Bulletin #1127

February 20, 2024

# NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective February 20, 2024.

**Included in this bulletin:**

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Drugs Reviewed and Not Listed
- Update on Quantities for Claims Submission

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 |
|---|---|---|---|---|---|
| Estradiol/Progesterone (Bijuva) | 1 mg / 100 mg capsule | 02505223 | KNI | ACDEFV | MLP |

## Special Authorization Benefit Additions

| Generic name (Brand name) | Strength | DIN | MFR | Plans | Cost Base |
|---|---|---|---|---|---|
| Finerenone (Kerendia) | 10 mg tablet<br>20 mg tablet | 02531917<br>02531925 | BAY | (SA) | MLP |

As an adjunct to standard care therapy to reduce the risk of end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease and type 2 diabetes mellitus and who meet all of the following criteria:

- Estimated glomerular filtration rate (eGFR) level greater than or equal to 25 mL/min/1.73 $m^2$
- Urine albumin-creatinine ratio (UACR) greater than or equal to 3 mg/mmol
- Does not have New York Heart Association (NYHA) class II to IV heart failure

Clinical Notes:

1. eGFR and UACR lab values must be provided.
2. Treatment should be discontinued if the eGFR is less than 15 mL/min/1.73 $m^2$ or if the UACR has increased from baseline.

Claim Notes:

- Must be prescribed by, or in consultation with, a nephrologist.
- Combined use of more than one mineralocorticoid receptor antagonist (e.g., spironolactone, eplerenone) will not be reimbursed.
- Approvals will be for a maximum of 20 mg daily.
- Approval period: Long term.

| | | | | | |
|---|---|---|---|---|---|
| Methylphenidate (Foquest) | 25 mg controlled-release capsule<br>35 mg controlled-release capsule<br>45 mg controlled-release capsule<br>55 mg controlled-release capsule<br>70 mg controlled-release capsule<br>85 mg controlled-release capsule<br>100 mg controlled-release capsule | 02470292<br>02470306<br>02470314<br>02470322<br>02470330<br>02470349<br>02470357 | ELV | (SA) | MLP |

For the treatment of Attention Deficit Hyperactivity Disorder in patients 6 years of age and older.

Claim Notes:

- The maximum dose reimbursed is 100 mg daily.

- Approval period: 1 year.

| | | | | | |
|---|---|---|---|---|---|
| Somatropin (Norditropin FlexPro) | 5 mg / 1.5 mL prefilled pen<br>10 mg / 1.5 mL prefilled pen<br>15 mg / 1.5 mL prefilled pen | 02529181<br>02529203<br>02529211 | NNO | (SA) | MLP |

For the treatment of growth hormone deficiency in children under the age of 19.

Claim Note:
- Must be prescribed by, or in consultation with, an endocrinologist.

| | | | | | |
|---|---|---|---|---|---|
| Tezepelumab (Tezspire) | 210 mg / 1.91 mL prefilled syringe<br>210 mg / 1.91 mL prefilled pen | 02529548<br>02529556 | AZE | (SA) | MLP |

For the adjunctive treatment of severe asthma in patients 12 years of age and older who meet all of the following criteria:
- Inadequately controlled with high-dose inhaled corticosteroids (ICS), and one or more additional asthma controller(s) (e.g., long-acting beta-agonist)
- Two or more clinically significant asthma exacerbations in the past 12 months

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 oral corticosteroids (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 tezepelumab with other biologics used to treat asthma will not be reimbursed.

- Approvals will be for a maximum of 210 mg every four weeks.
- Approval period: 1 year.

## Changes to Existing Special Authorization Benefits

| Generic name (Brand name) | Strength | DIN | MFR | Plans | Cost Base |
|---|---|---|---|---|---|
| **Revised Criteria – Hepatitis C drugs** | | | | | |
| Please see the New Brunswick Drug Plans Formulary here for the full criteria. | | | | | |
| Glecaprevir/Pibrentasvir (Maviret) | 100 mg / 40 mg tablet | 02467550 | ABV | (SA) | MLP |
| Sofosbuvir (Sovaldi) | 400 mg tablet | 02418355 | GIL | (SA) | MLP |
| Sofosbuvir/Ledipasvir (Harvoni) | 400 mg / 90 mg tablet | 02432226 | GIL | (SA) | MLP |
| Sofosbuvir/Velpatasvir (Epclusa) | 400 mg / 100 mg tablet | 02456370 | GIL | (SA) | MLP |
| Sofosbuvir/Velpatasvir/ Voxilaprevir (Vosevi) | 400 mg / 100 mg / 100 mg tablet | 02467542 | GIL | (SA) | MLP |
| **New Indication** | | | | | |
| Cabozantinib (Cabometyx) | 20 mg tablet<br>40 mg tablet<br>60 mg tablet | 02480824<br>02480832<br>02480840 | IPS | (SA) | MLP |

**Differentiated Thyroid Cancer**
For the treatment of adult patients with locally advanced or metastatic differentiated thyroid cancer (DTC) who meet all of the following criteria:
- Refractory to prior radioactive iodine therapy (RAI) or not eligible for RAI
- Disease progression following treatment with one to two prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors

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

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients with anaplastic or medullary thyroid cancer are not eligible.
- Requests for cabozantinib will be considered for patients with RET fusion-positive DTC who received selpercatinib.
- Approval period: 1 year.

---

**New Indication**
Darolutamide (Nubeqa)

| | | | | |
|---|---|---|---|---|
| 300 mg tablet | 02496348 | BAY | (SA) | MLP |

**Metastatic Castration-Sensitive Prostate Cancer**
In combination with docetaxel and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer who have had no prior ADT, or are within 6 months of beginning ADT, in the metastatic setting.

