 30 (Note: A MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);
- o A FAST score of 4 to 5 (Note: A FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.); and
- o Stabilization or improvement in at least one target symptom.

**Request for Change to a Different of Cholinesterase Inhibitor**

Patients will be approved for an initial 180 days of therapy with a second ChEI when the following information is provided:

- o The reason for discontinuing the first ChEI; and
- o Any changes in target symptoms.

Patients who meet the following monitoring criteria will be approved for a second 180 days of therapy:

- o A MMSE score of 10 to 30;
- o A FAST score of 4 to 5; and
- o Stabilization or improvement in at least one target symptom.

Patients who meet the following monitoring criteria will be approved for 12 months of therapy at a time:

- o A MMSE score of 10 to 30 (Note: A MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);
- o A FAST score of 4 to 5 (Note: A FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.); and
- o Stabilization or improvement in at least one target symptom.

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:

**[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_continuation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_continuation.pdf)**

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_initiation.pdf)

### **Citalopram (generic 20mg/Celexa 20mg tablet)**

For patients requiring dosages that cannot be accommodated with a 40mg tablet strength.

Please note: PMS-Citalopram 10mg DIN 02270609, CPT 30mg DIN 02296152 are open benefits (do not require special authorization)

### **Ciprofloxacin/Dexamethasone Otic Solution (Ciprodex otic solution)**

- In patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment.
- In patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.

### **Clozapine (Gen-Clozapine 25mg, 50mg, 100mg, 200mg)**

For patients diagnosed with treatment resistant schizophrenia who have not obtained a satisfactory clinical response, despite treatment with appropriate courses of maximum tolerated\* therapeutic doses, of at least **two chemically unrelated** anti-psychotic medications.

\*intolerance is defined as the inability to achieve adequate benefit due to dose-limiting intolerable adverse effects such as parkinsonism, dystonia, akathisia and tardive dyskinesia.

### **Clopidogrel (Plavix 75mg tablet)**

For the **SECONDARY** prevention of the following vascular ischemic events:

- ischemic stroke or transient ischemic attack (TIA) when it has been demonstrated that there has been failed therapy with ASA, or for patients with documented severe ASA allergy (manifested by anaphylactic reaction, asthma, or nasal polyps) or GI hemorrhage while on ASA
- myocardial infarction (MI) in patients with documented severe ASA allergy (manifested by anaphylactic reaction, asthma, or nasal polyps) or GI hemorrhage while on ASA
- peripheral artery disease (PAD) in patients with documented severe allergy to ASA (manifested by anaphylactic reaction, asthma or nasal polyps) or GI hemorrhage while on ASA
- unstable angina in patients with documented severe ASA allergy (manifested by anaphylactic reaction, asthma or nasal polyps) or GI hemorrhage while on ASA
- in patients with intravascular\* stent implantation, the coverage period following insertion is:
  - Bare Metal Stents (BMS) - 30 days
  - Drug Eluting Stents (DES): – 12 months

For patients with non-ST-segment elevation acute coronary syndrome (i.e., unstable angina or non-ST-segment elevation myocardial infarction), in combination with ASA, for a **MAXIMUM** period of 3 months coverage.

12 months post NSTEMI-ACS for high risk patients as outlined below:

- 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 documented stroke, TIA or symptomatic PAD

**Note:** GI intolerance to ASA is **NOT** considered criterion for coverage

To facilitate this process a specific **Clopidogrel Special Authorization Form** has been developed and can be found at:

<http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Clopidogrel.pdf>

### **Codeine (Codeine Contin 50mg, 100mg, 150mg , 200mg tablets)**

For patients with persistent pain\* who have been stabilized on a titrated dose of an oral short-acting codeine product.

\* Please note: in order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- results of any xrays/CT scans/MRIs
- information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations)
- surgical history
- current analgesic uses, current dosage, and assessment of current level of pain control
- use of antidepressants and/or anticonvulsants if pain is neuropathic
- any other information you feel is pertinent to the request

### **Cyclosporine (Neoral 25mg, 50mg, 100mg, 100mg/ml oral liquid, & generics)**

- Upon request from a dermatologist for **severe psoriasis** unresponsive to conventional therapies
- Upon request from a rheumatologist for **severe rheumatoid arthritis** unresponsive to conventional therapies
- Upon request from a respirologist for **severe asthma** patients unresponsive to conventional therapies

### **Cyproterone Acetate/ Ethinyl Estradiol (Diane-35, Cyestra-35)**

For the treatment of acne in patients who have not responded to conventional therapy, including a trial of Norgestimate / Ethinyl Estradiol.

### **Dalteparin sodium (Fragmin)**

- Coverage is limited for treatment of acute VTE for 7 to 10 days or in patients with treatment failure on warfarin.

- Extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin.
- For extended treatment in symptomatic VTE in cancer patients who have had a recurrent VTE on warfarin therapy.
- For prophylaxis, our guidelines are limited to patients with concomitant anticoagulation syndromes or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy

**Darbepoetin (Aranesp 10ug, 20ug, 30ug, 40ug, 50ug, 60ug, 80ug, 100ug, 130ug, 150ug, 300ug, and 500ug )**

Chronic Renal Failure:

- For anemia of chronic renal failure\* (chronic kidney disease) for patients who have a serum creatinine level > 176umol/L (2mg/dL) or a GFR < 1ml/sec/1.73m<sup>2</sup> (60 mL/min/1.73m<sup>2</sup>) for three or more months and who have an anemia work-up showing hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia upon request from a medical specialist.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematologic malignancy\* in transfusion dependent patients with a baseline Hgb ≤ 90g/L whose transfusion requirements are ≥ 2 units of packed red blood cells (PRBC/month) over a 3 month period. An initial trial of 12 weeks (2.25ug/kg/week) with documentation of dose, Hgb and therapeutic outcome (#of transfusions). Further 12 week cycle can be approved dependent on evidence of clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to ≥ 2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 4.5ug/kg/week)

**Darifenacin (Enablex 7.5mg & 15mg tablet)**

For the treatment of overactive bladder (not stress incontinence) in patients with symptoms of urge incontinence, urinary urgency and urinary frequency (not stress incontinence) who cannot tolerate or have insufficient response to an appropriate trial\* of immediate-release oxybutynin.

\*an appropriate trial is considered to be of 12 weeks duration.

**Darunavir (Prezista 300mg, 400mg & 600mg tablet)**

- For the treatment of HIV-1 in patients who are treatment naïve for whom a protease inhibitor (PI) therapy is indicated.
- As an alternate protease inhibitor (PI) as part of a HIV treatment regimen for the treatment-experienced adult patients who have demonstrated failure to multiple PI's and in whom less expensive PI's are not a treatment option.

**Dasatinib monohydrate (Sprycel 20mg, 50mg and 70mg tablet)**

*Chronic Myelogenous Leukemia (CML):*

- For adult patients with chronic phase CML with primary or acquired resistance to imatinib (600mg/day) at doses of 100mg per day or 70mg two times daily

- For adult patients with chronic phase CML who progress to accelerated phase on imatinib 600mg per day. Dosing recommendation: 140mg per day
- For adult patients with chronic phase CML who has blast crisis while on imatinib 600mg per day. Dosing recommendation: 140mg per day
- For adult patients with CML have intolerance to imatinib or have experienced grade 3 or higher toxicities to imatinib
- Renewal criteria: Request for renewal must specify how the patient has benefited from therapy and is expected to continue to do so.

Duration of initial approval: 1 year

Duration of renewal: 1 year

*Philadelphia chromosome positive acute lymphoblastic leukemia:*

- For adult patients whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day)
- **OR** have experienced grade 3 non-hematologic toxicity,
- **OR** grade 4 hematologic toxicity to imatinib persisting for more than 7 days.

Request for renewal must specify that the patient has benefited from therapy and is expected to continue to do so.

**Deferasirox (Exjade 125mg, 250mg and 500mg tablets):**

For patients who require iron chelation but in whom desferoxamine is contraindicated.

