Bulletin #1099

February 27, 2023

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective February 27, 2023.

Included in this bulletin:

- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Drugs Reviewed and Not listed
- Change to Claim Submission Response Message

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

Special Authorization Benefit Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Ticagrelor (generic brands)	60 mg tablet	See NB Drug Plans Formulary or MAP List for Products		(SA)	MAP

In combination with ASA for patients with a history of ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEACS) in the previous 3 years who are at high risk for subsequent cardiovascular events.

Clinical Note:

- High risk for subsequent cardiovascular events is defined as age 65 years or older, diabetes, second prior spontaneous myocardial infarction, multivessel coronary artery disease, or chronic renal dysfunction (creatinine clearance < 60mL/min).

Claim Notes:

- Prescriptions written by cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Approval period: 3 years.

Changes to Existing Special Authorization Benefits

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Dosage Form					
Sevelamer carbonate (Renvela)	0.8 g sachet 2.4 g sachet	02485559 02485567	SAV	(SA)	MLP

For use in patients who have difficulty swallowing tablets.

Claim Note:

- Approval Period: 1 year

New Indication and Revised Criteria					
Osimertinib (Tagrisso)	40 mg tablet 80 mg tablet	02456214 02456222	AZE	(SA)	MLP

Adjuvant Non-Small Cell Lung Cancer

For the adjuvant treatment of patients with completely resected stage IB to IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

Renewal Criteria:

- Written confirmation that the patient has not experienced disease recurrence.

Clinical Notes:
1. Patients must have a good performance status.
2. Patients should initiate treatment within 26 weeks of complete surgical resection if treated with adjuvant chemotherapy, or within 10 weeks if chemotherapy was not given.
3. Treatment should continue until disease recurrence, unacceptable toxicity, or until a maximum treatment duration of 3 years, regardless of dose reduction and dose interruption.

Claim Notes:
- Requests for treatment beyond 3 years will not be considered.
- Approval period: 1 year.

Advanced Non-Small Cell Lung Cancer
1. For the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
2. For the treatment of patients with locally advanced (not amenable to curative therapy) or metastatic EGFR T790M mutation-positive NSCLC who have progressed on EGFR tyrosine kinase inhibitor therapy.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment.

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

Claim Notes:
- Requests for first line therapy will be considered for patients with de novo EGFR T790M mutation-positive NSCLC.
- Requests will not be considered for patients who progress on, or within 6 months of, treatment with adjuvant EGFR targeted therapy.
- Approval period: 1 year.

New Strength
Levofloxacin
(generic brand)

750 mg tablet	02325942	APX	BVW (SA)	MAP

1. For completion of treatment initiated in the hospital setting for patients with nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic obstructive pulmonary disease (AECOPD).
2. For the treatment of complicated AECOPD in patients who:
   - have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, trimethoprim-sulfamethoxazole, or macrolide), or
   - are intolerant or have contraindication(s) to at least two first-line therapies.
3. For the treatment of CAP in patients with radiographic confirmation of pneumonia who:
   - have failed treatment with at least one first-line therapy (macrolide, doxycycline, beta-lactams), or
   - are intolerant or have contraindication(s) to at least two first-line therapies.
4. For the treatment of pulmonary infections in patients with cystic fibrosis.

5. For the treatment of severe pneumonia in nursing home patients.
6. For the treatment of patients with complicated osteomyelitis or joint infections.
7. For the treatment of patients with pyelonephritis.

Clinical Notes:
1. If the patient has been treated with an antibiotic within the past 3 months consider an antibiotic from a different class.
2. Complicated AECOPD is defined as patients with COPD (FEV_1/FVC greater than 0.7) experiencing increased sputum purulence, and with increased dyspnea or sputum volume, and one of the following:
   - FEV_1 less than 50% predicted
   - At least 4 exacerbations per year
   - Ischemic heart disease
   - Home oxygen use
   - Chronic oral steroid use

Claim Notes:
- Prescriptions written by infectious disease specialists, internal medicine specialists, hematologists, medical microbiologists, oncologists, oncology clinical associates, general practitioners in oncology, respirologists or urologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Levofloxacin is a regular benefit for Plans BV.

Tuberculosis
For the treatment of tuberculosis in patients who have lab-verified drug resistance or a contraindication or intolerance to first-line drugs.

Claim Notes:
- Must be prescribed by, or in consultation with, an infectious disease specialist.
- Request will only be considered under Plans CP.

Revised Criteria

Afatinib (Giotrif)	20 mg tablet	02415666	BOE	(SA)	MLP
	30 mg tablet	02415674			
	40 mg tablet	02415682			

For the first-line treatment of patients with EGFR mutation-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment.

Clinical Note:
- Patients must have a good performance status.

Claim Notes:
- Approvals will be for a maximum of 40 mg daily.
- Approval period: 1 year.

Revised Criteria

Insulin detemir (Levemir)	100 U/mL penfill cartridge 100 U/mL FlexTouch prefilled pen	02412829 02271842	NNO	(SA)	MLP

1. For the treatment of patients with type 1 or type 2 diabetes who have taken other long acting insulin analogues (insulin glargine and insulin degludec), and have:
   - experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management; or
   - documented severe or continuing systemic or local allergic reaction.
2. For the treatment of pediatric and adolescent patients with type 1 diabetes.
3. For the treatment of pregnant individuals with type 1 or type 2 diabetes requiring insulin.

Revised Criteria

Ticagrelor (Brilinta and generic brands)	90 mg tablet	See NB Drug Plans Formulary or MAP List for Products	(SA)	MAP

1. In combination with ASA for patients with ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEACS) who receive percutaneous coronary intervention (PCI).

   Claim Notes:
   - Prescriptions written by cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
   - Approval period: 1 year.

2. For the treatment of patients who have recurrent cardiovascular events (STEMI or NSTEACS), or definite stent thrombosis, while on clopidogrel and ASA therapy.

   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 cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
   - Approval period: Long term.

Drugs Reviewed and Not Listed

Requests for special authorization of the following products will not be considered.

Generic name (Brand name)	Strength	DIN	MFR	Indication
Chlormethine (Ledaga)	160 mcg/g topical gel	02516764	RRD	For the topical treatment of stage IA and IB mycosis fungoides-type cutaneous T-cell Lymphoma in adult patients who have received prior skin-directed therapy.
IncobotulinumtoxinA (Xeomin)	50 unit / vial 100 unit / vial 100 unit / vial	02371081 02324032 02383489	MRZ	For the treatment of chronic sialorrhea associated with neurological disorders.

Change to Claim Submission Response Message

Effective February 28, 2023, pharmacies will receive the message "Special Authorization is Required" instead of "Drug is not a benefit" when submitting an electronic claim for a drug that requires special authorization approval for reimbursement.

This system change will inform pharmacies of a drug's benefit status on the NB Drug Plans Formulary.

More information on eligible benefits and special authorization criteria is available online.