Bulletin # 1024

April 23, 2020

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective April 23, 2020.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Update on Cholinesterase Inhibitors Special Authorization Request Forms

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

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

Regular Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Baclofen (Lioresal® Intrathecal and generic brand)	0.05 mg/mL injection 0.5 mg/mL injection 2 mg/mL injection	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP
Latanoprostene bunod (Vyzulta™)	0.024% ophthalmic solution	02484218	BSH	ADEFGV	MLP

Special Authorization Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Cladribine (Mavenclad™)	10 mg tablet	02470179	EMD	(SA)	MLP

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past year
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
- Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab)

Clinical Notes:

1. Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
2. A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Requests will be considered for individuals enrolled in Plans ADEFGV.
- Approvals will be for 1.75 mg/kg to a maximum of 200 mg per treatment year.
- Approval period: 2 years.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
Revised Criteria - Cholinesterase Inhibitors					
Donepezil (Aricept® and generic brands)	5 mg tablet 10 mg tablet	See NB Drug Plans Formulary or MAP List for Products		(SA)	MAP
	For the treatment of patients with mild to moderate dementia who meet the following criteria: • Mini-Mental State Exam (MMSE) score of 10 to 30 • Functional Assessment Staging Test (FAST) score of 4 to 5 <u>Clinical Note:</u> • A recent MMSE and FAST score must be provided. <u>Claim Note:</u> • Approval period: 1 year.				
Galantamine (generic brands)	8 mg extended-release capsule 16 mg extended-release capsule 24 mg extended-release capsule	See NB Drug Plans Formulary or MAP List for Products		(SA)	MAP
Rivastigmine (Exelon® and generic brands)	1.5 mg capsule 3 mg capsule 4.5 mg capsule 6 mg capsule	See NB Drug Plans Formulary or MAP List for Products		(SA)	MAP
	For the treatment of patients with mild to moderate dementia who have had an intolerance to donepezil and who meet the following criteria: • Mini-Mental State Exam (MMSE) score of 10 to 30 • Functional Assessment Staging Test (FAST) score of 4 to 5 <u>Clinical Notes:</u> 1. A recent MMSE and FAST score must be provided. 2. The nature of the intolerance must be described. <u>Claim Note:</u> • Approval period: 1 year.				
Rivastigmine (Exelon®)	2 mg/mL oral solution	02245240	NVR	(SA)	MLP
	For the treatment of patients with mild to moderate dementia for whom oral tablets or capsules are not an option and who meet the following criteria: • Mini-Mental State Exam (MMSE) score of 10 to 30 • Functional Assessment Staging Test (FAST) score of 4 to 5 <u>Clinical Note:</u> • A recent MMSE and FAST score must be provided.				

Claim Note:

- Approval period: 1 year.

New Indication and Revised Criteria

Dabrafenib (Tafinlar®)

50 mg capsule 75 mg capsule	02409607 02409615	NVR	(SA)	MLP

Adjuvant Melanoma

In combination with trametinib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8th edition)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

Claim Notes:

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Approval period: Up to 12 months.

Metastatic Melanoma

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with trametinib.

Renewal criteria:

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

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Dabrafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.

- Initial approval period: 6 months.
- Renewal approval period: 6 months.

New Indication and Revised Criteria

Trametinib (Mekinist®)

0.5 mg tablet 2 mg tablet	02409623 02409658	NVR	(SA)	MLP

Adjuvant Melanoma

In combination with dabrafenib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease
- (AJCC 8th edition)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

Claim Notes:

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Approval period: Up to 12 months.

Metastatic Melanoma

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with dabrafenib.

Renewal criteria:

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

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Trametinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.

- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Revised Criteria

Lansoprazole (Prevacid® and generic brands)	15 mg delayed-release capsule 30 mg delayed-release capsule	See NB Drug Plans Formulary or MAP List for Products	(SA)	MLP

- For patients who have had a therapeutic failure with all proton pump inhibitors listed as regular benefits (e.g. omeprazole, pantoprazole, rabeprazole).
- When compounded as an oral suspension for patients 18 years and younger, who require the use of a proton pump inhibitor and cannot use a tablet or capsule.

Clinical Note:

- Patients who have failed a minimum eight week trial of standard dose therapy may be considered for an eight week trial of double dose therapy. Coverage beyond eight weeks will be considered if step down to standard dose therapy is not successful.

Update on Cholinesterase Inhibitor Special Authorization Request Forms

The cholinesterase inhibitor special authorization forms to request coverage of donepezil, rivastigmine or galantamine should no longer be used. Requests for donepezil, rivastigmine or galantamine must now be submitted on the standard Special Authorization Request Form which can be found at: https://www.gnb.ca/SAonlineform.pdf