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.
- 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 severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

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

ABIRATERONE (ZYTIGA)
250 mg tablet and 500 mg film-coated tablet

In combination with prednisone for the treatment of metastatic prostate cancer (castration-resistant prostate cancer) in patients who:
- are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy, or
- have received prior chemotherapy containing docetaxel after failure of androgen deprivation therapy.

Claim Note:
- Sequential use of enzalutamide and abiraterone will not be reimbursed.

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.
ACAMPROSATE (CAMPRAL)
333 mg delayed release tablet

For the maintenance of abstinence from alcohol in patients with alcohol dependence who have been abstinent for at least four days, and who have contraindications to naltrexone (e.g. currently receiving opioids, acute hepatitis or liver failure).

Clinical Note:
- Treatment with acamprosate should be part of a comprehensive management plan that includes counseling.

ACLIDINIUM BROMIDE (TUDORZA GENUAIR)
400 mcg powder for inhalation

See criteria under Long-acting anticholinergics (LAAC)

ADALIMUMAB (HUMIRA)
40 mg / 0.8 mL (50 mg/mL) pen and prefilled syringe

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 40 mg every two weeks.
- 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 have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- 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: 1 year. Confirmation of continued response is required.

Hidradenitis Suppurativa
For the treatment of adult patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy and who meet all of the following criteria:
- A total abscess and nodule count of 3 or greater
- Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
- An inadequate response to a 90-day trial of oral antibiotics

Initial renewal criteria:
- Requests for renewal should provide objective evidence of a treatment response, defined as at least a 50% reduction in inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline at week 12.
Subsequent renewal criteria:
- Requests for renewal should provide objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count and draining fistula count should be compared to the count prior to initiating treatment with adalimumab).

Claim Notes:
- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- 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: 1 year.

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

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

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 80 mg followed by 40mg in one week, then 40 mg every two weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

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

Claim Notes:
- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- Approvals will be for a maximum of 40 mg every two weeks.

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 ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
• Approvals will be for a maximum of 40 mg every two weeks.
• Initial approval period: 16 weeks.
• Renewal approval period: 1 year. Confirmation of continued response is required.

Rheumatoid Arthritis
For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
• Must be prescribed by a rheumatologist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• Approvals will be for a maximum of 40 mg every two weeks.
• 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 > 4, and a rectal bleeding subscore ≥ 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score ≥ 2 from baseline, and
  - a decrease in the rectal bleeding subscore ≥ 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 > 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 of more than one biologic DMARD 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: 1 year.

AFATINIB (GIOTRIF)
20 mg, 30 mg and 40 mg film-coated tablets
For the first-line treatment of patients with EGFR mutation positive advanced or metastatic adenocarcinoma of the lung who have an ECOG performance status 0 or 1.

Renewal Criteria:
Written confirmation that the patient has responded to treatment and in whom there is no evidence of disease progression.
Claim Notes:
• Doses of more than 40 mg once daily will not be approved.
• Approval period: 6 months.

AFILBERCEPT (EYLEA)
40 mg/mL solution for intravitreal injection

1. Neovascular (wet) age-related macular degeneration (AMD)

Initial Coverage:
For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply to the eye to be treated:
• Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
• The lesion size is less than or equal to 12 disc areas in greatest linear dimension
• There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT))
• Administration is to be done by a qualified ophthalmologist experienced in intravitreal injections.
• The interval between doses should not be shorter than 1 month.

Continued Coverage:
Treatment should be continued only in people who maintain adequate response to therapy.

Clinical Notes:
1. Coverage will not be approved for patients:
   - With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines
   - Receiving concurrent treatment with verteporfin.
2. Aflibercept should be permanently discontinued if any one of the following occurs:
   - Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
   - Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
   - There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Claim Notes:
• An initial claim of up to two vials of aflibercept (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If additional medication is required, a request should be made through special authorization.
• Reimbursement will be limited to a maximum of 1 vial of aflibercept per eye treated every 30 days. Claims submitted for greater than 1 vial, or submitted within 30 days of a previous claim, will not be reimbursed.

2. Diabetic macular edema (DME)

Initial coverage:
For the treatment of visual impairment due to diabetic macular edema (DME) in patients who meet all of the following criteria:
• Clinically significant centre-involving macular edema for whom laser photocoagulation is also indicated
• Hemoglobin A1c test in the past 6 months with a value of less than or equal to 11%
• Best corrected visual acuity of 20/32 to 20/400
• Central retinal thickness greater than or equal to 250 micrometers

Renewal Criteria:
• Confirm that a hemoglobin A1c test in the past 6 months had a value of less than or equal to 11%
• Date of last visit and results of best corrected visual acuity at that visit
• Date of last OCT and central retinal thickness on that examination
• If aflibercept is being administered monthly, please provide details on the rationale

Clinical Notes:
1. Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on aflibercept). Thereafter, visual acuity should be monitored monthly.
2. Treatment should be resumed when monitoring indicates a loss of visual acuity due to DME and continued until stable visual acuity is reached again for three consecutive months.

Claim Notes:
• Approval Period: 1 year.
3. **Retinal vein occlusion (RVO)**

   For the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO).

   **Clinical Notes:**
   1. Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on aflibercept). Thereafter, visual acuity should be monitored monthly.
   2. Treatment should be resumed when monitoring indicates a loss of visual acuity due to macular edema secondary to retinal vein occlusion and continued until stable visual acuity is reached again for three consecutive months.

   **Claim Notes:**
   - Approval Period: 1 year.

**ALECTINIB (ALECENSARO)**

**150 mg capsule**

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
- following disease progression on, or intolerance to, crizotinib.

   **Renewal Criteria**
   - Written confirmation that the patient is responding to treatment.

   **Clinical Note:**
   - Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

   **Claim Notes:**
   - Requests for alectinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib.
   - No further ALK inhibitor will be reimbursed following disease progression on alectinib.
   - Initial approval period: 1 year.
   - 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.

**ALEMTUZUMAB (LEMTRADA)**

**12 mg/1.2 mL single-use vial**

For the treatment of relapsing-remitting multiple sclerosis (RRMS) in adult patients who meet all the following criteria:
- Inadequate response to a full and adequate course (at least 6 months) of interferon beta or other disease modifying therapies.
- Experienced one or more clinically disabling relapses in the previous year.
- Current Expanded Disability Status Scale (EDSS) score of less than or equal to 5.

   Documentation must be submitted outlining details of the patient’s most recent neurological examination within 90 days of the submitted request. This must include a description of any recent attacks, the dates of the attacks and the neurological findings.

   **Clinical Note:**
   - Combination therapy of alemtuzumab with other disease modifying therapies (e.g. interferon beta, glatiramer, fingolimod, natalizumab, teriflunomide, dimethyl fumarate) will not be funded.

   **Claim Notes:**
   - Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis
   - Requests will be considered for individuals enrolled in Plans ADEFGV.
   - Maximum approval quantity and period: 8 vials in 2 years (5 vials approved in year 1 and 3 vials approved in year 2).
   - For information regarding re-treatment, please contact the NB Drug Plans.

**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 and 150 mg/mL prefilled pen and 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 ezetimibe due to an intolerance or contraindication, details must be provided.

Claim Notes:
- Approvals will be for a maximum of 300mg every 4 weeks.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

ALTEPLASE (CATHFLO)
2 mg vial
For the treatment of central venous catheter occlusion in home hemodialysis patients.

AMBRISENTAN (Volibris and generic brand)
5 mg and 10 mg tablets
For treatment of patients with pulmonary arterial hypertension (PAH), of at least World Health Organization (WHO) functional class III, which is associated with either idiopathic or connective tissue disease and who have failed to respond to or who have contraindications to, or who are not a candidate for sildenafil.
Clinical Notes:
1. Diagnosis of PAH should be confirmed by cardiac catheterization
2. Ambrisentan will not be approved when used concurrently with other endothelin receptor antagonists, epoprostenol, treprostinil or sildenafil.

Claim Note:
• The maximum dose of ambrisentan that will be reimbursed is 10mg daily

AMIKACIN (generic brand)
250 mg/mL single-use vial

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.

APIXABAN (ELIQUIS)
2.5 mg and 5 mg tablets

Atrial fibrillation
For the prevention of stroke and systemic embolism in at-risk patients (CHADS$_2$ score ≥ 1) with non-valvular atrial fibrillation for whom:
• Anticoagulation is inadequate following at least a two month trial on warfarin; or
• Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Clinical Note:
• Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period.

