

**New Brunswick Drug Plans  
Special Authorization Criteria**

**ABATACEPT (ORENCIA)  
250 mg / 15 mL vial**

**Polyarticular Juvenile Idiopathic Arthritis**

For the treatment of children (age 6-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant to, or who have not had an adequate response from etanercept.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Abatacept will not be reimbursed in combination with anti-TNF agents.
- Combined use of more than one biologic drug will not be reimbursed.
- Intravenous infusion: initial IV infusion dose is administered at 0, 2, and 4 weeks then every 4 weeks thereafter.
- Initial treatment is limited to a maximum of 16 weeks. Retreatment is permitted for children who demonstrated an adequate initial treatment response and who are experiencing a disease flare.

**ABATACEPT (ORENCIA)  
250 mg / 15 mL vial and 125 mg/mL prefilled syringe**

**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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Intravenous infusion: 500 mg for patients less than 60 kg, 750 mg for patients 60-100 kg and 1000 mg for patients greater than 100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter.
- Subcutaneous injection: a single IV loading dose of up to 1,000 mg may be given, followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg subcutaneous injections.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**ABEMACICLIB (VERZENIO)  
50 mg, 100 mg, and 150 mg tablets**

In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor positive, HER2-negative resected invasive early-stage breast cancer at high risk of disease recurrence who meet one of the following criteria:

- Pathological tumour involvement in 4 or more ipsilateral axillary lymph nodes (ALNs); or
- Pathological tumour involvement in 1 to 3 ipsilateral ALNs and at least one of:
  - histologic grade 3 disease
  - primary tumour size of 5 cm or greater
  - Ki-67 index score of 20% or greater

Renewal Criteria:

- Written confirmation that the patient has not experienced disease recurrence.

Clinical Notes:

1. Patients must have a good performance status and no evidence of metastatic disease or inflammatory breast cancer.
2. Patients must have undergone definitive surgery of primary breast tumour within 16 months of initiating treatment.
3. Treatment with abemaciclib should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 2 years of therapy, whichever occurs first.

Claim Notes:

- Requests will not be considered for patients previously treated with a CDK4/6 inhibitor or olaparib.
- Approval period: 1 year.

**ABOBOTULINUMTOXINA (DYSPORT THERAPEUTIC)  
300 unit/vial and 500 unit/vial**

1. For the treatment of cervical dystonia (spasmodic torticollis) in adults.
2. For the treatment of upper and lower limb focal spasticity in adults.
3. For the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

Renewal Criteria:

- Documentation of continued benefit including the patient's functional and/or symptomatic improvement, as well as the dosage and injection schedule.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 3 years.

**ABROCITINIB (CIBINQO)  
50 mg, 100 mg and 200 mg tablets**

For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all of the following criteria:

- Refractory or have contraindications to an adequate trial of topical prescription therapies combined with phototherapy (where available).
- Refractory, intolerant or have contraindications to an adequate trial of topical prescription therapies combined with methotrexate, cyclosporine, mycophenolic acid, or azathioprine.
- Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1 or greater.

Renewal Criteria:

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

Claim Notes:

- Must be prescribed by a dermatologist, pediatrician or clinical immunologist with experience in the treatment of moderate to severe AD.
- Combined use of more than one immunomodulatory drug (e.g., biologics or janus kinase inhibitors) for the treatment of moderate to severe AD will not be reimbursed.
- Approvals will be for a maximum of 200 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**ACALABRUTINIB (CALQUENCE)  
100 mg capsule and tablet**

1. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).
2. As monotherapy for adult patients with relapsed or refractory CLL / SLL who have received at least one prior 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:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Patients who experience disease progression during or within one year of completing ibrutinib in combination with venetoclax are not eligible for acalabrutinib in the relapsed setting.
- Approval period: 1 year.

**ADALIMUMAB**

**Abrilada 20 mg / 0.4 mL prefilled syringe, 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Amgevita 20 mg / 0.4 mL prefilled syringe, 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Hadlima 40 mg / 0.4 mL autoinjector and prefilled syringe**  
**Hadlima 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Hulio 20 mg / 0.4 mL prefilled syringe, 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Hyrimoz 20 mg / 0.2 mL prefilled syringe, 40 mg / 0.4 mL autoinjector and prefilled syringe, 80 mg / 0.8 mL autoinjector and prefilled syringe**  
**Hyrimoz 20 mg / 0.4 mL prefilled syringe, 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Idacio 40 mg / 0.8 mL autoinjector and prefilled syringe**  
**Simlandi 40 mg / 0.4 mL autoinjector and prefilled syringe, 80 mg / 0.8 mL prefilled syringe**  
**Yuflyma 40 mg / 0.4 mL autoinjector and prefilled syringe, 80 mg / 0.8 mL autoinjector and prefilled syringe**

**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 with other biologic drugs or janus kinase inhibitors 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 2 years of age and older 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 with other biologic drugs or janus kinase inhibitors 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 with other biologic drugs or janus kinase inhibitors 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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators 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.

### **AFATINIB (GIOTRIF and generic brand) 20 mg, 30 mg and 40 mg film-coated tablets**

For the first-line treatment of patients with EGFR mutation-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer.

#### Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

#### Clinical Note:

- Patients must have a good performance status.

Claim Notes:

- Requests for afatinib will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with osimertinib.
- Approval period: 1 year.

**AFLIBERCEPT (ENZEEVU and YESAFILI)  
2 mg / 0.05 mL prefilled syringe**

1. For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).
2. For the treatment of myopic choroidal neovascularization (myopic CNV)
3. For the treatment of patients with diabetic macular edema (DME).
4. For the treatment of macular edema secondary to central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO).

Claim Notes:

- An initial claim of up to two syringes (one per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 syringe per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

**ALECTINIB (ALECENSARO)  
150 mg capsule**

**Adjuvant Non-Small Cell Lung Cancer**

For the adjuvant treatment of patients with completely resected stage IB (tumour > 4 cm) to stage IIIA (AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 2 years of therapy, whichever occurs first.

Claim Notes:

- Approval period: 2 years.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Advanced Non-Small Cell Lung Cancer**

For the treatment of patients with ALK-positive locally advanced (not amenable to curative therapy) or metastatic NSCLC when used as:

- first-line therapy, or
- second-line therapy following disease progression on, or intolerance to, crizotinib.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with alectinib.
- 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](#).

**ALGLUCOSIDASE ALFA (MYOZYME)  
50 mg vial**

For the treatment of infantile-onset Pompe disease, as demonstrated by onset of symptoms and confirmed cardiomyopathy within the first 12 months of life.

Monitoring of therapy

The monitoring of markers of disease severity and response to treatment must include at least:

1. Weight, length and head circumference.
2. Need for ventilatory assistance, including supplementary oxygen, CPAP, BiPAP, or endotracheal intubation and ventilation.

3. Left ventricular mass index (LVMI) as determined by echocardiography (not ECG alone).
4. Periodic consultation with cardiology.
5. Periodic consultation with respirology.

Withdrawal of therapy

1. Patients to be considered for reimbursement of drug costs for alglucosidase alfa treatment must be willing to participate in the long-term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.
2. The development of the need for continuing invasive ventilatory support after the initiation of ERT should be considered a treatment failure. Funding for ERT should not be continued for infants who fail to achieve ventilator-free status, or who deteriorate further, within 6 months after the initiation of ventilatory support.
3. Deterioration of cardiac function, as shown by failure of LV hypertrophy (as indicated by LV mass index) to regress by more than Z=1 unit, or persistent clinical or echocardiographic findings of cardiac systolic or diastolic failure without evidence of improvement, in spite of 24 weeks of ERT, should be considered a treatment failure and funding for ERT should be discontinued.

**ALIROCUMAB (PRALUENT)  
75 mg/mL, 150 mg/mL and 300 mg / 2 mL autoinjectors**

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
  - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
  - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial Renewal Criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent Renewal Criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

1. LDL-C levels must be provided.
2. Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
  - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
  - at least one statin was initiated at the lowest daily starting dose; and
  - other known causes of intolerance have been ruled out.
3. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Approvals will be for a maximum of 300 mg every 4 weeks.
- Combined use with other PCSK9 inhibitors will not be reimbursed.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**AMBRISENTAN (VOLIBRIS and generic brands)  
5 mg and 10 mg tablets**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class III or IV.

Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Combined use of more than one endothelin receptor antagonist will not be reimbursed.

- The maximum dose of ambrisentan that will be reimbursed is 10 mg daily.
- Approval period: Long term.

**AMIFAMPRIDINE (FIRDAPSE)  
10 mg tablet**

For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 18 years of age or older.

Initial Renewal Criteria:

- An improvement of at least 30% on the Triple Timed Up and Go (3TUG) test compared to baseline measurement.

Subsequent Renewal Criteria:

- The patient continues to maintain an improvement of at least 30% on the 3TUG test compared to baseline measurement.

Clinical Note:

- The 3TUG test score must be provided with initial and renewal requests.

Claim Notes:

- Must be prescribed by a neurologist.
- Approvals will be up to a maximum daily dose of 80 mg.
- Initial approval period: 3 months.
- Renewal approval period: 1 year.

**AMIFAMPRIDINE (RUZURGI)  
10 mg tablet**

For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age or older.

Initial Renewal Criteria:

- An improvement of at least 30% on the Triple Timed Up and Go (3TUG) test compared to baseline measurement.

Subsequent Renewal Criteria:

- The patient continues to maintain an improvement of at least 30% on the 3TUG test compared to baseline measurement.

Clinical Note:

- The 3TUG test score must be provided with initial and renewal requests.

Claim Notes:

- Must be prescribed by a neurologist.
- Approvals will be up to a maximum daily dose of 40 mg for patients weighing less than 45 kg and 100 mg for patients weighing 45 kg or more.
- Initial approval period: 3 months.
- Renewal approval period: 1 year.

**AMLODIPINE (pdp-AMLODIPINE)  
1 mg/mL oral solution**

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.

**ANIFROLUMAB (SAPHNELO)  
300 mg vial**

For the treatment of adult patients with moderate to severe autoantibody positive, systemic lupus erythematosus (SLE) who meet all of the following criteria:

- Systemic lupus erythematosus disease activity index 2000 (SLEDAI-2K) score of 6 or greater.
- Refractory to oral corticosteroids (OCS) at a dose of at least 10 mg per day of prednisone or its equivalent, in addition to standard of care.

Renewal Criteria:

- OCS dose has decreased to less than or equal to 7.5 mg per day of prednisone or its equivalent; and

- Reduction in disease activity as measured by:
  - Reduction in the SLEDAI-2K index score to 5 or less; or
  - British isles lupus assessment group (BILAG)-2004 index score improvement in involved organ systems and no new worsening in other organ systems.

**Subsequent Renewal Criteria:**

- Initial response achieved after the first twelve months of treatment with anifrolumab has been maintained.

**Clinical Notes:**

1. Standard of care is defined as using an immunosuppressive drug (e.g., rituximab, hydroxychloroquine, mycophenolic acid, or azathioprine) with or without NSAIDs.
2. A baseline SLEDAI-2K must be provided. If BILAG-2004 is used for assessment on renewal, then a baseline BILAG-2004 assessment of organ systems must also be provided. The same scale should be used on all subsequent renewals.
3. Improvement in organ systems is defined as a reduction of all severe (BILAG-2004 A) or moderately severe (BILAG-2004 B) to lower rating levels.
4. Worsening in organ systems is defined as at least one new BILAG-2004 A item or at least two new BILAG-2004 B items.

**Exclusion Criteria:**

- Severe or unstable neuropsychiatric SLE.
- Active severe SLE nephritis.

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs will not be reimbursed.
- Approvals will be for a maximum of 300 mg every four weeks.
- Approval period: 1 year.

**APALUTAMIDE (ERLEADA)  
60mg and 240 mg tablets**

**Metastatic Castration-Sensitive Prostate Cancer**

In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) 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 no risk factors for seizures.
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 darolutamide or enzalutamide are not eligible.
- Approval period: 1 year.

**Non-Metastatic Castration-Resistant Prostate Cancer**

In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who meet all of the following criteria:

- No detectable distant metastases by either CT, MRI or technetium-99m bone scan
- Prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases)

**Renewal Criteria:**

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

**Clinical Notes:**

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with apalutamide.
3. Patients must have a good performance status and no risk factors for seizures.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide or darolutamide.
- Approval period: 1 year.

**APREPITANT (EMEND)**

**80 mg and 125 mg capsules**

**Tri-Pack 2x80 mg capsules + 125 mg capsule**

In combination with a 5-HT<sub>3</sub> antagonist and dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:

- highly emetogenic chemotherapy, or
- moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT<sub>3</sub> antagonist and dexamethasone in a previous cycle.

Claim Note:

- Prescriptions written by hematologists, oncologists, oncology clinical associates, or general practitioners in oncology who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.

**ARIPIPIRAZOLE (ABILIFY MAINTENA)**

**300 mg and 400 mg vials**

For the treatment of patients who are:

- not adherent to an oral antipsychotic, or
- currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

Claim Notes:

- Requests will not be considered for the treatment of psychotic symptoms related to dementia.
- Approval period: Long term.

**ASCIMINIB (SCEMBLIX)**

**20 mg and 40 mg tablets**

For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase who have resistance or intolerance to at least two tyrosine kinase inhibitors and no evidence of T315i or V299L mutations.

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 will not be considered for patients with CML in accelerated or blast phase.
- Approval period : 1 year.

**ASENAPINE (SAPHRIS)**

**5 mg and 10 mg sublingual tablets**

For the acute treatment of bipolar I disorder as either:

- Monotherapy, after inadequate response to a trial of lithium or divalproex sodium, and there is a history of inadequate response or intolerance to at least one less expensive antipsychotic agent; or
- Co-therapy with lithium or divalproex sodium, and there is a history of inadequate response or intolerance to at least one less expensive antipsychotic agent.

Claim Note:

- Approval period: Long term.

**ASFOTASE ALFA (STRENSIQ)**

**18 mg / 0.45 mL, 28 mg / 0.7 mL, 40 mg / 1 mL and 80 mg / 0.8 mL single-use vials**

For the treatment of patients with perinatal, infantile, or juvenile-onset hypophosphatasia (HPP).

Clinical Note:

- Eligibility for the treatment of HPP is determined by the Canadian HPP Clinical Expert Committee. Please contact the NB Drug Plans at 1-800-332-3691 for the request form.

Claim Notes:

- Must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**ATOGEPAANT (QULIPTA)  
10 mg, 30 mg and 60 mg tablets**

For the prevention of migraine in adult patients with a confirmed diagnosis of episodic or chronic migraine who are refractory, intolerant or have contraindications to at least two classes of oral prophylactic migraine medications.

Renewal Criteria:

- A reduction of at least 50% in the average number of migraine days per month at the time of initial renewal compared with baseline.
- At subsequent renewals, the patient continues to maintain the reduction of at least 50% in average number of migraine days per month.

Clinical Notes:

1. The average number of headache days per month and migraine days per month must be provided on initial and renewal requests.
2. According to the International Headache Society criteria, episodic or chronic migraine are defined as:
  - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
  - Chronic migraine: migraine headaches on at least 8 days per month and more than 15 headache days per month for more than 3 months.

Claim Notes:

- Combined use with other calcitonin gene-related peptide (CGRP) antagonists will not be reimbursed.
- Maximum dose reimbursed is 60 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**AVAPRITINIB (AYVAKYT)  
25 mg, 50 mg, 100 mg and 200 mg tablets**

For the treatment of adult patients with advanced systemic mastocytosis (AdvSM), which includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL), based on the WHO diagnostic criteria.

Renewal Criteria:

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

Clinical Notes:

1. Patients must not have any of the following:
  - platelet count less than 50 x 10<sup>9</sup>/L or receiving platelet transfusions
  - high risk of intracranial bleeding as per clinician judgement
  - primary brain malignancy or metastasis
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for use in combination with other systemic therapy for advanced systemic mastocytosis will not be considered.
- The maximum dose reimbursed is 200 mg per day.
- 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](#).

**AXITINIB (INLYTA)  
1 mg and 5 mg tablets**

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:**

- Patients must have a good performance status.
- 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](#).

**AZACITIDINE (ONUREG)  
200 mg and 300 mg tablets**

As maintenance therapy for the treatment of adult patients with newly diagnosed acute myeloid leukemia (de novo or secondary to prior MDS or CMML) who meet all of the following criteria:

- Intermediate or poor risk cytogenetics
- Complete remission or complete remission with incomplete blood count recovery following induction therapy, with or without consolidation treatment, within the previous 4 months
- Not eligible for hematopoietic stem cell transplantation

**Renewal Criteria:**

- Written confirmation that the patient continues to be in complete remission or complete remission with incomplete blood count recovery.

**Clinical Note:**

- Treatment should be discontinued upon disease relapse (i.e., appearance of greater than 5% blasts in the bone marrow or peripheral blood), unacceptable toxicity or the patient becomes eligible for allogeneic bone marrow or stem cell transplantation.

**Claim Notes:**

- Requests will not be considered for patients who experience disease progression on hypomethylating agents.
- Approvals will be for a maximum of 300 mg daily for 14 days every 28-day cycle.
- 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](#).

**AZITHROMYCIN (generic brands)  
600 mg tablet**

For the prevention of disseminated Mycobacterium Avium Complex (MAC) in HIV positive patients who are severely immunocompromised with CD4 levels  $<0.1 \times 10^9/L$ .

**AZTREONAM (CAYSTON)  
75 mg powder for inhalation**

For the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections, when used as a cyclic treatment, in patients with moderate to severe cystic fibrosis and deteriorating clinical condition despite treatment with inhaled tobramycin.

**Clinical Note:**

- Cyclic treatment measured in 28-day cycles is defined as 28 days of treatment, followed by 28 days without treatment.

Claim Notes:

- Combined use of aztreonam either concurrently or for antibiotic cycling during off-treatment periods, with other inhaled antibiotics (e.g, tobramycin, levofloxacin) will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.

**BARICITINIB (OLUMIANT)**

**2 mg tablet**

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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 2 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of response is required.

**BELIMUMAB (BENLYSTA)**

**120 mg and 400 mg vial  
200 mg/mL autoinjector**

For the adjunctive treatment of adult patients with active lupus nephritis who meet all of the following criteria:

- International Society of Nephrology/Renal Pathology Society class III, IV, or V.
- Have initiated standard induction therapy within the previous 60 days.
- Have an estimated glomerular filtration rate (eGFR)  $\geq 30$  mL/min/1.73 m<sup>2</sup>.

Initial Renewal Criteria:

The patient must meet all of the following criteria:

- Reduction in the glucocorticoid dose to  $\leq 7.5$  mg/day of prednisone or its equivalent.
- An eGFR  $\geq 60$  mL/min/1.73 m<sup>2</sup>, or no more than 20% below the value before the renal flare (i.e., preflare value).
- Proteinuria less than 0.7 g/24 hours after:
  - 12 months of treatment if baseline proteinuria was  $< 3.5$  g/24 hours; or
  - 18 to 24 months of treatment if baseline proteinuria was in the nephrotic range ( $> 3.5$  g/ 24 hours).

Subsequent Renewal Criteria:

- Initial response achieved after the first twelve months of treatment with belimumab has been maintained.

Clinical Notes:

1. Baseline eGFR and urine protein-creatinine ratio (i.e., proteinuria) must be provided with the initial request and for subsequent renewals. Initial requests must also include an eGFR from before the renal flare.
2. Induction therapy is defined as corticosteroids combined with either cyclophosphamide or mycophenolate.

Exclusion Criteria:

- eGFR less than 30 mL/min/1.73 m<sup>2</sup>.

Claim Notes:

- Must be prescribed by a nephrologist or a rheumatologist experienced in the management of lupus nephritis.
- Combined use with other biologic drugs will not be reimbursed.
- Intravenous Infusion: Approvals will be for a maximum of 10 mg/kg every two weeks for the first three doses and every 4 weeks thereafter.

- Subcutaneous injection: Approvals will be for a maximum of 400 mg weekly for 4 doses then 200 mg weekly thereafter.
- Approval period: 1 year.

**BELZUTIFAN (WELIREG)  
40 mg tablet**

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 tumours, 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](#).

**BENRALIZUMAB (FASENRA)  
30 mg/mL autoinjector and prefilled syringe**

For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high dose inhaled corticosteroids (ICS) 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  $\geq 0.3 \times 10^9/L$  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  $\geq 0.15 \times 10^9/L$  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:

- 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 ICS 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.
- Approval period: 1 year.

**BEROTRALSTAT (ORLADEYO)  
150 mg capsule**

For the prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment.

Discontinuation Criteria:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with berotralstat compared to the number of attacks observed before initiating treatment with berotralstat; or
- Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with berotralstat.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to berotralstat.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the diagnosis and treatment of HAE.
- Not to be used in combination with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor or plasma kallikrein inhibitor).
- Approvals will be for a maximum of 150 mg once daily every 28 days.
- Initial approval period: 3 months.
- Renewal approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**BICTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE (BIKTARVY)  
50 mg / 200 mg / 25 mg tablet**

For the treatment of adult patients with HIV-1 infection with no known substitution associated with resistance to the individual components of Biktarvy.

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**BIMEKIZUMAB (BIMZELX)  
160 mg/mL and 320 mg / 2 mL autoinjectors and prefilled syringes**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 160 mg every 4 weeks.
- Initial approval duration: 6 months.
- Renewal approval duration: 1 year.

**Plaque Psoriasis**

For the treatment of adult 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 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 drug will not be reimbursed.
- Approvals will be for 320 mg every 4 weeks for 16 weeks then 320 mg every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**Psoriatic Arthritis**

- For the treatment of adult 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 adult 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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 160 mg every 4 weeks.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**BINIMETINIB (MEKTOVI)  
15 mg film-coated tablet**

For the treatment of patients with BRAF V600 mutation-positive locally advanced unresectable or metastatic melanoma when used in combination with encorafenib.

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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

**BOSENTAN (TRACLEER and generic brands)  
62.5 mg and 125 mg tablets**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class II, III or IV.

Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Combined use of more than one endothelin receptor antagonist will not be reimbursed.
- The maximum dose of bosentan that will be reimbursed is 125 mg twice daily.
- Approval period: Long term.

**BOSUTINIB (BOSULIF and generic brand)  
100 mg and 500 mg tablets**

For the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) who have resistance or intolerance to prior tyrosine kinase inhibitor therapy.

Clinical Note:

- Patients must have a good performance status.

Claim Note:

- Approval period: 1 year.

**BRIGATINIB (ALUNBRIG)  
30 mg, 90 mg and 180 mg tablets**

For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who have not been previously treated with an ALK inhibitor.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests for brigatinib will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with alectinib.
- 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](#).

**BRIVARACETAM (BRIVLERA and generic brands)  
10 mg, 25 mg, 50 mg, 75 mg and 100 mg tablets**

For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response or intolerance to at least three other antiepileptic drugs.

Claim Note:

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

**BRODALUMAB (SILIQ)  
210 mg / 1.5 mL prefilled syringe**

For the treatment of adult 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 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 drug will not be reimbursed.
- Approvals will be for 210 mg at week 0, 1, and 2, then 210 mg every two weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**BROLUCIZUMAB (BEOVU)  
6 mg / 0.05 mL prefilled syringe**

**Diabetic Macular Edema**

For the treatment of patients with diabetic macular edema who meet all of the following criteria:

- Clinically significant center-involving macular edema for whom laser photocoagulation is also indicated
- Central retinal thickness greater than or equal to 250 micrometers

Claim Notes:

- An initial claim of up to two prefilled syringes (1 per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 prefilled syringe per eye every 6 weeks for 30 weeks, followed by 1 prefilled syringe per eye every 8 weeks thereafter.
- Approval period: 1 year. Confirmation of continued response is required.

**Neovascular (wet) age-related macular degeneration**

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).

Discontinuation Criteria:

- Reduction in Best Corrected Visual Acuity (BCVA) in the treated eye of 15 letters or more on 2 consecutive visits, attributed to AMD in the absence of other pathology, or
- Reduction in BCVA in the treated eye of 30 letters or more compared to either baseline and/or best recorded level, or
- There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Clinical Note:

- BCVA must be provided with initial request and with subsequent renewal requests.

Claim Notes:

- An initial claim of up to two prefilled syringes (1 per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 prefilled syringe per eye every 4 weeks for 12 weeks, followed by 1 prefilled syringe per eye every 8 weeks thereafter.
- Approval period: 1 year.

**BUDESONIDE (PULMICORT NEBUAMP and generic brands)  
0.125 mg/mL, 0.25 mg/mL and 0.5 mg/mL suspension for inhalation**

1. For patients who have tried using a budesonide inhaler and
  - cannot follow instructions, or cannot hold the device long enough to actuate it due to cognitive or physical limitations; or
  - have difficulty generating adequate inspiratory effort to achieve therapeutic benefit.

Claim Note:

- Approval period: Long term.

2. For patients who require budesonide for sinonasal irrigation when it is prescribed by, or in consultation with, a specialist (e.g., ENT, allergists, immunologists).

Claim Notes:

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

**BUPROPION (ZYBAN)  
150 mg tablet**

For smoking cessation in adults 18 years of age and older.

Clinical Notes:

1. The patient should be participating in a form of smoking cessation counselling.
2. For information on quitting smoking or to obtain the special authorization request form, visit our website [Smoking Cessation Therapies](#).

Claim Notes:

- A maximum of 12 weeks of standard therapy (168 tablets) will be reimbursed annually without special authorization.
- Patients who have a high probability of quitting with additional therapy may be approved under special authorization for another 168 tablets.
- Requests for nicotine replacement therapy (patches/gum/lozenge) for use in combination with a non-nicotine prescription smoking cessation drug (varenicline or bupropion) will not be considered.
- Requests for special authorization should be submitted on the Smoking Cessation Therapy Special Authorization Request Form.

**BUROSUMAB (CRYSVITA)  
10 mg/mL, 20 mg/mL and 30 mg/mL single-use vials**

For the treatment of patients with X-linked hypophosphatemia (XLH) who meet the following criteria:

- Initiated in a pediatric patient who is at least one year of age and in whom epiphyseal closure has not yet occurred
- Fasting hypophosphatemia
- Normal renal function (defined as a serum creatinine below the age-adjusted upper limit of normal)
- Radiographic evidence of rickets with a rickets severity score (RSS) of two or greater
- Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance

Discontinuation Criteria:

In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred and who met the above criteria, treatment should be discontinued if:

- there is no demonstrated improvement in the 12-month RSS total score from baseline RSS total score; or
- the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently.

In adolescent patients who are 13 to 17 years of age in whom epiphyseal closure has occurred and who met the above criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:

- Hyperparathyroidism; or
- Nephrocalcinosis; or
- Evidence of fracture or pseudo-fracture based on radiographic assessment.

In adult patients who met the above criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur:

- Hyperparathyroidism; or
- Nephrocalcinosis; or
- Evidence of fracture or pseudo-fracture based on radiographic assessment.

Clinical Note:

- A baseline and annual assessment of the RSS score must be provided for pediatric patients in whom epiphyseal closure has not occurred.

Claim Notes:

- Requests will not be considered for treatment-naïve adults.
- Must be prescribed by a physician working in a multidisciplinary team of health care providers who are experienced in the diagnosis and management of XLH.
- Approvals for children (1-17 years of age) will be up to a maximum of 90 mg every 2 weeks.
- Approvals for adults (18 years of age and older) will be up to a maximum of 90 mg every 4 weeks.
- 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](#).

**CABOTEGRAVIR (APRETUDE)****30 mg tablet****600 mg vial**

For at-risk individuals aged 12 years and older and weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

Renewal Criteria:

- Confirmation of adherence to treatment.

Clinical Note:

- HIV-1 negative status should be confirmed at each subsequent injection.

Claim Note:

- Approval period: 1 year.

**CABOTEGRAVIR (VOCABRIA)****30 mg tablet****CABOTEGRAVIR and RILPIVIRINE (CABENUVA)****600 mg / 3 mL and 900 mg / 3 mL dosing kit****400 mg / 2 mL and 600 mg / 2 mL dosing kit**

For the treatment of adult patients with HIV-1 infection who are virologically stable and suppressed (HIV-1 RNA less than 50 copies per mL).

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**CABOZANTINIB (CABOMETYX)****20 mg, 40 mg, and 60 mg tablets****Advanced Hepatocellular Carcinoma**

For the second-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all of the following criteria:

- Disease progression on sorafenib or lenvatinib
- Child-Pugh class status of A
- ECOG performance status of 0 or 1

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and continues to experience clinical benefit.

Clinical Note:

- Treatment should continue until the patient no longer experiences clinical benefit or experiences unacceptable toxicity.

Claim Notes:

- Requests for cabozantinib will not be considered for patients who experience disease progression on regorafenib or immunotherapy (atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab).
- Approval period: 6 months.

**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.

**Metastatic Renal Cell Carcinoma**

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.

**CANAGLIFLOZIN (INVOKANA and generic brands)  
100 mg and 300 mg tablets**

For the treatment of adult patients with type 2 diabetes mellitus when added to:

- metformin for patients who have inadequate glycemic control on metformin; or
- metformin and a sulfonylurea for patients who have inadequate glycemic control on metformin and a sulfonylurea.

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea due to contraindications or intolerances, details must be provided.

**CANAKINUMAB (ILARIS)  
150 mg/mL solution for injection**

For the treatment of active systemic juvenile idiopathic arthritis, in patients 2 years of age or older, who have an inadequate response or intolerance to systemic corticosteroids (with or without methotrexate) and tocilizumab.

Clinical Note:

- Intolerance is defined as a serious adverse effect as described in the product monograph. The nature of the intolerance(s) must be clearly documented.

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.
- Approvals will be for 4 mg/kg for patients weighing more than 9 kg, to a maximum of 300 mg, administered every four weeks.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. 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](#).

**CAPIVASERTIB (TRUQAP)**  
**160 mg and 200 mg film-coated tablet**

In combination with fulvestrant for the treatment of patients with hormone receptor positive, HER2-negative locally advanced or metastatic breast cancer with one or more PIK3CA / AKT1 / PTEN alterations following disease progression on at least one endocrine based therapy in the metastatic setting, or recurrence during or within 12 months of completing adjuvant endocrine 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 and no active or uncontrolled metastases to the central nervous system.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests will not be considered for patients who have progressed on prior treatment with fulvestrant, received more than 2 lines of hormone therapy, or received more than 1 line of chemotherapy in the metastatic setting.
- 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](#).

**CAPTOPRIL (NOYADA)**  
**5 mg / 5 mL and 25 mg / 5 mL oral solution**

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.

**CARIPRAZINE (VRAYLAR)**  
**1.5 mg, 3 mg, 4.5 mg and 6 mg capsules**

For the treatment of adult patients with schizophrenia.

**Claim Note:**

- Approval period: Long term.

**CEFTOLOZANE AND TAZOBACTAM (ZERBAXA)**  
**1 g / 0.5 g vial**

For the treatment of patients with multidrug-resistant *Pseudomonas aeruginosa* when alternative agents are not an option.

**Claim Notes:**

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**CENOBAMATE (XCOPRI)**  
**12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg tablets**

For the adjunctive treatment of refractory partial-onset seizures in adult patients who are currently receiving two or more antiepileptic drugs and who have had an inadequate response or intolerance to at least three other antiepileptic drugs.

**Claim Notes:**

- The patient must be under the care of a physician experienced in the treatment of epilepsy.
- Approval period: Long term.

**CERITINIB (ZYKADIA)**  
**150 mg Capsule**

As monotherapy treatment for patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who experience disease progression on, or intolerance to, crizotinib.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests for ceritinib will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with alectinib.
- Approval: 1 year.

**CERLIPONASE ALFA (BRINEURA)**

**150 mg / 5 mL solution for intracerebroventricular infusion**

For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, if all of the following criteria are met:

- Confirmed diagnosis of CLN2 disease based on tripeptidyl peptidase 1 (TPP1) enzyme activity and CLN2 genotype analysis
- Score of greater than or equal to 1 in each of the motor and language domains of the CLN2 Clinical Rating Scale
- Aggregate motor-language score of greater than or equal to 3 on the CLN2 Clinical Rating Scale

Discontinuation Criteria:

- Reduction of greater than or equal to 2 points in the aggregate motor–language score of the CLN2 Clinical Rating Scale that is maintained over any two consecutive 24-week assessments; or
- Aggregate motor–language score of 0 on the CLN2 Clinical Rating Scale at two consecutive 24-week assessments.

Clinical Note:

- Documentation of the most recent motor and language domain scores of the CLN2 Clinical Rating Scale must be provided with all requests.

Claim Notes:

- Must be prescribed by, or in consultation with, a specialist with experience in the treatment of CLN2 disease.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**CERTOLIZUMAB PEGOL (CIMZIA)**

**200 mg/mL autoinjector and prefilled syringe**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitor will not be reimbursed.
- Approvals will be for a maximum of 400 mg at weeks 0, 2, and 4, then 200 mg every two weeks (or 400 mg every four weeks).
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 400 mg at weeks 0, 2, and 4, then 200 mg every two weeks (or 400 mg every four weeks).
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued 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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 400 mg at weeks 0, 2, and 4, then 200 mg every two weeks (or 400 mg every four weeks)
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**CETIRIZINE (REACTINE and generic brands)  
20 mg film-coated tablet**

For the treatment of patients with moderate to severe chronic urticaria who have had hives, angioedema, or both for at least six weeks.

Claim Note:

- Approval period: Long term.

**CIPROFLOXACIN (CILOXAN and generic brand)  
0.3% ophthalmic solution  
0.3% ophthalmic ointment**

- For the treatment of ophthalmic infections caused by susceptible bacteria.
- For the prevention of ophthalmic infections associated with non-elective eye surgery.

Claim Note:

- Prescriptions written by ophthalmologists and prescribing optometrists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.

**CIPROFLOXACIN (CIPRO and generic brands)  
250 mg, 500 mg and 750 mg tablets**

1. For the treatment of patients with any of the following:
  - Acute exacerbations of chronic obstructive pulmonary disease who are at risk of Pseudomonas infection
  - Bacterial prostatitis
  - Cystic fibrosis-related pulmonary infections
  - Febrile neutropenia
  - Gram-negative infections (e.g., osteomyelitis, joint infections) which are resistant to other oral antibacterials
  - Infections with Pseudomonas aeruginosa (susceptible strains).
  - Severe bacterial gastroenteritis when other antibacterials (e.g., macrolides, sulfamethoxazole/trimethoprim) are ineffective, not tolerated, or contraindicated
  - Severe ("malignant") otitis externa
  - Urinary tract infections or acute uncomplicated pyelonephritis when caused by resistant bacteria or when other antibacterials are ineffective, not tolerated or are contraindicated
2. For chemoprophylaxis of close contacts of a patient with invasive meningococcal disease.
3. For the prevention of endophthalmitis in patients who have had cataract surgery with unplanned vitrectomy.

Claim Notes:

- Prescriptions written by infectious disease specialists, internal medicine specialists, hematologists, medical microbiologists, oncologists, oncology clinical associates, or general practitioners in oncology, respirologists or urologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Ciprofloxacin 250 mg, 500 mg, and 750 mg tablets are regular benefits for beneficiaries of Plan B.

**CIPROFLOXACIN (CIPRO)  
500 mg / 5 mL oral suspension**

For use in patients when oral tablets are not an option and who otherwise meet special authorization criteria for ciprofloxacin tablets.

Claim Note:

- Prescriptions written by infectious disease specialists, internal medicine specialists, hematologists, medical microbiologists, oncologists, oncology clinical associates, or general practitioners in oncology, respirologists or urologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.

**CLADRIBINE (MAVENCLAD and generic brand)  
10 mg tablet**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past year
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
- Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab)

Clinical Notes:

1. Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
2. A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

Claim Notes:

- Must be prescribed by a neurologist.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approvals will be for 1.75 mg/kg to a maximum of 200 mg per treatment year.
- Approval period: 2 years.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**COBIMETINIB (COTELLIC)  
20 mg tablet**

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with vemurafenib.

**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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Cobimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

**CODEINE (CODEINE CONTIN)  
50 mg, 100 mg, 150 mg, and 200 mg controlled release tablets**

For the treatment of cancer-related or chronic non-cancer pain in patients previously treated with an immediate-release codeine product.

**Claim Notes:**

- Approvals will be for a maximum of 200 mg twice daily.
- Approval period: 1 year.

**CRIZOTINIB (XALKORI)  
200 mg and 250 mg capsules**

1. For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer when used as:
  - first-line therapy, or
  - second-line therapy following chemotherapy.
2. As monotherapy for the first-line treatment of patients with ROS1-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

**Renewal Criteria:**

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

**Clinical Note:**

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

**Claim Notes:**

- Requests for crizotinib will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with alectinib.
- Approval period: 1 year.

**CYCLOSPORINE (VERKAZIA)  
0.1% ophthalmic emulsion**

For the treatment of pediatric patients between the age of 4 and 18 years of age with severe vernal keratoconjunctivitis (VKC) who meet the following criteria:

- Grade 3 (severe) or 4 (very severe) on the Bonini scale, or
- Grade 4 (marked) or 5 (severe) on the modified Oxford scale.

**Discontinuation Criteria:**

- Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed, or
- Treatment should be discontinued if signs and symptoms of VKC have resolved.

**Clinical Note:**

- Documentation of the severity of signs and symptoms of VKC at treatment initiation and renewal must be provided.

Claim Notes:

- The patient must be under the care of a physician experienced in the diagnosis and treatment of VKC.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**CYSTEAMINE (CYSTADROPS)  
0.37% ophthalmic solution**

For the treatment of corneal cystine crystal deposits (CCCDs) in patients 2 years of age and older with cystinosis.

Clinical Note:

- Diagnosis of cystinosis confirmed by cystinosis (lysosomal cystine transporter) gene mutation or elevated white blood cell cystine levels. Documentation must be provided.

Claim Note:

- Must be prescribed by an ophthalmologist experienced in the treatment of CCCDs.

**CYSTEAMINE (PROCYSBI)  
25 mg and 75 mg delayed-release capsules**

For the treatment of infantile nephropathic cystinosis with documented cystinosis (lysosomal cystine transporter) gene mutation or elevated white blood cell cystine levels.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician with experience in the diagnosis and management of cystinosis.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**DABIGATRAN ETEXILATE (generic brand)  
110 mg and 150 mg capsules**

For the prevention of stroke and systemic embolism in patients with atrial fibrillation.

Claim Note:

- Approval period: Long term

**DABRAFENIB (TAFINLAR)  
50 mg and 75 mg capsules**

**Adjuvant Melanoma**

In combination with trametinib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8<sup>th</sup> edition)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

Claim Notes:

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Patients with a pathological partial or nonresponse after neoadjuvant immunotherapy are eligible for up to 11 months of adjuvant BRAF targeted therapy.
- Approval period: Up to 12 months.

**Metastatic Melanoma**

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with trametinib.

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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Dabrafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

**DALTEPARIN (FRAGMIN)**

**12,500 IU/mL prefilled syringe**

**25,000 IU/mL multidose vial and prefilled syringe**

1. For the treatment of venous thromboembolism (VTE) and/or pulmonary embolism (PE) for a maximum of 30 days.
2. For the extended treatment of recurrent symptomatic venous thromboembolism (VTE) that has occurred while patients are on therapeutic doses of warfarin.
3. For the prophylaxis of venous thromboembolism (VTE) up to 35 days following elective hip replacement or hip fracture surgery.
4. For the prophylaxis of VTE up to 14 days following elective knee replacement surgery.
5. For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumour for up to 28 days.
6. For the treatment and secondary prevention of symptomatic venous thromboembolism (VTE) or pulmonary embolism (PE) for a period of up to 6 months in patients with cancer for whom warfarin therapy is not an option.

Claim Note:

- An annual quantity of 35 days of therapy is available without special authorization.

**DAPTOMYCIN (CUBICIN RF and generic brands)**

**500 mg single-use vial**

For the treatment of patients with resistant gram-positive infections, including methicillin-resistant *Staphylococcus aureus* (MRSA) who failed to respond, or have a contraindication or intolerance to vancomycin, or for whom IV vancomycin is not appropriate.

Clinical Note:

- Daptomycin is inhibited by pulmonary surfactant and should not be used to treat respiratory tract infections.

Claim Note:

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

**DARBEPOETIN ALFA (ARANESP)**

**10 mcg / 0.4 mL, 20 mcg / 0.5 mL, 30 mcg / 0.3 mL, 40 mcg / 0.4 mL, 50 mcg / 0.5 mL, 60 mcg / 0.3 mL, 80 mcg / 0.4 mL, 100 mcg / 0.5 mL, 130 mcg / 0.65 mL, 150 mcg / 0.3 mL, 200 mcg / 0.4 mL, 300 mcg / 0.6 mL and 500 mcg/mL prefilled syringes**

1. For the treatment of anemia associated with chronic renal failure.

Claim Notes:

- Patients on dialysis (end-stage renal disease) receive darbepoetin through the dialysis units.
- Approval period: Long term.

2. For the treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are  $\geq 2$  units of packed red blood cells per month over 3 months.

Renewal Criteria:

- Written confirmation of a satisfactory clinical response or a reduction in transfusion requirements.

Claim Notes:

- Initial approval period: 12 weeks.
- Renewal approval period: 1 year.

**DAROLUTAMIDE (NUBEQA)  
300 mg film-coated tablet**

**Non-Metastatic Castration-Resistant Prostate Cancer**

In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer who have a prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases).

**Renewal Criteria:**

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

**Clinical Notes:**

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with darolutamide.
3. Patients must have a good performance status.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests for darolutamide will not be considered for patients who experience disease progression on apalutamide or enzalutamide.
- Approval period: 1 year.

**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.

**DARUNAVIR AND COBICISTAT (PREZCOBIX)  
800 mg / 150 mg film-coated tablet**

For treatment of HIV-1 infection in treatment-naïve and treatment-experienced patients without darunavir resistance-associated mutations.

**Claim Notes:**

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**DASATINIB (SPRYCEL and generic brands)  
20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg tablets**

1. For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic, accelerated, or blast phase.
2. For the treatment of patients with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).

**Renewal Criteria:**

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

**Claim Note:**

- Approval period: 1 year.

**DECITABINE / CEDAZURIDINE (INQOVI)  
35 mg / 100 mg tablet**

For the treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria:

- De novo or secondary MDS including all French-American-British subtypes (i.e., refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia)
- Intermediate-1, intermediate-2, or high-risk MDS, according to the International Prognostic Scoring System
- Have not experienced disease progression on a hypomethylating agent

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 Note:

- Approval period: 1 year.

**DEFERASIROX (JADENU and generic brands)  
90 mg, 180 mg and 360 mg film-coated tablets**

For the treatment of chronic iron overload.

**DEFERIPRONE (FERRIPROX and generic brand)  
1000 mg tablet and 100 mg/mL oral solution  
DEFERIPRONE (FERRIPROX MR)  
1000 mg extended-release tablet**

For the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Claim Note:

- Combined use of more than one iron chelating therapy will not be reimbursed.

**DENOSUMAB (JUBBONTI and STOBOCLO)  
60 mg/mL prefilled syringe**

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  $\geq 5$  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 risk of fracture based on a clinician's evaluation of the individual's risk of fractures that may include prior fragility fracture history and the Fracture Risk Assessment (FRAX) scores or another validated tool.

Claim Note:

- Approval period: Long term.

**DENOSUMAB (OSENVELT and WYOST)  
120 mg / 1.7 mL single-use vial**

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.

**DESMOPRESSIN (generic brands)  
0.1 mg and 0.2 mg tablets  
DESMOPRESSIN (DDAVP MELT)  
60 mcg and 120 mcg orally disintegrating tablets**

- For the management of diabetes insipidus.
- For the treatment of patients 18 years and older with nocturnal enuresis.

Claim Note:

- Desmopressin oral formulations are a regular benefit for Plans CDEF-18G.

**DESMOPRESSIN (generic brand)  
10 mcg metered dose nasal spray**

For the treatment of patients with diabetes insipidus.

Clinical Note:

- The nasal formulations are no longer indicated for nocturnal enuresis due to the risk of hyponatremia.

**DIENOGEST (VISANNE and generic brands)  
2 mg tablet**

For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or cannot be used.

Clinical Note:

- Continuous combined oral contraceptives and medroxyprogesterone are examples of less costly hormonal options.

**DIMETHYL FUMARATE (TECFIDERA and generic brands)  
120 mg and 240 mg delayed-release capsules**

**Radiologically Isolated Syndrome**

For the treatment of adult patients with a confirmed diagnosis of radiologically isolated syndrome (RIS) based on the most recent McDonald criteria.

Claim Notes:

- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat RIS will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.

**Relapsing Remitting Multiple Sclerosis**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Approval Period: 2 years.

**DORNASE ALFA (PULMOZYME)  
1 mg/mL solution**

For the treatment of patients with cystic fibrosis with clinical evidence of lung disease (e.g., frequent pulmonary exacerbations, FEV<sub>1</sub> less than 90% predicted, difficulty clearing secretions).

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACBDEFGV
- Approval period: Long term.

**DOLUTEGRAVIR AND RILPIVIRINE (JULUCA)  
50 mg / 25 mg tablet**

As a complete regimen to replace the current antiretroviral regimen for the treatment of HIV-1 infection in adult patients who are virologically stable and suppressed (i.e. HIV-1 RNA less than 50 copies per mL).

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**DORAVIRINE (PIFELTRO)  
100 mg tablet**

For use in combination with other antiretrovirals in adult patients with HIV-1 infection, who have no known mutations associated with resistance to doravirine.

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**DULOXETINE (CYMBALTA and generic brands)  
30 mg and 60 mg delayed release capsules**

**Chronic Pain**

For the treatment of patients with chronic pain.

Claim Note:

- The maximum dose reimbursed is 60 mg daily.

**Major Depressive Disorder**

For the treatment of major depressive disorder in patients 18 years and older, who have failed treatment with at least one less costly antidepressant.

Claim Note:

- The maximum dose reimbursed is 60 mg daily.

**DUPILUMAB (DUPIXENT)  
200 mg / 1.14 mL and 300 mg / 2 mL autoinjector and prefilled syringe**

**Asthma**

1. For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype in patients aged 6 to 11 years of age who are inadequately controlled with medium-to high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) or high-dose ICS alone and meet the following criteria:
  - blood eosinophil count  $\geq 0.15 \times 10^9/L$  within the past 12 months; and
  - uncontrolled asthma with at least one clinically significant asthma exacerbation in the past 12 months.

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- The 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
- The 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. Medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 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 pediatric respirologist or allergist experienced in the treatment of severe asthma.
  - Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
  - Approvals will be for a maximum of 200 mg every two weeks or 300 mg every four weeks.
  - Approval period: 1 year.
2. For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS) dependent severe asthma in patients 12 years of age and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) and meets one of the following criteria:
    - blood eosinophil count  $\geq 0.15 \times 10^9/L$  within the past 12 months, or
    - have OCS dependent asthma.

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 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 dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Approval period: 1 year.

**Atopic Dermatitis**

For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all of the following criteria:

- Refractory or have contraindications to an adequate trial of topical prescription therapies combined with phototherapy (where available)
- Refractory, intolerant or have contraindications to an adequate trial of methotrexate, cyclosporine, mycophenolic acid, or azathioprine
- Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1 or greater.

Renewal Criteria:

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

Claim Notes:

- Must be prescribed by a dermatologist, pediatrician or clinical immunologist with experience in the treatment of moderate to severe AD.

- Combined use of more than one immunomodulatory drug (e.g., biologics or janus kinase inhibitors) for the treatment of moderate to severe AD will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**ECULIZUMAB (SOLIRIS)**  
**300 mg / 30 mL single-use vial**

For the treatment of paroxysmal nocturnal hemoglobinuria (PNH).

Clinical Notes:

1. A Request for Coverage including the completed consent and specific special authorization forms must be submitted and the patient must:
  - a) Satisfy the Clinical Criteria for eculizumab (initial or continued coverage, as appropriate);
  - b) Not meet any of the criteria specified in Contraindications to Coverage or Discontinuance of Coverage.
2. Please contact the NB Drug Plans at 1-800-332-3691 for a packet containing the Clinical Criteria and required forms.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**EDARAVONE (RADICAVA)**  
**105 mg / 5 mL oral solution**

For the treatment of patients with probable or definite amyotrophic lateral sclerosis (ALS) who meet all the following criteria:

- ALS Functional Rating Scale – Revised (ALSFRS-R) score of at least two points on each item
- Forced vital capacity (FVC) greater than or equal to 80% of predicted
- ALS symptoms for two years or less
- Permanent non-invasive or invasive ventilation is not required

Discontinuation Criteria:

- The patient is non-ambulatory (ALSFRS-R score less than or equal to 1 for item 8) and unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy tube is in place (ALSFRS-R score less than 1 for item 5a or 5b); or
- The patient requires permanent non-invasive or invasive ventilation.

Clinical Note:

- ALSFRS-R scores and FVC must be provided.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician with experience in the diagnosis and management of ALS.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**ELEXACAFTOR / TEZACAFTOR / IVACAFTOR and IVACAFTOR (TRIKAFTA)**  
**80 mg / 40 mg / 60 mg granules and 59.5 mg granules**  
**100 mg / 50 mg / 75 mg granules and 75 mg granules**

For the treatment of cystic fibrosis (CF) in patients aged 2 to 5 years of age who have at least one eligible mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor, tezacaftor and ivacaftor based on clinical and/or in vitro data.

Initial Renewal Criteria:

The patient must meet one of the following criteria:

- Decrease in the total number of days for which the patient received treatment with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment.
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment.
- No decrease in Body Mass Index (BMI) z-score compared with baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit must be provided for at least one of the parameters noted above at the end of each 12-month period.

Clinical Notes:

1. Eligible mutations include F508del and other mutations as listed in the Trikafta product monograph.
2. The following baseline measurements must be provided prior to initiation of treatment:
  - Total number of days treated with oral and/or 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
  - BMI z-score
3. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans DFG.
- 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.
- 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](#).

**ELEXACAFTOR / TEZACAFTOR / IVACAFTOR and IVACAFTOR (TRIKAFTA)  
50 mg / 25 mg / 37.5 mg tablets and 75 mg tablets  
100 mg / 50 mg / 75 mg tablets and 150 mg tablets**

For the treatment of cystic fibrosis (CF) in patients 6 years of age and older who have at least one eligible mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor, tezacaftor and ivacaftor based on clinical and/or in vitro data.

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 intravenous (IV) antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment.
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment.
- Decrease in the number of CF-related hospitalizations compared with the 6-month period prior to initiating treatment.
- No decrease in Body Mass Index (BMI) or BMI z-score for children at 6-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 for at least one of the parameters noted above at the end of each 12-month period.

Clinical Notes:

1. Eligible mutations include F508del and other mutations as listed in the Trikafta product monograph.
2. The following baseline measurements must be provided prior to initiation of treatment:
  - ppFEV1 measured within the 3-month period prior to initiation of treatment
  - Total number of days treated with oral and/or 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 or BMI z-score for children
  - CFQ-R Respiratory Domain score
3. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- 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](#).

**ELOSULFASE ALFA (VIMIZIM)**  
**5 mg / 5 mL single-use vial**

For the treatment of patients with mucopolysaccharidosis type IVA (MPS IVA).

Clinical Note:

- Please contact the NB Drug Plans at 1-800-332-3691 for the complete criteria.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**EMPAGLIFLOZIN (JARDIANCE)**  
**10 mg and 25 mg tablets**

1. For the treatment of adult patients with type 2 diabetes mellitus when added to:
  - metformin for patients who have inadequate glycemic control on metformin; or
  - metformin and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea.
2. As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular death in patients with type 2 diabetes mellitus who have:
  - inadequate glycemic control despite an adequate trial of metformin, or a contraindication or intolerance to metformin; and
  - established cardiovascular disease.

Clinical Notes:

1. For patients who cannot take metformin and/or a sulfonylurea due to contraindications or intolerances, details must be provided.
2. Established cardiovascular disease is defined as one of the following (details must be provided):
  - History of myocardial infarction (MI).
  - Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status).
  - Single-vessel coronary artery disease with significant stenosis and a positive non-invasive stress test.
  - Unstable angina with either coronary multi-vessel or single-vessel disease.
  - History of ischemic or hemorrhagic stroke.
  - Occlusive peripheral artery disease.

**EMPAGLIFLOZIN AND METFORMIN (SYNJARDY)**  
**5 mg / 500 mg, 5 mg / 850 mg, 5 mg / 1000 mg, 12.5 mg / 500 mg, 12.5 mg / 850 mg and 12.5 mg / 1000 mg tablets**

For the treatment of type 2 diabetes mellitus in patients who are already stabilized on therapy with empagliflozin and metformin, to replace the individual components of empagliflozin and metformin.

**EMTRICITABINE, RILPIVIRINE AND TENOFOVIR ALAFENAMIDE (ODEFSEY)**  
**200 mg / 25 mg / 25 mg tablet**

For the treatment of adult patients with HIV-1 infection who meet the following criteria:

- No known mutations associated with resistance to tenofovir, emtricitabine or non-nucleoside reverse transcriptase inhibitor (NNRTI) class.
- Viral load less than or equal to 100,000 copies/mL

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**EMTRICITABINE, TENOFOVIR ALAFENAMIDE, ELVITEGRAVIR AND COBICISTAT (GENVOYA)**  
**200 mg / 10 mg / 150 mg / 150 mg tablet**

For the treatment of HIV-1 infection in patients 12 years of age and older (weighing at least 35kg) with no known mutations associated with resistance to the individual components of Genvoya.

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**EMTRICITABINE, TENOFOVIR DISOPROXIL, ELVITEGRAVIR AND COBICISTAT (STRIBILD)  
200 mg / 300 mg / 150 mg / 150 mg tablet**

As a complete regimen for antiretroviral treatment naïve HIV-1 infected patients in whom efavirenz is not indicated.

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**ENCORAFENIB (BRAFTOVI)  
75 mg capsule**

**Metastatic Colorectal Cancer**

In combination with panitumumab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria:

- Presence of BRAF V600E mutation
- Disease progression following at least one prior therapy in the metastatic setting
- No previous treatment with an EGFR inhibitor

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:

- Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Approval period: 6 months.

**Metastatic Melanoma**

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with binimetinib.

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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

**ENTRECTINIB (ROZLYTREK)  
100 mg and 200 mg capsules**

**Non-Small Cell Lung Cancer**

As monotherapy for the first-line treatment of patients with ROS1-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer.

Renewal Criteria:

- Written confirmation that the patient is responding 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 Note:

- Approval period: 1 year.

### **Solid Tumours with NTRK gene fusion**

As monotherapy for the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumours who meet all of the following criteria:

- Tumours have a NTRK gene fusion without a known acquired resistance mutation
- No other satisfactory treatment options
- Not a candidate for surgery and/or radiation due to risk of substantial morbidity

Renewal Criteria:

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

Clinical Notes:

1. Patients must have a good performance status.
2. If central nervous system metastases are present, patients must be asymptomatic.
3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a NTRK inhibitor.
- Approval period: 6 months.

### **ENZALUTAMIDE (XTANDI and generic brands) 40 mg capsule**

#### **Metastatic Castration-Resistant Prostate Cancer**

For the treatment of patients with metastatic castration-resistant prostate cancer.

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 risk factors for seizures.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide.
- Approval period: 1 year.

#### **Metastatic Castration-Sensitive Prostate Cancer**

In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) 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 no risk factors for seizures.
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 darolutamide are not eligible.
- Approval period: 1 year.

#### **Non-Metastatic Castration-Resistant Prostate Cancer**

In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer who have a prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases).

Renewal Criteria:

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

Clinical Notes:

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with enzalutamide.
3. Patients must have a good performance status and no risk factors for seizures.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide or darolutamide.
- Approval period: 1 year.

