Bulletin # 939

November 30, 2016

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective November 30, 2016.

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.

To unsubscribe from the NB Drug Plans Formulary emailed announcements, please send a message to info@nbdrugs-medicamentsnb.ca. The Updates are available on the NBPDP webpage: http://www.gnb.ca/0212/BenefitUpdates-e.asp.

Regular Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Insulin Aspart (NovoRapid® FlexTouch®)	100U/mL pre-filled pen	02377209	NNO	ADEFGV	MLP
Special authorization no longer required					
Etidronic Acid	200mg tablet	See NB Drug Plans Formulary or MAP List for products		ADEFGV	MAP
Etidronic Acid / Calcium	400mg/500mg tablet	See NB Drug Plans Formulary or MAP List for products		ADEFGV	MAP
Insulin Aspart (NovoRapid®, NovoRapid® Penfill®)	100U/mL vial 100U/mL penfill cartridge	02245397 02244353	NNO	ADEFGV	MLP
Levetiracetam (Keppra® and generic brands)	250mg tablet 500mg tablet 750mg tablet	See NB Drug Plans Formulary or MAP List for products		ADEFGV	MAP

Special Authorization Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Dapagliflozin (Forxiga®)	5mg tablet 10mg tablet	02435462 02435470	AZE	(SA)	MLP
	For the treatment of type 2 diabetes mellitus, in addition to metformin or a sulfonylurea, in patients who have inadequate glycemic control on, or intolerance to, metformin or a sulfonylurea and for whom insulin is not an option.				
Nintedanib (Ofev™)	100mg capsule 150mg capsule	02443066 02443074	BOE	(SA)	MLP
	For the treatment of adult patients with mild to moderate idiopathic pulmonary fibrosis (IPF) confirmed by a respirologist and a high-resolution CT scan within the previous 24 months. <u>Initial renewal criteria:</u> Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted forced vital capacity (FVC) of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.				

Subsequent renewal criteria:
Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Clinical notes:

- Mild to moderate IPF is defined as a FVC ≥ 50% predicted.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded before initiating treatment.

Claim notes:

- Must be prescribed by, or in consultation with, physicians experienced in the treatment of IPF.
- Combination therapy of pirfenidone with nintedanib will not be reimbursed.
- Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)
- Initial renewal approval period: 6 months
- Subsequent renewal approval period: 12 months

Changes to Existing Special Authorization Benefits

Special Authorization Coverage of Infliximab (Inflectra®)

Inflectra® (infliximab) is a "biosimilar" version of Remicade® (infliximab). Inflectra® was approved by Health Canada and supported by the national Common Drug Review for the treatment of Crohn's disease and ulcerative colitis based on data demonstrating similarity and no meaningful differences compared to Remicade®.

In 2015-16, total expenditures for Remicade® for all indications covered by the NB Drug Plans were approximately $8 million. Through the pan-Canadian Pharmaceutical Alliance (pCPA), federal, provincial and territorial public drug plans negotiated a significantly lower list price for Inflectra®, enabling savings that can be reinvested into other priorities.

Effective November 30, 2016, Inflectra® will be added to the Formulary for the treatment of Crohn's disease and ulcerative colitis according to the Special Authorization (SA) criteria which are listed below.

Requests for coverage of infliximab for infliximab-naïve patients for Crohn's disease will be approved for Inflectra® only. Patients who received SA approval for Remicade® for the treatment of Crohn's disease before November 30, 2016 will continue to have Remicade® covered; they will also be eligible for coverage of Inflectra®. Requests for coverage of infliximab for the treatment of ulcerative colitis will be approved for Inflectra® only since Remicade® is not listed for this indication.

An Inflectra® Patient Assistance Program (IPAP) is available through the manufacturer. The Inflectra® Navigator for the program can assist with enrollment into the program and ensure treatment is initiated in a timely fashion. The Inflectra® Navigator for NB can be contacted through the IPAP Call Center at 1-844-466-6627.

For information on Health Canada's decision, please see the Summary Basis of Decision available at:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/rds-sdr/drug-med/rds-sdr-infectra-184564-eng.php

For the Common Drug Review's review and recommendation, please see: https://www.cadth.ca/infliximab-19

Product	Strength	DIN	MFR	Plans	Cost Base
New Indication					
Infliximab (Inflectra®)	100mg vial	02419475	HOS	(SA)	MLP

Crohn's Disease

- For the treatment of moderately to severely active Crohn's disease in patients who are refractory, or have contraindications, to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All requests for coverage for infliximab-naïve patients (including those on induction therapy) will be approved for Inflectra only.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Ulcerative Colitis

- For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score ≥ 2 from baseline, and
  - a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

1. Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of the intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All requests will be approved for Inflectra only; requests for coverage of Remicade will not be considered.
- Initial Approval: 12 weeks.

- Renewal Approval: 1 year.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

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.

Product	Strength	Indication	DIN	MFG
Dapagliflozin (Forxiga®)	5mg tablet 10mg tablet	For the treatment of type 2 diabetes mellitus to improve glycemic control in combination with metformin and a sulfonylurea	02435462 02435470	AZE
Ivermectin (Rosiver™)	1% cream	Rosacea	02440342	GAC
Macitentan (Opsumit®)	10mg film-coated tablet	Pulmonary arterial hypertension	02415690	ACT