Venous thromboembolic events treatment
For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

Clinical Note:
• When used for greater than 6 months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Claim Note:
• Approval Period: Up to 6 months.

APIXABAN (ELIQUIS)
2.5 mg tablet

Venous thromboembolic event prophylaxis following total knee or total hip replacement surgery
• For the prevention of venous thromboembolic events in patients who have undergone elective total knee replacement (TKR) surgery or total hip replacement (THR) surgery.

Clinical Note:
• The total duration of therapy includes the period during which doses are administered post-operatively in an acute care (hospital) setting, and the approval period is for the balance of the total duration after discharge.

Claim Notes:
• Maximum reimbursement without special authorization will be limited to 14 days of therapy (28 tablets) for TKR or 35 days of therapy (70 tablets) for THR, within a 6 month period.
• Subsequent reimbursement for prophylaxis within a 6 month period (i.e. second joint replacement procedure within the 6 month period) will require special authorization.

APOMORPHINE HYDROCHLORIDE (MOVAPO)
30 mg / 3 mL prefilled pen

For the acute, intermittent treatment of hypomobility “off” episodes in patients with advanced Parkinson’s Disease (PD) who are receiving optimized PD treatment (i.e. levodopa and derivatives and dopaminergic agonists).

Clinical Note:
• “Off” episodes are defined as “end of dose wearing off” and unpredictable “on/off” episodes.
Claim Notes:
- The patient must be under the care of a physician experienced in the diagnosis and treatment of PD.
- Approval period: 1 year.

APREPIHANT (EMEND)
80 mg and 125 mg capsules;
Tri-Pack 2x80 mg capsules + 125 mg capsule

In combination with a 5-HT3 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-HT3 antagonist and dexamethasone in a previous cycle.

Claim Note:
- Prescription claims for up to a maximum of 2 Tri-packs, or 6 capsules will be reimbursed every 28 days when the prescription is written by an oncologist, an oncology clinical associate, or a general practitioner in oncology.

ARIPIPRAZOLE (ABILIFY and generic brands)
2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg tablets

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of intolerance or inadequate response to at least one less expensive antipsychotic agent, or who have a contraindication to less expensive agents.

ARIPIPRAZOLE (ABILIFY MAINTENA)
300 mg and 400 mg vial

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.

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.

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 Note:
- Must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP.

AXITINIB (INLYTA)
1 mg and 5 mg tablets

As second line therapy for the treatment of patients with metastatic renal cell carcinoma after failure of prior therapy with either a cytokine or 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 have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
Claim Notes:
- Sequential use of axitinib and everolimus will not be reimbursed. Exceptions may be considered in cases of intolerance or contraindication without disease progression.
- Initial approval period: 6 months.
- Renewal period: 1 year.

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 x 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 ADEFGV.

BENRALIZUMAB (FASENRA)
30 mg/mL prefilled syringe

For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g. long-acting beta-agonist), and meets one of the following criteria:
- blood eosinophil count of ≥ 0.3 x 10^9/L within the past 12 months and has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
- blood eosinophil count of ≥ 0.15 x 10^9/L and is receiving maintenance treatment with oral corticosteroids (OCS).

Initial Discontinuation Criteria:
- Baseline asthma control questionnaire score has not improved at 12 months since the initiation of treatment, or
- No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months

Subsequent Discontinuation Criteria:
- Baseline asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months

Clinical Notes:
1. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
2. High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
3. A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.

Claim Notes:
- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe eosinophilic asthma.
- Combined use of benralizumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 30 mg every four weeks for 12 weeks, then every eight weeks thereafter.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.
BETAHISTINE (SERC and generic brands)
8 mg, 16 mg and 24 mg tablets
For the symptomatic treatment of the recurrent episodes of vertigo associated with Ménière’s disease.

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 Note:
- Prescriptions written for beneficiaries of Plan U 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.

BOSENTAN (TRACLEER and generic brands)
62.5 mg and 125 mg tablets
For treatment of pulmonary arterial hypertension (PAH) in patients with World Health Organization (WHO) functional class III or IV

Clinical Notes:
3. Idiopathic pulmonary arterial hypertension (IPAH) in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers.
4. Pulmonary arterial hypertension associated with connective tissue disease or congenital heart disease or human immunodeficiency virus (HIV) who do not respond adequately to conventional therapy.

BOSUTINIB (BOSULIF)
100 mg and 500 mg tablets
For the treatment of patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who:
- have resistance/disease progression after prior use of two tyrosine kinase inhibitors (TKIs) where bosutinib would be the third line therapy, or
- have resistance or intolerance to prior TKI therapy and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate.

Clinical Notes:
1. Patients must have an ECOG performance status of 0-2.
2. Patients may be considered inappropriate for dasatinib or nilotinib if they have a genetic mutation that predicts reduced efficacy or if patients have co-morbidities that may predispose them to a drug-related adverse event.

BREXPIPRAZOLE (REXULTI)
0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg tablets
For the treatment of schizophrenia and related psychotic disorders (not dementia related) in adult patients with a history of intolerance or inadequate response to at least one less expensive antipsychotic agent, or who have a contraindication to less expensive agents.

BRIVARACETAM (BRIVLERA)
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 Notes:
- 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 patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria:
- Psoriasis Area Severity Index (PASI) > 10 and Dermatology Life Quality Index (DLQI) > 10, or major involvement of visible areas, scalp, genitals, or nails
- Refractory, intolerant or unable to access phototherapy
- Refractory, intolerant or have contraindications to one of the following:
  - Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥ 15mg if patient is ≥ 65 years of age) for a minimum of 12 weeks
  - Cyclosporine for a minimum of 6 weeks
Clinical Notes:
1. For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 210mg at week 0, 1, and 2, then 210mg every two weeks thereafter.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

BUPRENORPHINE HYDROCHLORIDE (PROBUPHINE)
80 mg subdermal implant
For the treatment of patients with opioid use disorder who have been stabilized on a dose of no more than 8 mg of sublingual buprenorphine for the preceding 90 days.

Clinical Note:
- Insertion of the subdermal implants should be performed by a healthcare provider who has completed the training program.

Claim Note:
- Approval period: 2 years.

BUPRENORPHINE AND NALOXONE (SUBOXONE and generic brands)
2 mg / 0.5 mg and 8 mg / 2 mg sublingual tablets
For the treatment of patients with opioid use disorder.

BUPROPION (ZYBAN)
150 mg tablet
For smoking cessation in adults 18 years of age and older.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine prescription smoking cessation drug (varenicline or bupropion).

Claim Notes:
- A maximum of 168 tablets will be reimbursed annually without special authorization.
- Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for 168 additional tablets.
- All special authorization requests for additional tablets will require confirmation the individual has agreed, or is already registered with, Go Smoke-Free NB (1-866-366-3667) or is participating in another form of smoking cessation counselling to be specified.

For additional information on quitting smoking or to obtain the appropriate NB Drug Plans special authorization request form, visit our website Smoking Cessation Therapies.

CABERGOLINE (DOSTINEX and generic brand)
0.5 mg tablet
For the treatment of patients with hyperprolactinemia who have failed or are intolerant to bromocriptine

CANAGLIFLOZIN (INVOKANA)
100 mg and 300 mg tablets
For the treatment of type 2 diabetes mellitus as a third drug 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.
CANAKINUMAB (ILARIS)
150 mg powder for solution for injection
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 used of more than one biologic DMARD will not be reimbursed.
• Approvals will be for 4 mg/kg for patients weighing more than 9 kg, to a maximum of 300mg, 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.

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

For the treatment of patients with multidrug-resistant gram-negative infections, specifically caused by extended spectrum beta lactamase (ESBL)-producing Enterobacteriaceae and 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.

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.

Clinical Note:
• Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:
• Requests for ceritinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib.
• No further ALK inhibitor will be reimbursed following disease progression on ceritinib.
• Initial approval: 1 year.
• Renewal approval: 1 year.