**Non-Metastatic Castration-Sensitive Prostate Cancer**

As monotherapy, or in combination with androgen deprivation therapy, for the treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence after radical prostatectomy (RP) or radiation therapy (RT) who are at high risk of metastasis and meet all of the following criteria:

- Prostate-specific antigen (PSA) doubling time of 9 months or less
- Screening PSA level of 1 mcg/L or higher after RP (with or without postoperative RT) or PSA level at least 2 mcg/L above nadir after RT
- Testosterone level of 5.2 nmol/L (150 ng/dL) or higher

Renewal Criteria:

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

Clinical Notes:

1. Patient must have a good performance status and no evidence of metastases on imaging.
2. Patients who are candidates for salvage radiation therapy following RP are not eligible for enzalutamide.
3. Treatment should be held after 36 weeks if PSA level is suppressed to less than 0.2 mcg/L. Enzalutamide may be restarted if PSA increases to at least 5 mcg/L in patients with no prior RP or if PSA increases to at least 2 mcg/L in patients with prior RP. Enzalutamide should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

**EPLERENONE (INSPRA and generic brands)  
25 mg and 50 mg tablets**

For the treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction less than or equal to 40%), as an adjunct to standard care therapy.

Clinical Note:

- Patients must be on optimal therapy with an angiotensin-converting-enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB), and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

**EPLONTERSEN (WAINUA)  
45 mg / 0.8 mL autoinjector**

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.
- Approvals will be for a maximum of 45 mg once a month.
- 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](#).

#### **EPOETIN ALFA (EPREX)**

**1,000 IU / 0.5 mL, 2,000 IU / 0.5 mL, 3,000 IU / 0.3 mL, 4,000 IU / 0.4 mL, 5,000 IU / 0.5 mL, 6,000 IU / 0.6 mL, 8,000 IU / 0.8 mL, 10,000 IU/mL, 20,000 IU/mL, 30,000 IU / 0.75 mL and 40,000 IU/mL prefilled syringes**

1. Treatment of anemia associated with chronic renal failure.

##### Claim Notes:

- Patients on dialysis (end-stage renal disease) receive epoetin through the dialysis units.
- Approval period: Long term.

2. Treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are  $\geq 2$  units of packed red blood cells per month over 3 months.

##### Renewal Criteria:

- Written confirmation of a satisfactory clinical response or a reduction in transfusion requirements.

##### Claim Notes:

- Initial approval period: 12 weeks.
- Renewal approval period: 1 year.

#### **EPOPROSTENOL (CARIPUL and FLOLAN)**

**0.5 mg and 1.5 mg vials**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class III or IV.

##### Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

##### Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Approval period: Long term.

#### **EPTINEZUMAB (VYEPTI)**

**100 mg and 300 mg vial**

For the prevention of migraine in adult patients with a confirmed diagnosis of episodic or chronic migraine who are refractory, intolerant or have contraindications to at least two classes of oral prophylactic migraine medications.

##### Renewal Criteria:

- A reduction of at least 50% in the average number of migraine days per month at the time of initial renewal compared with baseline.
- At subsequent renewals, the patient continues to maintain the reduction of at least 50% in average number of migraine days per month.

##### Clinical Notes:

1. The average number of headache days per month and migraine days per month must be provided on initial and renewal requests.
2. According to the International Headache Society criteria, episodic or chronic migraine are defined as:
  - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
  - Chronic migraine: migraine headaches on at least 8 days per month and more than 15 headache days per month for more than 3 months.

##### Claim Notes:

- Combined use with other calcitonin gene-related peptide (CGRP) antagonists will not be reimbursed.
- Approvals will be for a maximum of 1 vial every 12 weeks.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**ERDAFITINIB (BALVERSA)  
3 mg, 4 mg and 5 mg tablets**

For the treatment of adult patients with locally advanced unresectable or metastatic urothelial carcinoma who meet all of the following criteria:

- Confirmation of a susceptible FGFR3 genetic alteration using a validated test
- Disease progression during or following at least one prior line of therapy for advanced disease, or disease recurrence during or within 12 months of neoadjuvant or adjuvant therapy
- Previously treated with PD-1 or PD-L1 inhibitor therapy or unable to receive due to contraindication

Renewal Criteria:

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

Clinical Note:

- 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](#).

**ESLICARBAZEPINE (APTIOM and generic brands)  
200 mg, 400 mg, 600 mg and 800 mg tablets**

For the adjunctive treatment of refractory partial-onset seizures in patients who are currently receiving two or more antiepileptic drugs and have had an inadequate response or intolerance to at least three other antiepileptic drugs.

Claim Note:

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

**ETANERCEPT**

**Brenzys 50 mg/mL autoinjector and prefilled syringe**

**Erelzi 25 mg / 0.5 mL prefilled syringe and 50 mg/mL autoinjector and prefilled syringe**

**Rymti 50 mg/mL autoinjector and prefilled syringe**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitor 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 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 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 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 0.8 mg/kg, up to 50 mg 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 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 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 with other biologic drugs or janus kinase inhibitors 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 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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors 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. Confirmation of response is required.

**ETRASIMOD (VELSIPITY)  
2 mg tablet**

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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum of 2 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of continued response is required.

**ETRAVIRINE (INTELENCE)  
100 mg and 200 mg tablets**

For the treatment of HIV-1 infection in patients who are antiretroviral experienced and have virologic failure due to HIV-1 strains resistant to multiple antiretroviral agents, including other non-nucleoside reverse transcriptase inhibitors.

**EVEROLIMUS (AFINITOR and generic brands)  
2.5 mg, 5 mg and 10 mg tablets**

**Advanced Breast Cancer**

For the treatment of hormone-receptor positive, HER2 negative advanced breast cancer in postmenopausal patients, after recurrence or progression following a non-steroidal aromatase inhibitor, when used in combination with exemestane.

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 Note:

- Approval period: 1 year.

**Metastatic Renal Cell Carcinoma**

For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor 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: 6 months.
- Renewal approval period: 1 year.

**Neuroendocrine Tumours**

1. For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumours (pNET).
2. For the treatment of patients with unresectable, locally advanced or metastatic, well-differentiated, non-functional neuroendocrine tumours (NETs) of gastrointestinal or lung origin (GIL) with documented radiological disease progression within six months.

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 everolimus will not be considered for patients who experience disease progression on sunitinib for pNET.
- Approval period: 1 year.

**EVINACUMAB (EVKEEZA)**

**345 mg / 2.3 mL single-use vial**

For the treatment of homozygous familial hypercholesterolemia (HoFH) in patients aged 5 years and older with a genetically or clinically confirmed diagnosis who have an elevated low density lipoprotein cholesterol (LDL-C) despite an adequate trial of other accessible lipid lowering therapies and who meet the following criteria:

Genetically confirmed diagnosis of HoFH, defined as:

- Documented functional mutation or mutations in both low-density lipoprotein receptor (LDLR) alleles; or
- Documented homozygous or compound heterozygous mutations in apolipoprotein B (Apo B) or proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1), or at least 2 such variants at different loci.

Clinically confirmed diagnosis of HoFH defined as:

- Untreated LDL-C > 10 mmol/L; and
- Both parents with documented untreated elevated total cholesterol (TC) or LDL-C levels, consistent with heterozygous familial hypercholesterolemia (HeFH), or patient with cutaneous or tendinous xanthoma before the age of 10 years.

Renewal Criteria:

- Request for renewal must provide documentation of beneficial clinical effect, defined as at least a 20% reduction in LDL-C from baseline.
- Documentation of maintenance of reduction in LDL-C from baseline must be provided for subsequent renewals.

Clinical Notes:

- The baseline LDL-C must be provided with the initial request for coverage and after all other treatment options of lipid-lowering therapies have been exhausted.
- An elevated LDL-C despite an adequate trial of other accessible lipid lowering therapies is defined as an LDL-C greater than 1.8 mmol/L at baseline for adult patients and greater than 3.4 mmol/L for children.
- Standard of care therapies may include maximally tolerated statins, ezetimibe, and PCSK9 inhibitors.

Claim Notes:

- Must be prescribed by a specialist experienced in the diagnosis and treatment of HoFH.
- Approvals will be for a maximum of 15 mg/kg every 4 weeks.
- Initial approval: 6 months.
- Renewal approval: 1 year.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**EVOLOCUMAB (REPATHA)**  
**140 mg/mL autoinjector**

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
  - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
  - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance

Initial Renewal Criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent Renewal Criteria:

- The patient continues to maintain a reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

1. LDL-C levels must be provided.
2. Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
  - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
  - at least one statin was initiated at the lowest daily starting dose; and
  - other known causes of intolerance have been ruled out.
3. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Approvals will be for a maximum of 140 mg every 2 weeks.
- Combined use with other PCSK9 inhibitors will not be reimbursed.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**FARICIMAB (VABYSMO)**  
**6 mg / 0.05 mL solution for intravitreal injection**

**Diabetic macular edema**

For the treatment of patients with diabetic macular edema who meet all of the following criteria:

- Clinically significant center-involving macular edema for whom laser photocoagulation is also indicated.
- Central retinal thickness greater than or equal to 250 micrometers.

Claim Notes:

- An initial claim of up to two vials (1 vial per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 4 weeks.
- Approval period: 1 year. Confirmation of continued response is required.

**Neovascular (wet) age-related macular degeneration**

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).

Discontinuation Criteria:

- Reduction in Best Corrected Visual Acuity (BCVA) in the treated eye of 15 letters or more on 2 consecutive visits, attributed to AMD in the absence of other pathology, or
- Reduction in BCVA in the treated eye of 30 letters or more compared to either baseline and/or best recorded level, or
- There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Clinical Note:

- BCVA must be provided with initial request and with subsequent renewal requests.

Claim Notes:

- An initial claim of up to two vials (1 vial per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.

- Approvals will be for a maximum of 1 vial per eye every 4 weeks for 16 weeks, followed by 1 vial per eye every 8 weeks thereafter.
- Approval period: 1 year.

**FEBUXOSTAT (generic brands)  
80 mg tablet**

For the treatment of symptomatic gout in patients who are refractory, intolerant or have a contraindication to allopurinol.

**FEDRATINIB (INREBIC)  
100 mg capsule**

For the treatment of splenomegaly and/or disease-related symptoms in adult patients with primary myelofibrosis (MF), post-polycythemia vera MF, or post-essential thrombocythemia MF who meet all of the following criteria:

- Intermediate-2 or high-risk MF as assessed using DIPSS Plus
- A contraindication or intolerance to ruxolitinib

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by a reduction in spleen size or symptom improvement.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued in patients who have progressive increase in spleen size, return of constitutional symptoms or development of serious adverse events.

Claim Notes:

- Requests will not be considered for patients who experience disease progression following treatment with ruxolitinib or momelotinib.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**FENTANYL (generic brands)  
12 mcg/hr, 25 mcg/hr, 37 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr transdermal patch**

For the treatment of cancer-related or chronic non-cancer pain in adult patients who were previously receiving at least 60 mg per day of oral morphine equivalents and who:

- had an inadequate response, intolerance, or contraindication to oral opioids; or
- are unable to take oral therapy.

**FERRIC DERISOMALTOSE (MONOFERRIC)  
100 mg/mL vial**

For the treatment of iron deficiency anemia (IDA) in patients who:

- are intolerant to oral iron replacement products, or
- have not responded to a 4 week trial period of oral iron.

Clinical Notes:

1. IDA is defined as a hemoglobin (Hgb) level  $\leq$  130 g/L and a ferritin level  $\leq$  30 mcg/L or transferrin saturation (TSAT) level  $\leq$  30%.
2. The most recent Hgb and ferritin/TSAT must be provided with the request.

**FESOTERODINE (TOVIAZ and generic brand)  
4 mg and 8 mg extended-release tablets**

For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of a regular benefit OAB drug (e.g. immediate-release oxybutynin, solifenacin or tolterodine).

Clinical Notes:

1. Requests for the treatment of stress incontinence will not be considered.
2. Not to be used in combination with other pharmacological treatments of OAB.

**FIDAXOMICIN (DIFICID)  
200 mg film-coated tablet**

For the treatment of patients with Clostridium difficile infection (CDI), where the patient has:

- a second or subsequent recurrence following treatment with oral vancomycin; or
- treatment failure with oral vancomycin for the current CDI episode; or
- an intolerance or contraindication to oral vancomycin.

Re-treatment Criteria:

- Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

Clinical Notes:

1. Treatment failure is defined as 14 days of vancomycin therapy without acceptable clinical improvement.
2. Intolerance is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Should be prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist.
- Requests will be approved for 200 mg twice a day for 10 days.

**FILGRASTIM**

**Grastofil 300 mcg / 0.5 mL and 480 mcg / 0.8 mL prefilled syringe**

**Nivestym 300 mcg / 0.5 mL and 480 mcg / 0.8 mL prefilled syringe, 300 mcg/mL and 480 mcg / 1.6 mL vial**

**Nypozi 300 mcg / 0.5 mL and 480 mcg / 0.8 mL prefilled syringe**

**Chemotherapy Support**

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 filgrastim for prevention of febrile neutropenia.

**Non-Malignant Indications**

- To increase neutrophil count and reduce the incidence and duration of infection in patients with congenital, idiopathic or cyclic neutropenia.
- For the prevention and treatment of neutropenia in patients with HIV infection.

**Stem Cell Transplantation Support**

- For mobilization of peripheral blood progenitor cells for the purpose of stem cell transplantation.
- To enhance engraftment following stem cell transplantation.

Claim Note:

- All requests for coverage of filgrastim will be approved for the biosimilar versions only.

**FINERENONE (KERENDIA)**

**10 mg and 20 mg tablets**

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 (CKD) 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<sup>2</sup>
- 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<sup>2</sup> or if the UACR has increased from baseline.

Claim Notes:

- Must be prescribed by a clinician with experience in the diagnosis and management of patients with CKD and type 2 diabetes mellitus, 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.

**FINGOLIMOD (generic brands)  
0.5 mg capsule**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Approval period: 2 years.

**FLUCONAZOLE (DIFLUCAN)  
50 mg / 5 mL powder for oral suspension**

For the treatment of patients who have:

- oropharyngeal candidiasis which failed to respond to nystatin, or
- systemic infections and oral fluconazole tablets are not an option.

**FLUOROURACIL (generic brand)  
5 g vial**

When compounded as an ophthalmic drop for the treatment of patients with one of the following ocular malignancies:

- Malignant melanoma of the conjunctiva
- Ocular surface squamous neoplasia (also known as conjunctival-corneal intraepithelial neoplasia)

Renewal Criteria:

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

Claim Notes:

- Must be prescribed by an ophthalmologist or oncologist.
- Approval period: 6 months.

**FLUOXETINE (generic brands)  
20 mg / 5 mL oral solution**

For use in patients for whom oral capsules are not an option.

**FOSFOMYCIN (MONUROL and generic brand)  
3 g sachet**

For the treatment of uncomplicated urinary tract infections in adult female patients where:

- The infecting organism is resistant to other oral agents, OR
- Other less costly agents are not tolerated.

Clinical Note:

- Fosfomycin is not indicated in the treatment of pyelonephritis or perinephric abscess.

**FOSLEVODOPA/FOSCARBIDOPA (VYALEV)  
240 mg/mL / 12 mg/mL vial**

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](#).

**FREMANEZUMAB (AJOVY)  
225 mg / 1.5 mL autoinjector and prefilled syringe**

For the prevention of migraine in adult patients with a confirmed diagnosis of episodic or chronic migraine who are refractory, intolerant or have contraindications to at least two classes of oral prophylactic migraine medications.

**Renewal Criteria:**

- A reduction of at least 50% in the average number of migraine days per month at the time of initial renewal compared with baseline.
- At subsequent renewals, the patient continues to maintain the reduction of at least 50% in average number of migraine days per month.

**Clinical Notes:**

1. The average number of headache days per month and migraine days per month must be provided on initial and renewal requests.
2. According to the International Headache Society criteria, episodic or chronic migraine are defined as:
  - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
  - Chronic migraine: migraine headaches on at least 8 days per month and more than 15 headache days per month for more than 3 months.

**Claim Notes:**

- Combined use with other calcitonin gene-related peptide (CGRP) antagonists will not be reimbursed
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**FRUQUINTINIB (FRUZAQLA)  
1 mg and 5 mg capsules**

For the treatment of adult patients with metastatic colorectal adenocarcinoma who have been previously treated with or are not considered candidates for the following therapies:

- fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- anti-VEGF therapy
- anti-EGFR therapy (if RAS wild-type)
- trifluridine-tipiracil-based therapy
- immune checkpoint inhibitor (if MSI-H or dMMR tumour)
- BRAF inhibitor (if BRAF-mutant tumour)

**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:

- Requests will be considered for patients with small bowel or appendiceal adenocarcinoma.
- Patients who experience disease progression during or within 6 months of completing neoadjuvant/adjuvant chemotherapy may be considered as having received one prior chemotherapy regimen for advanced disease.
- Approval period: 6 months.

**GALCANEZUMAB (EMGALITY)**  
**120 mg/mL autoinjector and prefilled syringe**

For the prevention of migraine in adult patients with a confirmed diagnosis of episodic or chronic migraine who are refractory, intolerant or have contraindications to at least two classes of oral prophylactic migraine medications.

Renewal Criteria:

- A reduction of at least 50% in the average number of migraine days per month at the time of initial renewal compared with baseline.
- At subsequent renewals, the patient continues to maintain the reduction of at least 50% in average number of migraine days per month.

Clinical Notes:

1. The average number of headache days per month and migraine days per month must be provided on initial and renewal requests.
2. According to the International Headache Society criteria, episodic or chronic migraine are defined as:
  - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
  - Chronic migraine: migraine headaches on at least 8 days per month and more than 15 headache days per month for more than 3 months.

Claim Notes:

- Combined use with other calcitonin gene-related peptide (CGRP) antagonists will not be reimbursed.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**GILTERITINIB (XOSPATA)**  
**40 mg tablet**

As monotherapy for the treatment of adult patients with relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia who meet all of the following criteria:

- Confirmed positive for FLT3 mutation at the time of relapse or determination of refractory disease
- Presence of FLT3-ITD, FLT3-TKD/D835 or FLT3-TKD/I836 mutation

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs.

Claim Notes:

- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**GIVOSIRAN (GIVLAARI)**  
**189 mg/mL single-use vial**

For the treatment of acute hepatic porphyria (AHP) in adult patients who meet all of the following criteria:

- Diagnosis of AHP confirmed by urinary delta-aminolevulinic acid (ALA), urinary porphobilinogen (PBG), or genetic testing
- Four or more porphyria attacks requiring either hospitalization, an urgent health care visit, or IV hemin in the year prior to initiating treatment with givosiran

Renewal Criteria:

- A reduction in the annualized attack rate of attacks that required hospitalization, an urgent health care visit, or IV hemin after 12 months of therapy compared to baseline.

Clinical Notes:

1. Documentation of a confirmed diagnosis of AHP must be provided.

- The number of porphyria attacks within the year prior to initiation of givosiran, including the approximate dates and the management of each attack (i.e., hospitalization, urgent health care visit, IV hemin) must be provided on the initial request.
- The annualized attack rate (i.e., the number of attacks over a specific time period) must be provided on each renewal request.

**Claim Notes:**

- Must be prescribed by a clinician experienced in the management of AHP.
- Requests for givosiran in combination with prophylactic hemin will not be considered.
- Approvals will be for a maximum of 2.5 mg/kg once a month.
- 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](#).

**GLUCAGON (BAQSIMI)  
3 mg nasal powder**

For patients receiving insulin who are at high risk of hypoglycemia.

**Claim Notes:**

- A maximum of 2 doses will be reimbursed annually without special authorization.
- Special authorization requests for additional doses will be considered for up to 1 dose per month.
- Requests should detail the clinical need for greater than 2 doses per 12 months, including the number of doses anticipated.

**GLYCEROL PHENYL BUTYRATE (RAVICTI)  
1.1 g/mL oral liquid**

For the treatment of patients with urea cycle disorders (UCDs).

**Clinical Note:**

- Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing.

**Claim Notes:**

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**GLECAPREVIR AND PIBRENTASVIR (MAVIRET)  
100 mg / 40 mg tablet  
50 mg / 20 mg sachet**

For treatment-naïve or treatment-experienced patients aged 3 and older with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value within the last 12 months.

<b>Approval Period</b>	
<b>Genotypes 1, 2, 3, 4, 5 or 6</b> <ul style="list-style-type: none"> <li>Treatment-naïve</li> </ul>	8 weeks
<b>Genotypes 1, 2, 4, 5 or 6</b> <ul style="list-style-type: none"> <li>Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)</li> </ul>	8 weeks (12 weeks with cirrhosis)
<b>Genotype 1</b> <ul style="list-style-type: none"> <li>NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing:               <ul style="list-style-type: none"> <li>Boceprevir/PR; or</li> <li>Simeprevir (SMV)/SOF; or</li> <li>SMV/PR; or</li> <li>Telaprevir/PR</li> </ul> </li> </ul>	12 weeks

<p><b>Genotype 1</b></p> <ul style="list-style-type: none"> <li>• NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: <ul style="list-style-type: none"> <li>– Daclatasvir (DCV)/SOF; or</li> <li>– DCV/PR; or</li> <li>– Ledipasvir/SOF</li> </ul> </li> </ul>	<p>16 weeks</p>
<p><b>Genotype 3</b></p> <ul style="list-style-type: none"> <li>• Treatment-experienced with regimens containing PR and/or SOF</li> </ul>	<p>16 weeks</p>

Clinical Note:

- Genotype must be provided for treatment-experienced patients.

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Sachets will only be considered for pediatric patients 3 years of age and older weighing between 12 kg and 45 kg.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**GOLIMUMAB (SIMPONI)**

**50 mg / 0.5 mL and 100 mg/mL autoinjectors and prefilled syringes**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitor will not be reimbursed.
- Approvals will be for a maximum of 50 mg per month.
- Initial approval period: 4 months.
- Renewal approval period: 1 year.

**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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 50 mg per month.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued 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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 50 mg once a month.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**Ulcerative colitis**

For the treatment of adult 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. aminosaliclates for a minimum of four weeks, and prednisone greater than or equal to 40 mg 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 Criteria:

- 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 aminosaliclates 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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum of 200 mg at week 0, 100 mg at week 2 then 100 mg every four weeks thereafter.
- Initial approval period: 3 months.
- Renewal approval period: 1 year.

**GRASS POLLEN ALLERGEN EXTRACT (ORALAIR)  
100 IR and 300 IR sublingual tablets**

For the seasonal treatment of grass pollen allergic rhinitis in patients who have not adequately responded to, or tolerated, conventional pharmacotherapy.

Clinical Notes:

- Treatment with grass pollen allergen extract must be initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
- Treatment should be initiated four months before the onset of pollen season and should only be continued until the end of the season
- Treatment should not be taken for more than three consecutive years

**GUANFACINE XR (generics)  
1 mg, 2 mg, 3 mg and 4 mg extended-release tablets**

For the treatment of attention-deficit hyperactivity disorder (ADHD) in patients 6 to 17 years of age who meet the following criteria:

- As monotherapy in patients who are intolerant or have contraindications to at least one amphetamine-based psychostimulant and one methylphenidate-based psychostimulant; or
- As adjunctive treatment in patients who have had an inadequate response to psychostimulants.

Clinical Note:

- An inadequate response is defined as a suboptimal response and unable to titrate or tolerate a full dose of at least one amphetamine-based psychostimulant and one methylphenidate-based psychostimulant due to intolerance or adverse events.

Claim Notes:

- Approvals will be up to a maximum of 7 mg daily for monotherapy and up to 4 mg daily for adjunctive therapy.
- Approval period: 1 year.

**GUSELKUMAB (TREMIFYA)  
100 mg/mL patient-controlled injector and prefilled syringe**

**Plaque Psoriasis**

For the treatment of adult 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 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 will not be reimbursed.
- Approvals will be for a maximum of 100 mg at week 0 and 4, then every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**Psoriatic Arthritis**

- For the treatment of adult 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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 100 mg at week 0 and 4, then every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**IBRUTINIB (IMBRUVICA)  
140 mg capsule**

**Chronic Lymphocytic Leukemia**

1. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, del 11q or unmutated IGHV).

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 Note:

- Approval period: 1 year.

2. In combination with venetoclax for adult patients with previously untreated CLL / SLL.

Clinical Notes:

1. Patients must have a good performance status and no central nervous system involvement or Richter's transformation.
2. Treatment should be given for a total of 15 months (three months as monotherapy followed by 12 months in combination with venetoclax), or until disease progression or unacceptable toxicity, whichever occurs first.

Claim Notes:

- Requests for re-treatment with ibrutinib in combination with venetoclax will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
- Approval period: 15 months.

3. As monotherapy for the treatment of adult patients with CLL / SLL who have received at least one prior 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:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase inhibitor or idelalisib.
- Patients who experience disease progression during or within one year of completing ibrutinib in combination with venetoclax are not eligible for ibrutinib in the relapsed setting.
- Approval period: 1 year.

**Mantle Cell Lymphoma**

As monotherapy for the treatment of patients with relapsed or refractory mantle cell lymphoma who have received at least one prior 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:

- 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](#).

**Waldenström Macroglobulinemia**

As monotherapy, or in combination with rituximab, for the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

Renewal Criteria:

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

Clinical Notes:

1. Patients must meet at least one criterion for treatment as per IWWM consensus panel.
2. Patients must have a good performance status and no evidence of disease transformation.
3. Patients who relapse during or within 6 months of completing rituximab-based therapy are eligible for ibrutinib monotherapy.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

**ICATIBANT (FIRAZYR and generic brand)  
30 mg / 3 mL prefilled syringe**

For the treatment of acute attacks of hereditary angioedema (HAE) in adult patients who experience acute laryngeal attacks or non-laryngeal attacks of at least moderate severity.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the diagnosis and treatment of HAE.
- The maximum quantity that will be reimbursed at one time is two doses in a 28-day period.
- Approval period: Long term.

**IDELALISIB (ZYDELIG)  
100 mg and 150 mg film-coated tablets**

For the treatment of patients with relapsed chronic lymphocytic leukemia/small lymphocytic lymphoma, in combination with rituximab.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor, except as a bridge to transplant.
- Initial approval period: 6 months.
- Renewal approval period: 12 months.

**ICOSAPENT ETHYL (VASCEPA)  
1 g capsule**

To reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) in statin treated patients with elevated triglycerides who meet all of the following criteria:

- 45 years of age and older
- Established cardiovascular disease
- Baseline fasting triglyceride between 1.7 mmol/L and 5.6 mmol/L measured within the three months prior to initiating treatment with Vascepa
- Baseline low-density lipoprotein cholesterol (LDL-C) between 1.0 mmol/L and 2.6 mmol/L
- Receiving a maximally tolerated statin dose for a minimum of 4 weeks, targeted to achieve an LDL-C lower than 2.0 mmol/L

Clinical Note:

- LDL-C and triglyceride levels must be provided.

Claim Notes:

- Approvals will be for a maximum of 4 g daily.
- Approval period: 1 year.

**IMIQUIMOD (ALDARA P and generic brand)  
5% cream**

1. For the treatment of external genital and external perianal/condyloma acuminata warts.

Claim Note:

- Approval period: 16 weeks

2. For the treatment of actinic keratosis in patients who have failed treatment with 5-Fluorouracil (5-FU) and cryotherapy.

Claim Note:

- Approval period: 16 weeks.

3. For the treatment of biopsy-confirmed primary superficial basal cell carcinoma:

- with a tumour diameter of  $\leq 2$  cm
- AND
- located on the trunk, neck or extremities (excluding hands and feet)
- AND
- where surgery or irradiation therapy is not medically indicated
  - recurrent lesions in previously irradiated area
  - OR
  - multiple lesions, too numerous to irradiate or remove surgically.

Clinical Note:

- Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

Claim Note:

- Approval period: 6 weeks.

