Bulletin #1083

July 25, 2022

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective July 25, 2022.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefit Additions
- Benefit Status Changes
- Drugs Reviewed and Not Listed
- Update on Changes for Submissions of Claims over $9, 999.99

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
Terbinafine (Lamisil)	1% topical spray	02238703	NVR	ADEFGV	MLP
Special Authorization No Longer Required					
Lurasidone (Latuda and generic brands)	20 mg film-coated tablet 40 mg film-coated tablet 60 mg film-coated tablet 80 mg film-coated tablet 120 mg film-coated tablet	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP

Special Authorization Benefit Additions

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Adalimumab (Yuflyma)	40 mg / 0.4 mL prefilled pen	02523779	CTL	(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.

Onasemnogene abeparvovec (Zolgensma)	2×10^{13} vector genomes/mL solution for infusion	02509695	NVR	(SA)	MLP

For the treatment of spinal muscular atrophy (SMA) in individuals who meet all of the following criteria:
- Genetic documentation of 5q SMA with biallelic mutations in the survival motor neuron 1 (SMN1) gene; and
- Patient is 180 days of age or younger at the time onasemnogene abeparvovec is administered; and
- Patient is pre-symptomatic or symptomatic with one to three copies of the survival motor neuron 2 (SMN2) gene; and
- Patient does not require permanent ventilatory support (invasive or non-invasive) or a permanent feeding tube.

Clinical Note:
- Permanent ventilatory support is defined as the need for a tracheostomy or requirement of 16 hours or more of respiratory assistance per day (via non-invasive ventilatory support) for 14 or more consecutive days in the absence of an acute reversible illness excluding perioperative ventilation.

Claim Notes:
- The patient must be under the care of a specialist experienced in the diagnosis and treatment of SMA.

- No treatment with nusinersen, risdiplam or other medications indicated for the treatment of SMA will be considered after the patient has received a dose of onasemnogene abeparvovec.
- Approvals will be limited to one lifetime administraton of 1.1 x 10^{14} vector genomes/kg.
- Patients who have received a prior dose of onasemnogene abeparvovec accessed by any mechanism (e.g. private insurance plan, clinical trial, compassionate access) will not be funded.
- Patients with 4 or more copies of the SMN2 gene will not be funded.

Trientine (MAR-Trientine)

250 mg capsule	02504855	MAR	(SA)	MLP

For the treatment of patients with Wilson's disease (WD) who are intolerant, or have contraindications, to d-penicillamine.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment. Supporting documentation must be provided.

Clinical Note:
- Details of d-penicillamine intolerances and/or contraindications must be provided.

Claim Notes:
- In adult patients, trientine therapy must be initiated by a clinician experienced in the management of WD.
- In pediatric patients, initiation and renewal of trientine therapy must be overseen by a clinician experienced in the management of WD.
- Approvals will be for a maximum of 2000 mg per day.
- Approval period: 1 year.

Vitamins B and C (Replavite)

tablet	80007498	WNP	(SA)	MLP

For the replacement of water-soluble vitamins in patients with end-stage renal disease who are on dialysis.

Claim Note:
- Approval Period: Long term.

Changes to Existing Special Authorization Benefits

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
New Dosage Form and Strength					
Risankizumab (Skyrizi)	150 mg/mL prefilled syringe 150 mg/mL autoinjector	02519283 02519291	ABV	(SA)	MLP

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 than10 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 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

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.
- Approvals will be for a maximum of 150 mg at weeks 0 and 4, then every 12 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

New Indication					
Lenalidomide (Revlimid and generic brands)	2.5 mg capsule 5 mg capsule 10 mg capsule 15 mg capsule 20 mg capsule 25 mg capsule	See NB Drug Plans Formulary or MAP List for Products	(SA)	MAP	

Multiple Myeloma

1. As first-line treatment for patients with newly diagnosed multiple myeloma who are not eligible for stem cell transplant when used:
   - in combination with dexamethasone, with or without bortezomib; or
   - in combination with daratumumab and dexamethasone.

2. For the treatment of patients with multiple myeloma when used in combination with bortezomib and dexamethasone as induction therapy prior to autologous stem cell transplant.

3. For the treatment of relapsed or refractory multiple myeloma when used:
   - in combination with dexamethasone for patients who have not progressed on lenalidomide; or
   - in combination with carfilzomib and dexamethasone for patients who have not progressed on bortezomib or lenalidomide; or
   - in combination with daratumumab and dexamethasone for patients who have not progressed on lenalidomide.

4. For the maintenance treatment of patients with newly diagnosed multiple myeloma who have stable or improved disease following stem cell transplant and no evidence of disease progression.

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

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

Claim Note:
- Approval period: 1 year.

New Indication

Olaparib (Lynparza)	100 mg tablet 150 mg tablet	02475200 02475219	AZE	(SA)	MLP

Metastatic Castration-Resistant Prostate Cancer
For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who meet all of the following criteria:
- deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM; and
- Disease progression on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy.

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:
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

New Strength and Revised Criteria

Elexacaftor / Tezacaftor / Ivacaftor and Ivacaftor (Trikafta)	50 mg / 25 mg / 37.5 mg and 75 mg tablet	02526670	VTX	(SA)	MLP

For the treatment of patients 6 years of age and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Initial Renewal Criteria:
The patient must meet one of the following criteria:

- Increase in ppFEV1 by at least 5% compared with baseline.
- Decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six month period prior to initiating treatment.
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six month period prior to initiating treatment.
- Decrease in the number of CF-related hospitalizations compared with the six month period prior to initiating treatment.
- No decrease in Body Mass Index (BMI) at six months compared with baseline.
- Increase of 4 points or more on the CF Questionnaire-Revised (CFQ-R) Respiratory Domain Scale compared with baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit must be provided (e.g., ppFEV1, CFQ-R, pulmonary exacerbations).

Clinical Notes:

1. The following baseline measurements must be provided prior to initiation of treatment:
    - Spirometry of FEV1 and ppFEV1 measured within the 3 month period prior to initiation of treatment
    - Total number of days treated with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations in the 6 months prior to initiation of treatment
    - Total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the 6 months prior to initiation of treatment
    - Number of CF-related hospitalizations in the 6 months prior to initiation of treatment
    - BMI
    - CFQ-R Respiratory Domain score
2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ADEFGV.
- The patient must be under the care of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Initial approval period: 7 months.
- Renewal 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.

Benefit Status Changes

Generic name (Brand name)	Strength	DIN	MFR	Plans	Cost Base
Delisted					
Deferasirox (Exjade and generic brands)	125 mg tablet 250 mg tablet 500 mg tablet	See NB Drug Plans Formulary or MAP List for Products			

Effective July 25, 2022 deferasirox tablets (Exjade and generics) will be delisted as a benefit on the New Brunswick Drug Plans Formulary. Requests for special authorization will not be considered.

There are equally effective and less costly iron chelating agents currently listed as special authorization benefits.

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
Insulin Aspart (Kirsty)	100 unit/mL prefilled pen 100 unit/mL multidose vial	02520974 02520982	BGP	For the treatment of patients with diabetes mellitus.
Risperidone (Perseris)	90 mg prefilled syringe 120 mg prefilled syringe	02507838 02507846	HLS	For the treatment of schizophrenia in adults.

Update on Changes for Submission of Claims over $9, 999.99

Changes have been made to add efficiency to the submission process for claims that exceed the maximum claim amount of $9,999.99. The drugs and applicable DINs and PINs affected are listed here.

Effective August 31, 2022, pharmacies must use the DIN, one PIN (each subsequent claim is submitted with the same PIN) and Intervention and Exception Code "MG" to submit claims over the amount of $9,999.99. This new process will simplify the submissions of these claims.

Until August 31, 2022, claims that exceed the maximum claim amount of $9,999.99 can be submitted either with the DIN, one PIN (each subsequent claim is submitted with the same PIN) and Intervention and Exception Code "MG" or the DIN and multiple PINs.

More information on the NB Drug Plans Claim Submissions are available online.

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