CERTOLIZUMAB PEGOL (CIMZIA)
200 mg/mL auto-injector and prefilled syringe

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg 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 ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg 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 or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg every four weeks)
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.
CHOLINESTERASE INHIBITORS (Donepezil, Galantamine, Rivastigmine)
- For the treatment of mild to moderate Alzheimer’s disease

**To initiate therapy:**
Requests must be submitted on the appropriate NB Drug Plans special authorization form. [https://www2.gnb.ca/content/gnb/en/departments/health/MedicarePrescriptionDrugPlan/TheNewBrunswickPrescriptionDrugProgram/DrugsForTheTreatmentOfAlzheimersDisease.html](https://www2.gnb.ca/content/gnb/en/departments/health/MedicarePrescriptionDrugPlan/TheNewBrunswickPrescriptionDrugProgram/DrugsForTheTreatmentOfAlzheimersDisease.html)

| For a patient being started on a first cholinesterase inhibitor (ChEI): | Patients who meet all of the following reimbursement criteria will be approved for an initial 6 months of therapy:
- a diagnosis of probable Alzheimer’s disease or possible Alzheimer’s disease with vascular component or Lewy bodies;
- a Mini Mental Score Exam (MMSE) score of 10 to 30; and
- a Functional Assessment & Staging Test (FAST) score of 4 to 5 |
| --- | --- |
| For a patient who has previously taken no more than one other ChEI and is switching: | Patients will be approved for an initial 6 months of therapy with a second ChEI when the following information is provided:
- the reason for discontinuing the first ChEI

Requests to switch from one agent in the class to another will not be considered beyond the initial 6 month approval. |

**To continue therapy for 1 year period (once initial 6 month approval has been completed):**
Patients who meet the following monitoring criteria will be approved for 1 year periods of therapy:
- MMSE score of 10 to 30 (Note: MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);
- FAST score of 4 to 5 (Note: FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.)

Note: Monitoring of target symptoms will no longer be required; however, physicians will be asked at the initial and subsequent reassessments if, in their opinion, the patient is benefiting from the drug.

**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 New Brunswick ophthalmologists and prescribing optometrists do not require special authorization.

**CIPROFLOXACIN (CIPRO and generic brands)**
250 mg, 500 mg and 750 mg tablets
500 mg/5mL oral suspension

For the treatment of:
- Complicated urinary tract infections caused by resistant bacteria.
- Skin, soft tissue, bone and joint infections caused by Gram negative bacteria.
- Severe ("malignant") otitis externa.
- Infections with *Pseudomonas aeruginosa* (susceptible strains – resistance is now common).

**Claim Notes:**
- Prescriptions written by New Brunswick urologists, infectious disease specialists, medical oncologists, hematologists, respiratory medicine specialists or medical microbiologists do not require special authorization.
- Ciprofloxacin 250mg, 500mg, and 750mg tablets are regular benefit for Plan B.

**CIPROFLOXACIN (CIPRO XL)**
1000 mg tablet

For the treatment of complicated urinary tract infection and acute uncomplicated pyelonephritis when alternative agents are ineffective, not tolerated or contraindicated.
Claim Note:
- Prescriptions written by New Brunswick urologists, infectious disease specialists and medical microbiologists do not require special authorization.

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:
5. Patients must have a good performance status.
6. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
7. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Cobimetinib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

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

For the treatment of mild to moderate cancer-related or chronic non-cancer pain.

CRIZOTINIB (XALKORI)
200 mg and 250 mg capsules

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.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment.

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

Claim Notes:
- Requests for crizotinib will not be considered for patients who have experienced disease progression on prior ALK inhibitor therapy.
- Initial approval period: 1 year.
- 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 cystinosin (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 capsule

For the treatment of infantile nephropathic cystinosis with documented cystinosin (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 ETIXILATE (PRADAXA and generic brand)
110 mg and 150 mg capsules
For the prevention of stroke and systemic embolism in at-risk patients (CHADS\textsubscript{2} score ≥ 1) with non-valvular atrial fibrillation for whom:
- Anticoagulation is inadequate following at least a two month trial on warfarin; or
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Clinical Note:
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period.

DABRAFENIB (TAFINLAR)
50 mg and 75 mg capsules
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:
8. Patients must have a good performance status.
9. If brain metastases are present, patients should be asymptomatic or have stable symptoms
10. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Dabrafenib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

DACLATASVIR (DAKLINZA)
30 mg and 60 mg tablets
For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without cirrhosis</td>
<td>12 weeks in combination with sofosbuvir</td>
</tr>
<tr>
<td>With compensated or decompensated cirrhosis</td>
<td>12 weeks in combination with sofosbuvir and ribavir</td>
</tr>
<tr>
<td>Post-liver transplant with no cirrhosis or with compensated cirrhosis</td>
<td></td>
</tr>
</tbody>
</table>

The following information is also required:
- Lab-confirmed hepatitis C genotype 3
- Quantitative HCV RNA value within the last 6 months
- Fibrosis stage

Clinical Notes:
1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen and has not experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan\textsuperscript{®}), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination
3. 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 ADEFGV.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

DALTEPARIN (FRAGMIN)
Prefilled syringes, ampoule, single-dose vial, and multi-dose vial
See criteria under Low Molecular Weight Heparins.

DAPAGLIFLOZIN (FORXIGA)
5 mg and 10 mg tablets
For the treatment of type 2 diabetes mellitus as a second drug added to:
- metformin for patients who have inadequate glycemic control on metformin and a contraindication or intolerance to a sulfonylurea and in whom insulin is not an option; or
- a sulfonylurea for patients who have inadequate glycemic control on a sulfonylurea and a contraindication or intolerance to metformin 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.

DAPAGLIFLOZIN AND METFORMIN (XIGDUO)
5 mg / 850 mg, 5 mg / 1000 mg film-coated tablets
For the treatment of type 2 diabetes mellitus in patients who are already stabilized on therapy with dapagliflozin and metformin, to replace the individual components of dapagliflozin and metformin.

DAPTOMYCIN (CUBICIN RF)
500 mg / 10mL 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/0.4mL, 20 mcg/0.5mL, 30 mcg/0.3mL, 40 mcg/0.4mL, 50 mcg/0.5mL, 60 mcg/0.3mL, 80 mcg/0.4mL, 100 mcg/0.5mL, 130 mcg/0.65mL, 150 mcg/0.3mL, 200 mcg/0.4mL, 300 mcg/0.6mL and 500 mcg/1mL SingleJect® prefilled syringes
- For the treatment of anemia associated with chronic renal failure.

Claim Note:
- Patients on dialysis (end-stage renal disease) receive darbepoetin through the dialysis units.
- For the treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months.

Clinical Note:
- Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

Claim Note:
- Initial approval for 12 weeks.
DARIFENACIN (ENABLEX)
7.5 mg and 15 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.

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

For treatment of human immunodeficiency virus (HIV) infection in treatment-naïve and treatment-experienced patients without darunavir resistance-associated mutations.

Claim Note:
• Prescriptions written for beneficiaries of Plan U 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.

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

Chronic Myeloid Leukemia (CML)
For adult patients with chronic phase CML
• with primary or acquired resistance to imatinib 600mg per day. Dosing recommendation: 100mg per day or 70mg two times daily
• who progress to accelerated phase on imatinib 600mg per day. Dosing recommendation: 140mg per day
• who have blast crisis while on imatinib 600mg per day. Dosing recommendation: 140mg per day
• who have intolerance to imatinib or have experienced grade 3 or higher toxicities to imatinib

Renewal Criteria:
• Request for renewal must specify how the patient has benefited from therapy and is expected to continue to do so.

Claim Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

Acute Lymphoblastic Leukemia (ALL)
For adult patients with Philadelphia chromosome positive acute lymphoblastic leukemia (ALL) whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day) or have experienced grade 3 non-hematologic toxicity, or grade 4 hematologic toxicity persisting for more than 7 days as a result of therapy with imatinib.

Renewal Criteria:
• Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Claim Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

DEFERASIROX (JADENU and generic brand)
90 mg, 180 mg and 360 mg film-coated tablet

For the treatment of chronic iron overload.

DEFERASIROX (EXJADE and generic brands)
125 mg, 250 mg and 500 mg dispersible tablets for oral suspension

For the treatment of chronic iron overload.

DEFERIPRONE (FERRIPROX)
1000 mg tablet and 100 mg/mL oral solution

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 (PROLIA)
60 mg/mL prefilled syringe

For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria:
- Have a contraindication to oral bisphosphonates
- High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.

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 other available osteoporosis therapies.
2. High fracture risk is defined as:
   - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization’s Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
   - High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.

DENOSUMAB (XGEVA)
120 mg/1.7 mL single use vial

For the prevention of skeletal-related events (SREs) in patients with castrate-resistant prostate cancer (CRPC) with one or more documented bone metastases and an ECOG performance status of 0-2*.

Clinical Note:
- *Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

DESMOPRESSIN (DDAVP and generic brands)
0.1 mg and 0.2 mg tablets
DESMOPRESSIN (DDAVP MELT)
60 mcg, 120 mcg and 240 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 DEF-18G.

DESMOPRESSIN (DDAVP and generic brand)
10 mcg metered dose nasal spray
0.1 mg/mL intranasal solution

- 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.

DEXAMETHASONE AND CIPROFLOXACIN (CIPRODEX)
0.1% / 0.3% otic suspension

- For the treatment of patients with acute otitis media with otorrhea through tympanostomy tubes; or with known or suspected tympanic membrane perforation with otorrhea.
- For the treatment of patients with acute otitis externa in the presence of a tympanostomy tube or with known or suspected perforation of the tympanic membrane.

Claim Note:
- Prescriptions written by certified New Brunswick otolaryngologists do not require special authorization.

DIENOGEST (VISANNE)
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)
120 mg and 240 mg delayed-release capsules
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 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.

DIPYRIDAMOLE AND ACETYLSALIC ACID (AGGRENOX)
200 mg / 25 mg capsule
For the secondary prevention of ischemic stroke/TIA in patients who have experienced a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA.

DONEPEZIL (ARICEPT and generic brands)
5 mg and 10 mg tablets
See criteria under Cholinesterase Inhibitors.

DORNASE ALFA (PULMOZYME)
1 mg/mL solution
For reducing the frequency of respiratory infections requiring parenteral antibiotics and to improve pulmonary function in patients with cystic fibrosis who have a FEV1 <70%predicted with clinically significant decline in FEV1 not responsive to usual treatment.

Claim Note:
- Requests will be considered for individuals enrolled in Plans ABDEFGV

DOLUTEGRAVIR AND LAMIVUDINE (DOVATO)
50 mg / 300 mg tablets
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 Note:
- Prescriptions written for beneficiaries of Plan U 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.

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 Note:
- Prescriptions written for beneficiaries of Plan U 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.

DULOXETINE (CYMBALTA and generic brands)
30 mg and 60 mg delayed release capsules
Chronic Pain
For the treatment of chronic pain in patients who have had an inadequate response or intolerance to at least one first-line agent.
Clinical Note:
- First-line agents include tricyclic antidepressants for chronic neuropathic pain and non-steroidal anti-inflammatory drugs for chronic non-neuropathic pain.

Claim Note:
- The maximum dose reimbursed is 60mg 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 60mg daily.

**ECULIZUMAB (SOLIRIS)**
30 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.

**EDOXABAN (LIXIANA)**
15 mg, 30 mg and 60 mg tablets

Atrial fibrillation
For the prevention of stroke and systemic embolism in at-risk patients (CHADS2 score ≥ 1) with non-valvular atrial fibrillation for whom:
- Anticoagulation is inadequate following at least a two month trial on warfarin; or
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Clinical Note:
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period.

Venous thromboembolic events treatment
For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

Clinical Note:
- When used for greater than 6 months, edoxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Claim Note:
- Approval period: 6 months.
ELBASVIR AND GRAZOPREVIR (ZEPATIER)  
50 mg / 100 mg tablet  
For treatment-naive or treatment-experienced adult patients with chronic hepatitis C virus (HCV) without cirrhosis or with compensated cirrhosis who meet the following criteria:

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Approval Period</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>12 weeks</td>
<td>8 weeks may be considered in treatment-naive genotype 1b patients without significant fibrosis or cirrhosis</td>
</tr>
<tr>
<td>Genotype 1b</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Genotype 4</td>
<td>12 weeks</td>
<td></td>
</tr>
</tbody>
</table>

The following information is also required:
- Lab-confirmed hepatitis C genotype 1 or 4
- Quantitative HCV RNA value within the last 6 months
- Fibrosis stage

**Clinical Notes:**
1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin (PegIFN/RBV) based regimen, including regimens containing HCV protease inhibitors (for genotype 1) and who has not experienced an adequate response.
2. Treatment-experienced prior relapsers is defined as a patient who has undetectable HCV RNA at the end of previous PegIFN/RBV therapy, including regimens containing NS3/4A protease inhibitors (for genotype 1), but with a subsequent detectable HCV RNA during follow-up.
3. Treatment-experienced on-treatment virologic failure is defined as a patient who has been previously treated with PegIFN/RBV regimen, including regimens containing HCV protease inhibitors (for genotype 1), and who has not experienced adequate response, including a null response, partial response, virologic breakthrough or rebound.
4. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

**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 ADEFGV.
- 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 type 2 diabetes mellitus as a third drug 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.
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:
3. For patients who cannot take metformin and/or a sulfonylurea due to contraindications or intolerances, details must be provided.
4. 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 and 5 mg / 1000 mg,
12.5 mg/ 500 mg, 12.5 mg / 850 mg, 12.5 mg / 1000 mg tablet

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 ≤ 100,000 copies/mL

Claim Note:
- Prescriptions written for beneficiaries of Plan U 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.

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 ≥ 35kg) with no known mutations associated with resistance to the individual components of Genvoya.

Claim Note:
- Prescriptions written for beneficiaries of Plan U 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.

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

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

Claim Note:
- Prescriptions written for beneficiaries of Plan U 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.

ENOXAPARIN (LOVENOX)
Prefilled syringes and multi-dose vial
ENOXAPARIN (LOVENOX HP)
Prefilled syringes

See criteria under Low Molecular Weight Heparins.

ENZALUTAMIDE (XTANDI)
40 mg capsule

For treatment of patients with metastatic castration-resistant prostate cancer who:
- are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy and have not received prior chemotherapy,
  - OR
- have progressed on docetaxel-based chemotherapy and would be an alternative to abiraterone for patients in the post-docetaxel setting.
Clinical Notes:
1. Patient must have no risk factors for seizures.
2. When used as first line treatment, patient must have an ECOG performance status ≤ 1.
3. When used as second line treatment, patient must have an ECOG performance status ≤ 2.

Claim Notes:
• Enzalutamide will not be reimbursed in combination with abiraterone.
• Sequential use of enzalutamide and abiraterone will not be reimbursed.

EPLERENONE (INSPRA)
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 ≤ 35%), as a complement to standard 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.

EPOETIN ALFA (EPREX)
1,000IU/0.5mL, 2,000IU/0.5mL, 3,000IU/0.3mL, 4,000IU/0.4mL, 5,000IU/0.5mL, 6,000IU/0.6mL, 8,000IU/0.8mL, 10,000IU/mL, 20,000IU/mL, 30,000IU/0.75mL and 40,000IU/mL prefilled syringes
1. Treatment of anemia associated with chronic renal failure.

Claim Note:
• Patients on dialysis (end-stage renal disease) receive epoetin through the dialysis units
2. Treatment of transfusion dependent anemia related to therapy with zidovudine in HIV-infected patients.
3. Treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months.

Clinical Note:
• Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

Claim Note:
• Initial approval for 12 weeks.

EPOPROSTENOL (CARIPUL and FLOLAN)
0.5 mg and 1.5 mg vials
1. For the treatment of World Health Organization (WHO) class III or IV idiopathic pulmonary arterial hypertension in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers.
2. For the treatment of WHO class III or IV pulmonary arterial hypertension associated with scleroderma in patients who do not respond adequately to conventional therapy.

ESLICARBAZEPINE (APTIO)
200 mg, 400 mg, 600 mg, 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 Notes:
• The patient must be under the care of a physician experienced in the treatment of epilepsy.

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

**Rheumatoid Arthritis**
For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

**ETANERCEPT (ENBREL)**
25 mg/mL lyophilized powder for reconstitution
50 mg/mL prefilled syringe and autoinjector

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of 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: 1 year.

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

**Claim Notes:**
• Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
• All new requests for coverage of etanercept will be approved for the biosimilar versions only.
• Approvals will be for a maximum of 0.8 mg/kg, up to 50 mg, per week.

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

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

**Rheumatoid Arthritis**
For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15 mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 25 mg twice a week or 50 mg per week.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. Confirmation of continued response is required.

ETANERCEPT (ERELZI)
25 mg / 0.5mL prefilled syringe
50 mg/mL prefilled syringe and auto-injector

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

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

Claim Notes:
- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- All new requests for coverage of etanercept will be approved for the biosimilar version only.
- Approvals will be for a maximum of 0.8mg/kg, up to 50mg per week.