**INCLISIRAN (LEQVIO)  
284 mg / 1.5 mL prefilled syringe**

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with:
  - high-dose statin (e.g., atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
  - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial Renewal Criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent Renewal Criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

1. LDL-C levels must be provided.

2. Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
  - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
  - at least one statin was initiated at the lowest daily starting dose; and
  - other known causes of intolerance have been ruled out.
3. For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (i.e. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
4. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:

- Approvals will be for 284 mg initially, at 3 months, then every 6 months thereafter.
- Combined use with other PCSK9 inhibitors will not be reimbursed
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**INCOBOTULINUMTOXIN-A (XEOMIN)  
50 LD<sub>50</sub> units per vial and 100 LD<sub>50</sub> units per vial**

- For the treatment of blepharospasm in patients 18 years of age and older.
- For the treatment of cervical dystonia (spasmodic torticollis) in patients 18 years of age or older.

Renewal Criteria:

- Documentation of continued benefit including the patient's functional and/or symptomatic improvement, as well as the dosage and injection schedule.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 3 years.

**INDACATEROL, GLYCOPYRRONIUM BROMIDE, AND MOMETASONE (ENERZAIR BREEZHALER)  
160 mcg / 50 mcg / 150 mcg powder for inhalation**

For the treatment of asthma in patients who are inadequately controlled with a medium or high dose inhaled corticosteroid and a long-acting beta-2 agonist and have experienced one or more asthma exacerbations in the previous 12 months.

**INEBILIZUMAB (UPLIZNA)  
100 mg vial**

For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:

- Aquaporin-4 antibody positive
- Expanded Disability Status Scale (EDSS) score of 8 points or less
- Experienced at least one relapse in the previous 12 months or at least two relapses in the previous 24 months
- Relapse occurred despite an adequate trial of rituximab, or there has been an intolerance to rituximab

Renewal Criteria:

- Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.

Clinical Note:

- Inebilizumab should not be initiated during a NMOSD relapse.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of NMOSD.
- Combined use of more than one biologic drug for the treatment of NMOSD will not be reimbursed.
- Approvals will be for 300 mg at week 0 and 2 followed by 300 mg every 6 months (starting six months from the first infusion).
- 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](#).

**INFLIXIMAB (AVSOLA, IXIFI, REMDANTRY, RENFLEXIS)  
100 mg vial**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitor will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 6 months.
- Renewal approval period: Long term.

**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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 12 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

**Plaque Psoriasis**

For the treatment of adult 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 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 drug will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 16 weeks.
- 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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- 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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- 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 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. aminosaliclates for a minimum of four weeks, and prednisone greater than or equal to 40 mg 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 Criteria:**

- 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 aminosaliclates 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 intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 12 weeks.
- Renewal approval period: Long term.

**INFLIXIMAB (REMSIMA SC)  
120 mg/mL autoinjector**

**Crohn's Disease**

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

Clinical Note:

- For patients who are switching from intravenous infliximab, the first dose of Remsima SC should be administered 8 weeks after the last infliximab intravenous infusion.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 120 mg every two weeks, starting four weeks following completion of an intravenous induction regimen.
- Initial approval period: 6 months.
- 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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.
6. For patients who are switching from intravenous infliximab, the first dose of Remsima SC should be administered 8 weeks after the last infliximab intravenous infusion.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Subcutaneous (SC) induction: Approvals will be for a maximum of 120 mg administered SC at week 0, 1, 2, 3 and 4 and then 120 mg every two weeks, starting at week 6.
- Intravenous (IV) induction: Approvals will be for a maximum of 120 mg every two weeks, starting four weeks following completion of an IV induction regimen.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of response is required.

**Ulcerative Colitis**

For the treatment of adult 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 40 mg 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 Criteria:

- 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 intolerance(s) must be clearly documented.
4. For patients who are switching from intravenous infliximab, the first dose of Remsima SC should be administered 8 weeks after the last infliximab intravenous infusion.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum of 120 mg every two weeks, starting four weeks after completion of an intravenous induction regimen.
- Initial approval period: 6 months.
- Renewal approval period: Long term.

**INSULIN DETEMIR (LEVEMIR)  
100 U/mL Penfill cartridge**

1. For the treatment of patients with type 1 or type 2 diabetes who have taken other long acting insulin analogues (insulin glargine and insulin degludec), and have:
  - experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management; or
  - documented severe or continuing systemic or local allergic reaction.
2. For the treatment of pediatric and adolescent patients with type 1 diabetes.
3. For the treatment of pregnant individuals with type 1 or type 2 diabetes requiring insulin.

**INTERFERON BETA-1A (AVONEX PEN and AVONEX PS)  
30 mcg / 0.5 mL autoinjector and prefilled syringe**

1. For the treatment of adult patients who have experienced a clinically isolated syndrome.
2. For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:
  - Confirmed diagnosis based on McDonald criteria
  - Has experienced one or more disabling relapses or new MRI activity in the past two years
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGHV.
- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.
- Approval period: 2 years.

**INTERFERON BETA-1A (REBIF)  
22 mcg / 0.5 mL and 44 mcg / 0.5 mL prefilled syringes  
66 mcg / 1.5 mL and 132 mcg / 1.5 mL cartridges**

1. For the treatment of adult patients who have experienced a clinically isolated syndrome.
2. For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:
  - Confirmed diagnosis based on McDonald criteria
  - Has experienced one or more disabling relapses or new MRI activity in the past two years
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGHV.
- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.
- Approval Period: 2 years.

**INTERFERON BETA-1B (BETASERON)**

**0.3 mg single-use vial**

1. For the treatment of adult patients who have experienced a clinically isolated syndrome.
2. For the treatment of adult patients with relapsing-remitting multiple sclerosis who meet the following criteria:
  - Confirmed diagnosis based on McDonald criteria
  - Has experienced one or more disabling relapses or new MRI activity in the past two years
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
3. For the treatment of adult patients with secondary progressive multiple sclerosis who meet the following criteria.
  - History of RRMS
  - Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests for Betaseron will be considered for individuals enrolled in Plans ACDEFGHV.
- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.
- Approval period: 2 years.

**IPRATROPIUM BROMIDE (generic brands)**

**125 mcg/mL and 250 mcg/mL solution for inhalation**

For patients who have tried using an inhaler with spacer device and

- Are unable to follow instructions, hold the spacer device or hold the device long enough to actuate it due to cognitive or physical limitations; or
- Have difficulty generating adequate inspiratory effort to achieve therapeutic benefit.

Claim Notes:

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

**ISAVUCONAZOLE (CRESEMBA)**

**100 mg capsule**

- For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole and caspofungin.
- For the treatment of adult patients with invasive mucormycosis.

Claim Notes:

- Must be prescribed by an infectious disease specialist or medical microbiologist.
- Initial requests will be approved for a maximum of 3 months.

**ITRACONAZOLE (generic brands)**

**10 mg/mL oral solution**

For the treatment of immunocompromised adult patients with oral and/or esophageal candidiasis.

Clinical Note:

- Itraconazole oral solution is not interchangeable with itraconazole capsules due to differences in bioavailability.

**IVABRADINE (LANCORA)**

**5 mg and 7.5 mg film-coated tablets**

For the treatment of adult patients with New York Heart Association (NYHA) class II or III stable heart failure when administered in combination with standard care therapy to reduce the incidence of cardiovascular death and hospitalization who meet all of the following criteria:

- Left ventricular ejection fraction (LVEF) of less than or equal to 35%
- Sinus rhythm with a resting heart rate  $\geq 77$  beats per minute (bpm)
- NYHA class II to III symptoms despite at least four weeks of treatment with the following:
  - a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB)
  - a stable dose of a beta blocker
  - mineralocorticoid receptor antagonist (MRA).

Clinical Notes:

1. Resting heart rate must be documented as  $\geq 77$  bpm on average using either an ECG on at least three separate visits or by continuous monitoring.
2. For patients who have not received four weeks of therapy with an ACEI/ARB, beta blocker and MRA due to an intolerance or contraindication, details must be provided.
3. Initiation and up-titration should be under the supervision of a physician experienced in the treatment of heart failure.

Claim Note:

- Approval period: Long term.

**IVACAFTOR (KALYDECO)  
150 mg tablet**

For the treatment of cystic fibrosis in patients who are:

- age 6 years and older and have one of the following cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R; or
- age 18 years and older with an R117H mutation in the CFTR gene.

Renewal Criteria:

- Renewal requests will be considered in patients with documented response to treatment as evidenced by the following:

In cases where the baseline sweat chloride levels were greater than 60 mmol/L:

- the patient's sweat chloride level fell below 60 mmol/L; or
- the patient's sweat chloride level falls by at least 30%

In cases where the baseline sweat chloride levels were below 60 mmol/L:

- the patient's sweat chloride level falls by at least 30%; or
- the patient demonstrates a sustained absolute improvement in FEV<sub>1</sub> of at least 5% when compared to the FEV<sub>1</sub> test conducted prior to starting therapy. FEV<sub>1</sub> will be compared with the baseline pre-treatment level one month and three months after starting treatment

Clinical Notes:

1. The patient's sweat chloride level and FEV<sub>1</sub> must be provided with each request.
2. A sweat chloride test must be performed within a few months of starting ivacaftor therapy to determine if sweat chloride levels are reducing.
  - If the expected reduction occurs, a sweat chloride test must be performed again 6 months after starting therapy to determine if the full reduction has been achieved. Thereafter, sweat chloride levels must be checked annually.
  - If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, coverage will be discontinued.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- 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.
- Approved dose: 150 mg every 12 hours.
- 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](#).

**IVOSIDENIB (TIBSOVO)  
250 mg film-coated tablet**

In combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukemia with an isocitrate dehydrogenase1 (IDH1) R132 mutation who are ineligible for intensive induction chemotherapy.

Renewal Criteria:

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

#### Clinical Notes:

1. Treatment should be discontinued upon disease progression or unacceptable toxicity.
2. Ineligibility for intensive induction chemotherapy includes the following:
  - Age > 75 years
  - ECOG performance status > 2
  - Severe cardiac or pulmonary disorder
  - Creatinine clearance < 45 mL/minute
  - Bilirubin level > 1.5 times the upper limit of normal
  - Any other comorbidity incompatible with intensive induction chemotherapy

#### Claim Notes:

- Requests for patients previously treated with a hypomethylating agent or chemotherapy for myelodysplastic syndrome (MDS) will not be considered.
- Requests for patients with high-risk MDS will not be considered.
- 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](#).

### **IXEKIZUMAB (TALTZ) 80 mg/mL autoinjector and prefilled syringe**

#### **Plaque Psoriasis**

For the treatment of adult 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 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 drug will not be reimbursed.
- Approvals will be for 160 mg at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12 then 80 mg every four weeks.
- Initial approval period: 12 weeks.
- Renewal approval period: 1 year. Confirmation of continued 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 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 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. Intolerance 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.

- Approvals will be for 160 mg at week 0, followed by 80 mg every four weeks.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**LACTULOSE (various brands)  
667 mg/mL syrup**

For the treatment of hepatic encephalopathy in patients with liver disease.

Clinical Note:

- Please note requests for treatment of constipation will not be considered.

**LAMIVUDINE (generic brands)  
100 mg tablet**

For the treatment of Hepatitis B.

Claim Note:

- Must be prescribed by a hepatologist, gastroenterologist, infectious disease specialist or other physician with experience in the treatment of hepatitis B.

**LAMIVUDINE AND DOLUTEGRAVIR (DOVATO)  
50 mg / 300 mg tablet**

For the treatment of HIV-1 infection in patients 12 years of age or older and weighing at least 40kg, who meet the following criteria:

- HIV-1 treatment-naïve
- Viral load less than or equal to 500,000 copies/mL

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**LAMIVUDINE, TENOFOVIR DISOPROXIL AND DORAVIRINE (DELSTRIGO)  
300 mg / 300 mg / 100 mg tablet**

For the treatment of adult patients with HIV-1 infection with no known mutations associated with resistance to the individual components of Delstrigo.

Claim Notes:

- Prescriptions written for beneficiaries of Plans CU by infectious disease specialists and medical microbiologists who are licensed by the College of Physicians and Surgeons of New Brunswick, do not require special authorization.
- Approval period: Long term.

**LANADELUMAB (TAKHZYRO)  
300 mg vial and prefilled syringe**

For the prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment.

Discontinuation Criteria:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to the number of attacks observed before initiating treatment with lanadelumab; or
- Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with lanadelumab.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to lanadelumab.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the diagnosis and treatment of HAE.

- Not to be used in combination with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor or plasma kallikrein inhibitor).
- Approvals will be for a maximum of 300 mg every two weeks.
- Initial approval period: 3 months.
- Renewal approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**LANSOPRAZOLE (PREVACID and generic brands)  
15 mg and 30 mg delayed-release capsules**

- For patients who have had a therapeutic failure with all proton pump inhibitors listed as regular benefits (e.g. omeprazole, pantoprazole, rabeprazole).
- When compounded as an oral suspension for patients 18 years and younger, who require the use of a proton pump inhibitor and cannot use a tablet or capsule.

Claim Note:

- Approval period: Long term.

**LANSOPRAZOLE (PREVACID FASTAB)  
15 mg and 30 mg delayed-release tablets**

For patients who require drugs to be administered through a feeding tube or cannot use a tablet or capsule.

Claim Note:

- Approval period: Long term.

**LANTHANUM (generic brand)  
250 mg, 500 mg, 750 mg and 1000 mg chewable tablets**

For the treatment of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end-stage renal disease who are intolerant to, or have inadequate control of phosphate levels with, another phosphate binder.

Claim Note:

- Approval period: Long term.

**LAPATINIB (TYKERB)  
250 mg tablet**

In combination with capecitabine for the treatment of patients with unresectable locally advanced or metastatic HER2-positive breast cancer when used as:

- first-line therapy following disease relapse during or within six months of completing adjuvant treatment with trastuzumab or trastuzumab emtansine; or
- second-line therapy following disease progression on trastuzumab, with or without pertuzumab, in the advanced setting.

Renewal Criteria:

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

Clinical Note:

- Patients must have a good performance status.

Claim Note:

- Approval period: 6 months.

**LAROTRECTINIB (VITRAKVI)  
25 mg and 100 mg capsules  
20 mg / mL oral solution**

As monotherapy for the treatment of adult and pediatric patients with unresectable locally advanced or metastatic solid tumours who meet all of the following criteria:

- Tumours have a NTRK gene fusion without a known acquired resistance mutation
- No other satisfactory treatment options
- Not a candidate for surgery and/or radiation due to risk of substantial morbidity

Renewal Criteria:

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

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients must be asymptomatic.
3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a NTRK inhibitor.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**LENALIDOMIDE (REVLIMID and generic brands)  
2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg and 25 mg capsules**

**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.

**Myelodysplastic Syndrome**

For the treatment of patients with anemia due to myelodysplastic syndrome who meet all of the following:

- Presence of deletion 5q cytogenetic abnormality
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1
- Transfusion-dependent symptomatic anemia

Renewal Criteria:

- Patients who are transfusion-dependent must demonstrate at least fifty percent reduction in transfusion requirements.
- Renewal requests for patients who are not transfusion-dependent may be considered if the patient's serial CBC (pre- and post-lenalidomide) and any other objective evidence of response to therapy is included.

Clinical Note:

- Requests for patients who are not transfusion-dependent may be considered. Clinical evidence of symptomatic anemia affecting the patient's quality of life, rationale for why transfusions are not being used, and details pertaining to other therapies prescribed to manage anemia is required.

Claim Note:

- Approval period: 1 year.

## **LENVATINIB (LENVIMA)**

**4 mg, 8 mg, 10 mg, 12 mg, 14 mg, 20 mg and 24 mg per dose compliance packs**

### **Advanced Endometrial Carcinoma**

In combination with pembrolizumab for the treatment of patients with advanced, recurrent, or metastatic endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) and who meet all of the following criteria:

- Disease progression following prior platinum-based systemic therapy
- Not a candidate for curative surgery or radiation

#### 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 with lenvatinib should be discontinued upon disease progression or unacceptable toxicity.

#### Claim Note:

- Approval period: 1 year.

### **Advanced Hepatocellular Carcinoma**

For the treatment of patients with unresectable hepatocellular carcinoma with Child-Pugh class A liver function and an ECOG performance status of 0 or 1, when used as:

- first-line therapy, or
- second-line therapy after progression on immunotherapy.

#### Renewal Criteria:

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

#### Clinical Note:

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

#### Claim Notes:

- Requests for lenvatinib will not be considered for patients who have progressed on sorafenib.
- Approval period: 6 months.

### **Differentiated Thyroid Cancer**

For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet all of the following criteria:

- Refractory or resistant to radioactive iodine therapy
- Radiological evidence of disease progression within the previous 13 months
- Previously untreated or have received one prior tyrosine kinase inhibitor (TKI) 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:

- Requests will not be considered for patients with anaplastic or medullary thyroid cancer.
- Approval Period: 1 year.

### **Metastatic Renal Cell Carcinoma**

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

#### 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 with lenvatinib should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

**LETERMOVIR (PREVYMIS)  
240 mg and 480 mg tablets  
240 mg / 12 mL vial**

For the prevention of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) who have undetectable CMV viremia at baseline and meet one of the following criteria:

- umbilical cord blood as a stem cell source
- recipient of a haploidentical transplant
- recipient of T-cell depleted transplant
- treated with antithymocyte globulin (ATG) for conditioning
- requiring high-dose steroids or other immunosuppression for acute graft versus host disease (GVHD)
- treated with ATG for steroid-refractory acute GVHD
- documented history of CMV disease prior to transplantation

Clinical Note:

- High-dose steroids is defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid.

Claim Notes:

- Must be prescribed by a medical oncologist, hematologist, or infectious disease specialist or other physician with experience in the management of HSCT.
- Approvals will be for a maximum dose of 480 mg per day.
- Approval period: 100 days per HSCT.

**LEVETIRACETAM (pdp-LEVETIRACETAM and generic brands)  
100 mg/mL oral solution**

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

Claim Note:

- Approval period: 1 year.

**LEVOCARNITINE (CARNITOR and generic brand)  
100 mg/mL oral solution  
330 mg tablet**

1. For the treatment of patients with primary systemic carnitine deficiency.
2. For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency.

**LEVODOPA AND CARBIDOPA (DUODOPA)  
20 mg / 5 mg/mL intestinal gel**

For the treatment of adult patients with advanced levodopa-responsive Parkinson's disease who meet all the following criteria:

- Experiences severe, debilitating motor fluctuations and dyskinesia, with at least 25% of the waking day in the "off" state and/or ongoing 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 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 movement disorder subspecialist 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 movement disorder subspecialist who has appropriate training in the use of Duodopa and are practising in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa.

- 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](#).

### **LEVODOPA, CARBIDOPA AND ENTACAPONE (STALEVO)**

**50 mg / 12.5 mg / 200 mg, 75 mg / 18.75 mg / 200 mg, 100 mg / 25 mg / 200 mg, 125 mg / 31.25 mg / 200 mg and 150 mg / 37.5 mg / 200 mg tablets**

For the treatment of patients with Parkinson's disease

- who are currently receiving immediate-release levodopa/carbidopa and entacapone,  
OR
- who are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with levodopa/decarboxylase.

### **LEVOFLOXACIN (generic brands)**

**250 mg, 500 mg and 750 mg tablets**

1. For completion of treatment initiated in the hospital setting for patients with nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic obstructive pulmonary disease (AECOPD).
2. For the treatment of complicated AECOPD in patients who:
  - have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, trimethoprim-sulfamethoxazole, or macrolide), or
  - are intolerant or have contraindication(s) to at least two first-line therapies.
3. For the treatment of CAP in patients with radiographic confirmation of pneumonia who:
  - have failed treatment with at least one first-line therapy (macrolide, doxycycline, beta-lactams), or
  - are intolerant or have contraindication(s) to at least two first-line therapies.
4. For the treatment of pulmonary infections in patients with cystic fibrosis.
5. For the treatment of severe pneumonia in nursing home patients.
6. For the treatment of patients with complicated osteomyelitis or joint infections.
7. For the treatment of patients with pyelonephritis.

#### Clinical Notes:

1. If the patient has been treated with an antibiotic within the past 3 months consider an antibiotic from a different class.
2. Complicated AECOPD is defined as patients with COPD (FEV<sub>1</sub>/FVC greater than 0.7) experiencing increased sputum purulence, and with increased dyspnea or sputum volume, and one of the following:
  - FEV<sub>1</sub> less than 50% predicted
  - At least 4 exacerbations per year
  - Ischemic heart disease
  - Home oxygen use
  - Chronic oral steroid use

#### Claim Notes:

- Prescriptions written by infectious disease specialists, internal medicine specialists, hematologists, medical microbiologists, oncologists, oncology clinical associates, general practitioners in oncology, respirologists or urologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Levofloxacin is a regular benefit for Plans BV.

### **Tuberculosis**

For the treatment of tuberculosis in patients who have lab-verified drug resistance or a contraindication or intolerance to first-line drugs.

#### Claim Notes:

- Must be prescribed by, or in consultation with, an infectious disease specialist.
- Requests will only be considered under Plan P.

### **LEVOFLOXACIN (QUINSAIR)**

**240 mg / 2.4 mL solution for inhalation**

For the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections, when used as a cyclic treatment, in adult patients with cystic fibrosis who have experienced treatment failure with inhaled tobramycin.

#### Clinical Note:

- Cyclic treatment measured in 28-day cycles is defined as 28 days of treatment, followed by 28 days without treatment.

Claim Notes:

- Combined use of inhaled levofloxacin, either concurrently or for antibiotic cycling during off-treatment periods, with other inhaled antibiotics (e.g. tobramycin, aztreonam) will not be reimbursed.
- Requests will be considered for individuals in Plans ACDEFGV.

**LINEZOLID (generic brands)  
600 mg tablet**

- For treatment of proven vancomycin-resistant *enterocci* (VRE) infections.
- For the treatment of proven methicillin-resistant *Staphylococcus aureus* (MRSA) / methicillin-resistant *Staphylococcus epidermidis* (MRSE) infections in patients who are unresponsive to, or intolerant of, intravenous vancomycin or in whom intravenous vancomycin is not appropriate.

Claim Note:

- The drug must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

**LISDEXAMFETAMINE (VYVANSE and generic brands)  
10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg capsules and chewable tablets**

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

Claim Notes:

- The maximum dose reimbursed is 60 mg daily.
- Approval period: 1 year.

**LONG-ACTING BETA-2 AGONISTS (LABA)  
Formoterol (Oxeze Turbuhaler) 6 mcg, 12 mcg powder for inhalation  
Salmeterol (Serevent Diskus) 50 mcg powder for inhalation**

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who have failed or who are intolerant to a long-acting muscarinic antagonist (LAMA).

Claim Note:

- Approval period: Long term.

**LONG-ACTING BETA-2 AGONISTS/INHALED CORTICOSTEROID (LABA/ICS) COMBINATIONS  
Formoterol and Budesonide (Symbicort Turbuhaler) 6 mcg / 100 mcg, 6 mcg / 200 mcg powder for inhalation  
Formoterol and Mometasone (Zenhale) 5 mcg / 100mcg, 5 mcg / 200 mcg suspension for inhalation  
Indacaterol and Mometasone (Ateectura Breezhaler) 150 mcg / 80 mcg, 150 mcg / 160 mcg, 150 mcg / 320 mcg powder for inhalation  
Salmeterol and Fluticasone (Advair) 25 mcg / 125 mcg, 25 mcg / 250 mcg suspension for inhalation  
Salmeterol and Fluticasone (Advair Diskus and generic brands) 50 mcg / 100 mcg, 50 mcg / 250 mcg, 50 mcg / 500 mcg powder for inhalation  
Vilanterol and Fluticasone (Breo Ellipta) 25 mcg / 100 mcg, 25 mcg / 200 mcg powder for inhalation**

**Asthma**

For the treatment of asthma in patients who are using optimal doses of inhaled corticosteroids but are still poorly controlled.

Claim Note:

- Approval period: Long term.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD), in combination with a long-acting muscarinic antagonist (LAMA) in patients who cannot use a fixed-dose triple therapy inhaler (i.e., Breztri Aerosphere or Trelegy Ellipta) and who meet one of the following criteria:
  - Have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months.
  - Have experienced at least one exacerbation of COPD requiring hospitalization or an emergency room visit in the last 12 months.
  - Moderate symptom burden (e.g., modified Medical Research Council (mMRC) Dyspnea Scale  $\geq$  Grade 2 or a COPD Assessment test (CAT)  $\geq$  10) while being treated with a long-acting beta-2 agonist plus a long-acting muscarinic antagonist (LABA/LAMA) or a long-acting beta-2 agonist plus an inhaled corticosteroid (LABA/ICS) for at least 2 months.
- For the treatment of patients with asthma / chronic obstructive pulmonary disease (ACO) overlap, based on patient history and lung function studies indicating an ACO diagnosis.

Clinical Note:

- Fixed-dose LABA/LAMA/ICS inhalers are the preferred options for patients requiring triple therapy. Products which combine a LABA/LAMA/ICS in a single device are available as special authorization benefits.

Claim Notes:

- Atecura Breezhaler, Breo Ellipta 25 mcg / 200 mcg and Zenhale are not indicated for the treatment of COPD, therefore requests for these products will only be considered for asthma.
- Approval period: Long term.

**LONG-ACTING BETA-2 AGONIST/ LONG-ACTING MUSCARINIC ANTAGONIST (LABA/LAMA) COMBINATIONS**  
**Formoterol and Aclidinium (Duaklir Genuair) 12 mcg / 400 mcg powder for inhalation**  
**Indacaterol and Glycopyrronium (Ultibro Breezhaler) 110 mcg / 50 mcg powder for inhalation**  
**Olodaterol and Tiotropium (Inspiro Respimat) 2.5 mcg / 2.5 mcg solution for inhalation**  
**Vilanterol and Umeclidinium (Anoro Ellipta) 25 mcg / 62.5 mcg powder for inhalation**

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who meet one of the following criteria:

- Moderate to severe disease, as defined by modified Medical Research Council (mMRC) Dyspnea Scale  $\geq$  Grade 2 or a COPD Assessment test (CAT)  $\geq$  10.
- Have experienced at least one exacerbation in the previous 12 months while being treated with either a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA).

Clinical Note:

- LABA/LAMA combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LABA/LAMA/ICS) are met.

Claim Note:

- Approval period: Long term.

**LONG-ACTING BETA-2 AGONIST/ LONG-ACTING MUSCARINIC ANTAGONIST/INHALED CORTICOSTEROID (LABA/LAMA/ICS) COMBINATIONS**  
**Formoterol, Glycopyrronium and Budesonide (Breztri Aerosphere) 5 mcg / 7.2 mcg / 160 mcg suspension for inhalation**  
**Vilanterol, Umeclidinium and Fluticasone furoate (Trelegy Ellipta) 25 mcg / 62.5 mcg / 100 mcg dry powder for inhalation**

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who meet one of the following criteria:

- Have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months.
- Have experienced at least one exacerbation of COPD requiring hospitalization or an emergency department visit in the last 12 months.
- Moderate symptom burden (e.g., modified Medical Research Council (mMRC) Dyspnea Scale  $\geq$  Grade 2 or a COPD Assessment test (CAT)  $\geq$  10) while being treated with a long-acting beta-2 agonist plus a long-acting muscarinic antagonist (LABA/LAMA) or a long-acting beta-2 agonist plus an inhaled corticosteroid (LABA/ICS) for at least 2 months.

Claim Note:

- Approval period: Long term.

**LORLATINIB (LORBRENA)**  
**25 mg and 100 mg tablets**

As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests for lorlatinib will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with alectinib.
- 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](#).

**LUMASIRAN (OXLUMO)**  
**94.5 mg / 0.5 mL vial**

For the treatment of patients with primary hyperoxaluria type 1 (PH1) who meet all the following criteria:

- Genetically confirmed diagnosis of PH1;
- Unable to normalize urinary oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months based on one of the following levels:
  - 24-hour urinary oxalate (level must be at least 1.5 times the upper limit of normal), in patients in whom urinary oxalate can be measured; or
  - spot urine oxalate:creatinine ratio, in patients who are not continent; or
  - plasma oxalate, in patients with end-stage kidney disease (ESKD) or who are on dialysis.

Renewal Criteria:

The patient must meet all the following criteria:

- Has not received a liver transplant with or without a kidney transplant
- Continues to demonstrate a response. Response is defined as:
  - lowering of 24-hour urinary oxalate level to less than 1.5 times the upper limit of normal, or
  - a 30% reduction in urine oxalate:creatinine ratio in patients who are not continent; or
  - a 15% reduction in plasma oxalate level in patients with ESKD or who are on dialysis.

Claim Notes:

- Must be prescribed by a nephrologist or metabolic diseases specialist experienced in the treatment of PH1.
- Subsequent renewals can be prescribed by a pediatrician, nephrologist, or metabolic diseases specialist.
- Approvals will be for 6 mg/kg once monthly for three loading doses, then 3 mg/kg once monthly thereafter for patients weighing less than 10 kg.
- Approvals will be for 6 mg/kg once monthly for three loading doses, then 6 mg/kg every three months thereafter for patients weighing 10 to 20 kg.
- Approvals will be 3 mg/kg once monthly for three loading doses, then 3 mg/kg every three months thereafter for patients weighing greater than 20 kg.
- Initial approval period: 6 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](#).

**LUSPATERCEPT (REBLOZYL)**  
**25 mg and 75 mg vials**

**Beta-Thalassemia Anemia**

For the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with beta-thalassemia who are receiving regular transfusions.

Initial Renewal Criteria:

- A reduction of 33% or greater in transfusion burden measured as the number of RBC units required in the initial 24 weeks of luspatercept treatment compared to the 24 weeks prior to luspatercept initiation.

Subsequent Renewal Criteria:

- Maintenance of a 33% or greater reduction in transfusion burden measured as the number of RBC units required in the past 24 weeks compared to the 24 weeks prior to luspatercept initiation.

Clinical Notes:

1. Regular transfusions are defined as receiving 6 to 20 RBC units and having no transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment.
2. History of transfusion burden must be provided with the initial and renewal requests.
3. Treatment should be discontinued if there is no response (as defined in renewal criteria) after 3 doses at the maximum dose.

Claim Notes:

- Must be prescribed by a hematologist.
- Approvals will be for a maximum of 1.25 mg/kg (up to 120 mg per dose) every three weeks.
- Approval period: 7 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Myelodysplastic Syndromes (MDS) Associated Anemia**

For the treatment of adult patients with MDS-associated anemia who meet all of the following criteria:

- Diagnosed with very low- to intermediate-risk MDS with ringed sideroblasts in accordance with the Revised International Prognostic Scoring System (IPSS-R)
- Failed or are not suitable for erythropoietin stimulating agents (ESA)

- Red blood cell (RBC) transfusion-dependent anemia associated with MDS defined as having received at least 2 RBC units over 8 weeks
- Absence of deletion 5q cytogenetic abnormality
- Performance status of 0 to 2

**Initial Renewal Criteria:**

- Patient is RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment with luspatercept.

**Subsequent Renewal Criteria:**

- Patient maintains transfusion independence with luspatercept treatment.

**Clinical Notes:**

1. History of transfusion burden must be provided with the initial and renewal requests.
2. Confirmation must be provided that the patient remains very low- to intermediate risk.
3. Details of ESA use (i.e. name of treatment, dose(s), duration of use, response) must be provided.

**Claim Notes:**

- Must be prescribed by a hematologist or oncologist.
- Approvals will be for a maximum of 1.75 mg/kg (up to 168 mg per dose) every three weeks.
- Approval period: 7 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**MACITENTAN (OPSUMIT)**

**10 mg film-coated tablet**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class II, III or IV.

**Clinical Note:**

- The diagnosis of PAH should be confirmed by right heart catheterization.

**Claim Notes:**

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Combined use of more than one endothelin receptor antagonists will not be reimbursed.
- The maximum dose of macitentan that will be reimbursed is 10 mg daily.
- Approval period: Long term.

**MARAVIROC (CELSENTRI)**

**150 mg and 300 mg film-coated tablets**

For the treatment of HIV-1 infection in patients who have CCR5 tropic viruses and who have documented resistance to at least one agent from each of the three major classes of antiretrovirals (i.e. nucleoside/tide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors.)

**Clinical Note:**

- Requests for HIV-1 treatment-naïve patients will not be considered.

**MARIBAVIR (LIVTENCITY)**

**200 mg tablet**

For the treatment of adults with post-transplant cytomegalovirus (CMV) infection or disease who are refractory to one or more antivirals (valganciclovir, ganciclovir, foscarnet or cidofovir).

**Discontinuation Criteria:**

- No change or an increase in CMV viral load after at least 2 weeks of maribavir treatment; or
- Confirmed CMV genetic mutation associated with resistance to maribavir.

**Clinical Notes:**

1. Refractory to antiviral treatment is defined as a lack of change in CMV viral load or increase in CMV viral load after at least 2 weeks of appropriately dosed treatment.
2. Re-treatment for patients who have a recurrence of CMV viremia after a previous successful course of treatment with maribavir will be considered.

**Claim Notes:**

- Must be prescribed by an infectious disease specialist or physician with experience in transplant medicine.
- Approvals will be for a maximum dose of 800 mg per day.
- Approval period: 8 weeks.

**MAVACAMTEN (CAMZYOS)**  
**2.5 mg, 5 mg, 10 mg, and 15 mg capsules**

For the treatment of adult patients with New York Heart Association (NYHA) class II to III symptomatic obstructive hypertrophic cardiomyopathy who meet all of the following criteria:

- Left ventricular ejection fraction (LVEF)  $\geq$  55% at rest
- Left ventricular wall thickness  $\geq$  15 mm (or  $\geq$  13 mm with a family history of hypertrophic cardiomyopathy)
- Left ventricular outflow tract peak gradient  $\geq$  50 mm Hg at rest, after Valsava maneuver, or post-exercise
- Receiving a beta-blocker or calcium channel blocker and experiencing clinical deterioration in symptoms or echocardiography while receiving either of these treatments

Renewal Criteria:

- LVEF  $>$  30%; and
- Has not received septal reduction therapy.

Clinical Note:

- A copy of the most recent echocardiogram report must be provided with initial and renewal requests.

Claim Notes:

- Must be prescribed by, or in consultation with, a cardiologist.
- The maximum dose reimbursed is 15 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**MECASERMIN (INCRELEX)**  
**10 mg/mL multidose vial**

For the treatment of patients between 2 and 18 years of age with growth failure due to confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) in whom epiphyseal closure has not yet occurred and meet the following criteria:

- Documented genetic mutation recognized as a cause of SPIGFD; or
- Clinical and biochemical features of SPIGFD.

Renewal Criteria:

- Height velocity is 1 cm or greater per 6 months or 2 cm or greater per year; and
- Bone age is 16 years or less in boys and 14 years or less in girls.

Clinical Notes:

1. Clinical and biochemical features of SPIGFD are defined as:
  - height standard deviation score less than or equal to  $-3.0$ ; and
  - basal insulin-like growth factor-1 (IGF-1) levels below the 2.5th percentile for age and gender; and
  - random or stimulated growth hormone (GH) level  $>$  10 ng/mL and failure to increase IGF-1 by 50 ug/L in response to exogenous GH during an IGF-1 generation test.
2. Exclusion of secondary forms of IGF-1 deficiency such as malnutrition, hypopituitarism, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

Claim Notes:

- Must be prescribed by a pediatric endocrinologist.
- Mecasermin will not be reimbursed in combination with recombinant growth hormone treatment.
- Approvals will be for a maximum of 0.12 mg/kg/dose twice daily.
- Approval period: 1 year.
- Claims that exceed the maximum claim amount of \$9,999 must be divided and submitted as separate transactions as outlined [here](#).

**MEPOLIZUMAB (NUCALA)**  
**100 mg/mL autoinjector and prefilled syringe**

**Chronic Rhinosinusitis with Nasal Polyps**

For the treatment of severe chronic rhinosinusitis with nasal polyps in combination with intranasal corticosteroids in adult patients who meet all of the following criteria:

- Endoscopically or CT-documented bilateral nasal polyps
- At least one prior surgical intervention for nasal polyps or have a contraindication to surgery
- Refractory to 3 months of intranasal corticosteroids alone at maximally tolerated doses

Renewal Criteria:

- Patients must exhibit a clinically meaningful response on the Sino-nasal Outcome Test (SNOT-22) or endoscopic nasal polyp score (NPS) relative to their baseline score.

Subsequent Renewal Criteria:

- Initial response achieved after the first twelve months of treatment with mepolizumab has been maintained.

Clinical Notes:

1. A baseline and annual SNOT-22 or endoscopic NPS must be provided.
2. Clinically meaningful response is defined as a decrease of at least 8.9 points in SNOT-22 from baseline or a decrease of at least 1 point in endoscopic NPS from baseline.

Claim Notes:

- Must be prescribed by an otolaryngologist.
- Combined use with other biologic drugs will not be reimbursed.
- Approvals will be for a maximum of 100 mg every four weeks.
- Approval period: 1 year.

**Eosinophilic Asthma**

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

- blood eosinophil count of  $\geq 0.3 \times 10^9/L$  and has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
- blood eosinophil count of  $\geq 0.15 \times 10^9/L$  and is receiving treatment with daily 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:

- 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 ICS is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
3. 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 mepolizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 100 mg every four weeks.
- Approval period: 1 year.

**METFORMIN AND LINAGLIPTIN (JENTADUETO)**

**500 mg / 2.5 mg, 850 mg / 2.5 mg and 1000 mg / 2.5 mg tablets**

For the treatment of type 2 diabetes mellitus in patients who are already stabilized on therapy with linagliptin and metformin, to replace the individual components of linagliptin and metformin.

**METFORMIN AND SAXAGLIPTIN (KOMBOGLYZE)**

**500 mg / 2.5 mg, 850 mg / 2.5 mg and 1000 mg / 2.5 mg tablets**

For the treatment of type 2 diabetes mellitus in patients who are already stabilized on therapy with saxagliptin and metformin, to replace the individual components of saxagliptin and metformin.

**METHADONE**

**Compounded Oral Solution**

For the management of severe cancer-related or chronic non-malignant pain.

Claim Note:

- Claims submitted by pharmacies must be billed using PIN 00999801

**METHADONE (METADOL and generic brands)**  
**1 mg, 5 mg, 10 mg and 25 mg tablets**  
**1 mg/mL oral solution and 10 mg/mL oral concentrate**

For the management of severe cancer-related or chronic non-malignant pain.

Claim Note:

- Requests will not be considered for the treatment of opioid use disorder.

**METHYLPHENIDATE (BIPHENTIN and generic brand)**  
**10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 80 mg controlled release capsules**

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.

**MIDOSTAURIN (RYDAPT)**  
**25 mg capsule**

For the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) when used in combination with standard cytarabine and daunorubicin (7+3) induction and cytarabine consolidation chemotherapy.

Claim Notes:

- Requests for midostaurin will not be considered when used as maintenance therapy, or as part of re-induction and/or re-consolidation.
- Requests for midostaurin in combination with idarubicin containing 7+3 induction and cytarabine consolidation chemotherapy will be considered.
- Approval period: Up to 6 cycles (maximum of 2 cycles of induction and 4 cycles of consolidation).
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**MIGALASTAT (GALAFOLD)**  
**123 mg capsule**

For the treatment of Fabry Disease in adults with a lab-confirmed alpha-galactosidase (alpha-Gal A) mutation, determined to be amenable by an in vitro assay.

Clinical Note:

- Eligibility for the treatment of Fabry Disease is determined by the Canadian Fabry Disease Initiative. Please contact the NB Drug Plans at 1-800-332-3691 for the request form.

Claim Notes:

- Combined use of more than one disease specific therapy (i.e. enzyme replacement therapy or chaperone therapy) will not be reimbursed.
- Approval period: 1 year. 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](#).

**MIRABEGRON (MYRBETRIQ and generic brand)**  
**25 mg and 50 mg extended-release tablets**

For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of a regular benefit OAB drug (e.g. immediate-release oxybutynin, solifenacin or tolterodine).

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

**MIRIKIZUMAB (OMVOH)**  
**100 mg/mL autoinjector and prefilled syringe**  
**300 mg vial**

For the treatment of adult 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. aminosaliclates 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 Criteria:**

- 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 aminosaliclates 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 intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Intravenous (IV) infusion: Initial approvals will be for a maximum of 300 mg at week 0, 4, and 8.
- Subcutaneous injection: Approvals will be for a maximum of 200 mg every 4 weeks after completion of induction dosing.
- Requests for an additional 3 doses of 300 mg IV at week 12, 16, and 20 will be considered for patients who do not have adequate therapeutic response at Week 12.
- Initial approval period: 24 weeks.
- Renewal approval period: 1 year.

**MIRTAZAPINE (REMERON RD and generic brand)  
15 mg, 30 mg, and 45 mg orally disintegrating tablets**

For use in patients when regular mirtazapine tablets are not an option.

**MITOMYCIN FOR INJECTION (generic brand)  
20 mg vial**

When compounded as an ophthalmic drop for the treatment of patients with one of the following ocular malignancies:

- Malignant melanoma of the conjunctiva
- Ocular surface squamous neoplasia (also known as conjunctival-corneal intraepithelial neoplasia)

**Renewal Criteria:**

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

**Claim Notes:**

- Must be prescribed by an ophthalmologist or oncologist.
- Approval period: 6 months.

**MODIFIED RAGWEED POLLEN TYROSINE ADSORBATE (POLLINEX-R)  
105 PNU / 0.5 mL, 250 PNU / 0.5 mL, 700 PNU / 0.5 mL and 2150 PNU / 0.5 mL prefilled syringes**

For the treatment of patients with severe, seasonal (lasting two or more years) IgE dependent allergic rhinoconjunctivitis when optimal therapy (i.e. intranasal corticosteroids and H<sub>1</sub> antihistamines) and allergen avoidance have not been sufficiently effective in controlling symptoms.

**Clinical Notes:**

1. Treatment with ragweed pollen allergen extract must be initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
2. Treatment should be initiated one month before the onset of ragweed season.
3. Optimal duration of therapy is unknown; therefore, if there is no improvement in symptoms after three years, treatment should be discontinued.

**MOMELOTINIB (OJJAARA)  
100 mg, 150 mg and 200 mg tablets**

For the treatment of splenomegaly and/or disease-related symptoms in adult patients with primary myelofibrosis (MF), post-polycythemia vera MF or post-essential thrombocythemia MF who meet all of the following criteria:

- Intermediate-2 or high-risk MF, or intermediate-1 risk associated with symptomatic splenomegaly and/or hepatomegaly, as assessed using DIPSS Plus
- Palpable splenomegaly of at least 5 cm
- Moderate to severe anemia, defined by a hemoglobin level of less than 100 g/L

**Renewal Criteria:**

- Written confirmation that the patient has responded to treatment as evidenced by a reduction in transfusion requirements, a reduction in splenic volume, or an improvement in symptoms of MF.

**Clinical Notes:**

- Patients must have a good performance status.
- Treatment should be discontinued if no response has been demonstrated after 6 months of treatment or upon disease progression, splenic progression, or unacceptable toxicity.

**Claim Note:**

- Approval period: 6 months.

**MOXIFLOXACIN (generic brands)  
400 mg tablet**

1. For completion of treatment initiated in the hospital setting for patients with nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic obstructive pulmonary disease (AECOPD).
2. For the treatment of complicated AECOPD in patients who:
  - have failed treatment with at least one first-line therapy (doxycycline, beta-lactam, trimethoprim-sulfamethoxazole, or macrolide), or
  - are intolerant or have contraindication(s) to at least two first-line therapies.
3. For the treatment of CAP in patients with radiographic confirmation of pneumonia who:
  - have failed treatment with at least one first-line therapy (macrolide, doxycycline, beta-lactams), or
  - are intolerant or have contraindication(s) to at least two first-line therapies.
4. For the treatment of pulmonary infections in patients with cystic fibrosis.
5. For the treatment of severe pneumonia in nursing home patients.
6. For the treatment of patients with complicated osteomyelitis or joint infections.

**Clinical Notes:**

1. If the patient has been treated with an antibiotic within the past 3 months consider an antibiotic from a different class.
2. Complicated AECOPD is defined as patients with COPD (FEV<sub>1</sub>/FVC greater than 0.7) experiencing increased sputum purulence, and with increased dyspnea or sputum volume, and one of the following:
  - FEV<sub>1</sub> less than 50% predicted
  - At least 4 exacerbations per year
  - Ischemic heart disease
  - Home oxygen use
  - Chronic oral steroid use

**Claim Notes:**

- Prescriptions written by infectious disease specialists, internal medicine specialists, hematologists, medical microbiologists, oncologists, oncology clinical associates, general practitioners in oncology, or respirologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Moxifloxacin is a regular benefit for Plans BV.

**Tuberculosis**

For the treatment of tuberculosis in patients who have lab-verified drug resistance or a contraindication or intolerance to first-line drugs.

**Claim Notes:**

- Must be prescribed by, or in consultation with, an infectious disease specialist.
- Requests will only be considered under Plan P.

**NADROPARIN (FRAXIPARIN)  
9,500 IU/mL prefilled syringe  
NADROPARIN (FRAXIPARIN FORTE)  
19,000 IU/mL prefilled syringe**

1. For the treatment of venous thromboembolism (VTE) and/or pulmonary embolism (PE) for a maximum of 30 days.
2. For the extended treatment of recurrent symptomatic venous thromboembolism (VTE) that has occurred while patients are on therapeutic doses of warfarin.

3. For the prophylaxis of venous thromboembolism (VTE) up to 35 days following elective hip replacement or hip fracture surgery.
4. For the prophylaxis of VTE up to 14 days following elective knee replacement surgery.
5. For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumour for up to 28 days.
6. For the treatment and secondary prevention of symptomatic venous thromboembolism (VTE) or pulmonary embolism (PE) for a period of up to 6 months in patients with cancer for whom warfarin therapy is not an option.

Claim Note:

- An annual quantity of 35 days of therapy is available without special authorization.

**NARATRIPTAN (generic brands)  
1 mg and 2.5 mg tablets**

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, eletriptan, rizatriptan, sumatriptan, zolmitriptan).

Claim Notes:

- Coverage limited to 6 doses per month.
- Requests for patients who have more than 3 migraines a month despite migraine prophylaxis therapy will be considered for a maximum of 12 doses per month.

**NATALIZUMAB (TYSABRI)  
300 mg / 15 mL single-use vial**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the past year
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
- Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab)

Renewal Criteria:

- Evidence of continued benefit must be provided (i.e. stability or reduction in the number of relapses in the past year or stability or improvement of EDSS score obtained within the previous 90 days).

Clinical Notes:

1. Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
2. A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

Claim Notes:

- Must be prescribed by a neurologist.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial approval period: 1 year.
- Renewal approval period: 2 years.

**NETUPITANT AND PALONOSETRON (AKYNZEO)  
300 mg / 0.5 mg capsule**

In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:

- highly emetogenic chemotherapy, or
- moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT<sub>3</sub> antagonist and dexamethasone in a previous cycle.

Claim Note:

- Prescriptions written by hematologists, oncologists, oncology clinical associates, or general practitioners in oncology who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.

**NICOTINE (generic brands)**  
**2 mg gum**  
**7 mg, 14 mg and 21 mg patches**  
**1 mg, 2 mg and 4 mg lozenges**

For smoking cessation.

Clinical Notes:

1. The patient should be participating in a form of smoking cessation counselling.
2. For information on quitting smoking or to obtain the special authorization request form, visit our website [Smoking Cessation Therapies](#).

Claim Notes:

- A maximum of 24 weeks of standard therapy (168 patches and 960 pieces of nicotine gum or nicotine lozenges) will be reimbursed annually without special authorization.
- Patients being treated within a program or clinic that participates in the Ottawa Model may be approved for additional patches based on degree of dependence (e.g. number of cigarettes smoked prior to initiating cessation therapy).
- Requests for nicotine replacement therapy (patches/gum/lozenge) for use in combination with a non-nicotine prescription smoking cessation drug (varenicline or bupropion) will not be considered.
- Requests for special authorization should be submitted on the Smoking Cessation Therapy Special Authorization Request Form.

**NILOTINIB (TASIGNA and generic brands)**  
**150 mg and 200 mg capsules**

1. For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
2. For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic or accelerated phase who have resistance or intolerance to tyrosine kinase inhibitor therapy.

Renewal Criteria:

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

Claim Note:

- Approval period: 1 year.

**NINTEDANIB (OFEV and generic brands)**  
**100 mg and 150 mg capsules**

**Chronic Fibrosing Interstitial Lung Diseases**

For the treatment of adult patients with chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype and a forced vital capacity (FVC) greater than or equal to 45% of predicted.

Renewal Criteria:

- Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% over the preceding 12 months of treatment with nintedanib.

Claim Notes:

- Must be prescribed by, or in consultation with a physician experienced in the treatment of ILD.
- Combination therapy of pirfenidone with nintedanib will not be reimbursed.
- Approval period: 1 year.

**Idiopathic Pulmonary Fibrosis**

For the treatment of adult patients with mild to moderate idiopathic pulmonary fibrosis (IPF) confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

Initial Renewal Criteria:

- Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted forced vital capacity (FVC) of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period).

Subsequent Renewal Criteria:

- Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period.

Clinical Note:

- Mild to moderate IPF is defined as a FVC greater than or equal to 50% predicted.

Claim Notes:

- Must be prescribed by, or in consultation with, physicians experienced in the treatment of IPF.
- Combination therapy of pirfenidone with nintedanib will not be reimbursed.
- Initial approval period: 7 months.
- Initial renewal approval period: 6 months.
- Subsequent renewal approval period: 1 year.

**NIRAPARIB (ZEJULA)  
100 mg capsule and tablet**

1. As monotherapy maintenance treatment for adult patients with newly diagnosed epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
  - Complete or partial radiologic response after at least 4 cycles of first-line platinum-based chemotherapy
  - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
  - High-grade serous or endometrioid tumours classified as Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.
- Requests for treatment beyond 3 years will not be considered.

Clinical Notes:

1. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.
2. Treatment should continue until unacceptable toxicity, disease progression, or completion of 3 years of therapy, whichever occurs first.

Claim Notes:

- Requests for niraparib in combination with bevacizumab will not be considered.
- 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](#).

2. As monotherapy maintenance treatment for adult patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer with high grade serous or endometrioid histology who meet all of the following criteria:
  - Completed at least 2 prior lines of platinum-based chemotherapy
  - Received at least 4 cycles of the most recent platinum-based chemotherapy and in complete or partial radiologic response
  - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks

Renewal Criteria:

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

Clinical Notes:

1. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
2. Patients should have good performance status and no active or uncontrolled metastases to the central nervous system.
3. Treatment should continue until unacceptable toxicity or disease progression.

Claim Notes:

- Requests for niraparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy.
- 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](#).

**NIRAPARIB AND ABIRATERONE (AKEEGA)  
50 mg / 500 mg and 100 mg / 500 mg tablets**

In combination with prednisone for the first-line treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who meet all of the following criteria:

- Presence of deleterious or suspected deleterious germline and/or somatic mutation in BRCA1 or BRCA2 genes; and
- Have not received prior treatment with an androgen receptor pathway inhibitor for metastatic castration-sensitive prostate cancer or non-metastatic castration-resistant prostate cancer.

**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 receiving abiraterone and prednisone as first-line therapy for mCRPC for less than 4 months may switch to niraparib and abiraterone (AKEEGA) with prednisone once BRCA mutation is confirmed provided there has been no disease progression on treatment.
- Requests will not be considered for patients previously treated with a PARP inhibitor or who experience disease progression on abiraterone in any setting.
- Approval period: 1 year.

**NIRMATRELVIR and RITONAVIR (PAXLOVID)  
300 mg and 100 mg dose packs  
150 mg and 100 mg dose packs**

For the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult patients with a positive COVID-19 test who are within 5 days of symptom onset and meet one of the following criteria:

- Severely immunosuppressed due to one or more of the following conditions:
  - Solid organ transplant
  - Receiving treatment for a malignant hematologic condition
  - Bone marrow transplant, stem cell transplant or transplant-related immunosuppressant use
  - Received an anti-CD20 therapy or B-cell depleting therapy (such as rituximab) in the previous two years
  - Severe primary immunodeficiencies
- Moderately immunosuppressed due to one or more of the following conditions:
  - Receiving treatment for cancer, including solid tumours
  - Receiving treatment with significantly immunosuppressing drugs (e.g., biologic in the past three months, oral immune-suppressing drug in the past month, oral glucocorticoid [20 mg per day of prednisone equivalent taken on an ongoing basis] in the past month, or immune-suppressing infusion or injection in the past three months)
  - Advanced HIV infection
  - Moderate primary immunodeficiencies
  - Renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis treated with a glucocorticoid, estimated glomerular filtration rate [eGFR] less than 15 mL/min/1.73m<sup>2</sup>)

**Clinical Notes:**

1. COVID-19 testing to confirm diagnosis can be performed by polymerase chain reaction (PCR) or point-of-care test (POCT).
2. Treatment should be initiated as soon as possible after a diagnosis of COVID-19 is confirmed.
3. Patients are not eligible for coverage if they are asymptomatic or if more than 5 days have elapsed since symptom onset.
4. Requests for patients who are moderately or severely immunosuppressed due to other conditions may be considered.

**Claim Notes:**

- Pharmacies must submit claims electronically using the applicable intervention codes, as outlined [here](#), if:
  - the patient meets the criteria for coverage, and
  - the Nirmatrelvir/Ritonavir (Paxlovid) special authorization request form is completed and retained by the pharmacy with the prescription.
- The [nirmatrelvir/ritonavir \(Paxlovid\) special authorization request form](#) does not need to be faxed to the NB Drug Plans.
- If a prescription for future use is written, the patient must meet eligibility criteria at the time of filling the prescription.
- Approval period: 5 days.

**NITISINONE (ORFADIN and generic brand)  
2 mg, 5 mg, 10 mg and 20 mg capsules**

For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

**Claim Notes:**

- Must be prescribed by, or in consultation with, a physician with experience in the diagnosis and management of HT-1.
- 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](#).

**NORETHINDRONE (NORLUTATE)  
5 mg tablet**

For the treatment of abnormal uterine bleeding in patients not able to be treated with other hormonal treatments.

**NUSINERSEN (SPINRAZA)  
2.4 mg/mL intrathecal injection**

For the treatment of 5q spinal muscular atrophy (SMA), if the following criteria are met:

- Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygous mutation; and
- Patient is not requiring permanent invasive ventilation; and
- Patient who:
  - is pre-symptomatic with genetic documentation of two or three copies of the survival motor neuron 2 (SMN2) gene, or
  - has had disease duration less than 6 months, two copies of the SMN2 gene, and symptom onset after the first week of birth and on or before 7 months of age, or
  - is under the age of 18 with symptom onset after 6 months of age.

**Discontinuation Criteria:**

Prior to the fifth dose or every subsequent dose:

- There is failure to demonstrate achievement or maintenance of motor milestone function as assessed using age-appropriate scales since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation; or
- There is failure to demonstrate maintenance in motor milestone function as assessed using age-appropriate scales since treatment initiation in patients who were symptomatic at the time of treatment initiation; or
- Permanent invasive ventilation is required.

**Clinical Notes:**

1. An age-appropriate scale is defined as the Hammersmith Infant Neurological Examination (HINE) Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Hammersmith Functional Motor Scale-Expanded (HFMSSE).
2. A baseline assessment using an age-appropriate scale must be completed prior to initiation of nusinersen treatment.
3. Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

**Claim Notes:**

- The patient must be under the care of a specialist experienced in the treatment of SMA.
- Combination therapy with risdiplam will not be reimbursed.
- Requests for nusinersen will not be considered for patients who have received adeno-associated virus (AAV) vector-based gene therapy
- Patients currently receiving SMA drug therapy may be eligible to switch to an alternate SMA drug therapy; however, patients will not be permitted to switch back to a previously trialed SMA drug.
- 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](#).

**OBETICHOLIC ACID (OCALIVA)  
5 mg and 10 mg tablets**

For the treatment of adult patients with primary biliary cholangitis (PBC) as either:

- combination therapy with ursodeoxycholic acid (UDCA) in patients who have experienced an inadequate response to a minimum of 12 months of UDCA treatment; or
- monotherapy in patients who have experienced unmanageable intolerance to UDCA.

**Requirement for Initial Requests:**

- Alkaline phosphatase (ALP) and bilirubin levels prior to initiation of treatment with obeticholic acid must be provided.

**Renewal Criteria:**

- Requests for renewal will be considered if the patient achieved:
  - a reduction in the ALP to less than 1.67 times the upper limit of normal (ULN); or
  - at least a 15% reduction in the ALP level from baseline (i.e. prior to initiation of treatment with obeticholic acid).

Clinical Notes:

1. Diagnosis confirmed by positive antimitochondrial antibodies or liver biopsy results consistent with PBC.
2. An inadequate response is defined as:
  - ALP  $\geq$  1.67 times ULN, or
  - bilirubin > ULN and < 2 times the ULN, or
  - evidence of compensated cirrhosis.
3. For patients who experience unmanageable intolerance to UDCA, details must be provided.

Claim Notes:

- Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist or other physician experienced in the treatment of PBC.
- Approval period: 12 months.

**OCRELIZUMAB (OCREVUS)**  
**30 mg/mL single-use vial**

**Primary Progressive Multiple Sclerosis**

For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Recent Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5
- Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings
- Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5
- Diagnostic imaging features characteristic of inflammatory activity

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Relapsing Remitting Multiple Sclerosis**

For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the last two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**OFATUMUMAB (KESIMPTA)**  
**20 mg / 0.4 mL autoinjector**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.

**OFLOXACIN (OCUFLOX)**  
**0.3% ophthalmic solution**

- For the treatment of ophthalmic infections caused by susceptible bacteria.
- For the prevention of ophthalmic infections associated with non-elective eye surgery.

Claim Note:

- Prescriptions written by ophthalmologists and prescribing optometrists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.

**OLAPARIB (LYNPARZA)**  
**100 mg and 150 mg tablets**

**Breast Cancer**

1. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who have had upfront surgery followed by adjuvant chemotherapy and who meet one of the following criteria:
  - Triple negative breast cancer and either axillary node-positive or axillary node-negative with invasive primary tumour pathological size of at least 2 cm ( $\geq$  pT2 cm)
  - Hormone receptor positive, HER2-negative breast cancer with at least 4 pathologically confirmed positive lymph nodes
2. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who received neoadjuvant chemotherapy followed by surgery and who meet one of the following criteria:
  - Triple negative breast cancer with residual invasive disease in the breast and/or resected lymph nodes (non-pCR)
  - Hormone receptor positive, HER2-negative breast cancer with residual invasive disease in the breast, and/or the resected lymph nodes, and a CPS + EG score of 3 or higher

Clinical Notes:

1. Patients must have completed neoadjuvant or adjuvant chemotherapy containing an anthracycline and/or taxane.
2. Treatment should be initiated within 12 weeks of completion of the last treatment (i.e., surgery, chemotherapy, or radiation therapy).
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 1 year of therapy, whichever occurs first.

Claim Notes:

- Requests for patients determined to be at high-risk for relapse using a disease scoring system other than CPS + EG will be considered.
- Concurrent or sequential use of adjuvant olaparib and pembrolizumab will not be reimbursed.
- Requests will not be considered for patients previously treated with a CDK4/6 inhibitor.
- Approval period: 1 year.

**Metastatic Castration-Resistant Prostate Cancer**

1. 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 an androgen receptor pathway inhibitor.

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 Note:

- Approval period: 1 year.
2. In combination with abiraterone and prednisone for the first-line treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who meet all of the following criteria:
- Presence of deleterious or suspected deleterious germline and/or somatic mutation in BRCA1 or BRCA2 genes; and
  - Have not received prior treatment with an androgen receptor pathway inhibitor for metastatic castration-sensitive prostate cancer or non-metastatic castration-resistant prostate cancer.

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 receiving abiraterone and prednisone as first-line therapy for mCRPC for less than 4 months may have olaparib added once BRCA mutation is confirmed provided there has been no disease progression on treatment.
- Requests will not be considered for patients previously treated with a PARP inhibitor or who experience disease progression on abiraterone in any setting.
- Approval period: 1 year.

**Ovarian Cancer**

1. As monotherapy maintenance treatment for adult patients with newly diagnosed BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
  - Complete or partial radiologic response after at least 4 cycles of first-line platinum-based chemotherapy
  - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
  - High-grade serous or endometrioid tumours classified as Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.
- Requests for treatment beyond 2 years will not be considered if there is no evidence of disease.

Clinical Notes:

1. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.
2. Treatment should continue until unacceptable toxicity, disease progression, or completion of 2 years of therapy, whichever occurs first.

Claim Notes:

- Requests for olaparib in combination with bevacizumab will not be considered.
  - Approval period: 1 year.
2. As monotherapy maintenance treatment for patients with recurrent, platinum-sensitive, BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer with high grade serous or endometrioid histology who meet all of the following criteria:
- Completed at least 2 previous lines of platinum-based chemotherapy
  - Received at least 4 cycles of the most recent platinum-based chemotherapy and in complete or partial radiologic response
  - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks

Renewal Criteria:

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

Clinical Notes:

1. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
2. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for olaparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy.
- Approval period: 1 year.

**OMALIZUMAB (OMLYCLO)  
150 mg/mL prefilled syringe**

For the treatment of patients 12 years of age and older with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H1 antihistamines.

Renewal Criteria:

- Complete symptom control for less than 12 consecutive weeks; or
- Partial response to treatment, defined as at least a  $\geq 9.5$  point reduction in baseline Urticaria Activity Score over 7 days (UAS7).

Clinical Notes:

1. The baseline UAS7 must be provided with the initial request.
2. Requests for renewal will require two UAS7 questionnaires. One assessment every 12 weeks in a 24 week approval period (i.e., an assessment in the middle of the approval period and at the end).
3. Moderate to severe CIU is defined as a UAS7  $\geq 16$ .
4. Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period.
5. In patients who discontinue treatment due to temporary symptom control, re-initiation can be considered if CIU symptoms reappear (i.e., UAS7  $\geq 16$ ).

Claim Notes:

- Approvals will be for a maximum dose of 300 mg every four weeks.
- Approval period: 24 weeks.

**ONABOTULINUMTOXINA (BOTOX)  
50 and 100 Allergan units per vial**

1. For the treatment of equinus foot deformity in cerebral palsy in patients 2 years of age and older.
2. For the treatment of cervical dystonia (spasmodic torticollis) in adults.
3. For the treatment of blepharospasm, hemifacial spasm (VII nerve disorder) and strabismus in patients 12 years of age and older.
4. For the treatment of upper and lower limb (at or below the knee) focal spasticity following stroke in adults.

Renewal Criteria:

- Documentation of continued benefit including the patient's functional and/or symptomatic improvement, as well as the dosage and injection schedule.

Claim Notes:

- Initial approval period: 1 year.
  - Renewal approval period: 3 years.
5. For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in adult patients who have an intolerance or insufficient response to an adequate trial of at least two other pharmacologic treatments (e.g. anticholinergics, mirabegron).

Renewal Criteria:

- Requests for renewal should provide objective evidence of a treatment response, defined as a reduction of at least 50% in the frequency of urinary incontinence episodes.

Claim Notes:

- Must be prescribed and administered by a urologist.
- Initial approval period: 12 weeks (one dose).
- Renewal approval period: Maximum of 3 doses per year in responders, at a frequency of no more than once every twelve weeks.

**ONABOTULINUMTOXINA (BOTOX)  
200 Allergan units per vial**

For the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder associated with multiple sclerosis (MS) or subcervical spinal cord injury (SCI) if the following conditions are met:

- patient failed to respond to behavioural modification and anticholinergics and/or is intolerant to anticholinergics
- subsequent treatments are provided at intervals no less than every 36 weeks.

Clinical Note:

- Patients who fail to respond to initial treatment with onabotulinumtoxinA should not be retreated.

**ONASEMNOGENE ABEPARVOVEC (ZOLGENSMA)**  
**2 x 10<sup>13</sup> vector genomes/mL solution for infusion**

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 administration of 1.1 x 10<sup>14</sup> 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.

**ONDANSETRON (ZOFTRAN, ZOFTRAN ODT and generic brands)**  
**2 mg/mL injection**  
**4 mg / 5 mL oral solution**  
**4 mg and 8 mg tablets and orally disintegrating tablets**

1. For the prevention of nausea and vomiting in patients receiving:
  - highly or moderately emetogenic chemotherapy / radiation therapy, or
  - chemotherapy / radiation therapy who have had inadequate symptom control with other available antiemetics.

Claim Note:

- Prescription written for tablets and orally disintegrating tablets by oncologists, oncology clinical associates, or a general practitioner in oncology who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
2. For the treatment of nausea and vomiting in pediatric patients (under 18 years of age) receiving chemotherapy (e.g., methotrexate) for chronic non-oncology conditions who have experienced an episode of nausea and vomiting.
  3. For the management of nausea and vomiting in patients receiving palliative care.

**OSELTAMIVIR (TAMIFLU and generic brands)**  
**30 mg, 45 mg and 75 mg capsules**

For residents of nursing homes during an influenza outbreak when one of the following criteria is met:

- For treatment of nursing home residents with clinically suspected or lab confirmed influenza A or B. A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the nursing home or surrounding community.
- For prophylaxis of nursing home residents during an influenza A or B outbreak. Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the nursing home.

Claim Notes:

- Coverage is limited to individuals enrolled in Plan V, when recommended by a Medical Officer of Health as outlined [here](#).
- Oseltamivir is a regular benefit for individuals who meet eligibility criteria of the Avian Flu Drug Therapy program (Plan I), as outlined [here](#).
- Oseltamivir is a regular benefit for individuals who meet eligibility criteria of the Seasonal Influenza Drug Therapy for Residents of Adult Residential Facilities program (Plan I), as outlined [here](#).

**OSELTAMIVIR (TAMIFLU and generic brand)  
6 mg/mL powder for suspension**

1. For residents of nursing homes during an influenza outbreak when oral capsules are not an option and who otherwise meet special authorization criteria for oseltamivir capsules.
2. For the prevention and treatment of avian influenza when oral capsules are not an option, for individuals who meet eligibility criteria of the Avian Flu Drug Therapy program.
3. For the prevention and treatment of seasonal influenza when oral capsules are not an option, for individuals who meet eligibility criteria of the Seasonal Influenza Drug Therapy for Residents of Adult Residential Facilities program.

Claim Notes:

- Requests will be considered for individuals enrolled in Plan V, when recommended by a Medical Officer of Health as outlined [here](#).
- Requests will be considered for individuals who meet eligibility criteria of the Avian Flu Drug Therapy program (Plan I) as outlined [here](#).
- Requests will be considered for individuals who meet eligibility criteria of the Seasonal Influenza Drug Therapy for Residents of Adult Residential Facilities program (Plan I) as outlined [here](#).

**OSIMERTINIB (TAGRISSO)  
40 mg and 80 mg tablets**

**Adjuvant Non-Small Cell Lung Cancer**

For the adjuvant treatment of patients with completely resected stage IB to IIIA (AJCC 7th edition) or stage IB to IIIB (AJCC 8<sup>th</sup> edition) non-small cell lung cancer (NSCLC) whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

Renewal Criteria:

- Written confirmation that the patient has not experienced disease recurrence.

Clinical Notes:

1. Patients must have a good performance status.
2. Patients should initiate treatment within 26 weeks of complete surgical resection if treated with adjuvant chemotherapy, or within 10 weeks if chemotherapy was not given.
3. Treatment should continue until disease recurrence, unacceptable toxicity, or until a maximum treatment duration of 3 years, regardless of dose reduction and dose interruption.

Claim Notes:

- Requests for treatment beyond 3 years will not be considered.
- 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](#).

**Advanced Non-Small Cell Lung Cancer**

1. As monotherapy, or in combination with pemetrexed and platinum-based chemotherapy, for the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
2. As monotherapy for the treatment of patients with locally advanced (not amenable to curative therapy) or metastatic EGFR T790M mutation-positive NSCLC when used as:
  - first-line therapy for de novo T790M mutation, or
  - second-line therapy for T790M mutation following disease progression during treatment with an EGFR tyrosine kinase inhibitor.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

Clinical Notes:

1. Patients receiving osimertinib in combination with chemotherapy must have an ECOG performance status of 0 or 1.
2. Treatment with osimertinib should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with osimertinib.
- 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](#).

**Locally Advanced, Unresectable (Stage III) Non-Small Cell Lung Cancer, Post Chemoradiation Therapy**

For the treatment of patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following definitive platinum-based chemoradiation therapy.

**Renewal Criteria:**

- Written confirmation that the patient has not experienced clinically meaningful disease progression.

**Clinical Notes:**

1. Patients must have a good performance status.
2. Patients should initiate treatment within 10 weeks of completing chemoradiation therapy.
3. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests will not be considered for patients who experience disease recurrence during or within 6 months of completing adjuvant treatment with osimertinib.
- 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](#).

**OXCARBAZEPINE (TRILEPTAL and generic brand)**

**150 mg, 300 mg and 600 mg tablets  
60 mg/mL oral suspension**

For the treatment of epilepsy in patients who have had an inadequate response or are intolerant to at least 3 other antiepileptics including carbamazepine.

**OXYCODONE (OXY IR and generic brand and SUPEUDOL)**

**5 mg, 10 mg and 20 mg immediate release tablets**

For the treatment of moderate to severe cancer-related or chronic non-malignant pain.

**OZANIMOD (ZEPOSIA)**

**0.23 mg, 0.46 mg and 0.92 mg capsules**

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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum of 0.92 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**PALBOCICLIB (IBRANCE and generic brands)**

**75 mg, 100 mg, and 125 mg tablets**

1. In combination with an aromatase inhibitor for the treatment of patients with hormone receptor positive, HER2 negative advanced or metastatic breast cancer who meet all of the following criteria:
  - have not received prior endocrine therapy for advanced or metastatic disease, but may have received up to one prior line of chemotherapy
  - are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy
  - do not have active or uncontrolled metastases to the central nervous system

**Renewal Criteria:**

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

**Clinical Notes:**

1. For patients who received (neo)adjuvant NSAI therapy, a minimum disease-free interval of twelve months after stopping therapy is required.
2. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist.
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy.
  - Approval period: 1 year.
2. In combination with fulvestrant for the treatment of patients with hormone receptor positive, HER2 negative advanced or metastatic breast cancer who:
- have not received prior endocrine therapy or have experienced disease progression on endocrine therapy, and
  - may have received up to one prior line of chemotherapy for advanced or metastatic disease, and
  - do not have active or uncontrolled metastases to the central nervous system.

Renewal Criteria:

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

Clinical Notes:

1. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist.
2. Patients must have a good performance status.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy, or for patients who progress on a CDK4/6 inhibitor, fulvestrant or everolimus in the metastatic setting.
- Approval period: 1 year.

**PALIPERIDONE (INVEGA SUSTENNA)**

**50 mg / 0.5 mL, 75 mg / 0.75 mL, 100 mg/mL and 150 mg / 1.5 mL prefilled syringes**

For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who:

- are not adherent to an oral antipsychotic, or
- are currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

Claim Note:

- Approval period: Long term.

**PALIPERIDONE PALMITATE (INVEGA TRINZA)**

**175 mg / 0.875 mL, 263 mg / 1.315 mL, 350 mg / 1.75 mL and 525 mg / 2.625 mL prefilled syringes**

For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who have been stabilized on therapy with injectable paliperidone for at least four months.

Claim Note:

- Approval period: Long term.

**PATISIRAN (ONPATTRO)**

**2 mg/mL vial**

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.

- Approvals will be for a maximum of 30 mg every 3 weeks.
- 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](#).

**PAZOPANIB (VOTRIENT and generic brands)  
200 mg tablet**

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

- first-line therapy, or
- second-line therapy following disease progression on nivolumab and ipilimumab combination 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 Note:

- Approval period: 1 year.

**PEGCETACOPLAN (EMPAVELI)  
1080 mg / 20 mL vial**

For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) who have an inadequate response to, or intolerable adverse effects to a C5 inhibitor.

Clinical Notes:

1. A request for coverage including the completed specific special authorization form must be submitted and the patient must:
  - a) Satisfy the criteria for coverage for pegcetacoplan (initial or continued coverage, as appropriate);
  - b) Not meet any of the criteria specified in Contraindications to Coverage or Discontinuance of Coverage.
2. Please contact the NB Drug Plans at 1-800-332-3691 for a packet containing the criteria for coverage and required special authorization form.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**PEGFILGRASTIM  
Fulphila 6 mg / 0.6 mL prefilled syringe  
Lapelga 6 mg / 0.6 mL autoinjector and prefilled syringe  
Ziextenzo 6 mg / 0.6 mL prefilled syringe**

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.

**PEGINTERFERON-BETA 1A (PLEGRIDY)  
63 mcg / 0.5 mL, 94 mcg / 0.5 mL, and 125 mcg / 0.5 mL autoinjector and prefilled syringe**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses of MS in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Approval period: 2 years

**PEMIGATINIB (PEMAZYRE)  
4.5 mg, 9 mg and 13.5 mg tablets**

For treatment of adult patients with unresectable or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement who have received at least one prior line of systemic therapy for advanced disease.

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: 6 months
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**PERAMPANEL (FYCOMPA and generic brand)  
2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg tablets**

For the adjunctive treatment of refractory partial-onset seizures or primary generalized tonic-clonic seizures in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response to at least three other antiepileptic drugs.

Claim Note:

- The patient must be under the care of a physician experienced in the treatment of epilepsy.

**PILOCARPINE (SALAGEN)  
5 mg tablet**

- For the treatment of the symptoms of xerostomia (dry mouth) due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck.
- For the treatment of the symptoms of xerostomia (dry mouth) and xerophthalmia (dry eyes) in patients with Sjögren's syndrome.

**PIRFENIDONE (ESBRIET and generic brands)  
267 mg capsule  
267 mg and 801 mg tablets**

For the treatment of adult patients with mild to moderate idiopathic pulmonary fibrosis (IPF) confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

Initial Renewal Criteria:

Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted forced vital capacity (FVC) of  $\geq 10\%$  from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Subsequent Renewal Criteria:

Patients must not demonstrate progression of disease defined as an absolute decline in percent predicted FVC of  $\geq 10\%$  within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Clinical Notes:

1. Mild to moderate IPF is defined as a FVC  $\geq 50\%$  predicted.
2. All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded before initiating treatment.

Claim Notes:

- Must be prescribed by, or in consultation with, physicians experienced in the treatment of IPF.
- Combination therapy of pirfenidone with nintedanib will not be reimbursed.
- Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests).
- Initial renewal approval period: 6 months.
- Subsequent renewal approval period: 12 months.

**PLERIXAFOR (MOZOBIL and generic brands)  
24 mg / 1.2 mL solution for injection**

For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients who meet one of the following criteria:

- PBCD34+ count of less than 10 cells/ $\mu$ L after 4 days of filgrastim, or
- Less than 50% of the target CD34+ yield is achieved on the first day of apheresis (after being mobilized with filgrastim alone or following chemotherapy), or
- Failed a previous attempt for stem cell mobilization with filgrastim alone or following chemotherapy.

Claim Notes:

- Reimbursement is limited to a maximum of 4 doses (0.24 mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**POMALIDOMIDE (POMALYST)  
1 mg, 2 mg, 3 mg and 4 mg capsules**

For the treatment of relapsed or refractory multiple myeloma when used:

- in combination with dexamethasone, with or without cyclophosphamide, for patients who experience disease progression on lenalidomide and a proteasome inhibitor; or
- in combination with isatuximab and dexamethasone for patients who experience disease progression on lenalidomide and a proteasome inhibitor.

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.

**PONATINIB (ICLUSIG)  
15 mg film-coated tablet**

For the treatment of patients with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) who have:

- resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs), or
- confirmed T315i mutation positive disease.

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 an ECOG performance status of 0-2.
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](#).

**POSACONAZOLE (generic brands)  
100 mg delayed-release tablets**

- For the prevention of invasive fungal infections in patients who have recently (within the past three months) undergone an allogeneic bone marrow transplant or chimeric antigen receptor (CAR) T-cell therapy.

- For the treatment of patients with invasive aspergillosis or mucormycosis.
- For the treatment of patients with invasive candidiasis who have a documented resistance to fluconazole.

Claim Notes:

- Must be prescribed by a hematologist, infectious disease specialist or medical microbiologist.
- Initial requests will be approved for a maximum of 4 months.

**PROPIVERINE (MICTORYL PEDIATRIC)**

**5 mg tablet**

For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.

**PROPRANOLOL (HEMANGIOL)**

**3.75 mg/mL oral solution**

For the treatment of patients with proliferating infantile hemangioma that is:

- Life- or function-threatening, or
- Ulcerated with pain or not responding to simple wound care measures, or
- At risk of permanent scarring or disfigurement

**RANIBIZUMAB (BYOOVIZ and RANOPTO)**

**10 mg/mL solution for intravitreal injection**

1. For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).
2. For the treatment of patients with choroidal neovascularization secondary to pathologic myopia (PM).
3. For the treatment of patients with choroidal neovascularization secondary to ocular conditions other than AMD and PM.
4. For the treatment of patients with diabetic macular edema (DME).
5. For the treatment of macular edema secondary to central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO).

Claim Notes:

- An initial claim of up to two vials (1 vial per eye treated) will be automatically reimbursed when prescribed by a New Brunswick ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval period: 1 year. Confirmation of continued response is required.

**RAVULIZUMAB (ULTOMIRIS)**

**300 mg / 3 mL and 1,100 mg / 11 mL single-use vials**

For the treatment of atypical hemolytic uremic syndrome (aHUS).

Clinical Notes:

1. A request for coverage including the completed specific special authorization form must be submitted and:
  - a) satisfy the Clinical Criteria for ravulizumab (initial or renewal criteria, as appropriate); and
  - b) not meet any the criteria specified in Contraindications to Coverage or Discontinuation of Coverage.
2. Please contact the NB Drug Plans at 1-800-332-3691 for the criteria and form.

Claim Notes:

- Initial approval period: 6 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](#).

**REGORAFENIB (STIVARGA)**

**40 mg film-coated tablet**

**Advanced Hepatocellular Carcinoma**

For the second-line treatment of patients with unresectable hepatocellular carcinoma who meet all of the following criteria:

- Disease progression on sorafenib or lenvatinib
- Child-Pugh class status of A
- 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 Note:

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

Claim Notes:

- Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.
- Requests for regorafenib will not be considered for patients who experience disease progression on cabozantinib or immunotherapy.
- Approval period: 6 months.

**Gastrointestinal Stromal Tumour**

For the treatment of patients with unresectable or metastatic gastrointestinal stromal tumours who experience disease progression on, or intolerance to, imatinib and sunitinib.

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 Note:

- Approval period: 6 months.

**Osteosarcoma**

For the treatment of patients with metastatic osteosarcoma who have received at least one prior line of 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 Note:

- Approval period: 6 months.

**RIBOCICLIB (KISQALI)  
200 mg tablet**

1. In combination with an aromatase inhibitor for the treatment of patients with hormone receptor positive, HER2 negative advanced or metastatic breast cancer who meet all of the following criteria:
  - have not received prior endocrine therapy for advanced or metastatic disease, but may have received up to one prior line of chemotherapy
  - are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy
  - do not have active or uncontrolled metastases to the central nervous system

Renewal Criteria:

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

Clinical Notes:

1. For patients who received (neo)adjuvant NSAI therapy, a minimum disease-free interval of twelve months after stopping therapy is required.
2. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist.
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will be not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy.
  - Approval period: 1 year.
2. In combination with fulvestrant for the treatment of patients with hormone receptor positive, HER2 negative advanced or metastatic breast cancer who:

- have not received prior endocrine therapy or have experienced disease progression on endocrine therapy, and
- may have received up to one prior line of chemotherapy for advanced or metastatic disease, and
- do not have active or uncontrolled metastases to the central nervous system.

**Renewal Criteria:**

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

**Clinical Notes:**

1. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist.
2. Patients must have a good performance status.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests will not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy, or for patients who progress on a CDK4/6 inhibitor, fulvestrant or everolimus in the metastatic setting.
- Approval period: 1 year.

**RIFABUTIN (MYCOBUTIN)  
150 mg capsule**

For the prevention of disseminated Mycobacterium avium complex (MAC) disease in patients with advanced HIV infection.

**Claim Notes:**

- Must be prescribed by, or in consultation with, an infectious disease specialist.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.

**RIFAXIMIN (ZAXINE)  
550 mg tablet**

For reducing the risk of overt hepatic encephalopathy (HE) recurrence in patients who have had two or more episodes and are unable to achieve adequate control of HE with maximum tolerated doses of lactulose alone.

**Clinical Note:**

- Must be used in combination with lactulose unless lactulose is not tolerated.

**RIOCIGUAT (ADEMPAS and generic brand)  
0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg film-coated tablets**

For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH) World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (18 years of age or older) with WHO Functional Class II or III pulmonary hypertension.

**Clinical Note:**

- Requests will be considered from physicians with experience in the diagnosis and treatment of CTEPH.

**Claim Note:**

- Approval period: 1 year.

**RIPRETINIB (QINLOCK)  
50 mg tablet**

For the treatment of adult patients with advanced gastrointestinal stromal tumours who experience disease progression on, or intolerance to, imatinib, sunitinib, and regorafenib.

**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:**

- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**RISANKIZUMAB (SKYRIZI)**  
**600 mg vial**  
**360 mg / 2.4 mL cartridge with on-body injector**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 600 mg by intravenous infusion at weeks 0, 4, and 8, then 360 mg by subcutaneous injection at week 12 and every 8 weeks thereafter.
- Initial approval period: 12 weeks.
- Renewal approval period: 1 year. Confirmation of response is required.

**RISANKIZUMAB (SKYRIZI)**  
**150 mg/mL autoinjector and prefilled syringe**

For the treatment of adult 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 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 drug 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.

**RISDIPLAM (EVRYSDI)**  
**60 mg powder for oral solution**

For the treatment of 5q spinal muscular atrophy (SMA), if the following criteria are met:

- Genetic documentation of 5q SMA homozygous gene deletion, or compound heterozygous mutation; and
- Patient is not requiring permanent invasive ventilation; and
- Patient who is symptomatic with two or three copies of the SMN2 gene and is:
  - 2 months to 7 months of age, or
  - 8 months to 25 years of age and non-ambulatory.

Discontinuation Criteria:

- There is failure to demonstrate maintenance in motor milestone function as assessed using age-appropriate scales since treatment initiation; or
- Permanent invasive ventilation is required.

Clinical Notes:

1. An age-appropriate scale is defined as the Hammersmith Infant Neurological Examination (HINE) Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Hammersmith Functional Motor Scale-Expanded (HFMSE).
2. A baseline assessment using an age-appropriate scale must be completed prior to initiation of treatment.
3. Yearly assessments must be completed using an age-appropriate scale no more than 12 weeks prior to the renewal date.
4. Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

Claim Notes:

- The patient must be under the care of a specialist experienced in the treatment of SMA.

- Combination therapy with nusinersen will not be reimbursed.
- Requests for risdiplam will not be considered for patients who have received adeno-associated virus (AAV) vector-based gene therapy.
- Patients currently receiving SMA drug therapy may be eligible to switch to an alternate SMA drug therapy; however, patients will not be permitted to switch back to a previously trialed SMA drug.
- Approvals will be for a maximum of 0.2 mg/kg/day for patients 2 months to less than 2 years of age, 0.25 mg/kg/day for patients greater than or equal to 2 years of age weighing less than 20 kg, or 5 mg/day for patients greater than or equal to 2 years of age and weighing greater than or equal to 20 kg.
- 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](#).

**RISPERIDONE (RISPERDAL CONSTA)  
12.5 mg, 25 mg, 37.5 mg and 50 mg vials**

For the treatment of patients who are:

- not adherent to an oral antipsychotic, or
- currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

Claim Notes:

- Requests will not be considered for the treatment of psychotic symptoms related to dementia.
- Approval period: Long term.

