Bulletin # 1044

January 27, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective January 27, 2021.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Drugs Reviewed and Not Listed

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
Colistimethate sodium (Coly-Mycin® M Parenteral)	150 mg vial	00476420	ERF	ADEFGV	MLP

Special Authorization Benefits Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Lanadelumab (Takhzyro®)	300 mg / 2 mL vial	02480948	SHI	(SA)	MLP

For the prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment.

Discontinuation Criteria:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to the number of attacks observed before initiating treatment with lanadelumab; or
- Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with lanadelumab.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to lanadelumab.

Claim Notes:

- The patient must be under the care of a physician experienced in the diagnosis and treatment of HAE.
- Not to be used in combination with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor).
- Approvals will be for a maximum of 300 mg every two weeks.
- Initial approval period: 3 months.
- Renewal approval period: 6 months.

Progesterone (Prometrium® and generic brand)	100 mg capsule	See NB Drug Plans Formulary or MAP List for Products	(SA)		MAP

For persons with a singleton gestation who are:

- greater than 20 weeks gestation, and
- high-risk for pre-term birth (cervix less than 25 mm or past history of pre-term birth).

Ribavirin (Ibavyr™)	200 mg tablet 400 mg tablet	02439212 02425890	PDP	(SA)	MLP

For use in combination with other drugs for the treatment of chronic hepatitis C. The applicable criteria for the combination regimen must be met.

Claim note:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ADEFGV.

Sapropterin (Kuvan®)	100 mg tablet 100 mg sachet 500 mg sachet	02350580 02482207 02482215	BMR	(SA)	MLP

For the ongoing treatment of hyperphenylalaninemia due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) in conjunction with a phenylalanine (Phe)-restricted diet in patients who meet all of the following criteria:

- Confirmed diagnosis based on genetic testing.
- Response to Kuvan as demonstrated by a Kuvan responsiveness test.
- Baseline blood Phe levels greater than 360 umol/L despite compliance with a low protein diet and formulas (non-pregnant patients require at least 2 baseline levels and pregnant patients require at least 1 baseline level during a 3 to 6 month time frame).
- Achievement of the following during a 6-month trial of treatment:
  - For pregnant or non-pregnant patients, normal sustained blood Phe levels of 120 umol/L to 360 umol/L; or
  - For non-pregnant patients, sustained blood Phe reduction of at least 30% compared to baseline if the baseline blood Phe level is less than 1200 umol/L; or
  - For non-pregnant patients, sustained blood Phe reduction of at least 50% compared to baseline if the baseline blood Phe level is greater than 1200 umol/L.
- For non-pregnant patients, documented increase in dietary protein tolerance based on targets set between the clinician and patient.

Renewal Criteria:

- Confirmation of continued response to Kuvan based on Phe levels achieved during the 6-month trial. Two Phe levels taken at least 1 month apart must be provided.

Clinical Notes:

- Patients must be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of PKU.
- Phe blood levels and Phe tolerance levels must be provided.
- Pregnant patients who have maintained a decrease in Phe levels below 360 umol/L during the 6-month trial period will be eligible for coverage of Kuvan for the duration of the pregnancy.

Claim Notes:

- Approvals will be for a maximum of 20mg/kg per day.
- Renewals for Kuvan in pregnant patients will not be considered.
- Approval period: 1 year.

Drugs Reviewed and Not Listed

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

Product	Strength	DIN	MFR	Indication
Midostaurin (Rydapt®)	25 mg capsule	02466236	NVR	For the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia.