Bulletin #1143

October 21, 2024

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective October 21, 2024.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Update on Quantities for Claim Submissions

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

Regular Benefits Addition

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Listed on Additional Plans					
Buprenorphine / Naloxone (Suboxone)	2 mg / 0.5 mg film 4 mg / 1 mg film 8 mg / 2 mg film 12 mg / 3 mg film	02502313 02502321 02502348 02502356	IUK	ACDEFGV	MLP

Special Authorization Benefits Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Belzutifan (Welireg)	40 mg tablet	02528908	FRS	(SA)	MLP

For the treatment of adult patients with von Hippel-Lindau disease who require therapy for associated non-metastatic renal cell carcinoma, central nervous system hemangioblastomas, or non-metastatic pancreatic neuroendocrine tumors, not requiring immediate surgery.

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:

- 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.

Effective October 21, 2024, denosumab (Jubbonti and Wyost) will be added to the Formulary as special authorization (SA) benefits according to the criteria listed below.

As of this date, SA requests for denosumab will be considered for coverage of the biosimilar brands only. Patients who received SA approvals for the Prolia and Xgeva brands of denosumab prior to October 21, 2024 will continue to have coverage until their current SA approval expires, or April 30, 2025, whichever occurs first.

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Denosumab (Jubbonti)	60 mg/mL prefilled syringe	02545411	SDZ	(SA)	MLP

1. For the treatment of osteoporosis in patients who have a high fracture risk, and a contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates.
2. For the prevention of osteoporotic fractures in patients who have a contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates and who meet one of the following criteria:
   - Non-metastatic prostate cancer and receiving androgen deprivation therapy
   - Non-metastatic breast cancer and receiving adjuvant aromatase inhibitor therapy
   - Receiving long term systemic glucocorticoid therapy defined as ≥ 5 mg per day of prednisone or its equivalent for three months or more

Clinical Notes:

1. Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to osteoporosis therapy.
2. High fracture risk is defined as:
   - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
   - High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool

Claim Note:

- Approval period: Long term.

Denosumab (Wyost)	120 mg / 1.7 mL vial	02545764	SDZ	(SA)	MLP

For the prevention of skeletal-related events in patients with castrate-resistant prostate cancer with one or more documented bone metastases.

Claim Note:

- Approval period: 1 year.

Foslevodopa / Foscarbidopa (Vyalev)	240 mg/mL / 12 mg/mL vial	02537702	ABV	(SA)	MLP

For the treatment of adult patients with advanced levodopa-responsive Parkinson disease (PD) who meet all of the following criteria:

- Experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day)
- Received an adequate trial of maximally tolerated doses of levodopa, with previously demonstrated clinical response
- Failed an adequate trial of each of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of the prescriber: amantadine, a dopamine agonist, entacapone, and a monoamine oxidase (MAO-B) inhibitor

Renewal Criteria:

- The patient has a significant reduction in time spent in the "off" state and/or in ongoing levodopa-induced dyskinesias along with improvement in the related disability.

Clinical Note:

- Time in the "off" state, frequency of motor fluctuations, and severity of associated disability should be assessed by a neurologist who is a movement disorder subspecialist or has experience in managing advanced PD and be based on an adequate and reliable account (e.g., clinical interview of a patient or care partner, motor symptom diary).

Claim Notes:

- Must be prescribed by a neurologist who is a movement disorder subspecialist or who has experience in managing advanced PD.
- 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

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Indication					
Cabozantinib (Cabometyx)	20 mg tablet 40 mg tablet 60 mg tablet	02480824 02480832 02480840	IPS	(SA)	MLP

1. In combination with nivolumab for the treatment of patients with advanced (not amenable to curative therapy) or metastatic renal cell carcinoma (RCC) who have not received prior systemic therapy for advanced RCC.

2. As monotherapy for the second-line treatment of patients with advanced (not amenable to curative therapy) or metastatic RCC following disease progression on:
   - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or

- pembrolizumab in combination with either axitinib or lenvatinib.

3. As monotherapy for the third-line treatment of patients with advanced (not amenable to curative therapy) or metastatic RCC following disease progression on:
   - first-line VEGFR TKI (i.e., sunitinib or pazopanib) and second-line nivolumab monotherapy; or
   - first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib).

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 no active central nervous system metastases.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Patients who experience disease progression during or within 6 months of completing pembrolizumab in the adjuvant setting are not eligible for cabozantinib in combination with nivolumab for advanced RCC.
- Requests for cabozantinib will not be considered for patients who experience disease progression on axitinib monotherapy.
- Approval period: 1 year.

Revised Criteria

Axitinib (Inlyta)	1 mg tablet 5 mg tablet	02389630 02389649	PFI	(SA)	MLP

1. In combination with pembrolizumab for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have not received prior systemic therapy for advanced RCC.

2. As monotherapy for the second-line treatment of patients with advanced or metastatic RCC following disease progression on:
   - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or
   - immunotherapy in combination with a TKI (i.e., pembrolizumab in combination with lenvatinib or nivolumab in combination with cabozantinib).

3. As monotherapy for the third-line treatment of patients with advanced or metastatic RCC following disease progression on first-line immunotherapy (i.e., nivolumab in combination with ipilimumab) and second-line VEGFR TKI (i.e., sunitinib or pazopanib).

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:

- Requests for axitinib will not be considered for patients who experience disease progression on cabozantinib monotherapy or nivolumab monotherapy.
- 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.

Update on Quantities for Claim Submissions

Effective October 21, 2024, claims for all denosumab products must be submitted using the number of syringes or vials in the quantity field. This change will apply to all claims for prescriptions dispensed on, or after, October 21, 2024. Any claims for prescriptions dispensed prior to this date must follow the previous quantity for claim submission requirement (i.e. mL).

Please refer to the Maximum Allowable Price (MAP) List and Manufacturers List Price (MLP) List available online to confirm the correct quantity for claim submissions for a specific product.