**RITUXIMAB (RIXIMYO, RUXIENCE, TRUXIMA)  
10 mg/mL vial**

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.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**RIVASTIGMINE (EXELON)  
2 mg/mL oral solution**

For the treatment of patients with mild to moderate dementia for whom oral tablets or capsules are not an option and who meet the following criteria:

- Mini-Mental State Exam (MMSE) score of 10 to 30
- Functional Assessment Staging Test (FAST) score of 4 to 5

Clinical Note:

- Requests must contain an updated MMSE and FAST score completed within 6 months of the request.

Claim Note:

- Approval period: 1 year.

**ROMOSUZUMAB (EVENTITY)  
105 mg / 1.17 mL prefilled syringe**

For the treatment of osteoporosis in postmenopausal women who meet all of the following criteria:

- History of osteoporotic fracture
- High fracture risk
- Treatment naive to osteoporosis medications, except for calcium and vitamin D

Clinical Note:

- High fracture risk is defined as a 10-year fracture risk ( $\geq 20\%$ ) as defined by the Fracture Risk Assessment (FRAX) tool.

Claim Notes:

- Combined use of romosozumab with other osteoporosis medications will not be reimbursed.
- Approvals will be for a maximum of 210 mg monthly.
- Maximum approval period: 1 year.

## **ROTIGOTINE (NEUPRO)**

### **2 mg, 4 mg, 6 mg and 8 mg transdermal patch**

For adjunctive treatment of patients with advanced stage Parkinson's disease who are currently receiving a levodopa-decarboxylase inhibitor combination.

## **RUFINAMIDE (BANZEL and generic brand)**

### **100 mg, 200 mg and 400 mg film-coated tablets**

For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome for patients who meet all of the following criteria:

- are under the care of a physician experienced in treating Lennox-Gastaut syndrome-associated seizures,  
AND
- are currently receiving two or more antiepileptic drugs,  
AND
- in whom less costly antiepileptic drugs are ineffective or not appropriate.

## **RUXOLITINIB (JAKAVI)**

### **5 mg, 10 mg, 15 mg and 20 mg tablets**

#### **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.

#### Myelofibrosis

For the treatment of splenomegaly and/or disease-related symptoms in adult patients with primary myelofibrosis (MF), post-polycythemia vera MF, or post-essential thrombocythemia MF who meet all of the following criteria:

- Intermediate to high-risk MF, or low risk with symptomatic splenomegaly, as assessed using DIPSS Plus
- Previously untreated or refractory to other treatment (i.e., hydroxyurea, anagrelide or peginterferon)

#### Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by a reduction in spleen size or symptom improvement.

#### Clinical Notes:

1. Patients must have an ECOG performance status of less than or equal to 3.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

#### Claim Notes:

- Requests will not be considered for patients who experience disease progression following treatment with fedratinib or momelotinib.
- Approval period: 6 months.

#### Polycythemia Vera

For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU).

#### 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.
3. Resistance is considered if, after at least 3 months of HU therapy at the maximum tolerated dose, patients experience at least one of the following:
  - Need for phlebotomy to maintain hematocrit (HCT) < 45%
  - Uncontrolled myeloproliferation (i.e. platelet count > 400 x 10<sup>9</sup>/L and white blood cell count > 10 x 10<sup>9</sup>/L)
  - Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation
4. Intolerance to HU is considered if patients experience at least one of the following:
  - Absolute neutrophil count < 1.0 x 10<sup>9</sup>/L, platelet count < 100 x 10<sup>9</sup>/L or hemoglobin < 100 g/L at the lowest dose of HU required to achieve a response. A response to HU is defined as HCT < 45% without phlebotomy, and/or all of the following: platelet count ≤ 400 x 10<sup>9</sup>/L, white blood cell count ≤ 10 x 10<sup>9</sup>/L, and non-palpable spleen.

- Presence of leg ulcers or other unacceptable HU-related non-hematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever
- Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity

Claim Notes:

- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**SACUBITRIL AND VALSARTAN (ENTRESTO and generic brands)  
24 mg / 26 mg, 49 mg / 51 mg and 97 mg / 103 mg film-coated tablets**

For the treatment of patients with New York Heart Association (NYHA) class II or III heart failure to reduce the incidence of cardiovascular death and heart failure hospitalization who meet all of the following criteria:

- Left ventricular ejection fraction (LVEF) of less than or equal to 40%.
- NYHA class II to III symptoms despite at least four weeks of treatment of the following:
  - a stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB); and
  - a stable dose of a beta-blocker and other recommended therapies, including a mineralocorticoid receptor antagonist (MRA).
- Plasma B-type natriuretic peptide (BNP)  $\geq$  150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP)  $\geq$  600 pg/mL.

Clinical Notes:

1. A plasma BNP  $\geq$  100 pg/mL or NT-proBNP  $\geq$  400 pg/mL will be considered if the patient has been hospitalized for heart failure within the past 12 months.
2. For patients who have not received four weeks of therapy with a beta blocker or MRA due to an intolerance or contraindication, details must be provided.

Claim Note:

- Approval period: Long term.

**SALBUTAMOL (VENTOLIN and generic brands)  
0.5 mg/mL, 1 mg/mL, 2 mg/mL and 5 mg/mL solution for inhalation**

For patients who have tried using an inhaler with spacer device and

- are unable to follow instructions, hold the spacer device or hold the device long enough to actuate it due to cognitive or physical limitations; or
- have difficulty generating adequate inspiratory effort to achieve therapeutic benefit.

Claim Notes:

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

**SALBUTAMOL AND IPRATROPIUM BROMIDE (generic brands)  
2.5 mg / 0.5 mg / 2.5 mL solution for inhalation**

For patients who have tried using an inhaler with spacer device and

- are unable to follow instructions, hold the spacer device or hold the device long enough to actuate it due to cognitive or physical limitations; or
- have difficulty generating adequate inspiratory effort to achieve therapeutic benefit.

Claim Notes:

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

**SAPROPTERIN (KUVAN and generic brand)  
100 mg tablet  
100 mg and 500 mg sachets**

For the ongoing treatment of hyperphenylalaninemia due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) in conjunction with a phenylalanine (Phe)-restricted diet in patients who meet all of the following criteria:

- Confirmed diagnosis based on genetic testing.
- Response as demonstrated by a sapropterin responsiveness test.
- Baseline blood Phe levels greater than 360  $\mu$ mol/L despite compliance with a low protein diet and formulas (non-pregnant patients require at least 2 baseline levels and pregnant patients require at least 1 baseline level during a 3 to 6 month time frame).
- Achievement of the following during a 6-month trial of treatment:

- For pregnant or non-pregnant patients, normal sustained blood Phe levels of 120 umol/L to 360 umol/L; or
- For non-pregnant patients, sustained blood Phe reduction of at least 30% compared to baseline if the baseline blood Phe level is less than 1200 umol/L; or
- For non-pregnant patients, sustained blood Phe reduction of at least 50% compared to baseline if the baseline blood Phe level is greater than 1200 umol/L.
- For non-pregnant patients, documented increase in dietary protein tolerance based on targets set between the clinician and patient.

**Renewal Criteria:**

- Confirmation of continued response based on Phe levels achieved during the 6-month trial. Two Phe levels taken at least 1 month apart must be provided.

**Clinical Notes:**

1. Patients must be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of PKU.
2. Phe blood levels and Phe tolerance levels must be provided.
3. Pregnant patients who have maintained a decrease in Phe levels below 360 umol/L during the 6-month trial period will be eligible for coverage for the duration of the pregnancy.

**Claim Notes:**

- Approvals will be for a maximum of 20 mg/kg per day.
- Renewals in pregnant patients will not be considered.
- 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](#).

**SARILUMAB (KEVZARA)**

**150 mg / 1.14 mL autoinjector**

**200 mg / 1.14 mL autoinjector and prefilled syringe**

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, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

**Claim Notes:**

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 200 mg every other week.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**SATRALIZUMAB (ENSPRYNG)**

**120 mg/mL prefilled syringe**

For the treatment of patients 12 years of age and older with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria:

- Aquaporin-4 antibody positive
- Expanded Disability Status Scale (EDSS) score of 6.5 points or less
- Experienced at least one relapse in the previous 12 months
- Relapse occurred despite an adequate trial of rituximab, or there has been an intolerance to rituximab

Renewal Criteria:

- Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.

Clinical Note:

- Satralizumab should not be initiated during a NMOSD relapse.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of NMOSD.
- Combined use of more than one biologic drug for the treatment of NMOSD will not be reimbursed.
- Approvals will be for 120 mg at week 0, 2 and 4, then 120 mg every four weeks thereafter.
- 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](#).

**SAXAGLIPTIN (ONGLYZA and generic brands)**  
**2.5 mg and 5 mg tablets**

For the treatment of type 2 diabetes mellitus when added to metformin and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea and in whom insulin is not an option.

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea due to contraindications or intolerances, details must be provided.

**SEBELIPASE ALFA (KANUMA)**  
**20 mg vial**

For the treatment of patients with lysosomal acid lipase (LAL) deficiency. For the complete criteria, please contact the NB Drug Plans at 1-800-332-3691.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SECUKINUMAB (COSENTYX)**  
**75 mg / 0.5 mL prefilled syringe**  
**150 mg/mL autoinjector and prefilled syringe**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 150 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Requests for 300 mg monthly will be considered for patients who continue to have active disease while on the recommended monthly maintenance dose of 150 mg.
- Initial approval duration: 6 months.
- Renewal approval duration: 1 year.

**Hidradenitis Suppurativa**

For the treatment of adult patients with active moderate to severe hidradenitis suppurativa (HS) who are refractory, intolerant or have contraindications to conventional therapy.

#### Clinical Note:

- Treatment should be discontinued if there is no response after 16 weeks.

#### 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 300 mg given at weeks 0, 1, 2, 3, and 4, then every 4 weeks thereafter.
- Initial approval period: 24 weeks.
- Requests for 300 mg every 2 weeks will be considered for patients who have had a partial response after 24 weeks while on the recommended dose of 300 mg every 4 weeks.
- Renewal approval period: 1 year. Confirmation of response is required.

#### **Plaque Psoriasis**

For the treatment of patients aged 6 and older with chronic moderate to severe plaque psoriasis who meet all of the following criteria:

- For patients aged 17 and older, a 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
- For pediatric patients aged 6 to 16, a PASI greater than 10 or Children's Dermatology Life Quality Index (CDLQI) greater than 7, 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 65 years of age or older) 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.
4. For pediatric patients, an adequate trial of a weight-based appropriate dose of methotrexate will be considered.

#### Claim Notes:

- Must be prescribed by a dermatologist.
- Combined use with other biologic drugs will not be reimbursed.
- Approvals will be for a maximum of 300 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- For pediatric patients weighing less than 50 kg, approvals will be for a maximum of 75 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Initial approval duration: 12 weeks.
- Renewal approval duration: 1 year. Confirmation of continued response is required.

#### **Psoriatic Arthritis**

- For the treatment of adult 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 adult 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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 150 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Requests for 300 mg given at weeks 0, 1, 2, 3, and 4 then monthly will be considered for patients who have previously had an inadequate response to TNF-inhibitors.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**SELEXIPAG (UPTRAVI)****200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg tablets**

For the treatment of pulmonary arterial hypertension (PAH) in patients with World Health Organization functional class II to IV, if the following clinical criteria are met:

- Inadequate control with a first-line (i.e. phosphodiesterase-5 inhibitor) and second-line (i.e. endothelin receptor antagonist) PAH therapy.
- Diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Combination therapy with prostacyclin or prostacyclin analogs will not be reimbursed.
- Must be prescribed by a clinician with experience in the diagnosis and treatment of PAH.

**SELINEXOR (XPOVIO)****20 mg tablet**

In combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. If previously treated with a proteasome inhibitor then the patient must meet all of the following criteria:

- Achieved at least a partial response with any prior bortezomib and with the most recent proteasome inhibitor.
- Therapy with bortezomib was not discontinued due to grade 3 or greater related toxicity.
- A proteasome inhibitor treatment-free interval of at least 6 months.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests will be considered for patients with plasma cell leukemia and systemic light chain amyloidosis.
- 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](#).

**SELPERCATINIB (RETEVMO)****40 mg and 80 mg capsules****Differentiated Thyroid Cancer**

For the treatment of RET fusion-positive differentiated thyroid cancer in adult patients with advanced or metastatic disease, not amenable to surgery or radioactive iodine therapy, following prior treatment with lenvatinib.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

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](#).

**Medullary Thyroid Cancer**

For the treatment of patients 12 years of age and older with unresectable advanced or metastatic RET-mutant medullary thyroid cancer who have progressed on, are intolerant to, or have a contraindication to first-line therapy.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

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](#).

### **Non-Small Cell Lung Cancer**

For the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer as first-line therapy or after prior systemic therapy.

#### Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

#### Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
3. If central nervous system metastases are present, patients must be asymptomatic or have stable disease.

#### 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](#).

### **SELUMETINIB (KOSELUGO) 10 mg and 25 mg capsules**

For the treatment of pediatric patients aged 2 to 18 years of age with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

#### Renewal Criteria:

- Requests for renewal must include documentation of improvement or stabilization of clinical status from baseline on all of the following parameters, as determined through clinical assessment and/or imaging:
  - Reduction in PN-related pain
  - Improved function in PN-affected anatomical areas
  - Reduction in PN volume and/or size
  - Achievements in NF1 disease stabilization

#### Clinical Note:

- Request for coverage must include baseline information on the PN location(s) and size(s), PN-related pain, PN-related functional impairment, and description of overall NF1 disease activity.

#### Claim Notes:

- Must be prescribed by a neuro-oncologist or a pediatrician with expertise in neuro-oncology.
- Approvals will be for a maximum daily dose of 100 mg.
- Initial approval period: 18 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](#).

### **SEMAGLUTIDE (OZEMPIC) 2 mg / 1.5 mL, 2 mg / 3 mL and 4 mg / 3 mL autoinjectors**

For the treatment of adult patients with type 2 diabetes mellitus when added to:

- metformin for patients who have inadequate glycemic control on metformin; or
- metformin and a sulfonylurea for patients who have inadequate glycemic control on metformin and a sulfonylurea.

#### Clinical Notes:

1. For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
2. Inadequate glycemic control is defined as a glycosylated hemoglobin (HbA1C) of  $\geq 7.0\%$ .
3. The most recent HbA1C must be provided with the request.

#### Claim Note:

- Approvals will be for a maximum of 1 autoinjector every 4 weeks.

### **SILDENAFIL (REVATIO and generic brands) 20 mg film-coated tablet**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class II, III or IV.

#### Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- The maximum dose of sildenafil that will be reimbursed is 20 mg three times daily.
- Approval period: Long term.

**SILODOSIN (generic brands)  
4 mg and 8 mg capsules**

For the treatment of benign prostatic hyperplasia in male patients who have an intolerance or insufficient response to an adequate trial of tamsulosin and alfuzosin.

Claim Note:

- Approval period: Long term.

**SIPONIMOD (MAYZENT)  
0.25 mg and 2 mg tablets**

For the treatment of patients with active secondary progressive multiple sclerosis (SPMS) who meet all of the following criteria:

- History of relapsing-remitting multiple sclerosis and current active SPMS
- Recent Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Clinical Notes:

1. Active SPMS is defined as having had relapses in the past 2 years and/or having at least one T1 gadolinium-enhancing lesion prior to treatment initiation with siponimod.
2. Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist.
- Approvals will be for a maximum of 2 mg daily.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.

**SODIUM BICARBONATE (generic brands)  
500 mg tablets**

For the treatment of metabolic acidosis in patients with chronic kidney disease who have a serum bicarbonate (CO<sub>2</sub>) < 22mmol/L.

**SODIUM FERRIC GLUCONATE COMPLEX (FERRLECIT)  
12.5 mg/mL vial**

For the treatment of iron deficiency anemia (IDA) in patients who:

- are intolerant to oral iron replacement products, or
- have not responded to a 4 week trial period of oral iron.

Clinical Notes:

1. IDA is defined as a hemoglobin (Hgb) level ≤ 130 g/L and a ferritin level ≤ 30 mcg/L or transferrin saturation (TSAT) level ≤ 30%.
2. The most recent Hgb and ferritin/TSAT must be provided with the request.

**SODIUM PHENYLBUTYRATE (PHEBURANE)  
483 mg/g coated granules**

For the treatment of patients with urea cycle disorders (UCDs).

Clinical Note:

- Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOFOBUVIR (SOVALDI)  
400 mg tablet**

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value in the last 12 months.

<b>Approval Period</b>	
<b>Genotype 2</b> <ul style="list-style-type: none"> <li>• Without cirrhosis</li> <li>• With compensated cirrhosis</li> </ul>	12 weeks in combination with ribavirin (RBV)
<b>Genotype 3</b> <ul style="list-style-type: none"> <li>• Without cirrhosis</li> <li>• With compensated cirrhosis</li> </ul>	24 weeks in combination with RBV

Clinical Notes:

1. Genotype must be provided.
2. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOFOBUVIR AND LEDIPASVIR (HARVONI)  
400 mg / 90 mg tablet**

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value within the last 12 months.

<b>Approval Period</b>	
<b>Genotype 1</b> <ul style="list-style-type: none"> <li>• Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level &lt; 6 million IU/mL and mono-HCV infected only</li> </ul>	8 or 12 weeks
<b>Genotype 1</b> <ul style="list-style-type: none"> <li>• Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level ≥ 6 million IU/mL</li> <li>• Treatment-naïve with compensated cirrhosis</li> <li>• Treatment-naïve with advanced liver fibrosis (Fibrosis stage F3-F4)</li> <li>• Treatment-experienced without cirrhosis</li> <li>• HCV/HIV co-infected without cirrhosis or with compensated cirrhosis</li> <li>• Liver transplant recipients without cirrhosis or with compensated cirrhosis</li> </ul>	12 weeks
<b>Genotype 1</b> <ul style="list-style-type: none"> <li>• Treatment-experienced with compensated cirrhosis</li> <li>• Decompensated cirrhosis</li> </ul>	24 weeks

Clinical Notes:

1. Genotype must be provided.
2. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOFOBUVIR AND VELPATASVIR (EPCLUSA)  
400 mg / 100 mg tablet**

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) with a confirmed quantitative HCV RNA value within the last 12 months.

<b>Approval Period</b>	
<b>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</b> <ul style="list-style-type: none"> <li>• Patients with compensated cirrhosis</li> <li>• Patients without cirrhosis</li> </ul>	12 weeks
<b>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</b> <ul style="list-style-type: none"> <li>• Patients with decompensated cirrhosis</li> </ul>	24 weeks

Clinical Note:

- Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOFOBUVIR, VELPATASVIR AND VOXILAPREVIR (VOSEVI)  
400 mg / 100 mg / 100 mg tablet**

For treatment-experienced adult patients with chronic hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis with a quantitative HCV RNA value within the last 12 months.

<b>Approval Period</b>	
<b>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</b> <ul style="list-style-type: none"> <li>• Patients with compensated cirrhosis</li> <li>• Patients without cirrhosis</li> </ul>	12 weeks

Clinical Note:

- Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Notes:

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOMATROGON (NGENLA)  
24 mg / 1.2 mL and 60 mg / 1.2 mL autoinjectors**

For the treatment of isolated growth hormone deficiency or growth hormone deficiency as part of multiple pituitary hormone deficiency in pre-pubertal children who are at least 3 years of age.

Discontinuation Criteria:

- Height velocity is less than 2 cm per year and bone age is more than 16 years in boys and 14 years in girls; or
- Closure of the epiphyseal growth plates.

Clinical Notes:

1. Patient height and weight must be provided with all requests.
2. Confirmation there is no evidence of epiphyseal growth plate closure and a copy of the bone age report must be provided with all requests.
3. Bone age assessments may be based on the Greulich Pyle Atlas, Tanner-Whitehouse, or other appropriate methods of assessment.

Claim Notes:

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

- Approvals will be for a maximum of 0.66 mg/kg weekly.
- Approval period: 1 year.

**SOMATROPIN (GENOTROPIN)**

**0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg and 2 mg MiniQuick prefilled syringes  
5.3 mg and 12 mg GoQuick autoinjectors**

**Growth Hormone Deficiency in Children**

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

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

**Turner Syndrome**

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

Claim Note:

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

**SOMATROPIN (HUMATROPE)**

**6 mg, 12 mg and 24 mg cartridges**

**Growth Hormone Deficiency in Children**

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

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

**Turner Syndrome**

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

Claim Note:

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

**SOMATROPIN (NORDITROPIN NORDIFLEX)**

**5 mg / 1.5 mL, 10 mg / 1.5 mL and 15 mg / 1.5 mL autoinjectors**

**SOMATROPIN (NORDITROPIN FLEXPRO)**

**10 mg / 1.5 mL and 15 mg / 1.5 mL autoinjectors**

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

Claim Notes:

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

**SOMATROPIN (NUTROPIN AQ NuSpin)**

**5 mg / 2 mL, 10 mg / 2 mL, and 20 mg / 2 mL prefilled cartridges**

**SOMATROPIN (SAIZEN)**

**5 mg vials**

**6 mg, 12 mg and 20 mg cartridges**

**Growth Hormone Deficiency in Children**

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

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

**Turner Syndrome**

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

Claim Note:

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

**Chronic Renal Insufficiency**

For the treatment of children with growth failure associated with chronic renal insufficiency, up to the time of renal transplantation, who meet the following criteria:

- A glomerular filtration rate less than or equal to 1.25 mL/s/1.73m<sup>2</sup> (75 mL/min/1.73m<sup>2</sup>)
- Evidence of growth impairment:
  - Z score (HSDS) less than -1.88 (HSDS = height standard deviation score, a statistical comparison to the average of normal values for age and sex) or height-for-age at the 3rd percentile
  - OR
  - Height velocity-for-age SDS less than -1.88 or height velocity-for-age less than 3<sup>rd</sup> percentile, persisting for greater than 3 months despite treatment of nutritional deficiencies and metabolic abnormalities.

Claim Note:

- Somatropin must be prescribed by, or in consultation with, a specialist in pediatric nephrology.

**SOMATROPIN (OMNITROPE)**

**5 mg / 1.5 mL, 10 mg / 1.5 mL and 15 mg / 1.5 mL cartridges**

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

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

**SORAFENIB (NEXAVAR)**

**200 mg film-coated tablet**

**Advanced Hepatocellular Carcinoma**

For the treatment of unresectable hepatocellular carcinoma, as first-line or second-line therapy after progression on immunotherapy, for patients who meet all of the following criteria:

- Child-Pugh class status of A
- ECOG performance status of 0 or 1
- Progressed on trans-arterial chemoembolization (TACE) or not suitable for the TACE procedure

Renewal Criteria:

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

Claim Notes:

- Requests for sorafenib will not be considered for patients who have progressed on lenvatinib.
- Approval period: 6 months.

**Metastatic Renal Cell Carcinoma (MRCC)**

For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine 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 Note:

- Approval period: 1 year.

**STIRIPENTOL (DIACOMIT)**

**250 mg and 500 mg capsules**

**250 mg powder for suspension**

For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

Clinical Note:

- The patient must be under the care of a neurologist or a pediatrician.

**SUCROFERRIC OXYHYDROXIDE (VELPHORO)**

**500 mg iron chewable tablet**

For the treatment of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end-stage renal disease who are on dialysis.

Claim Note:

- Approval period: Long term.

**SUMATRIPTAN (IMITREX NASAL SPRAY)  
5 mg and 20 mg nasal sprays**

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to oral triptans listed as regular benefits.

Claim Notes:

- Coverage limited to 6 doses per month.
- Requests for patients who have more than 3 migraines a month despite migraine prophylaxis therapy will be considered for a maximum of 12 doses per month.

**SUMATRIPTAN (IMITREX INJECTION and generic brand)  
6 mg / 0.5 mL prefilled syringe**

For the treatment of patients with acute migraine attacks who have had an insufficient response to oral and nasal triptans, or nausea and/or vomiting precludes their use.

Claim Notes:

- Coverage limited to 6 doses per month.
- Requests for patients who have more than 3 migraines a month despite migraine prophylaxis therapy will be considered for a maximum of 12 doses per month.

**SUNITINIB (SUTENT and generic brands)  
12.5 mg, 25 mg and 50 mg capsules**

**Gastrointestinal Stromal Tumour**

For the treatment of patients with unresectable or metastatic gastrointestinal stromal tumour who experience disease progression on, or intolerance to, imatinib.

Renewal Criteria:

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

Clinical Note:

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

Claim Note:

- Approval period: 6 months.

**Metastatic Renal Cell Carcinoma**

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

- first-line therapy, or
- second-line therapy following disease progression on nivolumab and ipilimumab combination 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 Note:

- Approval period: 1 year.

**Pancreatic Neuroendocrine Tumours**

For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumours.

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 Note:

- Approval period: 1 year.

**TACROLIMUS (PROTOPIC)  
0.03% ointment**

For the treatment of atopic dermatitis in patients 2 years of age and older who have failed to respond to a site appropriate strength of topical corticosteroid therapy (i.e., low potency on face versus intermediate to high potency for trunk and extremities).

Claim Note:

- Approval period: 1 year.

**TACROLIMUS (PROTOPIC)  
0.1% ointment**

For the treatment of adults with moderate to severe atopic dermatitis who have failed to respond to a site appropriate strength of corticosteroid therapy (i.e. low potency for the face versus intermediate to high potency for the trunk and extremities).

Claim Note:

- Approval period: 1 year.

**TAFAMIDIS (VYNDAMAX)  
61 mg capsule  
TAFAMIDIS MEGLUMINE (VYNDALIQ)  
20 mg capsule**

For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria:

- New York Heart Association (NYHA) class I to III heart failure
- At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
- Has not previously undergone a heart or liver transplant
- Does not have an implanted cardiac mechanical assist device (CMAD)

Discontinuation Criteria:

The patient has:

- NYHA class IV heart failure, or
- received an implanted CMAD, or
- received a heart or liver transplant.

Clinical Notes:

1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following:
  - absence of a variant transthyretin (TTR) genotype
  - TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer
  - evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
  - positive findings on technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computerized tomography (SPECT) scanning or presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue)
2. Hereditary ATTR-CM consists of all of the following:
  - presence of a variant TTR genotype associated with CM and presenting with a CM phenotype
  - evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm
  - positive findings on technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computerized tomography (SPECT) scanning or presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue)

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR-CM will not be reimbursed.
- Initial approval period: 9 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](#).

**TEDUGLUTIDE (REVESTIVE)  
5 mg vial**

For the ongoing treatment of patients with Short Bowel Syndrome (SBS) as a result of major intestinal resection (e.g. volvulus, vascular disease, cancer, Crohn's disease, injury, congenital disease) who meet the following criteria:

- For pediatric patients:
  - Cumulative lifetime duration of parenteral support (PS) must be at least 12 months
  - PS must provide more than 30% of caloric and/or fluid and electrolyte needs
  - Prior to initiating teduglutide, PS frequency and volume must be stable for at least three months or there must be no improvement in enteral feeding for at least three months
- For adult patients:
  - Dependency on parenteral support (PS) for a least 12 months
  - Prior to initiating teduglutide, PS required at least three times weekly to meet caloric, fluid and electrolyte needs and stable PS frequency and volume for at least one month

A request for coverage for continued treatment will be considered if the patient has achieved at least a 20% reduction in PS volume compared to baseline, while on teduglutide therapy.

Renewal Criteria:

- Has maintained at least a 20% reduction in PS volume from baseline at 12 months.

Clinical Note:

- PS is defined as parenteral nutrition which encompasses parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and/or intravenous fluids which addresses fluid and electrolyte needs of patients.

Claim Notes:

- Must be prescribed by a gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
- 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](#).

**TERIFLUNOMIDE (generic brands)  
14 mg film-coated tablet**

**Radiologically Isolated Syndrome**

For the treatment of adult patients with a confirmed diagnosis of radiologically isolated syndrome (RIS) based on the most recent McDonald criteria.