**Dipyridamole/ASA (Aggrenox 200mg/25mg capsules)**

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)**

For the treatment of emesis in patients who:

- are receiving a course of highly emetogenic chemotherapy (i.e. contains cisplatin) or moderately emetogenic chemotherapy (i.e. contains cyclophosphamide, doxorubicin, epirubicin, melphalan)

AND

- have experienced adverse effects to metoclopramide, prochlorperazine or dexamethasone or have a specific contraindication which does not allow use of these drugs as antiemetics

OR

- have had continued episodes of nausea and vomiting related to intravenous chemotherapy or radiation therapy which have not responded to therapeutic doses of other antiemetics including metoclopramide, dexamethasone and prochlorperazine.

**Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.**

The dose and duration of therapy approved will be:

- Zofran 8mg up to TID per day of IV chemo

- Kytril 1mg up to BID per day of IV chemo
- Anzemet 100mg OD per day of IV chemo

Duration of approval will be for the full course of the chemotherapy regimen

### **Donepezil (Aricept 5mg, 10mg tablets)**

- See Cholinesterase Inhibitors (ChEI's)

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_continuation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_continuation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_initiation.pdf)

### **Duloxetine (Cymbalta 30mg & 60mg)**

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For treatment of neuropathic pain in diabetic patients who:

- are unresponsive to TWO adequate courses of less costly alternative agents such as a tricyclic antidepressant agent or an anticonvulsant agent.
- Dose to be limited to a maximum of 60mg daily.

### **Dutasteride (Avodart 0.5mg capsule)**

For the treatment of benign prostatic hypertrophy (BPH) where alpha agonists have failed or are contraindicated or not tolerated.

### **Efavirenz/emtricitabine/tenofovir (Atripla 600mg/200mg/300mg)**

For the treatment of HIV-1 infection where the virus is susceptible to each of tenofovir, emtricitabine and efavirenz AND:

- Atripla is used to replace existing therapy with its component drugs, OR
- The patient is treatment naïve, OR
- The patient has established viral suppression but requires antiretroviral therapy modification due to intolerance or adverse effects.

### **Emedastine (Emadine ophthalmic solution 0.05%)**

For the treatment of allergic conjunctivitis in patients with failure or intolerance to both sodium cromoglycate (Opticrom) and levocarbastine HCL (Livostin)

### **Emtricitabine/tenofovir (Truvada 200mg/300mg tablets)**

As a dual nucleoside/nucleotide option for the treatment of HIV patients where the virus is susceptible to both agents and efavirenz is not indicated due to adverse effects or antiretroviral resistance.

### **Enoxaparin sodium (Lovenox)**

Coverage is limited for treatment of acute VTE to a maximum of 7 to 10 days.

- Extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin.
- For prophylaxis, our guidelines are limited to patients with concomitant anticoagulation syndromes or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy

### **Epinephrine (Ana-kit, Epipen, Epipen Jr, Twinject 0.15, 0.30mg)**

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

**Note** - coverage is limited to one unit at a time.

Approval will be provided to replace used or expired units as needed

### **Epoprostenol sodium (Flolan 0.5mg, 1.5mg injection)**

Written request from a medical specialist

- For the treatment of patients with pulmonary arterial hypertension (primary (idiopathic) or scleroderma-associated) with NYHA functional class III or IV unresponsive to therapy with vasodilators and bosentan
- Severe/advanced (NYHA functional class IV) pulmonary arterial hypertension.

### **Erlotinib HCl (Tarceva 100mg, 150mg tablet)**

- As monotherapy for the 2nd- or 3rd-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) despite prior chemotherapy including both docetaxel and cisplatin or carboplatin.
- As monotherapy for the 3rd-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) despite prior chemotherapy including both cisplatin or carboplatin and pemetrexed or topotecan.
- As monotherapy for 2nd line treatment of NSCLC after 1st line platinum-based therapy, *where no other chemotherapy will be given and erlotinib is used as the last treatment for the patient.*

Dosage: 150 mg/day

Approval period: 3 months

Renewal Criteria:

- Physician assessment that patient has responded to treatment and disease has not progressed
- Approval period for renewal: 3 months

### **Erythropoietin Alpha (Eprex)**

Anemia of Chronic Renal Failure:

- For anemia of chronic renal failure\* (chronic kidney disease) for patients who have a serum creatinine level > 176umol/L (2mg/dL) or a GFR < 1ml/sec/1.73m<sup>2</sup> (60 mL/min/1.73m<sup>2</sup>) for three or more months and who have an anemia work-up showing

hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia upon request from a medical specialist.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematological malignancy\* for those patients who are transfusion dependent with a baseline Hgb  $\leq$  90g/L and whose transfusion requirements are  $\geq$  2 units of packed red blood cells per month (PRBC/month) over a 3 month period. Initial approval will be for a 12 week period only. Further consideration beyond this period (for 12 week approvals) can be considered dependent on evidence of satisfactory clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to  $\geq$  2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 60,000iu per week).

### **Estradiol (Oesclim)**

For hormone replacement therapy in women who are intolerant to benefit transdermal estrogen patches.

### **Etanercept (Enbrel 25mg, 50mg Powder for Injection)**

*Rheumatoid arthritis (RA):*

- have not responded or who have had intolerable toxicity to an adequate trial\*of combination therapy of at least two traditional DMARDs\*\*

**OR**

- if combination therapy is not an option, an adequate trial of at least **three** traditional DMARDs in sequence as monotherapy

**AND**

- patients must have had an adequate trial\* of leflunomide. Exceptions can be considered in cases where leflunomide is ineffective or contraindicated.

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 (ACR) of at least 20%.

\* 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.

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

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

Written request of a rheumatologist only

*Juvenile Rheumatoid Arthritis:*

- For the treatment of moderate to severely active, polyarticular juvenile rheumatoid arthritis in children (age 4-17) that have not responded to adequate treatment with one or more DMARDs for at least 3 months or have intolerance to DMARD, and do not have a contraindication to etanercept.

### *Psoriatic Arthritis:*

- For the treatment of psoriatic arthritis in patients that have not responded to an adequate trial of two DMARDs or have had intolerance or contraindication to DMARDs
- Traditional agents include methotrexate, IM gold, sulfasalazine, hydroxychloroquine, azathioprine, chloroquine, D-penicillamine and cyclosporine.

### *Ankylosing Spondylitis:*

- 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 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.

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

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- 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")

**Approvals will be for a maximum dose of 50mg per week and NOT be reimbursed in combination with other anti-TNF agents.**

To facilitate this process specific **RA Medications Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_initiation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_continuation\\_request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_continuation_request.pdf)

### *Chronic Plaque Psoriasis:*

For patients with severe debilitating psoriasis who meet all of the following criteria:

- Body surface involvement of greater than 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 to or unable to access phototherapy

Coverage will be approved initially for 3 months.

Can be reassessed for yearly coverage dependent on the patient achieving a response of greater than or equal to 75% reduction in PASI (Psoriasis Area Severity Index) score or

greater than 50% reduction in PASI with a greater than or equal to 5 point improvement in DLOI (Dermatology Life Quality Index) or a quantitative reduction in BSA (Body Surface Area) affecting the face, hands, feet or genital region.

**Dosage restricted to 50mg twice weekly for 3 months followed by a reduction to a maintenance dose of 50mg weekly.**

Written request from a dermatologist.  
Two biologicals cannot be given concurrently.

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:

**[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic Plaque Psoriasis Meds Coverage Request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic%20Plaque%20Psoriasis%20Meds%20Coverage%20Request.pdf)**

### **Entecavir (Baraclude 0.5mg tablets)**

For the treatment of chronic hepatitis B infection in patients with:

- documented cirrhosis on radiographic or histologic grounds AND
- a HBV DNA concentration above 2000 IU/ml.

### **Exemestane (Aromasin 25mg)**

Second line therapy in the treatment of breast cancer following failure of or intolerance or contraindication to tamoxifen.

