Bulletin #1124

January 22, 2024

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective January 22, 2024.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Drugs Reviewed and Not Listed

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

Regular Benefit Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Insulin Aspart (Trurapi)	100 units/mL vial	02529254	SAV	ACDEFGV	MLP

Effective January 22, 2024, insulin aspart (Trurapi) 100 units/mL vial will be added to the Formulary as a regular benefit for Plans ACDEFGV.

After this date, requests for coverage of the NovoRapid brand of insulin aspart vials will not be considered. Patients who had a claim paid between July 22, 2023 and January 21, 2024 will continue to have coverage of NovoRapid vials until July 31, 2024.

Special Authorization No Longer Required

Dapagliflozin/Metformin (XigDuo)	5 mg / 850 mg tablet 5 mg / 1000 mg tablet	See NB Drug Plans Formulary or MAP List for Products		ACDEFGV	MAP
Rivaroxaban (Xarelto)	2.5 mg tablet 10 mg tablet	See NB Drug Plans Formulary or MAP List for Products		ACDEFGV	MAP

Special Authorization Benefit Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Abemaciclib (Verzenio)	50 mg tablet 100 mg tablet 150 mg tablet	02487098 02487101 02487128	LIL	(SA)	MLP

In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor positive, HER2 negative, node-positive early breast cancer at high risk of disease recurrence and a Ki-67 score of at least 20% who meet one of the following criteria:

- Pathological tumour involvement in 4 or more ipsilateral axillary lymph nodes; or
- Pathological tumour involvement in 1 to 3 ipsilateral axillary lymph nodes and either histologic grade 3 disease or a primary tumor size of at least 5 cm

Renewal Criteria:

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

Clinical Notes:

1. Patients must have a good performance status and no evidence of metastatic disease or inflammatory breast cancer.
2. Patients must have undergone definitive surgery of primary breast tumor within 16 months of initiating treatment.
3. Treatment with abemaciclib should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 2 years of therapy, whichever occurs first.

Claim Notes:

- Requests will not be considered for patients previously treated with a CDK4/6 inhibitor or olaparib.
- Approval period: 1 year.

Anifrolumab (Saphnelo)	150 mg/mL single-use vial	02522845	AZE	(SA)	MLP

For the treatment of adult patients with moderate to severe autoantibody positive, systemic lupus erythematosus (SLE) who meet all of the following criteria:

- Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of 6 or greater
- Refractory to oral corticosteroids (OCS) at a dose of at least 10 mg per day of prednisone or its equivalent, in addition to standard of care

Renewal Criteria:

- OCS dose has decreased to less than or equal to 7.5 mg per day of prednisone or its equivalent; and
- Reduction in disease activity as measured by:
  - Reduction in the SLEDAI-2K index score to 5 or less; or
  - British Isles Lupus Assessment Group (BILAG)-2004 index score improvement in involved organ systems and no new worsening in other organ systems.

Subsequent Renewal Criteria:

- Initial response achieved after the first twelve months of treatment with anifrolumab has been maintained.

Clinical Notes:

1. Standard of care is defined as using an immunosuppressive drug (e.g., rituximab, hydroxychloroquine, mycophenolic acid, or azathioprine) with or without NSAIDs.
2. A baseline SLEDAI-2K must be provided. If BILAG-2004 is used for assessment on renewal, then a baseline BILAG-2004 assessment of organ systems must also be provided. The same scale should be used on all subsequent renewals.
3. Improvement in organ systems is defined as a reduction of all severe (BILAG-2004 A) or moderately severe (BILAG-2004 B) to lower rating levels.
4. Worsening in organ systems is defined as at least one new BILAG-2004 A item or at least two new BILAG-2004 B items.

Exclusion Criteria:

- Severe or unstable neuropsychiatric SLE.
- Active severe SLE nephritis.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs will not be reimbursed.
- Approvals will be for a maximum of 300 mg every four weeks.
- Approval period: 1 year.

Changes to Existing Special Authorization Benefits

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Indication and Dosage Form					
Elexacaftor/Tezacaftor/ Ivacaftor and Ivacaftor (Trikafta)	80 mg / 40 mg / 60 mg granules and 59.5 mg granules 100 mg / 50 mg / 75 mg granules and 75 mg granules	02542285 02542277	VTX	(SA)	MLP

For the treatment of cystic fibrosis (CF) in patients aged 2 to 5 years of age who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Initial Renewal Criteria:
The patient must meet one of the following criteria:

- Decrease in the total number of days for which the patient received treatment with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment.
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment.
- No decrease in Body Mass Index (BMI) z-score compared with baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit must be provided for at least one of the parameters noted above at the end of each 12-month period.

Clinical Notes:

1. The following baseline measurements must be provided prior to initiation of treatment:
   - Total number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the 6 months prior to initiation of treatment
   - Total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the 6 months prior to initiation of treatment
   - BMI z-score
2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans DFG.
- The patient must be under the care of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- 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.

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
Deferiprone (Ferriprox)	100 mg/mL oral solution 1000 mg tablet	02436523 02436558	CCC	For the treatment of transfusional iron overload due to sickle cell disease or other anemias.