Bulletin #1105

May 23, 2023

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective May 23, 2023.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits

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 (Kirsty)	3 mL prefilled pen	02520974	BGP	ACDEFGV	MLP
Special Authorization No Longer Required					
Progesterone (Prometrium and generic brands)	100 mg capsule	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
Larotrectinib (Vitrakvi)	25 mg capsule 100 mg capsule 20 mg/mL oral solution	02490315 02490323 02490331	BAY	(SA)	MLP

As monotherapy for the treatment of adult and pediatric patients with unresectable locally advanced or metastatic solid tumors who meet all of the following criteria:

- Tumors have a NTRK gene fusion without a known acquired resistance mutation
- No other satisfactory treatment options
- Not a candidate for surgery and/or radiation due to risk of substantial morbidity

Renewal Criteria:

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

Clinical Notes:

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

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a NTRK inhibitor.
- Approval period: 6 months.

Luspatercept (Reblozyl)	25 mg vial 75 mg vial	02505541 02505568	CEL	(SA)	MLP

Beta-Thalassemia Anemia
For the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with beta-thalassemia who are receiving regular transfusions.

Initial Renewal Criteria:
- A reduction of 33% or greater in transfusion burden measured as the number of RBC units required in the initial 24 weeks of luspatercept treatment compared to the 24 weeks prior to luspatercept initiation.

Subsequent Renewal Criteria:
- Maintenance of a 33% or greater reduction in transfusion burden measured as the number of RBC units required in the past 24 weeks compared to the 24 weeks prior to luspatercept initiation.

Clinical Notes:
1. Regular transfusions are defined as receiving 6 to 20 RBC units and having no transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment.
2. History of transfusion burden must be provided with the initial and renewal requests.
3. Treatment should be discontinued if there is no response (as defined in renewal criteria) after 3 doses at the maximum dose.

Claim Notes:
- Must be prescribed by a hematologist.
- Approvals will be for a maximum of 1.25mg/kg (up to 120mg per dose) every three weeks.
- Approval period: 7 months.

Myelodysplastic Syndromes (MDS) Associated Anemia:
For the treatment of adult patients with MDS-associated anemia who meet all of the following criteria:
- Diagnosed with very low- to intermediate-risk MDS with ringed sideroblasts in accordance with the Revised International Prognostic Scoring System (IPSS-R)
- Failed or are not suitable for erythropoietin stimulating agents (ESA)
- Red blood cell (RBC) transfusion-dependent anemia associated with MDS defined as having received at least 2 RBC units over 8 weeks
- Absence of deletion 5q cytogenetic abnormality
- Performance status of 0 to 2

Initial renewal criteria:
- Patient is RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment with luspatercept.

Subsequent renewal criteria:
- Patient maintains transfusion independence with luspatercept treatment.

Clinical Notes:
1. History of transfusion burden must be provided with the initial and renewal requests.
2. Confirmation must be provided that the patient remains very low- to intermediate risk.
3. Details of ESA use (i.e. name of treatment, dose(s), duration of use, response) must be provided.

Claim Notes:

- Must be prescribed by a hematologist or oncologist.
- Approvals will be for a maximum of 1.75 mg/kg (up to 168 mg per dose) every three weeks.
- Approval period: 7 months.

Zanubrutinib (Brukinsa)	80 mg capsule	02512963	BGN	(SA)	MLP

For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

Renewal Criteria:

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

Clinical Notes:

1. Patients must meet at least one criterion for treatment as per IWWM consensus panel.
2. Patients must have a good performance status and no evidence of disease transformation.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

Changes to Existing Special Authorization Benefits

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Indication					
Dupilumab (Dupixent)	200 mg / 1.14 mL prefilled syringe 200 mg / 1.14 mL prefilled pen 300 mg / 2 mL prefilled syringe 300 mg / 2 mL prefilled pen	02492504 02524252 02470365 02510049	SAV	(SA)	MLP

Asthma

1. For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype in patients aged 6 to 11 years of age who are inadequately controlled with medium-to high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) or high-dose ICS alone and meet the following criteria:
   - blood eosinophil count ≥ 0.15×10^9/L within the past 12 months; and
   - uncontrolled asthma with at least one clinically significant asthma exacerbation in the past 12 months.

   Initial Discontinuation Criteria:
   - Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
   - The number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

Clinical Notes:

1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
2. Medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
3. A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

Claim Notes:

- Must be prescribed by a pediatric respirologist or allergist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 200 mg every two weeks or 300 mg every four weeks.
- Approval period: 1 year.

2. For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS) dependent severe asthma in patients 12 years of age and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) and meets one of the following criteria:
   - blood eosinophil count ≥ 0.15×10^9/L within the past 12 months, or
   - have OCS dependent asthma.

   Initial Discontinuation Criteria:
   - Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
   - No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or
   - Number of clinically significant asthma exacerbations has increased within the previous 12 months.

   Subsequent Discontinuation Criteria:
   - Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
   - Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, or
   - Number of clinically significant asthma exacerbations has increased within the previous 12 months.

   Clinical Notes:
   1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.

2. A baseline and annual number of clinically significant asthma exacerbations must be provided.
3. High-dose ICS is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
4. A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

Claim Notes:
- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Approval period: 1 year.

New Strength

Adalimumab (Abrilada)	20 mg / 0.4 mL prefilled syringe	02511061	PFI	(SA)	MLP

Ankylosing Spondylitis
For the treatment of patients with active ankylosing spondylitis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 40 mg every two weeks.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Crohn's Disease
For the treatment of patients with moderately to severely active Crohn's disease who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 160 mg followed by 80 mg two weeks later, then 40 mg every two weeks.
- Initial approval period: 12 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Hidradenitis Suppurativa
For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- Combined use of more than one biologic drug will not be reimbursed.

- Approvals will be for a maximum of 160 mg followed by 80 mg two weeks later, then 40 mg every week
- beginning four weeks after the initial dose.
- Initial approval period: 12 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Plaque Psoriasis
For the treatment of patients with moderate to severe plaque psoriasis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 80 mg followed by 40 mg in one week, then 40 mg every two weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Polyarticular Juvenile Idiopathic Arthritis
For the treatment of patients with moderately to severely active polyarticular juvenile idiopathic arthritis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by, or in consultation with, a rheumatologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 40 mg every two weeks.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Psoriatic Arthritis
For the treatment of patients with active psoriatic arthritis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 40 mg every two weeks.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Rheumatoid Arthritis
For the treatment of patients with moderately to severely active rheumatoid arthritis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 40 mg every two weeks.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Ulcerative Colitis
For the treatment of patients with moderately to severely active ulcerative colitis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 160 mg followed by 80 mg two weeks later, then 40 mg every two weeks.
- Initial approval period: 8 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Uveitis
For the treatment of patients with non-infectious uveitis who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:
- Must be prescribed by, or in consultation with an ophthalmologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for a maximum of 80 mg followed by 40 mg in one week, then 40 mg every two weeks thereafter.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Revised Criteria

Lapatinib (Tykerb)	250 mg tablet	02326442	NVR	(SA)	MLP

In combination with capecitabine for the treatment of patients with unresectable locally advanced or metastatic HER2-positive breast cancer when used as:
- first-line therapy following disease relapse during or within six months of completing adjuvant treatment with trastuzumab or trastuzumab emtansine; or
- second-line therapy following disease progression on trastuzumab, with or without pertuzumab, in the advanced setting.

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

Clinical Note:
- Patients must have a good performance status.

Claim Note:
- Approval period: 6 months.