For the treatment of adjuvant treatment (upfront) (1-5years) of hormone receptor positive early stage breast cancer in post-menopausal patients who:

- have a definite contraindication to tamoxifen OR
- have demonstrated a severe intolerance to tamoxifen

### **Ezetimibe (Ezetrol 10mg tablet)**

- co-administration with statins for patients not reaching treatment goals on maximum tolerated doses of statins alone.
- for the treatment of hypercholesterolemia, as monotherapy, in patients who are intolerant to fibrates (where appropriate) and statins.

### **Fentanyl (Duragesic 12.5ug, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr transdermal system and generics)**

For the treatment of malignant or chronic non-malignant pain\* in **adult patients** who were previously receiving **continuous opioid administration (long-acting opioids)** or who are unable to take oral therapy.

\* Please note: in order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- results of any xrays/CT scans/MRIs
- information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations)
- surgical history
- current analgesic uses, current dosage, and assessment of current level of pain control

- use of antidepressants and/or anticonvulsants if pain is neuropathic
- any other information you feel is pertinent to the request

### **Feroterol/ipratropium nebules (Duovent nebules)**

Failure or intolerance to ipratropium/salbutamol nebules (Combivent)

### **Filgrastim (Neupogen 300ug, 480ug)**

Cancer patients receiving moderate to severely myelosuppressive chemotherapy:

Primary prophylaxis:

- For use in previously untreated patients receiving a moderate to severely myelosuppressive chemotherapy regimen (i.e.  $\geq 40\%$  incidence of febrile neutropenia). Febrile neutropenia is defined as a temperature  $\geq 38.5^{\circ}\text{C}$  or  $> 38^{\circ}\text{C}$  three times in a 24 hour period and neutropenia with an absolute neutrophil count (ANC)  $< 0.5 \times 10^9/\text{L}$

Secondary prophylaxis:

- For use in patients receiving myelosuppressive chemotherapy who have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
  - For use in patients who have experienced a dose reduction or treatment delay longer than one week due to neutropenia.

Dosing for chemotherapy support:

- The manufacturer recommends an initial dose of 5ug/kg/day
- Patients  $\leq 70\text{kg}$  use 1ml vial (300ug)
- Patients  $> 70\text{kg}$  use 1.6ml vial (480ug)

### **Finasteride (Proscar 5mg tablet)**

- For the treatment of Benign Prostatic Hypertrophy (BPH) where alpha antagonists are contraindicated, not tolerated or failed.
- In combination with an alpha blocker when alpha blocker therapy has been tried as monotherapy and partial response has been observed.

### **Fluticasone/Salmeterol (Advair Diskus 100ug, 250ug, 500ug, Advair MDI 125ug, 250ug)**

Reversible Obstructive Airway Disease:

For treatment of asthma in patients in whom a combination of an inhaled steroid and long-acting beta agonist is desirable due to the failure of optimal doses of inhaled steroids \*(failure defined as the need for frequent use of inhaled short-acting bronchodilators)

\*Optimal defined as:  
      $>400\text{mcg/day}$  budesonide  
      $>250\text{mcg/day}$  HFA- beclomethasone  
      $>250\text{mcg/day}$  fluticasone

COPD:

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).

- Coverage can be approved without a trial of a short-acting agent if:
  - There is spirometric evidence of at least moderate to severe airflow obstruction, i.e.  $FEV_1 < 60\%$  AND  $FEV_1/FVC$  ratio  $< 0.7$ , and significant symptoms i.e. MRC score 3-5.\*
- Combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist/corticosteroid (i.e. Spiriva plus Advair or Symbicort) will only be considered if:
  - There is spirometric evidence of a least moderate to severe airflow obstruction ( $FEV_1 < 60\%$  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 years (24 consecutive months) 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).

## \*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 walking 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.*

## Formoterol (Foradil 12mcg capsule for inhalation, Oxeze 6mg, 12mcg/dose turbuhaler)

Reversible Obstructive Airway Disease:

For the treatment of reversible airway disease where optimal doses of inhaled steroids\* are being used and breakthrough symptoms require frequent use of inhaled short-acting bronchodilators.

\*Optimal defined as:

- >400mcg/day budesonide
- >250mcg/day HFA- beclomethasone
- >250mcg/day fluticasone

COPD:

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).
- Coverage can be approved without a trial of a short-acting agent if:

- There is spirometric evidence of at least moderate to severe airflow obstruction, i.e.  $FEV_1 < 60\%$  AND  $FEV_1/FVC$  ratio  $< 0.7$ , and significant symptoms i.e. MRC score 3-5.\*

**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).

**\*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 walking 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.*

**Gabapentin (Neurontin 100mg, 300mg, 400mg, 600mg capsules and generics)**

For adjunctive management of epilepsy not satisfactorily controlled by conventional therapy.

For the treatment of neuropathic pain not satisfactorily controlled with a trial of a tricyclic antidepressant and for trigeminal neuralgia a trial of both a tricyclic antidepressant and carbamazepine.

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

See Cholinesterase Inhibitors (ChEI's)

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_continuation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_continuation.pdf)  
[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/chei_initiation.pdf)

**Gatifloxacin (Tequin 400mg tablet)**

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB)
- For the treatment of severe pneumonia in nursing home patients
- For the treatment<sup>1</sup> of CAP in patients
  - with co-morbidity<sup>2</sup> upon radiographic confirmation of pneumonia, *or*
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate)
- 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).

- <sup>1</sup> If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
- <sup>2</sup> Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.
- <sup>3</sup> Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea **AND**
  - FEV<sub>1</sub> < 50% predicted
  - OR**
  - FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

### **Glatiramer Acetate (Copaxone)**

For the treatment of Multiple Sclerosis (MS) in patients who meet the following criteria:

1. Written request from a neurologist
2. Subjects over 18 years.
3. Confident diagnosis of relapsing-remitting , relapsing-progressive, or secondary progressive MS
4. Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatible with MS, lasting greater than 24 hours and not due to a rise in temperature.)
5. Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

### **Granisetron HCL (Kytril 1mg tablet & generics)**

For the treatment of emesis in patients who:

- are receiving a course of highly emetogenic chemotherapy (i.e. contains cisplatin) or moderately emetogenic chemotherapy (i.e. contains cyclophosphamide, doxorubicin, epirubicin, melphalan)

**AND**

- have experienced adverse effects to metoclopramide, prochlorperazine or dexamethasone or have a specific contraindication which does not allow use of these drugs as antiemetics

**OR**

- have had continued episodes of nausea and vomiting related to intravenous chemotherapy or radiation therapy which have not responded to therapeutic doses of other antiemetics including metoclopramide, dexamethasone and prochlorperazine.

**Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.**

The dose and duration of therapy approved will be:

- Zofran 8mg up to TID per day of IV chemo
- Kytril 1mg up to BID per day of IV chemo

- Anzemet 100mg OD per day of IV chemo

Duration of approval will be for the full course of the chemotherapy regimen

### **Halobetasol (Ultravate 0.05% cream and ointment)**

For patients who have not responded satisfactorily to high-potency topical steroid preparations

### **H. Pylori eradication (Pantoloc 40mg, Losec 20mg, Prevacid 30mg, Pariet 10mg, generic Omeprazole 20mg)**

- H. Pylori eradication, in conjunction with clarithromycin and metronidazole/amoxicillin, at BID dosing for a 7 day period.
- A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori.

### **Hydromorphone (Hydromorph Contin 3mg, 6mg, 12mg, 18mg, 24mg, 30mg)**

For patients with persistent pain\* who have been stabilized on a titrated dose of an oral short-acting hydromorphone product OR whose pain is not adequately controlled or who are intolerant to oral sustained-release morphine or oxycodone products despite dose titration and adjuvant antiemetics and laxatives.

\* Please note: in order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- results of any xrays/CT scans/MRIs
- information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations)
- surgical history
- current analgesic uses, current dosage, and assessment of current level of pain control
- use of antidepressants and/or anticonvulsants if pain is neuropathic
- any other information you feel is pertinent to the request

### **Imatinib (Gleevec 100mg, 400mg)**

*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\*
- as secondary use in patients who demonstrate a hematologic relapse or cytogenetic progression after interferon-alpha (INF-a) therapy\*

*For the treatment of acute lymphoblastic leukemia (ALL):*

- as a single agent for induction and maintenance phase therapy in adult patients with

newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)\*

*For C-kit positive (CD117 positive), metastatic or locally advanced inoperable GIST who have an ECOG performance status of 0-2.*

\*written request of an oncologist/hematologist required

### **Imiquimod (Aldara 5% cream)**

- For the treatment of external genital and perianal warts and condyloma acuminata in adults.
- For the treatment of actinic keratosis on the head and neck in patients who have failed treatment with 5FU and cryotherapy

### **Infliximab (Remicade 100mg Powder for Injection)**

*Rheumatoid arthritis (RA):*

For the treatment of Rheumatoid Arthritis, in combination with methotrexate in patients who:

- have not responded or who have had intolerable toxicity to an adequate trial\*of combination therapy of at least two traditional DMARDs\*\*

**OR**

- if combination therapy is not an option, an adequate trial of at least **three** traditional DMARDs in sequence as monotherapy

**AND**

- patients must have had an adequate trial\* of leflunomide. Exceptions can be considered in cases where leflunomide is ineffective or contraindicated.

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 (ACR) of at least 20%.

\* 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.

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

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

Written request of a rheumatologist only

*Ankylosing Spondylitis:*

- 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 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.

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

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- 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")

**Approvals will be for a maximum dose of 5mg/kg at 0, 2, 6 weeks and then every 6 to 8 weeks thereafter and will NOT be reimbursed in combination with other anti-TNF agents.**

To facilitate this process specific **RA Medications Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_initiation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_continuation\\_request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_continuation_request.pdf)

*Crohn's disease:*

- For the treatment of patients with moderate or severe active disease\* with contraindications to or not achieving remission with glucocorticosteroids **AND** immunosuppressive therapy.
- Written request by Gastroenterologist or physician with a specialty in gastroenterology
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- **Initial approval, 3 infusions of infliximab 5mg/kg at week 0, 2 & 6**
- Continued coverage dependent on evidence of response using criteria such the 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.
- Coverage can be reassessed annually dependent on evidence of response. (as outlined above).
- **The maximum approved dose is 5mg/kg every 8 weeks.**

- Concurrent use of biologics not approved

\* Patients very ill & not candidates for surgery may qualify for immediate infliximab induction therapy, as they may require a more rapid response.

To facilitate this process a specific **Anti-TNF agents for Crohn's disease Special Authorization Form** has been developed and can be found at:  
[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/crohns\\_meds.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/crohns_meds.pdf)

#### *Chronic Plaque Psoriasis (PsO):*

For patients with severe, debilitating 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

Coverage will be initially approved for 12 week. Continuation of therapy beyond 12 weeks will depend on response. Patients not responding adequately at 12 weeks should have treatment discontinued with no further treatment recommended.

An adequate response is defined as either:

- A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) from when treatment started, or
- A 50% reduction in the PASI score (PASI 50) and a 5 point reduction in DLQI (Dermatology Life Quality Index) from when treatment started.

Written request of dermatologist only

Two biologics cannot be given concurrently

Dosage restricted to Infliximab 5mg/kg ay 0, 2 and 6 weeks then every 8 weeks

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic Plaque Psoriasis Meds Coverage Request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic_Plaque_Psoriasis_Meds_Coverage_Request.pdf)

#### **Insulin Aspart (NovoRapid)**

- For patients with insulin-dependant diabetes on multiple insulin dosing (greater or equal to 3 injections of regular insulin per day) and who are experiencing frequent hypoglycemia or poor glycemic control on their current regimen
- For patients with insulin-dependant diabetes who are using an insulin pump
- For patients with insulin-dependant diabetes who, for convenience purposes, wish to use this insulin and are willing to pay the difference in price from traditional regular insulin (i.e. NLPDP will pay the cost normally reimbursed for regular insulin (Novolin ge Toronto) and the patient would be responsible for the difference)

#### **Insulin glulisine (Apidra 100units/ml)**

- For patients with insulin-dependant diabetes on multiple insulin dosing (greater or equal to 3 injections of regular insulin per day) and who are experiencing frequent hypoglycemia or poor glycemic control on their current regimen
- For patients with insulin-dependant diabetes who are using an insulin pump

- For patients with insulin-dependant diabetes who, for convenience purposes, wish to use this insulin and are willing to pay the difference in price from traditional regular insulin (i.e. NLPDP will pay the cost normally reimbursed for regular insulin (Novolin ge Toronto) and the patient would be responsible for the difference)

### **Insulin Lispro (Humalog)**

- For patients with insulin-dependant diabetes on multiple insulin dosing (greater or equal to 3 injections of regular insulin per day) and who are experiencing frequent hypoglycemia or poor glycemic control on their current regimen
- For patients with insulin-dependant diabetes who are using an insulin pump
- For patients with insulin-dependant diabetes who, for convenience purposes, wish to use this insulin and are willing to pay the difference in price from traditional regular insulin (i.e. NLPDP will pay the cost normally reimbursed for regular insulin (Humulin R) and the patient would be responsible for the difference)

### **Interferon alfa-2a (Roferon A 3M iu, 9M iu, or 18M iu injection)**

- For chronic hepatitis B or C
- For chronic myelogenous leukemia (CML)
- For hairy cell leukemia

### **Interferon alfa-2b (Intron A 3M iu, 5M iu, or 10M iu injection)**

- For chronic Hepatitis B or C
- For malignant melanoma
- For basal cell carcinoma
- For chronic myelogenous leukemia (CML)
- For hairy cell leukemia

### **Interferon Beta-1A (Avonex, Avonex PS, Rebif, Rebif Initiation pack) and Interferon Beta-1B (Betaseron)**

For the treatment of patients with Multiple Sclerosis (MS) who meet the following criteria:

1. Written request from a neurologist
2. Subjects over 18 years.
3. Confident diagnosis of relapsing-remitting , relapsing-progressive, or secondary progressive MS
4. Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatible with MS, lasting greater than 24 hours and not due to a rise in temperature.)
5. Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

### **Isosorbide 5-mononitrate (Ismo 20mg)**

For the treatment of angina in patients who have not responded to benefit nitrate products.

### **Lactulose (generic)**

- For portal systemic encephalopathy

- For the management of chronic constipation in patients who have tried dietary intervention and in whom benefit bulk laxatives have been unsuccessful in controlling the problem

### **Lansoprazole (Prevacid 15mg, 30mg capsule Prevacid Fas Tab 15mg, 30mg)**

- see Proton Pump Inhibitor Guidelines
- Prevacid 30mg Fas Tabs are considered for patients who meet the criteria for coverage of a PPI **and** who require delivery of medication through a feeding tube.

### **Leflunomide (Arava 10mg, 20mg tablet and generics)**

Written request of a rheumatologist only.

For patients with a diagnosis of active rheumatoid arthritis (RA) who:

- have not responded or who have had intolerable toxicity to an adequate trial\* of combination therapy of at least two traditional DMARDs\*\*

**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 (ACR) of at least 20%

\* 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.

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

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

To facilitate this process specific **RA Medications Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_initiation.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_initiation.pdf)

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra\\_meds\\_continuation\\_request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/ra_meds_continuation_request.pdf)

### **Lenalidomide (Revlimid 5mg, 10mg, 15mg & 25mg capsules)**

For patients with a diagnosis of multiple myeloma that is refractory to or has relapsed after at least one prior therapy; and

1. is not a candidate for repeat autologous stem cell transplant; and
2. is not a candidate for/has contraindication to bortezomib second-line therapy.

One year approval period.

Renewal requires physician reassessment and request.