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 ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
- leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg once a week.
- Initial approval period: 16 weeks.
- Renewal approval period: 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 or intolerant to:

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

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of etanercept will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 50mg per week.
- Initial approval period: 6 months.
- Renewal approval period: 1 year. 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 brand)
2.5 mg, 5 mg and 10 mg tablets
For the treatment of hormone-receptor positive, HER2 negative advanced breast cancer in postmenopausal women, 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:
5. Patients must have a good performance status.
6. 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 CDK4/6 inhibitor therapy.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Metastatic Renal Cell Carcinoma
For the treatment of patients with metastatic renal cell carcinoma (mRCC) after failure of 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:
7. Patients must have a good performance status.
8. 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 axitinib.
- Sequential use of nivolumab and everolimus will not be reimbursed. Exceptions may be considered in the case of intolerance or contraindication without disease progression.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Neuroendocrine Tumors
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 tumors (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:
9. Patients must have a good performance status.
10. 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.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

EVOLOCUMAB (REPATHA)
140 mg/mL prefilled autoinjector
120 mg/mL automated mini-doser with prefilled cartridge

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 140mg every 2 weeks or 420mg monthly.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

FEBUXOSTAT (ULORIC and generic brand)
80 mg tablet
For the treatment of symptomatic gout in patients who have documented hypersensitivity to allopurinol.

FENTANYL (DURAGESIC AND generic brands)
12 mcg/hr, 25 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.

FESOTERODINE (TOVIAZ)
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:
11. Treatment failure is defined as 14 days of vancomycin therapy without acceptable clinical improvement.
12. 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

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 Notes:
- All requests for coverage of filgrastim for adult patients will be approved for Grastofil brand only.
- Patients who have existing coverage of the Neupogen brand will continue to have this brand covered until the current special authorization approval expires.

FILGRASTIM (NEUPOGEN)
300 mcg/1 mL and 480 mcg/1.6 mL single-use vials
As supportive therapy for pediatric oncology patients.

Claim Notes:
- All requests for coverage of filgrastim for adult patients will be approved for Grastofil brand only.
- Patients who have existing coverage of the Neupogen brand will continue to have this brand covered until the current special authorization approval expires.

FINGOLIMOD (GILENYA and generic brands)
0.5 mg capsule
For the treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS) who meet all of the following criteria:
- Failure to respond to full and adequate courses of at least one interferon OR glatiramer acetate; OR documented intolerance to both therapies
- Have experienced one or more clinically disabling relapses in the previous year
- Demonstrate a significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) OR have at least one gadolinium enhancing lesion
- Request is being made by and followed by a neurologist experienced in the management of RRMS
- Patient has a recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

Exclusion Criteria:
- Combination therapy of fingolimod with other disease modifying therapies (e.g. Avonex, Betaseron, Copaxone, Rebif, Extavia, Tysabri) will not be funded.
- Combination therapy of fingolimod with Fampyra will not be funded.
- Patients with EDSS > 5.5 will not be funded.
- Patients who have experienced a heart attack or stroke within the 6 months prior to the funding request will not be considered.
- Patients with a history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure will not be considered.
- Patients younger than 18 years of age will not be considered.
- Patients with needle phobia or those having a preference for an oral therapy over an injection and who do not have one or more clinical contraindications to interferon or glatiramer therapy will not be funded.
- Skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.
Requirements for Initial Requests:
• The patient’s physician must provide documentation setting out the details of the patient’s most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.

Renewal requests will be considered.
• Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days);
  AND
• Patient must be stable or have experienced no more than 1 disabling attack/relapse in the past year;
  AND
• The recent Expanded Disability Status Scale (EDSS) score must be less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

Clinical Notes:
1. "Failure to respond to full and adequate courses is defined as a trial of at least 6 months of interferon or glatiramer therapy AND experienced at least one disabling relapse (attack) while on interferon or glatiramer therapy (MRI report does not need to be submitted with the request)
2. "Intolerance is defined as documented serious adverse effects or contraindications that are incompatible with further use of that class of drug. (Note that skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.)

Claim Notes:
• Dosage: 0.5 mg once daily
• Initial approval period: 1 year.
• Renewal 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.

**FLUDARABINE (FLUDARA)**
10 mg film-coated tablet

• For the first-line treatment of patients with chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) when used in combination with rituximab (with or without cyclophosphamide).
• For the treatment of patients with CLL / SLL who have failed to respond to, or have relapsed during or after previous therapy with an alkylating agent.

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

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

**FLUTICASONE FUROATE, UMECLIDINIUM AND VILANTEROL (TRELEGY ELLIPTA)**
100 mcg / 62.5 mcg / 25 mcg dry powder for inhalation

For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting anticholinergic (LABA/LAAC).

Clinical Notes:
1. COPD is defined by spirometry as a post-bronchodilator FEV₁/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale Score grade).
2. Inadequate control while being treated with a LABA/LAAC is defined as persistent symptoms for at least two months, or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
3. Patients should not be started on a LABA, LAAC and an inhaled corticosteroid (triple inhaled therapy) as initial therapy.

**FORMOTEROL (FORADIL)**
12 mcg powder for inhalation

See criteria under Long-acting beta-2 agonists (LABA)
FORMOTEROL (OXEZE TURBUHALER)
6 mcg and 12 mcg turbuhalers
See criteria under Long-acting beta-2 agonists (LABA)

FORMOTEROL AND Aclidinium Bromide (DUAKLIR GENUAIR)
12 mcg / 400 mcg powder for inhalation
See criteria under Long-acting beta-2 agonist/Long-acting anticholinergic (LABA/LAAC) combinations

FORMOTEROL AND Budesonide (SYMBICORT TURBUHALER)
6 mcg / 100 mcg and 6 mcg / 200 mcg turbuhalers
See criteria under Long-acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) combinations

FORMOTEROL AND Mometasone (ZENHALE)
5 mcg / 50 mcg, 5 mcg / 100 mcg and 5 mcg / 200 mcg metered-dose inhalers
See criteria under Long-acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) combinations

FOSFOMYCIN (MONUROL)
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.

GALANTAMINE (Generic brands)
8 mg, 16 mg, and 24 mg extended release capsules
See criteria under Cholinesterase Inhibitors.

GLATIRAMER ACETATE (COPAXONE)
20 mg/mL prefilled syringe
1. For the treatment of patients with clinically definite multiple sclerosis (CDMS) including relapsing-remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis who meet the following criteria:
   • Two disabling attacks of MS in the previous two years, and
   • Ambulatory with or without aid (EDSS of less than or equal to 6.5)
2. For the treatment of patients who have experienced a clinically isolated syndrome and are considered at risk for developing CDMS.
Clinical Note:
• An attack/relapse is defined as the appearance of new or recurring 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:
• New requests for coverage of Copaxone for RRMS will not be considered.
• Glatect brand of glatiramer is listed as a regular benefit.

GLATIRAMER ACETATE (GLATECT)
20 mg/mL prefilled syringe
For the treatment of patients with relapsing-remitting multiple sclerosis (RRMS).
Claim Notes:
• Prescriptions written by New Brunswick neurologists do not require special authorization for the Multiple Sclerosis Plan (Plan H).
• Glatect brand of glatiramer is listed as a regular benefit for Plans ADEFGV.

GLYCEROL PHENYLBUTYRATE (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 Note:
- Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs

GLECAPREVIR AND PIBRENTASVIR (MAVIRET)
100 mg / 40 mg tablet

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Genotypes 1, 2, 3, 4, 5 or 6</th>
<th>Approval Period</th>
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<tbody>
<tr>
<td>Treatment-naïve</td>
<td>8 weeks</td>
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<td></td>
<td>(12 weeks with cirrhosis)</td>
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<table>
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<tr>
<th>Genotypes 1, 2, 3, 4, 5 or 6</th>
<th>Approval Period</th>
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<tbody>
<tr>
<td>Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)</td>
<td>8 weeks</td>
</tr>
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<td></td>
<td>(12 weeks with cirrhosis)</td>
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<thead>
<tr>
<th>Genotype 1</th>
<th>Approval Period</th>
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<tbody>
<tr>
<td>NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing:</td>
<td>12 weeks</td>
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<tr>
<td>Boceprevir/PR; or</td>
<td></td>
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<tr>
<td>Simeprevir (SMV)/SOF; or</td>
<td></td>
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<tr>
<td>SMV/PR; or</td>
<td></td>
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<tr>
<td>Telaprevir/PR</td>
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<tr>
<th>Genotype 1</th>
<th>Approval Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing:</td>
<td>16 weeks</td>
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<tr>
<td>Daclatasvir (DCV)/SOF; or</td>
<td></td>
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<tr>
<td>DCV/PR; or</td>
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<tr>
<td>Ledipasvir/SOF</td>
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<tr>
<th>Genotype 3</th>
<th>Approval Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-experienced with regimens containing PR and/or SOF</td>
<td>16 weeks</td>
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</tbody>
</table>

The following information is also required:
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6
- Quantitative HCV RNA value within the last 6 months
- Fibrosis stage

Clinical Note:
- Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

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 ADEFGV.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

GLYCOPYRRONIUM BROMIDE (SEEBRI BREEZHALER)
50 mcg powder for inhalation

See criteria under Long-acting anticholinergics (LAAC).
GOLIMUMAB (SIMPONI)
50 mg/0.5 mL and 100 mg/1 mL autoinjector and prefilled syringe

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg 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 ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg 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 or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg 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 > 4, and a rectal bleeding subscore ≥2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score ≥2 from baseline, and
  - a decrease in the rectal bleeding subscore ≥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 > 6).
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of the intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 200mg at week 0, 100mg at week 2 then 100mg every four weeks thereafter.
- Initial approval period: 3 months.
- Renewal approval period: 1 year.

GRASS POLLEN ALLERGEN EXTRACT (ORALAIR)
100IR and 300IR 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

IBRUTINIB (IMBRUVICA)
140 mg capsule
13. For the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is considered inappropriate due to high risk of relapse or refractory disease based on prognostic biomarkers.
14. For the treatment of patients with CLL/SLL who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen.
15. For the treatment of patients with relapsed or refractory mantle cell lymphoma.

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

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

Claim Notes:
- Ibrutinib will not be reimbursed when used in combination with rituximab.
• Sequential use of ibrutinib and idehalisib will not be reimbursed. Exceptions may be considered in the case of intolerance or contraindication without disease progression, or when required as a bridge to allogeneic stem cell transplant.
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

ICATIBANT (FIRAZYR)
30 mg/3 mL prefilled syringe
For the treatment of acute attacks of type I or type II hereditary angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency if the following conditions are met:
• Non-laryngeal attacks of at least moderate severity, OR
• Acute laryngeal attacks.

Clinical Notes:
1. Using more than three doses in a 24 hour period is not recommended.
2. The safety of more than eight injections per month has not been investigated in clinical trials.

Claim Notes:
• Must be prescribed by, or in consultation with, physicians experienced in the treatment of HAE.
• Coverage is limited to a single dose per attack.
• The maximum quantity that may be dispensed at one time is two doses.

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:
• Idelalisib will not be reimbursed for patients whose disease has progressed on ibrutinib therapy in the relapsed setting.
• Initial approval period: 6 months.
• Renewal approval period: 12 months.

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 ≤ 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.

**INCOBOTULINUMTOXIN-A (XEOMIN)**
50 LD_{50} units per vial and 100 LD_{50} 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.

**INDACATEROL (ONBREZ BREEZHALER)**
75 mcg powder for inhalation

See criteria under Long-acting beta-2 agonists (LABA)

**INDACATEROL AND GLYCOPYRRONIUM BROMIDE (ULTIBRO BREEZHALER)**
110mcg / 50 mcg powder for inhalation

See criteria under Long-acting beta-2 agonist/Long-acting anticholinergic (LABA/LAAC) combinations

**INFLIXIMAB (INFLECTRA)**
100 mg vial

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval 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](#).

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

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 12 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](#).

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

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

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval 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.

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 ≥ 20mg weekly (≥15mg if patient is ≥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. Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
3. For patients who have intolerances preventing the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
4. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.

Rheumatoid Arthritis
For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 6 months.
- 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.

Ulcerative Colitis
- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score ≥ 2 from baseline, and
  - a decrease in the rectal bleeding subscore ≥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 > 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 of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 12 weeks.
- 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.

INFLIXIMAB (REMCADIE)
100 mg vial

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Approvals will be for a maximum of 5 mg/kg at weeks 0, 2 and 6, then every 6-8 weeks thereafter.
- 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.

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

**Claim Notes:**
• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Approvals will be for a maximum of 5 mg/kg at weeks 0, 2 and 6, then every 8 weeks thereafter.
• Initial approval period: 12 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.

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

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

**Claim Notes:**
• Must be prescribed by a dermatologist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Approvals will be for a maximum of 5 mg/kg at weeks 0, 2, and 6, then every 8 weeks thereafter.
• 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.

**Rheumatoid Arthritis**
For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
• Methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥ 15 mg if patient is ≥ 65 years of age) for a minimum of 12 weeks; and
• Methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

**Claim Notes:**
• Must be prescribed by a rheumatologist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Approvals will be for a maximum of 3 mg/kg/dose at 0, 2 and 6 weeks, then every 8 weeks thereafter.
• Initial approval period: 6 months.
• 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.

INFLIXIMAB (RENFLEXIS)
100 mg vial

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

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

Claim Notes:
• Must be prescribed by a rheumatologist or internist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Initial approval 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.

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

Claim Notes:
• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Initial approval period: 12 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.

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

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

Claim Notes:
• Must be prescribed by a dermatologist.
Combined use of more than one biologic DMARD will not be reimbursed.
All new requests for coverage of infliximab will be approved for the biosimilar versions only.
Initial approval 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.

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 ≥ 20 mg weekly (≥15 mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval 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.

Rheumatoid Arthritis
For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥20 mg weekly (≥15 mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- All new requests for coverage of infliximab will be approved for the biosimilar versions only.
- Initial approval period: 6 months.
- 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.

Ulcerative Colitis
- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 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 requests must include information demonstrating the beneficial effects of the treatment, specifically:
  – a decrease in the partial Mayo score ≥ 2 from baseline, and
  – a decrease in the rectal bleeding subscore ≥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 > 6).
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of the intolerance(s) must be clearly documented.

Claim Notes:
• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
• Combined use of more than one biologic DMARD will not be reimbursed.
• All new requests for coverage of infliximab will be approved for the biosimilar versions only.
• Initial approval period: 12 weeks.
• 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.

INSULIN DETEMIR (LEVEMIR)
100U/mL penfill cartridge and FlexTouch prefilled pen
For the treatment of patients who have been diagnosed with type 1 or type 2 diabetes requiring insulin and have previously taken insulin NPH and/or pre-mix daily at optimal dosing, and have:
• experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management; or
• documented severe or continuing systemic or local allergic reaction to existing insulin(s).

INSULIN GLARGINE (LANTUS)
100U/mL vial, cartridge, and SoloSTAR prefilled pen
For the treatment of patients who have been diagnosed with type 1 or type 2 diabetes requiring long-acting insulin.

Claim Note:
• New requests for coverage of Lantus will not be considered. Basaglar brand of insulin glargine is listed as a regular benefit.

INSULIN LISPRO (HUMALOG)
100U/mL vial, cartridge, and KwikPen prefilled pen
For patients with type 1 or type 2 diabetes who:
• have experienced frequent episodes of postprandial hypoglycemia, or
• have unpredictable mealtimes, or
• have insulin resistance, or
• who are using continuous subcutaneous insulin infusion.

Claim Note:
• Prescriptions written by New Brunswick endocrinologists and internists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

INTERFERON BETA-1A (AVONEX PS)
30 mcg/0.5 mL prefilled syringe and Autoinjector
INTERFERON BETA-1A (REBIF)
22 mcg/0.5 mL and 44 mcg/0.5 mL prefilled syringe
66 mcg/1.5 mL and 132 mcg/1.5 mL prefilled cartridge
INTERFERON BETA-1B (BETASERON, EXTAVIA)
0.3 mg single-use vial
1. For the treatment of patients with clinically definite multiple sclerosis (CDMS) including relapsing-remitting multiple sclerosis, secondary progressive multiple sclerosis or relapsing progressive multiple sclerosis who meet the following criteria:
   • Two disabling attacks of MS in the previous two years, AND
   • Ambulatory with or without aid (EDSS of less than or equal to 6.5)
2. For the treatment of patients who have experienced a clinically isolated syndrome (CIS) and are considered at risk for developing CDMS.
Clinical Note:
- An attack/relapse is defined as the appearance of new or recurring 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 Note:
- Prescriptions written by New Brunswick neurologists do not require special authorization.

**IRON SUCROSE (VENOFER)**
20 mg/mL vial

For the treatment of iron deficiency anemia in patients who
- are intolerant to oral iron replacement products,
  OR
- have not responded to adequate therapy with oral iron.

**ISAVUCONAZOLE (CRESEMBA)**
100 mg capsule
200 mg vial

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

**ITRACONAZOLE (SPORANOX and generic brand)**
100 mg capsule

1. For the treatment of severe systemic fungal infections not responding to alternative therapy.
2. For the treatment of severe or resistant fungal infections in immunocompromised patients not responding to alternative therapy.
3. For the treatment of skin infections (excluding onychomycosis) caused by dermatophyte fungi not responding to alternative therapy.

**ITRACONAZOLE (SPORANOX)**
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 chronic heart failure therapies to reduce the incidence of cardiovascular death and hospitalization who meet all of the following criteria:
- Left ventricular ejection fraction (LVEF) of ≤35%
- Sinus rhythm with a resting heart rate ≥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
  - an aldosterone antagonist

Clinical Notes:
1. Resting heart rate must be documented as ≥ 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 aldosterone antagonist 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.
**IVACAFTOR (KALYDECO)**  
150mg 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 FEV1 of at least 5% when compared to the FEV1 test conducted prior to starting therapy. FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment

**Clinical Notes:**
18. The patient’s sweat chloride level and FEV1 must be provided with each request.  
19. 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 ADEFGV.  
- 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.

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

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

**Clinical Notes:**
1. For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.  
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.  
3. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.  
4. Treatment should be discontinued if a response has not been demonstrated after 12 weeks.

**Claim Notes:**
- Must be prescribed by a dermatologist.  
- Combined use of more than one biologic DMARD 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 ≥ 20mg weekly (≥15mg if patient is ≥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 of more than one biologic DMARD 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.

LACOSAMIDE (VIMPAT and generic brands)
50 mg, 100 mg, 150 mg and 200 mg film-coated tablets
For the adjunctive treatment of refractory partial-onset seizures 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 Notes:
- The patient must be under the care of a physician experienced in the treatment of epilepsy.

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 (HEPTOVIR and generic brand)
100 mg tablet and 5 mg/mL oral solution
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.

LANREOTIDE (SOMATULINE AUTOGEL)
60 mg/0.5 mL, 90 mg/0.5 mL, 120 mg/0.5 mL prefilled syringes
For the treatment of acromegaly.

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).

Clinical Note:
- Patients who have failed a minimum eight week trial of standard dose therapy may be considered for an eight week trial of double dose therapy. Coverage beyond eight weeks will be considered if step down to standard dose therapy is not successful.
LANSOPRAZOLE (PREVACID FASTAB)
15 mg and 30 mg delayed-release tablets

For patients who require drugs to be administered through a feeding tube or are unable to swallow.

LAPATINIB (TYKERB)
250 mg tablet

For use in combination with capecitabine, for the treatment of HER2-positive patients with advanced or metastatic breast cancer who have progressed on trastuzumab-based treatments (e.g. taxanes, anthracycline, trastuzumab) and who have an ECOG performance status of 0-2.

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

Clinical Note:
- Requests will not be considered for use in combination with trastuzumab for second-line HER2-positive metastatic breast cancer or in the adjuvant setting

Claim Notes:
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

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

Myelodysplastic Syndrome (MDS)
For the treatment of Myelodysplastic Syndrome (MDS) in patients with:
- Demonstrated diagnosis of MDS on bone marrow aspiration
- Presence of 5-q deletion documented by appropriate genetic testing
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1
- Presence of symptomatic anemia (defined as transfusion dependent)

Renewal criteria:
- For patients who were transfusion-dependent and have demonstrated a reduction in transfusion requirements of at least 50%.
- Renewal requests for all other patients may be considered if information describing the results of serial CBC (pre- and post-lenalidomide) and any other objective evidence of response is included.

Clinical Notes:
- 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 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.

Multiple Myeloma
1. For the treatment of multiple myeloma, in combination with dexamethasone, in patients who are not candidates for autologous stem cell transplant and have:
   - had no prior treatment, and
   - an ECOG performance status of ≤ 2.

2. For the treatment of multiple myeloma, in combination with dexamethasone, in patients who are not candidates for autologous stem cell transplant and:
   - are refractory to or have relapsed after the conclusion of initial or subsequent treatments; or
   - have completed at least one full treatment regimen as initial therapy and are experiencing intolerance to their current chemotherapy.

3. For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT), who have stable disease or better, with no evidence of disease progression.

Clinical Note:
- Recommended Dose: Initial dose of 10 mg daily. Dose adjustments (5-15 mg) may be necessary based on individual patient characteristics/responses.
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:
- Lenalidomide will not be reimbursed for patients who have had disease progression on prior lenalidomide therapy.
- Initial approval period: 1 year.
- 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.

LENVATINIB (LENVIMA)
10 mg, 14 mg, 20 mg and 24 mg per dose compliance packs
For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet the following criteria:
- Pathologically confirmed papillary or follicular thyroid cancer, and
- Disease that is refractory or resistant to radioactive iodine therapy, and
- Radiological evidence of disease progression within the previous 13 months, and
- Previous treatment with no more than one tyrosine kinase inhibitor (TKI).

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

LEUPROLIDE (LUPRON)
5 mg/mL multi-dose vial
1. For the palliative treatment of stage D2 carcinoma of the prostate (Plans D and F).
2. For the treatment of central precocious puberty.

Claim Note:
- Lupron 5mg injection is a regular benefit for Plans A and V.

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.

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 and 500 mg tablets

Pneumonia and Bronchitis
- For the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).
- For the treatment of severe pneumonia in nursing home patients (regular benefit for Plan V).
- For the treatment of CAP in patients:
  - with co-morbidity upon radiographic confirmation of pneumonia, OR
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment of AECB in complicated patients who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

Clinical Notes:
1. If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
2. Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDS, smoking, malnutrition or acute weight loss.
3. Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea AND
   - FEV₁ < 50% predicted OR
   - FEV₁ 50-65% and one of the following:
     - ≥ 4 exacerbations per year
     - Ischemic heart disease
     - Chronic oral steroid use
     - Antibiotic use in the past 3 months

Claim Notes:
- Prescriptions written by New Brunswick infectious disease specialists, medical microbiologists, medical oncologists, respirologists and internal medicine specialists will not require special authorization.
- Levofloxacin is a regular benefit for Plan V.

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 ADEFGV.

LINAGLIPTIN (TRAJENTA)
5 mg tablet

For the treatment of type 2 diabetes mellitus as a third drug 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.

LINEZOLID (ZYVOXAM and 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)
10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg capsules

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who:
- Demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and
- Have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results.

**Claim Notes:**
- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.
- The maximum dose reimbursed is 60mg daily.

LONG-ACTING ANTICHOLINERGICS (LAAC)
- Aclidinium bromide (Tudorza Genuair)
- Glycopyrronium bromide (Seebri Breezhaler)
- Tiotropium bromide (Spiriva, Spiriva Respimat)
- Umeclidinium bromide (Incruse Ellipta)

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience:
  - persistent symptoms, as defined by Medical Research Council (MRC) Dyspnea Scale of at least Grade 3 or a COPD Assessment test (CAT) score of at least 10 and have a post-bronchodilator FEV₁ less than 80% predicted; or
  - two or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids; or
  - at least one acute severe exacerbation of COPD requiring hospitalization.
- For the treatment of COPD, as defined by spirometry, in combination with a long-acting beta-2 agonist/inhaled corticosteroid (LABA/ICS), for patients who have inadequate control while being treated with a LABA/ICS or a long-acting beta-2 agonist/long-acting anticholinergic (LABA/LAAC).
Clinical Notes:
1. COPD is defined by spirometry as a post-bronchodilator FEV₁/FVC ratio less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale grade).
2. Inadequate control while being treated with a LABA/LAAC or LABA/ICS is defined as persistent symptoms for at least two months or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids, or at least 1 exacerbation of COPD requiring hospitalization.

Claim Notes:
- Requests for combination therapy of single agent long-acting bronchodilators, i.e. LABA and LAAC, will not be considered. Products which combine a LABA/LAAC in a single device are available as special authorization benefits with their own criteria.

