Bulletin # 1048

March 18, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective March 18, 2021.

Included in this bulletin:

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

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.

Regular Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Special Authorization No Longer Required					
Betahistine (Serc® and generic brands)	16 mg tablet 24 mg tablet	See NB Drug Plans Formulary or MAP List for Products	ADEFGV		MAP

Special Authorization Benefit Additions

Effective March 18, 2021, adalimumab biosimilars will be added to the Formulary as a special authorization (SA) benefit according to the criteria listed below.

All new SA requests for coverage of adalimumab will be approved for the biosimilar brand of adalimumab only. Patients who received SA approval for the Humira® brand of adalimumab before March 18, 2021 will continue to have this brand covered. They will also be eligible for coverage of the biosimilars.

Product	Strength	DIN	MFR	Plans	Cost Base
Adalimumab (Amgevita™)	20 mg / 0.4 mL prefilled syringe 40 mg / 0.8 mL prefilled syringe 40 mg / 0.8 mL SureClick® autoinjector	02459310 02459299 02459302	AGA	(SA)	MLP
Adalimumab (Hadlima™)	40 mg / 0.8 mL prefilled syringe 40 mg / 0.8 mL PushTouch™ autoinjector	02473097 02473100	FRS	(SA)	MLP
Adalimumab (Hulio®)	40 mg / 0.8 mL prefilled pen 40 mg / 0.8 mL prefilled syringe	02502402 02502399	BGP	(SA)	MLP
Adalimumab (Hyrimoz®)	20 mg / 0.4 mL prefilled syringe 40 mg / 0.8 mL prefilled syringe 40 mg / 0.8 mL SensoReady® pen	02505258 02492156 02492164	SDZ	(SA)	MLP
Adalimumab (Idacio®)	40 mg / 0.8 mL prefilled pen	02502674	FKB	(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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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 an ophthalmologist.
- Combined use of more than one biologic drug will not be reimbursed.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
Delisted					
Betahistine (Auro-Betahistine) (Teva-Betahistine)	8 mg tablet	02449145 02280183	ARO TEV	(SA)	MAP

Effective March 18, 2021, betahistine 8 mg tablets will be delisted as a benefit on the New Brunswick Drug Plans Formulary. Requests for special authorization will not be considered. Patients who had a claim paid between September 18, 2020 and March 18, 2021 will continue to have coverage.

New Dosage Form

Benralizumab (Fasenra™)	30 mg/mL autoinjector	02496135	AZE	(SA)	MLP

For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and meets one of the following criteria:

- blood eosinophil count of ≥ 0.3 x 10^9/L within the past 12 months and has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
- blood eosinophil count of ≥ 0.15 x 10^9/L and is receiving maintenance treatment with oral corticosteroids (OCS).

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since the 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:

- Baseline 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. High-dose inhaled corticosteroids is defined as greater than or equal to 500 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 respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe eosinophilic asthma.
- Combined use of benralizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 30 mg every four weeks for 12 weeks, then every eight weeks thereafter.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

New Indication

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

For the treatment of patients with advanced or metastatic renal cell carcinoma when used as:

- first-line therapy in combination with pembrolizumab; or
- second-line therapy following disease progression on a vascular endothelial growth factor receptor tyrosine kinase inhibitor (i.e., sunitinib or pazopanib); or
- third-line therapy following disease progression on first-line nivolumab and ipilimumab combination therapy and a second-line vascular endothelial growth factor receptor tyrosine kinase inhibitor (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 everolimus, cabozantinib or single-agent nivolumab.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Etanercept (Brenzys®)	50 mg/mL autoinjector 50 mg/mL prefilled syringe	02455331 02455323	FRS	(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 drug will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50 mg per week.
- Initial approval period: 6 months.
- Renewal approval period: Long term.

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 drug will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50 mg twice weekly for 12 weeks, then once weekly thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required

Polyarticular Juvenile Idiopathic Arthritis

For the treatment of children (age 4-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- Combined use of more than one biologic drug will not be reimbursed.

- All new requests for coverage of etanercept will be approved for the biosimilar version only.
- Approvals will be for a maximum of 0.8mg/kg, up to 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

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 drug will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg once a week.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

Rheumatoid Arthritis

For the treatment of moderately to 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 or equal to 20 mg 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.
   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 drug will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

Revised Criteria

Cabozantinib (Cabometyx™)	20 mg tablet	02480824			
	40 mg tablet	02480832	IPS	(SA)	MLP
	60 mg tablet	02480840			

For the treatment of patients with advanced or metastatic renal cell carcinoma who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy when used as:

- second-line therapy following disease progression on sunitinib, pazopanib or pembrolizumab in combination with axitinib; or
- third-line therapy following disease progression on immunotherapy and VEGFR TKI (i.e., sunitinib or pazopanib), used in any sequence.

Renewal Criteria:

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

Clinical Note:

- Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Drugs Reviewed and Not Listed

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

Product	Strength	DIN	MFR	Indication
Glasdegib (Daurismo®)	25 mg tablet	02498472	PFI	In combination with low-dose cytarabine for the treatment of adult patients with newly diagnosed and previously untreated acute myeloid leukemia, who are 75 years of age or older or who are not eligible to receive intensive induction chemotherapy.
	100 mg tablet	02498480		