### **Letrozole (Femara 2.5mg)**

- For the first-line treatment of post-menopausal patients with hormone receptor positive metastatic or locally advanced breast cancer.
- For the treatment of adjuvant treatment (upfront) (1-5years) of hormone receptor positive early stage breast cancer in post-menopausal patients who:
  - have a definite contraindication to tamoxifen OR
  - have demonstrated a severe intolerance to tamoxifen
- For adjuvant treatment of post-menopausal patients with hormone-receptor positive early stage breast cancer patients who require extended adjuvant treatment (after 5 years of tamoxifen).

### **Levetiracetam (Keppra 250mg, 500mg, 750mg tablets and generics)**

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

### **Levofloxacin (Levaquin 250mg, 500mg tablet a & generics)**

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB)
- For the treatment of severe pneumonia in nursing home patients
- For the treatment<sup>1</sup> of CAP in patients
  - with co-morbidity<sup>2</sup> upon radiographic confirmation of pneumonia, *or*
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate)
- 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).

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

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

<sup>3</sup> Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea **AND**

- FEV<sub>1</sub> < 50% predicted
- OR**
- FEV 50-65% and one of the following:
  - ≥ 4 exacerbations per year
  - Ischemic heart disease
  - Chronic oral steroid use
  - Antibiotic use in the past 3 months

### **Levonorgestrel (Mirena intrauterine system)**

For conception control in women of childbearing age

### **Linezolid (Zyvoxam 600mg tablet)**

Upon the request of an infectious disease specialist only.

- For treatment of VRE (Vancomycin resistant enterococcus) proven infections.
- For the treatment of MRSA/MRSE (Methicillin resistant s. aureus/methicillin resistant s.epidermidis) proven infections in those patients who are unresponsive to, or intolerant of vancomycin.

### **Loperamide (generic)**

For the treatment of chronic diarrhea associated with any of the following:

- ileostomy or colostomy
- bowel resection, including short bowel syndrome
- inflammatory bowel disease
- cancer

### **Maracirov (Celsentri 150mg, 300mg tablets)**

For the treatment of HIV-1 infection given in combination with other antiretroviral medications in patients:

- Who have CCR5 tropic viruses **and**
- Who have documented resistance to at least one agent from each of the three main classes of antiretroviral agents (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors)

### **Metformin and Rosiglitazone (Avandamet 1/500mg, 2/500mg, 4/500mg, 2/1000mg, 4/1000mg Tablet)**

For the treatment of Type II diabetes in patients who currently meet criteria for Avandia coverage and are stabilized on doses equivalent to the combinations available of metformin and rosiglitazone

### **Methadone For Addiction:**

Methadone Maintenance (PIN 00967211):

For patients diagnosed with opiate dependence who are being treated for opiate withdrawal and/or opiate addiction. Before coverage is considered, the following information is required for assessment:

- A diagnosis of substance abuse or opiate withdrawal
- History of drugs used, dose, route of administration and duration of dependence
- Other treatment options tried (eg. non-medical detox) and results
- Past history of addiction and outcomes
- Detailed treatment plan, including intent to perform random drug testing, and duration of Methadone therapy

To facilitate this process a specific **Methadone Special Authorization Form** has been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/methadone\\_specauth\\_form.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/methadone_specauth_form.pdf)

Consideration for coverage of Methadone will only be given for patients who are undergoing random urine screening and participating in regular addictions counseling.

**Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.**

Methadone Carry (PIN 00907555):

Carry doses can be considered in patients who meet the following criteria:

- Stable dose of Methadone for at least two months
- NLPDP claims history shows no gaps in Methadone dispensing dates for at least two months
- Statement from Methadone prescriber that client has demonstrated the social, cognitive and emotional stability necessary to assume responsibility for the care of the medication and to use it as prescribed
- Urine drug screens free from all mood-altering drugs for a minimum of 12 weeks

A facilitate this process a specific **Methadone Carry Dose Special Authorization Form** has been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/methadone\\_carry\\_dose.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/methadone_carry_dose.pdf)

Clients with sustained use of medications with abuse potential will be limited to one carry per week. These medications include benzodiazepines, stimulants (ie methylphenidate) and narcotics/opioids. Exceptions may be considered on a case by case basis.

Carry doses can be considered on a case by case basis for medical disability or compassionate basis with written request from the Methadone prescriber containing the appropriate documentation to support his/her request.

**Concurrent usage of opiates will result in termination of coverage of Methadone by this Department.**

**Methadone (Metadol 1mg, 5mg, 10mg, 25mg tablet)**

Palliative analgesia:

For use as a replacement for other narcotic analgesics in palliative care patients who are requiring frequent and continuous dosing of short-acting opiates

Chronic Non-Malignant Pain:

For use as a replacement for other narcotic analgesics in chronic non-malignant pain patients for patients who have been thoroughly investigated and in whom alternate treatments (including treatment with lower potency opioids) have been unsuccessful or are not feasible and are therefore requiring frequent and continuous dosing of higher potency narcotics.\*

\* Please note: in order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- results of any xrays/CT scans/MRIs
- information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations)
- surgical history

- past analgesic use and response; current analgesic use, dosage, and assessment of current level of pain control
- any other information you feel is pertinent to the request

*Requests are only considered for those physicians holding a valid license to prescribe methadone.*

**Methylphenidate (Biphentin 10mg, 15mg, 20mg, 30mg, 40mg, 50mg 60mg, 80mg tablet)**

In patients age 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, pediatric or a general practitioner with expertise in ADHD.

**AND**

- Have been tried on immediate release (IR-MPH) and slow release (SR-MPH) methylphenidate with unsatisfactory results.

**Modafinil (Alertec 100mg tablet and generics)**

For the treatment of narcolepsy in patients who have failed to respond or are intolerant to trials of both methylphenidate and dextroamphetamine.

**Montelukast (4mg oral granules, 4mg, 5mg chewable tablet and 10mg tablet )**

For the treatment of moderate to severe asthma in adults and children (2 – 14 years old) 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, social activities because of asthma symptoms

**AND**

- Require increasing amounts of short-acting beta2-agonists, indicative of poor control.

**Moxifloxacin (Avelox 400mg tablet)**

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB)
- For the treatment of severe pneumonia in nursing home patients
- For the treatment<sup>1</sup> of CAP in patients
  - with co-morbidity<sup>2</sup> upon radiographic confirmation of pneumonia,

**OR**

- who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate)
- 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).

- <sup>1</sup> If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
- <sup>2</sup> Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.
- <sup>3</sup> Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea **AND**
  - FEV<sub>1</sub> < 50% predicted
  - OR**
  - FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

### **Nabumetone (Relafen 500mg and 750mg tablets and generics)**

For patients requiring treatment with an NSAID where there has been failure or intolerance to at least three NSAIDS (including at least 1 enteric coated NSAID).

### **Nadroparin calcium (Fraxiparine)**

Coverage is limited for treatment of acute VTE for 7 to 10 days.

- Extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin.
- For prophylaxis, our guidelines are limited to patients with concomitant anticoagulation syndromes or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy

### **Naratriptan (Amerge 1mg and 2.5mg tablets and generics)**

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

OR

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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

**Olanzapine (Zyprexa 2.5mg, 5mg, 7.5mg, 10mg, 15mg, and generics) to a MAXIMUM daily dose of 30mg** will be considered for coverage as follows:

Schizophrenia and other psychotic disorders:

For patients with the following diagnosis, **following failure or intolerance to an adequate trial\* of risperidone and quetiapine:**

- Schizophrenia
- Schizoaffective disorder
- Schizophreniform disorder
- Psychosis NOS

\*an adequate trial is defined as: risperidone: 1-6mg for a period of no less than 4 weeks at a maximally tolerated dose within this range quetiapine: 400-800mg for a period of no less than 4 weeks at a maximally tolerated dose within this range

Bipolar Disorder:

- For the treatment of an acute manic or mixed episode of bipolar 1 disorder following failure or intolerance to another atypical antipsychotic.
- For continuation therapy for the treatment of bipolar I disorder, maintenance therapy, in those patients who have previously been approved through the Department for bipolar I, acute, mania or mixed phase.

