Bulletin # 1053

May 13, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective May 13, 2021.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Existing Special Authorization Benefit Additions
- Benefit Status Changes
- 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
Drosperinone/ Ethinyl Estradiol (YAZ® and generic brand)	3 mg / 0.02 mg tablet	See NB Drug Plans Formulary or MAP List for Products		DEFGV	MAP
Leuprolide (Zeulide Depot™)	3.75 mg powder for suspension 22.5 mg powder for suspension	02429977 02462699	VRT	ADEFV	MLP

Special Authorization Benefits Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Cerliponase Alfa (Brineura®)	150 mg / 5 mL solution for intracerebroventricular infusion	02484013	BMR	(SA)	MLP

For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, if all of the following criteria are met:

- Confirmed diagnosis of CLN2 disease based on tripeptidyl peptidase 1 (TPP1) enzyme activity and CLN2 genotype analysis
- Score of greater than or equal to 1 in each of the motor and language domains of the CLN2 Clinical Rating Scale
- Aggregate motor-language score of greater than or equal to 3 on the CLN2 Clinical Rating Scale

Discontinuation criteria:

- Reduction of greater than or equal to 2 points in the aggregate motor–language score of the CLN2 Clinical Rating Scale that is maintained over any two consecutive 24-week assessments; or
- Aggregate motor–language score of 0 on the CLN2 Clinical Rating Scale at two consecutive 24-week assessments.

Clinical Note:

- Documentation of the most recent motor and language domain scores of the CLN2 Clinical Rating Scale must be provided with all requests.

Claim Notes:

- Must be prescribed by, or in consultation with, a specialist with experience in the treatment of CLN2 disease.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Dupilumab (Dupixent®)	200 mg / 1.14 mL prefilled syringe 300 mg / 2 mL prefilled syringe	02492504 02470365	SAV	(SA)	MLP

For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria:

- Refractory or have contraindications to an adequate trial of topical prescription therapies
- Refractory, intolerant or have contraindications to an adequate trial of phototherapy (where available), methotrexate, and cyclosporine
- Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1 or greater

Renewal criteria

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

Clinical Note:

- Not to be used in combination with phototherapy or immunosuppressant drugs (e.g., methotrexate, cyclosporine).

Claim Notes:

- Must be prescribed by a dermatologist.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Tafamidis (Vyndaqel™)	20 mg capsule	02495732	PFI	(SA)	MLP

For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria:

- New York Heart Association (NYHA) class I to III heart failure
- At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
- Has not previously undergone a heart or liver transplant
- Does not have an implanted cardiac mechanical assist device (CMAD)

Discontinuation Criteria:
The patient has:

- NYHA class IV heart failure, or
- received an implanted CMAD, or
- received a heart or liver transplant.

Clinical Notes:

1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following:
   - absence of a variant transthyretin (TTR) genotype

- TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry
- evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
- presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue)

2. Hereditary ATTR-CM consists of all of the following:
   - presence of a variant TTR genotype associated with CM and presenting with a CM phenotype
   - evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
   - presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue)

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR-CM will not be reimbursed.
- Initial approval period: 9 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.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
New Dosage Form					
Lanadelumab (Takhzyro®)	300 mg / 2 mL prefilled syringe	02505614	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.

New Indication

Lenalidomide (Revlimid®)	2.5 mg capsule 5 mg capsule 10 mg capsule 15 mg capsule 20 mg capsule 25 mg capsule	02459418 02304899 02304902 02317699 02440601 02317710	CEL	(SA)	MLP

Multiple Myeloma

1. As first-line treatment for patients with newly diagnosed multiple myeloma who are not eligible for stem cell transplant when used in combination with dexamethasone, with or without bortezomib.
2. For the treatment of relapsed or refractory multiple myeloma when used:
   - In combination with dexamethasone for patients who have not progressed on lenalidomide; or
   - In combination with carfilzomib and dexamethasone for patients who have not progressed on bortezomib or lenalidomide; or
   - In combination with daratumumab and dexamethasone for patients who have not progressed on lenalidomide.
3. For the maintenance treatment of patients with newly diagnosed multiple myeloma who have stable or improved disease following stem cell transplant and no evidence of disease progression.

Renewal Criteria:

- Written confirmation that the patient has responded 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.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Myelodysplastic Syndrome

For the treatment of patients with anemia due to myelodysplastic syndrome who meet all of the following:

- Presence of deletion 5q cytogenetic abnormality
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1
- Transfusion-dependent symptomatic anemia

Renewal criteria:

- Patients who are transfusion-dependent must demonstrate at least fifty percent reduction in transfusion requirements.
- Renewal requests for patients who are not transfusion-dependent may be considered if the patient's serial CBC (pre- and post-lenalidomide) and any other objective evidence of response to therapy is included.

Clinical Note:

- Requests for patients who are not transfusion-dependent may be considered. Clinical evidence of symptomatic anemia affecting the patient's quality of life, rationale for why transfusions are not being used, and details pertaining to other therapies prescribed to manage anemia is required.

Claim Notes:

- Initial approval period: 1 year.
- 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.

Revised Criteria

Fingolimod (Gilenya® and generic brands)	0.5 mg capsule	See NB Drug Plans Formulary or MAP List for Products	(SA)	MAP

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

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Approval Period: 2 years.

Benefit Status Changes

Product	Strength	DIN	MFR	Plans	Cost Base
Delisted					
Atorvastatin / amlodipine (Caduet® and generic brands)	10 mg / 5 mg tablet 10 mg / 10 mg tablet 20 mg / 5 mg tablet 20 mg / 10 mg tablet 40 mg / 5 mg tablet 40 mg / 10 mg tablet 80 mg / 5 mg tablet 80 mg / 10 mg tablet	See NB Drug Plans Formulary or MAP List for Products			MAP

Effective May 13, 2021, atorvastatin/amlodipine tablets will be delisted as a benefit on the New Brunswick Drug Plans Formulary. Requests for special authorization will not be considered.

Patients who have had a claim paid between November 13, 2020 and May 13, 2021 will continue to have coverage. The individual drugs are listed as regular benefits on the New Brunswick Drug Plans Formulary.

Drugs Reviewed and Not Listed

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

Product	Strength	DIN	MFR	Indication
Ixekizumab (Taltz®)	80 mg/mL autoinjector 80 mg/mL prefilled syringe	02455102 02455110	LIL	For the treatment of ankylosing spondylitis.