Bulletin #1063

October 14, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective October 14, 2021.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Biosimilars Initiative Reminder

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

Regular Benefit Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Potassium citrate (K-Lyte, Jamp-K effervescent)	25 mEq effervescent tablet	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP

Special Authorization Benefits Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Elexacaftor / Tezacaftor / Ivacaftor and Ivacaftor (Trikafta)	100 mg / 50 mg / 75 mg tablet and 150 mg tablet	02517140	VER	(SA)	MLP

For the treatment of patients 12 years of age and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and a percent predicted forced expiratory volume in 1 second (ppFEV1) of less than or equal to 90%.

Initial Renewal Criteria:
The patient must meet one of the following criteria:

- Increase in ppFEV1 by at least 5% compared with baseline.
- Decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six month period prior to initiating treatment.
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six month period prior to initiating treatment.
- Decrease in the number of CF-related hospitalizations compared with the six month period prior to initiating treatment.
- No decrease in Body Mass Index (BMI) at six months compared with baseline.
- Increase of 4 points or more on the CF Questionnaire-Revised (CFQ-R) Respiratory Domain Scale compared with baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit must be provided (e.g., ppFEV1, CFQ-R, pulmonary exacerbations).

<u>Clinical Notes:</u>

1. The following baseline measurements must be provided prior to initiation of treatment:
    - Spirometry of FEV1 and ppFEV1 measured within the 3 month period prior to initiation of treatment
    - Total number of days treated with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations in the 6 months prior to initiation of treatment
    - Total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the 6 months prior to initiation of treatment

- Number of CF-related hospitalizations in the 6 months prior to initiation of treatment
- BMI
- CFQ-R Respiratory Domain score

2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ADEFGV.
- The patient must be under the care of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Initial approval period: 7 months.
- Renewal approval period: 1 year.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Entrectinib (Rozlytrek)

100 mg capsule 200 mg capsule	02495007 02495015	HLR	(SA)	MLP

As monotherapy for the first-line treatment of patients with ROS1-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

Renewal Criteria:

- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Treatment should be discontinued upon disease progression or unacceptable toxicity.
2. Patients must have a good performance status.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Prasugrel (Jamp Prasugrel)

10 mg tablet	02502429	JPC	(SA)	MAP

In combination with ASA for patients with:

- unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) managed with percutaneous coronary intervention (PCI); or
- ST-segment elevation myocardial infarction (STEMI) managed with primary or delayed PCI; or
- failure on clopidogrel and ASA therapy as defined by definite stent thrombosis, or recurrent STEMI, NSTEMI or UA after revascularization with PCI.

Clinical Note:

- 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.

Claim Notes:

- Prescriptions written by New Brunswick cardiologists do not require special authorization.
- Approval period: 1 year.

Changes to Existing Special Authorization Benefits

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Dosage Form					
Vedolizumab (Entyvio)	108 mg/0.68 mL prefilled syringe 108 mg/0.68 mL prefilled pen	02497875 02497867	TAK	(SA)	MLP

Crohn's Disease

For the treatment of adult patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic drug will not be reimbursed.
- Intravenous infusion: Approvals will be for maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks.
- Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab.
- Initial approval period: 14 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

Ulcerative Colitis

- For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score greater than 4, and a rectal bleeding subscore greater than or equal to 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone greater than or equal to 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 greater than or equal to 2 from baseline, and
  - a decrease in the rectal bleeding subscore greater than or equal to 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 greater than 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 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 drug will not be reimbursed.
- Intravenous infusion: Approvals will be for a maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks.
- Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab.
- Initial approval period: 14 weeks.
- Renewal approval period: 1 year.

Revised Criteria

Ticagrelor (Brilinta)	90 mg tablet	02368544	AZE	(SA)	MLP

In combination with ASA for patients with acute coronary syndrome (i.e. ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA), who meet one of the following criteria:

- STEMI, NSTEMI or UA patients undergoing primary percutaneous coronary intervention (PCI)
- NSTEMI or UA patients, irrespective of intent to perform revascularization, with the presence of one of the following high-risk features:
  - High GRACE risk score (>140)
  - High TIMI risk score (5-7)
  - Second ACS within 12 months
  - Complex or extensive coronary artery disease e.g. diffuse three vessel disease
  - Definite documented cerebrovascular or peripheral vascular disease
  - Previous CABG
- Failure on clopidogrel and ASA therapy as defined by definite stent thrombosis or recurrent STEMI, NSTEMI or UA after revascularization with PCI

Clinical Note:

- 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.

Claim Note

- Prescriptions written by New Brunswick cardiologists do not require special authorization.
- Approval period: 1 year.

Biosimilars Initiative Reminder

The Biosimilars Initiative, announced in the NB Drug Plans Formulary Update - Bulletin #1050, involves switching patients who use certain originator biologics to a biosimilar brand to maintain their coverage under the New Brunswick Drug Plans.

As a reminder, **coverage of the originator biologics listed in the table below will end on November 30, 2021** or on the last day of the current special authorization approval, whichever is sooner.

Drug	Originator (Switch from)	Biosimilar (Switch to)
Adalimumab	Humira	Idacio Amgevita Hadlima Hyrimoz Hulio
Etanercept	Enbrel	Brenzys Erelzi
Infliximab	Remicade	Inflectra Renflexis Avsola
Insulin glargine	Lantus	Basaglar
Insulin lispro	Humalog	Admelog
Rituximab	Rituxan	Ruxience Truxima Riximyo
Glatiramer	Copaxone	Glatect

More information and resources, including the Biosimilars Initiative Guide for Prescribers and Health Professionals and Guide for Patients, are available online at www.gnb.ca/biosimilars.