**Olanzapine Orally Disintegrating tablets (Zyprexa Zydis 5mg, 10mg, 15mg, 20mg tablets & generics) to a MAXIMUM daily dose of 30mg**

For patients who meet the above criteria for olanzapine tablets **AND** there are compliance issues or in patients who cannot swallow other listed benefit oral formulations of olanzapine.

**Olopatadine HCL (Patanol)**

For the treatment of allergies upon failure or intolerance to both sodium cromoglycate (Opticrom) and levocarbastine HCL (Livostin)

**Ondansetron (Zofran 4mg, 8mg tablet and generics, 4mg ODT, 8mg ODT, 4mg/ml oral solution and generics)**

For the treatment of emesis in patients who:

- are receiving a course of highly emetogenic chemotherapy (i.e. contains cisplatin) or moderately emetogenic chemotherapy (i.e. contains cyclophosphamide, doxorubicin, epirubicin, melphalan)

AND

- have experienced adverse effects to metoclopramide, prochlorperazine or dexamethasone or have a specific contraindication which does not allow use of these drugs as antiemetics

OR

- have had continued episodes of nausea and vomiting related to intravenous chemotherapy or radiation therapy which have not responded to therapeutic doses of other antiemetics including metoclopramide, dexamethasone and prochlorperazine.

**Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.**

The dose and duration of therapy approved will be:

- Zofran 8mg up to TID per day of IV chemo
- Kytril 1mg up to BID per day of IV chemo
- Anzemet 100mg OD per day of IV chemo

Duration of approval will be for the full course of the chemotherapy regimen

### **Oxcarbazepine (Trileptal 150mg, 300mg, 600mg tablets, liquid & generics)**

For use in patients who have a diagnosis of epilepsy AND have had an inadequate response or are intolerant to at least 3 other formulary agents (prior or current use) including carbamazepine.

### **Oxybutynin XL (Ditropan XL 5mg, 10mg, and Uromax CR 10mg, CR 15mg tablets)**

For the treatment of urinary frequency, urgency, or urge incontinence when a patient has had to discontinue oxybutynin immediate release due to intolerable side effects.

### **Oxycodone (Oxycontin 5mg, 10mg, 20mg, 40mg and 80mg tablets)**

For patients with persistent pain\* who have been stabilized on a titrated dose of an oral short-acting oxycodone product OR whose pain is not adequately controlled or who are intolerant to an oral sustained-release morphine product despite dose titration and adjuvant antiemetics and laxatives.

\* Please note: in order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- results of any xrays/CT scans/MRIs
- information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations)
- surgical history
- past analgesic use and response; current analgesic use, dosage, and assessment of current level of pain control
- use of antidepressants and/or anticonvulsants if pain is neuropathic
- any other information you feel is pertinent to the request

### **Pantoprazole (Pantoloc 40mg tablet & generics)**

See Proton Pump Inhibitor Guidelines

### **Peginterferon alfa-2b + Ribavirin (Pegatron and Pegatron Redipen)**

For the treatment of individuals with (Peginterferon/RBV –treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/hepatologist/other appropriate specialist)

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.

### **Peginterferon alfa -2a (Pegasys 180ug injection)**

#### *Hepatitis B:*

For the treatment of **HBeAg negative** Chronic Hepatitis B in patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic) with demonstrated **intolerance or failure to lamivudine** therapy

- written request of a hepatologist or other specialist in this area.
- Maximum duration of coverage **48 weeks**.

#### *Hepatitis C:*

For the treatment of individuals with (Peginterferon/RBV –treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/hepatologist/other appropriate specialist)

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.

### **Peginterferon alfa -2a + Ribavirin (Pegasys RBV)**

For the treatment of individuals with (Peginterferon/RBV –treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/hepatologist/other appropriate specialist)

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.

### **Pilocarpine (Salagen 5mg tablet)**

- For the treatment of the symptoms of xerostomia due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck, in addition to treatment with topical lubricants etc.
- For the treatment of Sjogren's syndrome where symptomatic treatment of topical lubricant etc fail to provide satisfactory control of symptoms

### **Pioglitazone HCL (Actos 15mg, 30mg, and 45mg tablets and generics)**

For the treatment of type II diabetes in patients who are inadequately controlled on a combination of a sulfonylurea and metformin, at maximum dosages, or in whom these agents are contraindicated or not tolerated.

### **Proton Pump Inhibitors (Lansoprazole, Lansoprazole FAS Tabs tabs<sup>†</sup>, Pantoprazole, Omeprazole and Rabeprazole)**

#### **Omeprazole and Rabeprazole doses > 20mg daily**

Requests for omeprazole and rabeprazole doses > 20mg daily will be considered for indications listed below when patients remain symptomatic despite an adequate trial of regular benefit PPI (i.e. omeprazole OR rabeprazole) at doses of 20mg daily for a minimum of 8 weeks.

**Lansoprazole (Prevacid 15mg & 30mg capsules) and Pantoprazole (Pantoloc 20mg & 40mg tablets and generics)**

Requests for lansoprazole and pantoprazole will be considered for patients in whom there has been a therapeutic failure with regular benefit PPIs (i.e. omeprazole 20mg AND rabeprazole 20mg daily for a minimum of 8 weeks).

Requests for lansoprazole, pantoprazole, and doses of omeprazole or rabeprazole greater than 20mg per day meeting criteria above will be considered for the following maximum approval periods:

Indication and Diagnostic Information	Maximum Approval Period
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain)	Considered for short-term (8 weeks) approval
Zollinger-Ellison Syndrome	Considered for long term approval
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks
H. pylori eradication	Omeprazole 20mg or rabeprazole 20mg BID will be reimbursed with special authorization as part of an approved H. pylori eradication regimen.  H. pylori regimens containing lansoprazole or pantoprazole will be reimbursed only under special authorization for 1 week duration.
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users)	Considered for one year with reassessment.

**Quinagolide (Norprolac 0.075mg, 0.150mg)**

For the treatment of hyperprolactinemic disorders in patients who have failed to respond or are intolerant to treatment with bromocriptine.

**Rabeprazole (Pariet 10mg, 20mg EC tablets)**

Rabeprazole doses ≤ 20mg daily (10mg and 20mg tablets) are listed as regular benefits.

Doses above 20mg daily require special authorization.

*see Proton Pump Inhibitor guidelines*

### **Raloxifene (Evista & generics)**

- For the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or contraindicated
- For the treatment of postmenopausal osteoporosis without documented fractures when patient at high 10-year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table) and bisphosphonates are not tolerated or contraindicated

### **Repaglinide (Gluconorm 0.5, 1, 2mg tablets)**

For patients who have failed to respond to or have experienced hypoglycemia from benefit sulfonylureas (glyburide and gliclazide)

### **Riluzole (Rilutek 50mg)**

Treatment with riluzole should be initiated by a neurologist with expertise in the management of ALS and when the patient has:

- probable or definite diagnosis of ALS as defined by the WFN criteria.
- ALS symptoms for less than five years
- FVC < 60% predicted
- no tracheostomy for invasive ventilation
- coverage will be reviewed every six months: coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or has a FVC < 60% predicted.

### **Risedronate (Actonel 30mg tablets & generics)**

For a 2 month approval period for the treatment of Paget's Disease

### **Risedronate (Actonel 5mg and 35mg tablets & generics)**

- For the treatment of osteoporosis associated with documented fracture
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table)
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months

### **Risperidone (Risperdal M-tab)**

For the treatment of schizophrenia or schizoaffective disorder in patients where there are compliance issues or in patients who cannot swallow other listed benefit oral formulations of risperidone.

### **Risperidone (Risperdal Consta 25/mg/vial, 37.5mg/vial and 50mg/vial)**

For the treatment of schizophrenia or schizoaffective disorder in patients:

- with documented compliance issues with an oral antipsychotic

OR

- who are currently receiving a conventional depot antipsychotic and are experiencing significant side effects (EPS or TD.) or lack of efficacy.

#### Dosing:

- For those patients who meet the above criteria, an initial dose of 25mg q 2 weeks will be approved for 4 weeks.
- A further dose increase to 37.5mg q 2 weeks may be considered no sooner than 4 weeks of therapy at 25mg.
- A final dose increase to 50mg q 2 weeks may be considered/approved following a minimum duration of 4 weeks of treatment at 37.5mg dosage.
- 50mg q 2 weeks will be the MAXIMUM dose approved under NLPDP.

#### Overlap with oral agents:

- Concurrent usage of an oral anti-psychotic agent and Risperdal Consta will be considered for a period to a maximum 8 week period following initiation of Risperdal Consta. This will allow adequate time for Risperdal Consta stabilization (dose titration) and subsequent tapering and discontinuation of the oral agent.
- After this initial period of overlap, coverage for concurrent use of an oral anti-psychotic and Risperdal Consta **will NOT** be approved for reasons other than short-term (defined as maximum of 4 weeks) treatment of an acute exacerbation of psychosis/relapse. Requests for such will be reviewed on a "case by case" basis.

#### **Rituximab (Rituxan 100mg and 500mg for intravenous 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.

- Rituximab not be used in combination with other anti-TNF agents.
- 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 prophylaxis of venous thromboembolism following total hip replacement (THR)
- for prophylaxis of venous thromboembolism following total knee replacement (TKR) surgery
- at a dose of 10mg daily for up to TWO weeks

#### **Rivastigmine (Exelon 1.5mg, 3mg, 4.5mg, 6mg and 2mg/ml oral solution & generics)**

See Cholinesterase Inhibitors (ChEI's)

To facilitate this process specific **Cholinesterase Inhibitor Special Authorization Forms** have been developed and can be found at:

[http://www.health.gov.ni.ca/health/nlpdp/Inhibitors/chei\\_continuation.pdf](http://www.health.gov.ni.ca/health/nlpdp/Inhibitors/chei_continuation.pdf)

[http://www.health.gov.ni.ca/health/nlpdp/Inhibitors/chei\\_initiation.pdf](http://www.health.gov.ni.ca/health/nlpdp/Inhibitors/chei_initiation.pdf)

#### **Rizatriptan benzoate (Maxalt 5 and 10mg tablets, 5 and 10mg wafers)**

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.

OR

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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

### **Rosiglitazone maleate (Avandia 2, 4, 8mg tablets)\***

For the treatment of type II diabetes in patients who are inadequately controlled on a combination of a sulfonylurea and metformin, in maximum dosages, or in whom these agents are contraindicated or not tolerated.

\*please note: due to manufacturer's pricing policies the cost of using 4mg BID is significantly higher than 8mg once daily dosing. The clinical literature supports the use of either dosage regimen. **As such, NLPDP will approve this product for ONCE daily dosing only unless substantive support is provided by the prescribing physician for BID dosing regimens.**

### **Salmeterol (Serevent Inhaler, Serevent Diskus)**

Reversible Obstructive Airway Disease:

For the treatment of reversible obstructive airway disease where optimal doses of inhaled steroids\* are being used and breakthrough symptoms require frequent use of inhaled short-acting bronchodilators.

\*Optimal defined as: >400mcg/day budesonide  
>250mcg/day HFA- beclomethasone  
>250mcg/day fluticasone

COPD:

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).
- Coverage can be approved without a trial of a short-acting agent if:
  - There is spirometric evidence of at least moderate to severe airflow obstruction, i.e.  $FEV_1 < 60\%$  AND  $FEV_1/FVC$  ratio  $< 0.7$ , and significant symptoms i.e. MRC score 3-5.\*

**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).

#### **\*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 walking 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.*

#### **Sevelamer HCL (Renagel 800mg capsule)**

For the management of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end stage renal disease (ESRD) who are on hemodialysis, are compliant with diet and drug therapy and also have persistent hypercalcemia (total serum calcium greater than 2.38mmol/L on at least two consecutive readings) upon request from a nephrologist or an internist within a dialysis unit.

- Initial approval is for 6 months then renewed at 1 year intervals when phosphate levels decrease more than 0.7 mmol/L and calcium levels remain over 2.38 mmol/L. Renewal requests require assessment from nephrologist of patient response and continued need for Renagel.
- Written request of a nephrologist.

To facilitate this process a specific **Sevelamer Special Authorization Form** has been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlmdp/Inhibitors/sevelamer\\_specauth\\_form.pdf](http://www.health.gov.nl.ca/health/nlmdp/Inhibitors/sevelamer_specauth_form.pdf)

#### **Sildenafil (Revatio 20mg)**

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

Written request of a PAH specialist only

Diagnosis of PAH should be confirmed by right heart catheterization

Dose of sildenafil will be limited to 20mg tid

#### **Solifenacin (Vesicare 5mg & 10mg tablets)**

For the treatment of overactive bladder in adults with symptoms of urge incontinence, urinary urgency and urinary frequency (not stress incontinence) who cannot tolerate or have insufficient response to an appropriate trial\* of immediate-release oxybutynin.

\*an appropriate trial is considered to be of 12 weeks duration.

### **Sorafenib (Nexavar 200mg tablets)**

#### *Hepatocellular carcinoma:*

For the treatment of advanced hepatocellular carcinoma is considered under the following criteria:

#### Initial approval criteria:

- For patients with Child-Pugh Class A advanced hepatocellular carcinoma; and
- Have ECOG status 0,1, or 2; and
- Patients who have either progressed on trans-arterial chemoembolization (TACE) or are not suitable for the TACE procedure.

Initial approval period: 3 months

#### Renewal criteria:

- Documentation of radiography and/or scan results indicating no progression.

Approval period for renewal: 3 months

- Not reimbursed if used with induction or adjuvant intent along with other curative-intent treatments.
- Not reimbursed if for maintenance therapy after trans-arterial chemoembolization.
- Not reimbursed if patients have Child-Pugh B or Child-Pugh C cirrhosis.

#### *Metastatic clear-cell renal carcinoma:*

For patients with histologically confirmed metastatic clear-cell renal-cell carcinoma AND

- the disease had progressed after prior cytokine therapy (ie interferon) within the previous 8 months locally advanced/metastatic renal cell (clear cell); and
- patient has a performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group criteria; and
- with favourable- to intermediate-risk disease according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score

Initial approval period: 1 year

Renewal criteria: Written confirmation from the clinical that the patient has benefited from therapy and is expected to continue to do so.

Renewal: 1 year

### **Sumatriptan (Imitrex 50mg, 100mg tablet, Imitrex DF 50mg, 100mg, and generics)**

For the treatment of migraine<sup>1</sup> headache when:

- Migraines are moderate<sup>2</sup> in severity and 2 or more therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective, or
- Migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

Coverage limited to 6 doses / 30 days<sup>3</sup>

- > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

### **Sumatriptan sc injection 6mg:**

For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when 2 or more 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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

### **Sumatriptan nasal spray (Imitrex 20mg nasal spray)**

For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when 2 or more 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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

## **Sunitinib (Sutent 12.5mg, 25mg and 50mg capsules)**

### *Unresectable or recurrent/metastatic GIST:*

For patients with histologically proven unresectable or recurrent/metastatic GIST who have failed or are unable to tolerate imatinib therapy.

- Response to sunitinib therapy should be reassessed every six months and therapy should be discontinued when there is objective evidence of disease progression.
- Sunitinab will not be funded concomitantly with imatinib.

### *Metastatic Renal Cell Carcinoma (MRCC):*

For the first-line treatment of metastatic renal cell carcinoma (MRCC) for patients with favourable- to intermediate-risk disease according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score.

- Initial approval period: 1 year
- Renewal criteria: Written confirmation from the clinical that the patient has benefited from therapy and is expected to continue to do so.
- Renewal: 1 year

## **Tacrolimus (Protopic) 0.03%, 0.1%**

### Protopic 0.03%:

For children greater than 2 years of age with refractory\* atopic dermatitis for a 12 month period.

\*failure to improve after adequate hydration of the skin and traditional topical corticosteroid therapy.

### Protopic 0.1%:

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 (high potency steroids) have been ineffective or are inappropriate
- For the treatment of acne when conventional therapies with benefit topical agents have failed

## **Temozolomide (Temodal 5, 20, 100, 140mg, 180mg, 250mg capsules)**

For the treatment of adult patients with glioblastoma multiforme or anaplastic astrocytoma and documented evidence of recurrence or progression after standard therapy (resection, radiotherapy, and chemotherapy)

## **Tenofovir (Viread 300mg tablets)**

### *HIV Infection:*

- For the treatment of adult patients with HIV infection who have experienced adverse events or virologic failure with nucleoside reverse transcriptase inhibitors.

*Chronic Hepatitis B:*

- For the treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds AND
- A HBV DNA concentration above 200IU/ml

**Testosterone topical (Androgel 2.5mg & 5mg sachets, Testim 1% gel, Androderm 25mg/24hr, 50mg/24hr patch)**

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

**Primary:** Cryptorchidism, Klinefelter's, orchiectomy, and other established causes.

**Secondary:** Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

**Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.**

Limited to 5 g/day gel or 5 mg patch

**Testosterone Undecanoate (Andriol 40mg capsule & generics)**

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

**Primary:** Cryptorchidism, Klinefelter's, orchiectomy, and other established causes.

**Secondary:** Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

**Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.**

**Thyrotropin alpha (Thyrogen 0.9mg/ml) DIN 02246016**

For preparation prior to radioiodine ablation in patients who have undergone thyroidectomy for papillary or follicular thyroid cancer.

**Tinzaparin sodium (Innohep)**

Coverage is limited for treatment of acute VTE for 7 to 10 days.

- Extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin.

- For prophylaxis, our guidelines are limited to patients with concomitant anticoagulation syndromes or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy

### **Tiotropium (Spiriva 18ug capsules)**

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persists after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at maximum dose of 8 puffs/day or ipatropium at maximum dose of 12 puffs/day).
- Coverage can be approved without a trial of a short-acting agent if:
  - There is spirometric evidence of at least moderate to severe airflow obstruction, i.e.  $FEV_1 < 60\%$  AND  $FEV_1/FVC$  ratio  $< 0.7$ , and significant symptoms i.e. MRC score 3-5.\*
- Combination therapy with tiotropium and a long-acting beta<sub>2</sub> agonist/corticosteroid (i.e. Spiriva plus Advair or Symbicort) will only be considered if:
  - There is spirometric evidence of a least moderate to severe airflow obstruction ( $FEV_1 < 60\%$  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 years (24 consecutive months) 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).

### **\*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 walking 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 HCL (Zanaflex 4mg tablet and generics)**

For treatment if spasticity caused by traumatic brain injury, multiple sclerosis (MS), spinal cord injury (SCI) or cerebral vascular accident (CVA) in patients whom baclofen is not indicated, ineffective or not tolerated.

### **Tolterodine (Detrol 1mg, 2mg, Detrol LA 2mg, 4mg tablets)**

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated and of appropriate length\* of oxybutynin IR is not tolerated.

\*an appropriate trial is considered to be of 12 weeks duration.

### **Topiramate (Topamax 25mg, 100mg, 200mg tablet and generics)**

For adjunctive management of epilepsy not satisfactorily controlled by conventional therapy

### **Torsemide (Demadex)**

For diuresis in patients where treatment with furosemide is deemed inappropriate or ineffective

### **Treprostinil (Remodulin 1mg/ml, 2.5mg/ml, 5mg/ml & 10mg/ml)**

For patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class III or IV disease who have:

1. failed to respond to non-prostanoid therapies, and:
2. who are not candidates for epoprostenol therapy because of:
  - a. prior recurrent complications with central line access (infec/thrombosis) **or**
  - b. inability to operate the complicated delivery system of epoprostenol, or
  - c. they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol therapy

### **Trospium chloride (Trosec 20mg)**

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated and of appropriate length of oxybutynin IR is not tolerated. An appropriate trial is considered to be of 12 weeks duration.

### **Ustekinumab (Stelara 45mg/0.5ml solution for subcutaneous injection)**

For adult patients with chronic severe, debilitating psoriasis who meet all of the of the following criteria:

1. Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
2. Failure to respond to, contraindications to, or intolerant to methotrexate and cyclosporine;
3. Failure to respond to, intolerant to, or unable to access phototherapy.

Stelara should initially be given at 0, 4 and 16 weeks. Response must be assessed prior to the fourth dose and further doses provided only for responders.

Criteria for defining response:

- achievement of a  $\geq 75\%$  reduction in Psoriasis Area Severity Index (PASI) score, OR
- a  $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in the Dermatology Life Quality Index (DLQI) OR
- a significant reduction in BSA involved, with consideration of important regions such as the face, hands, or genital region.

Ongoing coverage for ustekinumab maintenance therapy will only be provided for responders, as noted above.

To facilitate this process a specific **Chronic Plaque Psoriasis Special Authorization Form** has been developed and can be found at:

[http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic\\_Plaque\\_Psoriasis\\_Meds\\_Coverage\\_Request.pdf](http://www.health.gov.nl.ca/health/nlpdp/Inhibitors/Chronic_Plaque_Psoriasis_Meds_Coverage_Request.pdf)

### **Ursodiol (Ursofalk 250mg capsule & generics)**

- For dissolution of gallstones in patients who cannot undergo a cholecystectomy
- For management of cholestatic liver disease such as primary biliary cirrhosis

### **Valganciclovir (Valcyte 450mg)**

- For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist only.
- For the prevention of cytomegalovirus (CMV) disease post kidney, heart, liver or kidney-pancreas transplantation in patients as high-risk (Donor positive/Receptor negative).

Coverage will be for a maximum of 90 days.

### **Voriconazole (Vfend 50mg, 200mg tablets)**

For culture proven invasive candidiasis with documented resistance to fluconazole.

- Upon the request of an infectious diseases physician, respiratory medicine physician or other physician with specific expertise in invasive aspergillosis for the treatment of invasive aspergillosis.

### **Wet Nebulization Coverage Criteria (Ipratropium, salbutamol, ipratropium/salbutamol, sodium cromoglycate, budesonide nebulers and generics)**

Wet nebulization solutions will be approved upon the written request of a physician for those patients who meet the following criteria:

- Adult patients with a vital capacity of 900 ml or less
- Patients with a respiratory rate greater than 25 breaths per minute
- Patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it, **OR**
- Other situations as deemed appropriate, on a case by case basis

Please note coverage will not be provided for the concurrent use of nebulers and inhalers, with the exception of salbutamol inhaler for rescue therapy. Concurrent use will result in discontinuation of nebulized solution coverage.

### **Zafirlukast (Accolate 20mg tablet)**

For the treatment of asthma in patients uncontrolled on optimal doses of inhaled corticosteroids\* necessitating the frequent use of beta-agonists for symptom control.

\*Optimal defined as: >400mcg/day budesonide  
>250mcg/day HFA- beclomethasone

>250mcg/day fluticasone

### Ziprasidone (Zeldox 20mg, 40mg, 60mg & 80mg)

For the treatment of schizophrenia and schizoaffective disorders:

- in patients who have not achieved a satisfactory response from an adequate trial (\*an adequate trial is defined as a trial of the selected medication for a period of no less than 4 weeks at a maximally tolerated dose) of at least one other antipsychotic agent , **OR**
- in situations for which the clinician has not been able to implement an adequate trial of another antipsychotic medication due to the development of intolerable adverse effects

### Zolmitriptan (Zomig 2.5mg tablet, Rapiment tablets, nasal 2.5 & 5mg)

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

OR

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.

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - > 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days)

<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> Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

## Appendix 1

10 Year Absolute Fracture Risk based on BMD

Age (years)	WOMEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	< - 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to - 2.6	< - 2.6
70	> - 0.8	- 0.8 to - 2.2	< - 2.2
75	> - 0.7	- 0.7 to - 2.1	< - 2.1
80	> - 0.6	- 0.6 to - 2.0	< - 2.0
85	> - 0.7	- 0.7 to - 2.2	< - 2.2

Age (years)	MEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3