Bulletin # 1046

February 24, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective February 24, 2021.

Included in this bulletin:

- 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.

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.

Special Authorization Benefits Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Amlodipine (pdp-Amlodipine)	1 mg/mL oral solution	02484706	PDP	(SA)	MLP

For use in patients who require administration through a feeding tube or in pediatric patients when oral tablets or capsules are not an option.

Claim Note:

- Approval Period: 1 year

Infliximab (Avsola™)	100 mg vial	02496933	AGA	(SA)	MLP

Ankylosing Spondylitis

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score greater than or equal to 4 on 10 point scale) who:
  - have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months or in whom NSAIDs are contraindicated, or
  - have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work").

Clinical Note:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial Approval: 6 months.
- Renewal Approval: Long term.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Crohn's Disease

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.

- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial Approval: 12 weeks.
- Renewal Approval: Long term. Confirmation of response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Plaque Psoriasis

For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria:

- Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, or major involvement of visible areas, scalp, genitals, or nails
- Refractory, intolerant or unable to access phototherapy
- Refractory, intolerant or have contraindications to one of the following:
  - Methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks
  - Cyclosporine for a minimum of 6 weeks

Clinical Notes:

1. For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial Approval: 16 weeks.
- Renewal Approval: Long term. Confirmation of response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Psoriatic Arthritis

- For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each.
- For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:
  - the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each; and
  - methotrexate (oral or parenteral) at a dose of greater than or equal to 20mg weekly (greater than or equal to 15mg if patient is greater than or equal to 65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

Clinical Notes:

1. For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.

2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial Approval: 16 weeks.
- Renewal Approval: Long term. Confirmation of response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Rheumatoid Arthritis

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of greater than of equal to 20mg weekly (greater than or equal to 15mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

1. For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
2. Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
3. For patients who have intolerances preventing the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
4. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
5. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only
- Initial Approval: 6 months.
- Renewal Approval: Long term. Confirmation of response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Ulcerative Colitis

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score greater than 4, and a rectal bleeding subscore greater than or equal to 2 and are:

- refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone greater than or equal to 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).

- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score greater than or equal to 2 from baseline, and
  - a decrease in the rectal bleeding subscore greater than or equal to 1.

Clinical Notes:

1. Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score greater than 6).
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of the intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial Approval: 12 weeks.
- Renewal Approval: Long term.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Patisiran (Onpattro™) | 2 mg/mL vial | 02489252 | ALN | (SA) | MLP

For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:

- Confirmed genetic diagnosis of hATTR
- Symptomatic early-stage neuropathy
- Does not have New York Heart Association class III or IV heart failure
- Has not previously undergone a liver transplant

Discontinuation Criteria:

- The patient is permanently bedridden and dependent on assistance for basic activities of daily living, or
- The patient is receiving end-of-life care.

Clinical Note:

- Symptomatic early stage neuropathy is defined as Polyneuropathy disability stage I to IIIB or Familial amyloidotic polyneuropathy stage I or II.

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers

used to treat hATTR will not be reimbursed.
- Initial approval period: 9 months.
- Renewal approval period: 12 months. Confirmation of continued response is required.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Pegfilgrastim (Ziextenzo®)	6 mg / 0.6 mL prefilled syringe	02497395	SDZ	(SA)	MLP

For the prevention of febrile neutropenia in patients receiving myelosuppressive chemotherapy with curative intent who:
- are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or
- have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
- have had a dose reduction, or treatment delay greater than one week due to neutropenia.

Clinical Note:
- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.

Trifluridine / Tipiracil (Lonsurf®)	15 mg / 6.14 mg tablet 20 mg / 8.19 mg tablet	02472104 02472112	TAI	(SA)	MLP

For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria:
- Previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate, with HER2-targeted therapy
- ECOG performance status of 0 or 1

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

Clinical Notes:
1. Trifluridine / tipiracil should be used in combination with best supportive care.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
New Strength					
Dalteparin (Fragmin®)	16 5000 IU / 0.66 mL prefilled syringe	02494582	PFI	W (SA)	MLP
	Refer to the NB Drug Plans Formulary for the special authorization criteria.				
Revised Criteria					
Rituximab (Riximyo™)	10 mg/mL single-use vial	02498316	SDZ	(SA)	MLP
Rituximab (Ruxience™)	10 mg/mL single-use vial	02495724	PFI	(SA)	MLP
Rituximab (Truxima™)	100 mg /10 mL single-use vial 500 mg / 50 mL single-use vial	02478382 02478390	TMP	(SA)	MLP
	For the treatment of patients with rheumatoid arthritis, vasculitis, or other autoimmune disease. Claim Notes: • Must be prescribed by a specialist. • Initial approval period: 6 months. • Renewal approval period: Long term. Confirmation of response is required.				

Drugs Reviewed and Not Listed

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

Product	Strength	DIN	MFR	Indication
Esketamine (Spravato®)	28 mg nasal spray	02499290	JAN	For the treatment of major depressive disorder in adults.

Update on Quantities for Claims Submission

Effective February 24, 2021, claims for pegfilgrastim (Lapelga® and Fulphila™) must be submitted using the number of syringes in the quantity field. This change will apply to all claims for prescriptions dispensed on, or after, February 24, 2021. Any claims for prescriptions dispensed prior to this date must follow the previous quantity for claim submission requirement (i.e. 0.6 mL).

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.