Bulletin #893 October 3, 2014

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective October 3, 2014.

Included in this bulletin:

- Special Authorization Benefit Additions

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.

Special Authorization Benefit Additions

Product	Strength	DIN	MFG	Plans	Cost Base
Dabrafenib (Tafinlar™)	50mg capsule 75mg capsule	02409607 02409615	GSK	(SA)	MLP

- As monotherapy for the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable.
- As monotherapy for the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable.

Clinical Notes:
- Recommended Dose: 150 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of dabrafenib.
- Dabrafenib will not be reimbursed in patients who have progressed on a prior BRAF therapy.

Claim Notes:
- Initial approval duration: 6 months
- Renewal approval duration: 6 months

Dimethyl fumarate (Tecfidera™)	120mg DR capsule 240mg DR capsule	02404508 02420201	BIG	(SA)	MLP

For the treatment of relapsing-remitting multiple sclerosis (RRMS) in patients who meet the following criteria:
- Two disabling attacks of MS in the previous two years, and
- Ambulatory with or without aid (EDSS of less than or equal to 6.5)

Clinical Notes:
- An attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, and preceded by stability for at least one month.

Claim Notes:
- Prescriptions written by New Brunswick neurologists do not require special authorization.

Product	Strength	DIN	MFG	Plans	Cost Base
Pirfenidone (Esbriet®)	267mg capsule	02393751	ITM	(SA)	MLP

Initial approval criteria:
Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

*Mild-moderate IPF is defined as: a FVC between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted.

Initial renewal criteria:
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted 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.

Second renewal (12 months after initiation of therapy):
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% since initiation of therapy (baseline). 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.

Claim Notes:
- Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)
- Renewal Approval period: 6 months
- Second renewal approval period: 12 months

Trametinib (Mekinist®)	0.5mg tablet 2mg tablet	02409623 02409658	GSK	(SA)	MLP

- As monotherapy for the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma with ECOG performance status of 0 or 1. If brain metastases are present, patients should be stable.
- As monotherapy for the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting with ECOG performance status of 0 or 1. If brain metastases are present, patients should be stable.

Clinical Notes:
- Recommended Dose: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib.
- Trametinib will not be reimbursed in patients who have progressed on a prior BRAF therapy.

Claim Notes:
- Initial approval duration: 6 months
- Renewal approval duration: 6 months