Claim Notes:

- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat RIS will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years.

**Relapsing Remitting Multiple Sclerosis**

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Prescriptions written by neurologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ACDEFGV.
- Approval period: 2 years

**TERIPARATIDE (generic brands)  
250 mcg/mL autoinjector**

For the treatment of severe osteoporosis in patients who meet all of the following criteria:

- History of fragility fracture

- Documented bone mineral density (BMD) T-score of less than or equal to -2.5
- Contraindication or are refractory to bisphosphonates (oral and IV) and denosumab

Clinical Notes:

- Refractory is defined as a fragility fracture, or evidence of a decline in BMD below pre-treatment baseline levels, despite treatment with a bisphosphonate and denosumab. A trial of one year is required for both anti-resorptive drugs.

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Requests for teriparatide will not be considered for patients who have previously been treated with romosozumab.
- Approvals will be for a maximum of one autoinjector every 4 weeks.
- Maximum approval period: 18 months.

**TESTOSTERONE (ANDROGEL and generic brand)**

**1% gel (2.5 g and 5 g packets)**

**TESTOSTERONE (TESTIM)**

**1% gel (5 g tube)**

1. For the treatment of congenital and acquired primary or secondary hypogonadism in males with a diagnosis of:
  - Primary: cryptorchidism, Klinefelter's, orchiectomy, and other established causes
  - Secondary: pituitary-hypothalamic injury due to tumours, trauma, radiation

Clinical Notes:

1. Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate free testosterone measurements before initiating any replacement therapy.
2. Older males with non-specific symptoms of fatigue, malaise, or depression who have low testosterone levels do not satisfy these criteria.

Claim Notes:

- Approvals will be for a maximum of 5 g daily.
  - Approval period: 1 year.
2. For use in gender affirming hormone therapy when regular benefit testosterone options are not appropriate.

Claim Notes:

- Approvals will be for a maximum of 5 g daily.
- Approval period: 1 year.

**TESTOSTERONE UNDECANOATE (generic brands)**

**40 mg capsule**

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

- Primary: cryptorchidism, Klinefelter's, orchiectomy, and other established causes
- Secondary: pituitary-hypothalamic injury due to tumours, trauma, radiation

Clinical Notes:

1. Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate free testosterone measurements before initiating any replacement therapy.
2. Older males with non-specific symptoms of fatigue, malaise, or depression who have low testosterone levels do not satisfy these criteria.

Claim Note:

- Approval period: 1 year.

**TEZPELUMAB (TEZSPIRE)**

**210 mg / 1.91 mL autoinjector and prefilled syringe**

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.

**THYROTROPIN (THYROGEN)**

**0.9 mg/mL vial**

1. For on-going evaluation in patients who have documented evidence of thyroid cancer, have undergone appropriate surgical and/or medical management, and require monitoring for recurrence and metastatic disease. This includes:
  - The patient has failed to respond to, or relapsed during:
    - Primary use in patients with inability to raise an endogenous TSH level ( $\geq 25$  mu/L) with thyroid hormone withdrawal.
    - Primary use in patients with one of the following documented comorbidities in whom severe hypothyroidism could be life threatening:
      - unstable angina
      - recent myocardial infarction
      - class III-IV congestive heart failure
      - uncontrolled psychiatric illness
      - other medical condition in which the clinical course could lead to a potential life threatening situation
    - Secondary use in patients with previous thyroid hormone withdrawal resulting in a documented life threatening event.
2. As an adjunctive treatment as pre-therapeutic stimulation for radioiodine ablation of thyroid tissue remnants in patients maintained on thyroid hormone suppression therapy who have undergone near-total or total thyroidectomy for well-differentiated thyroid cancer without evidence of distant metastatic thyroid cancer.

**TICAGRELOR (generic brands)**

**60 mg tablet**

In combination with ASA for patients with a history of ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEMI) in the previous 3 years who are at high risk for subsequent cardiovascular events.

**Clinical Note:**

- High risk for subsequent cardiovascular events is defined as age 65 years or older, diabetes, second prior spontaneous myocardial infarction, multivessel coronary artery disease, or chronic renal dysfunction (creatinine clearance  $< 60$  mL/min).

**Claim Notes:**

- Prescriptions written by cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Approval period: 3 years.

**TICAGRELOR (BRILINTA and generic brands)  
90 mg tablet**

1. In combination with ASA for patients with ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEMACS) who receive percutaneous coronary intervention (PCI).

Claim Notes:

- Prescriptions written by cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Approval period: 1 year.

2. For the treatment of patients who have recurrent cardiovascular events (STEMI or NSTEMACS), or definite stent thrombosis, while on clopidogrel and ASA therapy.

Clinical Note:

- Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours.

Claim Notes:

- Prescriptions written by cardiologists who are licensed by the College of Physicians and Surgeons of New Brunswick do not require special authorization.
- Approval period: Long term.

**TIGECYCLINE (TYGACIL)  
50 mg vial**

For the treatment of patients with multi-drug resistant infections when alternative agents are not an option.

Claim Note:

- Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

**TINZAPARIN (INNOHEP)  
10,000 IU/mL multidose vial and prefilled syringes  
20,000 IU/mL multidose vial and prefilled syringes**

1. For the treatment of venous thromboembolism (VTE) and/or pulmonary embolism (PE) for a maximum of 30 days.
2. For the extended treatment of recurrent symptomatic venous thromboembolism (VTE) that has occurred while patients are on therapeutic doses of warfarin.
3. For the prophylaxis of venous thromboembolism (VTE) up to 35 days following elective hip replacement or hip fracture surgery.
4. For the prophylaxis of VTE up to 14 days following elective knee replacement surgery.
5. For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumour for up to 28 days.
6. For the treatment and secondary prevention of symptomatic venous thromboembolism (VTE) or pulmonary embolism (PE) for a period of up to 6 months in patients with cancer for whom warfarin therapy is not an option.

Claim Note:

- An annual quantity of 35 days of therapy is available without special authorization.

**TILDRAKIZUMAB (ILUMYA)  
100 mg/mL prefilled syringe**

For the treatment of adult 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 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 dose and for duration of treatment 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.
- Approvals will be for a maximum of 100 mg at weeks 0 and 4, then every 12 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of response is required.

**TIOTROPIUM (SPIRIVA RESPIMAT)  
2.5 mcg solution for inhalation**

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who have failed all other regular benefit long-acting muscarinic antagonists (LAMAs).

Claim Note:

- Approval period: Long term.

**TOBRAMYCIN (TOBI PODHALER)  
28 mg powder for inhalation**

For the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections, when used as a cyclic treatment, in patients with cystic fibrosis.

Clinical Note:

- Cyclic treatment measured in 28-day cycles is defined as 28 days of treatment, followed by 28 days without treatment.

Claim Notes:

- Combined use of tobramycin either concurrently or for antibiotic cycling during off-treatment periods, with other inhaled antibiotics (e.g. aztreonam, levofloxacin) will not be reimbursed.
- Requests will be considered for individuals enrolled in Plans ABCDEFGV.

**TOCILIZUMAB (TYENNE)  
80 mg / 4 mL, 200 mg / 10 mL, and 400 mg / 20 mL single-use vials  
162 mg / 0.9 mL autoinjector and prefilled syringe**

**Giant Cell Arteritis**

For the treatment of adult patients with new onset or relapsed giant cell arteritis (GCA) in combination with oral glucocorticoids.

Renewal Criteria:

- Requests for renewal must include all of the following:
  - Confirmation of response to treatment (e.g., absence of flares, normalization of C-reactive protein)
  - Description of attempts to taper or discontinue glucocorticoids
  - Rationale for the need for ongoing treatment

Clinical Note:

- A flare is defined as the recurrence of signs or symptoms and/or erythrocyte sedimentation rate greater than or equal to 30 mm/hour.

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist or other physician experienced in the treatment of GCA.
- Combined use of more than one biologic drug will not be reimbursed.
- Subcutaneous injection: Approvals will be for a maximum of 162 mg every week.
- Approval period: 1 year.

**Polyarticular Juvenile Idiopathic Arthritis**

For the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who are refractory, intolerant or have contraindications to conventional therapy.

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist experienced in the treatment of pJIA.
- Combined use of more than one biologic drug will not be reimbursed.
- Intravenous infusion: Approvals will be for 10 mg/kg for patients < 30 kg, or 8 mg/kg for patients ≥ 30 kg, to a maximum of 800 mg, administered every four weeks.
- Subcutaneous injection: Approvals will be for a maximum of 162 mg every three weeks for patients weighing < 30 kg, or 162 mg every two weeks for patients weighing ≥ 30 kg.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Intravenous infusion: Initial approvals will be for 4 mg/kg/dose every four weeks, with a maximum maintenance dose escalation up to 8 mg/kg, to a maximum of 800 mg per infusion for patients > 100 kg.
- Subcutaneous injection: Initial approvals will be for 162 mg every two weeks for patients < 100 kg, with a maximum maintenance dose escalation to weekly dosing permitted. Patients ≥ 100 kg will be approved for 162 mg every week, with no dose escalation permitted.
- Initial approval period: 6 months.
- Renewal approval period: Long term. Confirmation of continued response is required.

### **Systemic Juvenile Idiopathic Arthritis**

For the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA), who are refractory, intolerant or have contraindications to conventional therapy.

#### Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist experienced in the treatment of sJIA.
- Combined use of more than one biologic drug will not be reimbursed.
- Intravenous infusion: Approvals will be for 12 mg/kg for patients < 30 kg or 8 mg/kg for patients ≥ 30 kg, to a maximum of 800 mg, administered every two weeks.
- Subcutaneous injection: Approvals will be for a maximum of 162 mg every two weeks for patients weighing < 30 kg or 162 mg every week for patients ≥ 30 kg.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

### **TOFACITINIB (generic brands) 5 mg and 10 mg film-coated tablets TOFACITINIB (generic brand) 11 mg extended-release tablet**

### **Rheumatoid Arthritis**

For the treatment of moderately to severely active rheumatoid arthritis, alone or in combination with methotrexate, in adult patients who are refractory, intolerant or have contraindications to:

- methotrexate (oral or parenteral), alone or in combination with another disease-modifying antirheumatic drug (DMARD), 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; 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 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. The nature of intolerance(s) must be clearly documented.

#### Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum dose of 5 mg twice daily or 11 mg once daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

### **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 40 mg 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 Criteria:**

- 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 with other biologic drugs or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum dose of 10 mg twice daily.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year.

**TOPIRAMATE (TOPAMAX)  
15 mg and 25 mg sprinkle capsules**

For patients who cannot take the tablet form of topiramate and require sprinkle capsules for proper administration.

**TRAMETINIB (MEKINIST)  
0.5 mg and 2 mg tablets**

**Adjuvant Melanoma**

In combination with dabrafenib for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8<sup>th</sup> edition)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

**Clinical Notes:**

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

**Claim Notes:**

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Patients with a pathological partial or nonresponse after neoadjuvant immunotherapy are eligible for up to 11 months of adjuvant BRAF targeted therapy.
- Approval period: Up to 12 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Metastatic Melanoma**

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with dabrafenib.

**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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Trametinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.

- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**TREPROSTINIL (REMODULIN)**  
**1 mg/mL, 2.5 mg/mL, 5 mg/mL and 10 mg/mL multi-use vials**

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class III or IV who have failed to respond to non-prostanoid therapies.

Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Approval period: Long term.

**TRIENTINE (generic brands)**  
**250 mg capsule**

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.

**TRIFLURIDINE AND TIPIRACIL (LONSURF)**  
**15 mg / 6.14 mg and 20 mg / 8.19 mg tablets**

**Metastatic Colorectal Cancer**

In combination with bevacizumab for the treatment of adult patients with metastatic colorectal (mCRC) who have been previously treated with or are not considered candidates for the following therapies:

- fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- anti-VEGF therapy
- anti-EGFR therapy (if RAS wild-type)
- immune checkpoint inhibitor (if MSI-H or dMMR tumour)
- BRAF inhibitor (if BRAF-mutant tumour)

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:

- Requests will be considered for patients with small bowel or appendiceal adenocarcinoma.
- Patients who experience disease progression during or within 6 months of completing neoadjuvant/adjuvant chemotherapy may be considered as having received one prior chemotherapy regimen for advanced disease.
- Approval period: 6 months.

**Metastatic Gastric or Adenocarcinoma of the Gastroesophageal Junction**

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 and 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.
- Approval period: 6 months.

**TRIEPTANOIN (DOJOLVI)  
100% w/w oral solution**

For the treatment of patients with an acute life-threatening long-chain fatty acid oxidation disorder (LC-FAOD) who meet all of the following criteria:

- Alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation is required; and
- One of the following circumstances is met:
  - The patient has a confirmed diagnosis of one of the types of LC-FAOD and is experiencing acute life-threatening events; or
  - The patient lacks a confirmed diagnosis of LC-FAOD but is presenting with acute life-threatening events consistent with LC-FAOD.

**Renewal Criteria:**

Renewals will be considered for patients meeting all of the following criteria:

- Patient who was initiated on triheptanoin without a confirmed diagnosis of LC-FAOD has subsequently received a confirmed diagnosis established by a specialist in metabolic diseases experienced in the treatment and management of LC-FAOD with the type of LC-FAOD specified and the genetic and other findings provided to confirm the diagnosis.
- Patient is optimized on, and adherent to, appropriate dietary management.
- Patient continues to benefit from triheptanoin therapy. Requesters must include a description of the patient's current response to triheptanoin therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

**Clinical Notes:**

1. Acute life-threatening events consistent with LC-FAOD may include:
  - A catastrophic presentation with acute or recurrent rhabdomyolysis with severe pain, compartment syndrome, acute renal failure requiring hospitalization and life-saving interventions including dialysis, treatment of hyperkalemia, and surgical treatment of compartment syndrome.
  - Severe hypoglycemia, recurrent or acute with or without seizures.
  - Cardiomyopathy with or without arrhythmia.
2. Requests should specify the acute life-threatening events that the patient presents with that are consistent with LC-FAOD and include clinical and biochemical findings of impacted organ systems which support warranted triheptanoin initiation.
3. Individualized treatment goals for triheptanoin treatment must be submitted with the initial coverage request.
4. Patient's Daily Caloric Intake (DCI) requirements must be provided with all requests.

**Claim Notes:**

- Must be prescribed by a physician with experience in the management of LC-FAOD.
- Approvals will be for a maximum of 35% of the patient's total DCI.
- 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](#).

**TUCATINIB (TUKYSA)  
50 mg and 150 mg film-coated tablets**

In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab and a HER2-targeted antibody-drug conjugate (e.g., Kadcyla, Enhertu), where at least one was given in the advanced or 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.
2. Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued.

Claim Notes:

- Approval period: 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**UPADACITINIB (RINVOQ)**

**15 mg, 30 mg and 45 mg extended-release tablets**

**Ankylosing Spondylitis**

For the treatment of adult 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 2 weeks each 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 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal Criteria:

- A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score, or
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**Atopic Dermatitis**

For the treatment of moderate to severe atopic dermatitis (AD) in patients aged 12 years and older who meet all of the following criteria:

- Refractory or have contraindications to an adequate trial of topical prescription therapies combined with phototherapy (where available).
- Refractory, intolerant or have contraindications to an adequate trial of topical prescription therapies combined with methotrexate, cyclosporine, mycophenolic acid, or azathioprine.
- Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1 or greater.

Renewal Criteria:

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations.

Claim Notes:

- Must be prescribed by a dermatologist, pediatrician or clinical immunologist with experience in the treatment of moderate to severe AD.
- Combined use of more than one immunomodulatory drug (e.g., biologics or janus kinase inhibitors) for the treatment of moderate to severe AD will not be reimbursed.
- Approvals will be for a maximum of 30 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**Crohn's Disease**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 45 mg daily for 12 weeks followed by a maximum of 30 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. 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 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 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

#### **Rheumatoid Arthritis**

For the treatment of moderately to severely active rheumatoid arthritis, alone or in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory, intolerant or have contraindications 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 15 mg 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 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. The nature of intolerance(s) must be clearly documented.

#### Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of response is required.

#### **Ulcerative Colitis**

For the treatment of adult 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 40 mg 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 Criteria:

- 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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Approvals will be for a maximum of 45 mg daily for 8 weeks followed by a maximum of 30 mg daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**USTEKINUMAB (JAMTEKI)  
45 mg / 0.5 mL and 90 mg/mL prefilled syringes**

**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.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg at week 0 and 4, then every 12 weeks thereafter.
- Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of continued response is required.

**Psoriatic Arthritis**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg at week 0 and 4, then every 12 weeks thereafter.
- Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

**USTEKINUMAB (OTULFI)  
45 mg / 0.5 mL and 90 mg/mL prefilled syringes  
USTEKINUMAB (OTULFI IV)  
130 mg vial**

**Crohn's Disease**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than or equal to 55 kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 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.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter. Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of continued response is required

### **Psoriatic Arthritis**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter. Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **Ulcerative Colitis**

For the treatment of adult 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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than or equal to 55 kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **USTEKINUMAB (STEQEYMA)**

**45 mg / 0.5 mL and 90 mg/mL prefilled syringes**

**USTEKINUMAB (STEQEYMA IV)**

**130 mg vial**

### **Crohn's Disease**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than or equal to 55 kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 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.

- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter. Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of continued response is required.

### **Psoriatic Arthritis**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter. Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **Ulcerative Colitis**

For the treatment of adult 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 with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than or equal to 55 kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **USTEKINUMAB (WEZLANA)**

**45 mg / 0.5 mL and 90 mg/mL autoinjectors and prefilled syringes**

**USTEKINUMAB (WEZLANA IV)**

**45 mg and 130 mg vials**

### **Crohn's Disease**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than  $\geq 55$  kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **Plaque Psoriasis**

For the treatment of patients aged 6 and older 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.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Pediatrics: Approvals will be for 0.75 mg/kg by subcutaneous injection for patients less than 60 kg and 45 mg for patients greater than or equal to 60 kg administered at week 0 and 4, then every 12 weeks thereafter.
- Adults: Approvals will be 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter. Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of continued response is required.

### **Psoriatic Arthritis**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for 45 mg by subcutaneous injection at week 0 and 4, then every 12 weeks thereafter.
- Requests for 90 mg every 12 weeks will be considered for patients greater than 100 kg.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **Ulcerative Colitis**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- All new requests for coverage of ustekinumab will be approved for the biosimilar versions only.
- Approvals will be for a single intravenous induction dose of 260 mg for patients less than or equal to 55 kg, 390 mg for patients 56-85 kg and 520 mg for patients greater than 85 kg, followed by 90 mg by subcutaneous injection every 8 weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: Long term. Confirmation of response is required.

### **VALGANCICLOVIR (VALCYTE and generic brand) 50 mg/mL oral suspension**

For the prevention and treatment of cytomegalovirus (CMV) in patients for whom oral tablets are not an option.

### **VANDETANIB (CAPRELSA) 100 mg and 300 mg tablets**

For the treatment of symptomatic and/or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.

#### 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 Note:

- Approval period: 1 year.

### **VARENICLINE (generic brands) 0.5 mg and 1 mg tablets**

For smoking cessation in adults 18 years of age and older.

#### Clinical Notes:

1. The patient should be participating in a form of smoking cessation counselling.
2. For information on quitting smoking visit our website [Smoking Cessation Therapies](#).

#### Claim Notes:

- A maximum of 24 weeks of standard therapy (336 tablets) will be reimbursed annually without special authorization. Special authorization requests for additional tablets will not be considered.
- Requests for nicotine replacement therapy (patches/gum/lozenge) for use in combination with a non-nicotine prescription smoking cessation drug (varenicline or bupropion) will not be considered.

**VEDOLIZUMAB (ENTYVIO)**  
**108 mg / 0.68 mL autoinjector and prefilled syringe**  
**300 mg vial**

**Crohn's Disease**

For the treatment of adult 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 with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Intravenous infusion: Approvals will be for maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks.
- Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab.
- Initial approval period: 14 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**Ulcerative Colitis**

For the treatment of adult 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. aminosaliclates for a minimum of four weeks, and prednisone greater than or equal to 40 mg 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 Criteria:

- 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 aminosaliclates 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 intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs, janus kinase inhibitors or sphingosine 1-phosphate receptor modulators will not be reimbursed.
- Intravenous infusion: Approvals will be for maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks.
- Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab.
- Initial approval period: 14 weeks.
- Renewal approval period: 1 year.

**VELAGLUCERASE ALFA (VPRIV)**  
**400 units per vial**

For the treatment of patients with symptomatic Gaucher disease type 1 (GD1).

Clinical Note:

- Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy. These criteria are consistent with the Ontario Guidelines for the Treatment of Gaucher Disease. Please contact the NB Drug Plans at 1-800-332-3691 for the criteria.

Claim Notes:

- Approvals will be for a maximum of 60 units/kg every 2 weeks.
- Initial approval period: 6 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](#).

**VEMURAFENIB (ZELBORAF)  
240 mg film-coated tablet**

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with cobimetinib.

**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. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Vemurafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

**VENETOCLAX (VENCLEXTA)  
10 mg, 50 mg and 100 mg film-coated tablets**

**Acute Myeloid Leukemia**

In combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia who are 75 years of age or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

**Renewal Criteria:**

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

**Clinical Note:**

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

**Claim Notes:**

- Requests for patients previously treated with a hypomethylating agent or chemotherapy for myelodysplastic syndrome will not be considered.
- Requests for patients with high-risk myelodysplastic syndrome will not be considered.
- Approval period: 1 year.

**Chronic Lymphocytic Leukemia**

1. In combination with obinutuzumab for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL).

**Clinical Notes:**

1. Patient must have a good performance status.
2. Treatment should be given for a total of 12 months (six 28-day cycles in combination with obinutuzumab, followed by six months of monotherapy), or until disease progression or unacceptable toxicity, whichever occurs first.

**Claim Notes:**

- Requests for re-treatment with venetoclax in combination with obinutuzumab will not be considered.
- Approval period: 1 year.

2. In combination with ibrutinib for adult patients with previously untreated CLL / SLL.

**Clinical Notes:**

1. Patients must have a good performance status and no central nervous system involvement or Richter's transformation.
2. Combination treatment should be initiated following three months of ibrutinib monotherapy and continued for 12 months, or until disease progression or unacceptable toxicity, whichever occurs first.

**Claim Notes:**

- Requests for re-treatment with venetoclax in combination with ibrutinib will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
- Approval period: 1 year.

3. In combination with rituximab for the treatment of patients with CLL / SLL who have received at least one prior therapy.

**Renewal Criteria:**

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

**Clinical Notes:**

1. Patient must have a good performance status.
2. Treatment should be continued until disease progression or unacceptable toxicity, up to a maximum of two years.

**Claim Notes:**

- Requests will not be considered for patients previously treated with anti-CD20 therapy if relapse occurs less than six months following completion of therapy. However, for patients previously treated with venetoclax, the relapse-free interval must be 12 months or greater.
- Approval period: 1 year.

4. As monotherapy for the treatment of patients with CLL / SLL who have received at least one prior therapy which must include disease progression on or intolerance to a B-cell receptor inhibitor.

**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 will not be considered for patients previously treated with venetoclax-based therapy if relapse occurs less than 12 months following completion of therapy.
- Approval period: 1 year.

**VERICIGUAT (VERQUVO)  
2.5 mg, 5 mg, and 10 mg tablets**

For the treatment of adult patients with symptomatic chronic heart failure (HF) in combination with standard care therapy who meet all of the following criteria:

- Left ventricular ejection fraction (LVEF) of less than or equal to 45%
- Recent HF decompensation event requiring hospitalization and/or intravenous diuretic therapy without hospitalization

**Clinical Note:**

- Standard care therapy includes one medication from each of the following categories for at least 4 weeks, unless there is a contraindication or intolerance:
  - angiotensin converting enzyme inhibitor (ACEI), an angiotensin II receptor blocker (ARB), or angiotensin receptor-nepriylsin inhibitor (ARNI);
  - beta blocker; and
  - mineralocorticoid receptor antagonist (MRA).

**Claim Note:**

- Approval period: Long term.

**VIGABATRIN (SABRIL)  
500 mg tablet  
500 mg sachet**

1. For the treatment of epilepsy in those patients who respond inadequately to alternative treatment combinations or in whom other drug combinations have not been tolerated.
2. For the treatment of infantile spasms.

**Clinical Note:**

- Potential benefits conferred by the use of vigabatrin should outweigh the risk of ophthalmologic abnormalities.

**VISMODEGIB (ERIVEDGE)  
150 mg capsule**

Initial Requests:

- For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery<sup>1</sup> AND inappropriate for radiotherapy<sup>2</sup>  
AND
- Patient 18 years of age or older;  
AND
- Patient has ECOG  $\leq$  2
- Patient preference for oral therapy will not be considered

Information Required:

- Physicians must provide rationale for why surgery<sup>1</sup> AND radiation<sup>2</sup> cannot be considered
- The request must include a surgical consultation report that provides a preoperative/surgical evaluation why surgery is not appropriate for the patient;  
AND
- A consultation report as to why radiation therapy is not appropriate for the patient
- Both of the above evaluations must come from a physician who is not the requesting physician
- Confirmation that the patient has been discussed at a multi-disciplinary cancer conference or equivalent (e.g. Regional Tumour Board).

Renewal Criteria:

- The physician has confirmed that the patient has not experienced disease progression while on Erivedge therapy.

Clinical Notes:

1. <sup>1</sup>Considered inoperable or inappropriate for surgery for one of the following reasons:
  - Technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible)
  - Recurrence of BCC after two or more surgical procedures and curative resection unlikely
  - Substantial deformity and/or morbidity anticipated from surgery
2. <sup>2</sup>Considered inappropriate for radiation for one of the following reasons:
  - Contraindication to radiation (e.g. Gorlin syndrome)
  - Prior radiation to lesion
  - Suboptimal outcomes expected due to size/location/invasiveness of BCC
3. Dose: 150 mg orally once daily taken until disease progression or unacceptable toxicity.

Claim Note:

- 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](#).

**VITAMINS B AND C (REPLAVITE)  
Tablet**

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

Claim Note:

- Approval period: Long term.

**VORICONAZOLE (VFEND and generic brands)  
50 mg and 200 mg tablets**

- For the management of invasive aspergillosis.
- For culture proven invasive candidiasis with documented resistance to fluconazole.

Claim Notes:

- Must be prescribed by a hematologist, infectious disease specialist or medical microbiologist.
- Initial requests will be approved for a maximum of 3 months.

**VUTRISIRAN (AMVUTTRA)  
25 mg / 0.5 mL prefilled syringe**

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.
- Approvals will be for a maximum of 25 mg every 3 months.
- 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](#).

**ZANAMIVIR (RELENZA)  
5 mg powder for inhalation**

For beneficiaries residing in long-term care facilities meeting the same criteria as for oseltamivir and for whom there is suspected or confirmed oseltamivir resistance, or for whom oseltamivir is contraindicated.

**ZANUBRUTINIB (BRUKINSA)  
80 mg capsule  
160 mg tablet**

**Chronic Lymphocytic Leukemia**

1. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, del 11q or unmutated IGHV).
2. As monotherapy for the treatment of adult patients with relapsed or refractory CLL / SLL who have received at least one prior systemic 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 and no evidence of prolymphocytic leukemia or Richter's transformation.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

**Claim Notes:**

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Patients who experience disease progression during or within one year of completing ibrutinib in combination with venetoclax are not eligible for zanubrutinib in the relapsed setting.
- Approval period: 1 year.

**Waldenström Macroglobulinemia**

For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

**Renewal Criteria:**

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

**Clinical Notes:**

1. Patients must meet at least one criterion for treatment as per IWWW consensus panel.
2. Patients must have a good performance status and no evidence of disease transformation.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

**ZOLMITRIPTAN (ZOMIG NASAL SPRAY)  
2.5 mg and 5 mg nasal sprays**

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to oral triptans listed as regular benefits.

Claim Notes:

- Coverage limited to 6 doses per month.
- Requests for patients who have more than 3 migraines a month despite migraine prophylaxis therapy will be considered for a maximum of 12 doses per month.