Renewal Criteria:

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

Clinical Notes:

1. Patients must have a good performance status and be eligible for chemotherapy.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who are within 1 year of completing adjuvant ADT in the non-metastatic setting.
- Patients who experience disease progression on apalutamide or enzalutamide are not eligible.
- Approval period: 1 year.

---

**New Indication**
Ruxolitinib (Jakavi)

| | | | | |
|---|---|---|---|---|
| 5 mg tablet<br>10 mg tablet | 02388006<br>02434814 | NVR | (SA) | MLP |

**Acute Graft-Versus-Host Disease**
For the treatment of patients aged 12 years and older with corticosteroid-refractory or corticosteroid-dependent acute graft-versus-host disease (aGvHD) and a confirmed diagnosis of grade II to IV aGvHD according to the National Institute of Health (NIH) criteria.

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by an overall response (i.e., complete response, very good partial response, partial response, or stable disease with significant reduction in corticosteroid dose), according to NIH criteria at day 28 of treatment.
- Requests for renewal will not be considered upon the occurrence of any of the following:
  - Progression of aGvHD, defined as worsening of symptoms or occurrence of new symptoms
  - Unacceptable toxicity
  - Addition of systemic therapies (except calcineurin inhibitors) for aGvHD after day 28
  - Recurrence or relapse of underlying hematological malignancy

Clinical Notes:

1. Clinical details supporting the diagnosis of grade II to IV aGvHD must be provided at baseline (e.g., organ involvement and staging).
2. Corticosteroid refractory is defined according to the EBMT-NIH-CIBMTR Task Force position statement criteria, as one or more of the following:
   - Progressing based on organ assessment after at least 3 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid with or without a calcineurin inhibitor.
   - Failure to achieve, at a minimum, partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid with or without a calcineurin inhibitor.
   - Patients who fail corticosteroid taper, defined as either an increase in the corticosteroid dose to methylprednisolone greater than or equal to 2 mg/kg per day (or equivalent prednisone dose of greater than or equal to 2.5 mg/kg per day) or failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum 7 days.
3. Corticosteroid dependence is defined as the inability to taper prednisone under 2 mg/kg/day after an initially successful treatment of at least 7 days or as the recurrence of aGvHD activity during steroid taper.
4. Treatment with ruxolitinib must not be added to concurrent systemic therapies for the treatment of aGvHD other than corticosteroids with or without a calcineurin inhibitor.

Claim Notes:

- Must be prescribed by a physician with experience in the treatment of aGvHD.
- Approvals will be for a maximum dose of 10 mg twice daily.
- Initial approval period: 4 weeks.
- Renewal approval period: 12 weeks.

**Chronic Graft-Versus-Host Disease**

For the treatment of patients aged 12 years and older with chronic graft-versus-host disease (cGvHD) who meet all of the following criteria:

- Confirmed diagnosis of moderate to severe cGvHD according to National Institutes of Health (NIH) consensus criteria
- Refractory to corticosteroids or other systemic therapies

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by an overall response (i.e., complete response, partial response, or stable disease with significant reduction in corticosteroid dose), according to NIH criteria, after 24 weeks of therapy.
- Requests for renewal will not be considered upon the occurrence of any of the following:
  - Progression of cGvHD, defined as worsening of symptoms or occurrence of new symptoms.
  - Recurrence or relapse of underlying hematological malignancy.

Clinical Notes:

1. Clinical details supporting the diagnosis of cGvHD must be provided including the affected organs or systems.
2. Corticosteroid refractory is defined, according to NIH consensus criteria irrespective of the concomitant use of a calcineurin inhibitor, by any of the following:
   - Lack of response, or disease progression, after administration of a minimum dose of 1 mg/kg/day of prednisone for at least 1 week (or equivalent).

- Disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).
- Increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

3. Treatment with ruxolitinib must not be added to concurrent systemic therapies for the treatment of cGvHD other than corticosteroids with or without a calcineurin inhibitor.

Claim Notes:

- Must be prescribed by a physician with experience in the treatment of cGvHD.
- Approvals will be for a maximum dose of 10 mg twice daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**Revised Criteria**

| | | | | |
|---|---|---|---|---|
| Methylphenidate (Biphentin) | 10 mg controlled release capsule<br>15 mg controlled release capsule<br>20 mg controlled release capsule<br>30 mg controlled release capsule<br>40 mg controlled release capsule<br>50 mg controlled release capsule<br>60 mg controlled release capsule<br>80 mg controlled release capsule | See NB Drug Plans Formulary or MAP List for Products | (SA) | MAP |

For the treatment of Attention Deficit Hyperactivity Disorder in patients 6 years of age and older.

Claim Notes:

- The maximum dose reimbursed is 80 mg daily.
- Approval period: 1 year.

## 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 |
|---|---|---|---|---|
| Deucravacitinib (Sotyktu) | 6 mg tablet | 02533030 | BRI | For the treatment of moderate to severe plaque psoriasis. |

## Update on Quantities for Claim Submissions

Effective February 20, 2024, the quantity for claim submissions will be changing for the following drugs:

| Drugs | Quantity for Claim Submissions |
|---|---|
| Somatropin (Omnitrope)<br>Somatropin (Nutropin AQ NuSpin) | cartridge |
| Somatropin (Norditropin Nordiflex) | pen |

This change will apply to all claims for prescriptions dispensed on, or after, February 20, 2024. Any claims for prescriptions dispensed prior to this date must follow the previous quantity for claim submission requirement.

Please refer to the Maximum Allowable Price (MAP) List and Manufacturers List Price (MLP) List at Drug Price Lists and Pricing Policy to confirm the correct quantity for claim submissions for a specific product.