Bulletin #878 December 19, 2013

NBPDP Formulary Update

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective December 19, 2013.

Included in this bulletin:

- **Regular Benefit Additions**
- **Special Authorization Benefit Additions**
- **Changes to Existing Special Authorization Benefits**
- **Drugs Reviewed and Not Listed**

If you have any questions, please contact our office at 1-800-332-3691.

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Regular Benefit Additions

Drug/Form/Route/Strength			Brand Name	DIN	Manufacturer	Plans
Somatropin Liq	SC	5mg/mL	Nutropin AQ® NuSpin	02376393	HLR	T

Special Authorization Benefit Additions

Enzalutamide *(Xtandi®)* 40mg tablet	For treatment of patients with metastatic castration resistant prostate cancer, who have progressed on docetaxel-based chemotherapy with an ECOG performance status ≤2 and no risk factors for seizures and would be an alternative to abiraterone for patients in the post-docetaxel setting but would not be an add-on therapy to abiraterone treatment.
Epoprostenol Sodium (Caripul®) 0.5mg, 1.5mg /vial	1. For the treatment of World Health Organization (WHO) class III or IV idiopathic pulmonary arterial hypertension in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers. 2. For the treatment of WHO class III or IV pulmonary arterial hypertension associated with scleroderma in patients who do not respond adequately to conventional therapy.
Glycopyrronium bromide *(Seebri® Breezhaler)* 50mcg capsule	• For the treatment of chronic obstructive pulmonary disease (COPD) with EITHER glycopyrronium bromide OR a long-acting beta2-adrenergic agonist (LABA) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day). • Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV_1 < 60% and FEV_1 /FVC ratio < 0.7) and significant symptoms (i.e. MRC score of 3-5**). • Combination therapy with glycopyrronium bromide AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if: - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e. MRC score of 3-5**) AND - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids. Note: If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Glycopyrronium bromide *(Seebri® Breezhaler)* 50mcg capsule (continued)

**Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

Methadone HCl (Methadose™) 10mg/mL dye-free, sugar-free, unflavored oral concentrate

Requests from New Brunswick physicians authorized to prescribe methadone will be considered:

1. For the treatment of opioid dependence.

All requests must meet requirements set out in the NBPDP methadone reimbursement policies.

Pharmacy Claims:
Claims submitted by pharmacies must be billed using DIN 02394618 and is subject to a maximum allowable price (MAP).

Prasugrel hydrochloride *(Effient®)* 10mg tablet

In combination with ASA for patients with:

- ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab. Treatment must be initiated in hospital.

  OR

- Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis1, or recurrent STEMI, or NSTEMI or UA after prior revascularization via PCI.

Notes:

1. Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. Definite stent thrombosis must be confirmed by angiography or by pathologic evidence of acute thrombosis.

2. As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as gastrointestinal bleeding or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).

Prasugrel hydrochloride *(Effient®)* 10mg tablet (continued)	3. As per the product monograph, prasugrel is not recommended in patients ≥ 75 years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight < 60 kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel. Approval will be for a maximum of 12 months. Prescriptions written by invasive (interventional) cardiologists do not require special authorization.
Ruxolitinib *(Jakavi®)* 5mg, 15mg, 20mg tablets	For patients with intermediate to high risk symptomatic Myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status ≤3 and be either previously untreated or refractory to other treatment.
Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir disoproxil fumarate *(Stribild™)* 150mg/150mg/200mg/300mg tablet	As a complete regimen for antiretroviral treatment naïve HIV-1 infected patients in whom efavirenz is not indicated.

Changes to Existing Special Authorization Benefits

New Strength

Darunavir *(Prezista®)* 800mg tablet	• As part of a HIV treatment regimen for treatment-experienced adult patients (Plan U beneficiaries) who have demonstrated failure to multiple protease inhibitors (PIs), and in whom less expensive PIs are not a treatment option. • As part of a HIV treatment regimen for treatment-naïve patients (Plan U beneficiaries) for whom protease inhibitor therapy is indicated. • As part of a HIV treatment regimen for treatment-experienced HIV-1 pediatric patients (Plan U beneficiaries).
IncobotulinumtoxinA *(Xeomin®)* 50 LD_{50} units/ vial	• For the treatment of blepharospasm in patients 18 years of age and older. • For the treatment of cervical dystonia (spasmodic torticollis) in patients 18 years of age or older.

Revised Criteria

Everolimus *(Afinitor®)* 2.5mg, 5mg, 10mg tablets	For the treatment of metastatic renal cell carcinoma (mRCC) with clear cell morphology, in patients previously treated with a tyrosine kinase inhibitor. Dosing: 10mg daily

New Indication

Everolimus *(Afinitor®)* 2.5mg, 5mg, 10mg tablets	1. In combination with exemestane, for the treatment of hormone-receptor positive, HER2 negative advanced breast cancer, in postmenopausal women with ECOG performance status ≤ 2 after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI), if the treating oncologist would consider using exemestane. Dosing: 10 mg daily 2. For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumours (pNET) with good performance status (ECOG 0-2), until disease progression. Dosing: 10mg daily

Drugs Reviewed and Not Listed

The review of the following products found that they did not offer a significant therapeutic and/or cost advantage over existing therapies. Requests for special authorization will not be considered.

Eculizumab - for the treatment of atypical hemolytic uremic syndrome (aHUS)	*Soliris®*	10mg/mL vial
Levofloxacin	*Levaquin®*	750mg tablet
Methadone HCl	*Methadose™*	10mg/mL cherry flavored oral concentrate