LONG-ACTING BETA-2 AGONISTS (LABA)
- Formoterol (Oxeze Turbuhaler)
- Formoterol (Foradil)
- Indacaterol (Onbrez Breezhaler)
- Salmeterol (Serevent Diskus)

Asthma
For the treatment of patients with reversible obstructive airway disease who are using optimal corticosteroid treatment, but are still poorly controlled.

Chronic Obstructive Pulmonary Disease
For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience:
- persistent symptoms, as defined by Medical Research Council (MRC) Dyspnea Scale of at least Grade 3 or a COPD Assessment test (CAT) score of at least 10, and have a post-bronchodilator FEV₁ less than 80% predicted; or
- two or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids; or
- at least one acute severe exacerbation of COPD requiring hospitalization.

Clinical Note:
- COPD is defined by spirometry as a post-bronchodilator FEV₁/FVC ratio less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale grade).

Claim Notes:
- Requests for combination therapy of single agent long-acting bronchodilators, i.e. long-acting beta-2 agonist (LABA) and long-acting anticholinergic (LAAC), will not be considered. Products which combine a LABA/LAAC in a single device are available as special authorization benefits with their own criteria.
- Oxeze Turbuhaler is not indicated for the treatment of COPD, therefore requests will only be considered for the treatment of asthma.
- Onbrez Breezhaler is not indicated for the treatment of asthma, therefore requests will only be considered for the treatment of COPD.

LONG-ACTING BETA-2 AGONISTS/INHALED CORTICOSTEROID (LABA/ICS) COMBINATIONS
- Formoterol/budesonide (Symbicort Turbuhaler)
- Formoterol/mometasone (Zenhale)
- Salmeterol/fluticasone (Advair, Advair Diskus)
- Vilanterol/fluticasone (Breo Ellipta)

Asthma
For patients with reversible obstructive airways disease who are:
- Stabilized on an inhaled corticosteroid and a long-acting beta-2 agonist, or
- Using optimal doses of inhaled corticosteroids but are still poorly controlled.

Chronic Obstructive Pulmonary Disease
- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in combination with a long-acting anticholinergic (LAAC), in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting anticholinergic (LABA/LAAC).
- 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 Notes:
1. COPD is defined by spirometry as a post-bronchodilator FEV₁/FVC ratio less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale grade).
2. Inadequate control while being treated with a LABA/LAAC is defined as persistent symptoms for at least two months or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.

Claim Note:
- Breo Ellipta 25mcg/200mcg and Zenhale are not indicated for the treatment of COPD, therefore requests for these products will only be considered for asthma.

LONG-ACTING BETA-2 AGONIST/ LONG-ACTING ANTICHOLINERGIC (LABA/LAAC) COMBINATIONS
- Formoterol/aclidinium bromide (Duaklir Genuair)
- Indacaterol/glycopyrronium bromide (Ultibro Breezhaler)
- Olodaterol/tiotropium bromide (Inspiolti Respimat)
- Vilanterol/umeclidinum bromide (Anoro Ellipta)

For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with either a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Clinical Notes:
1. COPD is defined by spirometry as a post-bronchodilator FEV₁/FVC ratio less than 0.70. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. Medical Research Council (MRC) Dyspnea Scale grade).
2. Inadequate control is defined as persistent symptoms (e.g. MRC Dyspnea Scale of at least grade 3 or COPD Assessment test (CAT) score of at least 10) after at least one month of a LAAC or LABA.
3. LABA/LAAC combinations are not intended to be used with an inhaled corticosteroid (ICS) unless criteria for triple inhaled therapy (LABA/LAAC/ICS) is met.
LOW MOLECULAR WEIGHT HEPARINS (Dalteparin, Enoxaparin, Nadroparin, Tinzaparin)

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 tumor for up to 28 days (enoxaparin only).
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 limit of approximately 35 days of therapy is applied to all Low Molecular Weight Heparin DINs listed in the table. If the DIN does not appear in the table or if an additional quantity is required, a request must be made through special authorization.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>DIN</th>
<th>Approximate 35 Day Treatment Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dalteparin (Fragmin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2,500IU/0.2mL prefilled syringe</td>
<td>02132621</td>
<td>0.2mL x 35 syringes = 7mL</td>
</tr>
<tr>
<td>• 3,500IU/0.28mL prefilled syringe</td>
<td>02430789</td>
<td>0.28mL x 35 syringes = 9.8mL</td>
</tr>
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<td>02132648</td>
<td>0.2mL x 35 syringes = 7mL</td>
</tr>
<tr>
<td>• 7,500IU/0.3mL prefilled syringe</td>
<td>02352648</td>
<td>0.3mL x 35 syringes = 10.5mL</td>
</tr>
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<td>02352656</td>
<td>0.4mL x 35 syringes = 14mL</td>
</tr>
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<td>• 12,500IU/0.5mL prefilled syringe</td>
<td>02352664</td>
<td>0.5mL x 35 syringes = 17.5mL</td>
</tr>
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<td>• 15,000IU/0.6mL prefilled syringe</td>
<td>02352672</td>
<td>0.6mL x 35 syringes = 21mL</td>
</tr>
<tr>
<td>• 18,000IU/0.72mL prefilled syringe</td>
<td>02352680</td>
<td>0.72mL x 35 syringes = 25.2mL</td>
</tr>
<tr>
<td>• 25,000IU/mL multi-dose vial</td>
<td>02231171</td>
<td>3.8mL x 7 vials = 26.6mL</td>
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<td>Enoxaparin (Lovenox &amp; Lovenox HP)</td>
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<td>• 30mg/0.3mL prefilled syringe</td>
<td>02012472</td>
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</tr>
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<td>• 40mg/0.4mL prefilled syringe</td>
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</tr>
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<td>• 80mg/0.8mL prefilled syringe</td>
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<td>• 100mg/mL prefilled syringe</td>
<td>02378442</td>
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<tr>
<td>Nadroparin (Fraxiparin &amp; Fraxiparin Forte)</td>
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<td>• 5,700IU/0.6mL prefilled syringe</td>
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<td>Tinzaparin (Innohep)</td>
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</tr>
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<td>0.6mL x 35 syringes = 21mL</td>
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<td>• 14,000IU/0.7mL prefilled syringe</td>
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<td>02358182</td>
<td>0.9mL x 35 syringes = 31.5mL</td>
</tr>
</tbody>
</table>
LURASIDONE (LATUDA)
20 mg, 40 mg, 60 mg, 80 mg and 120 mg film-coated tablets

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of intolerance or inadequate response to at least one less expensive antipsychotic agent, or who have a contraindication to less expensive agents.

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.

MEPOLIZUMAB (NUCALA)
100 mg/mL single-use vial

For the adjunctive treatment of severe eosinophilic asthma in adult patients who are inadequately controlled with high-dose inhaled corticosteroids and one or more additional asthma controller(s) (e.g. a long-acting beta-agonist), and meets one of the following criteria:
• blood eosinophil count of ≥ 0.3 x 10^9/L and has experienced two or more clinically significant asthma exacerbations in the past 12 months, or
• blood eosinophil count of ≥ 0.15 x 10^9/L and is receiving 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:
• Baseline asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
• Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, or
• Number of clinically significant asthma exacerbations has increased within the previous 12 months

Clinical Notes:
20. A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
21. 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.
22. High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.

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 100mg every four weeks.
• Initial approval period: 1 year.
• Renewal 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)
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)
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 (ADHD) in patients who demonstrate significant symptoms and who have tried immediate release or slow release methylphenidate with unsatisfactory results.

Claim Notes:
- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.
- The maximum dose reimbursed is 80mg daily.

METHYLPHENIDATE (CONCERTA and generic brands)
18 mg, 27 mg, 36 mg and 54 mg extended-release tablets

For the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in patients who demonstrate significant symptoms and who have tried immediate release or slow release methylphenidate with unsatisfactory results.

Claim Notes:
- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.
- The maximum dose reimbursed is 72mg daily.

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.
- Initial approval period: 1 year.
- 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.

MIRABEGRON (MYRBETRIQ)
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 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.

MODAFINIL (ALERTEC and generic brands)
100 mg tablet

For the treatment of narcolepsy confirmed by a sleep study.

MODIFIED RAGWEED POLLEN TYROSINE ADSORBATE (POLLINEX-R)
105PNU/0.5ml, 250 PNU/0.5ml, 700 PNU/0.5ml, 2150 PNU/0.5ml 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 H1 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.

MOXIFLOXACIN (AVELOX and generic brands)
400 mg tablet

Pneumonia and Bronchitis
- For the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).
- For the treatment of severe pneumonia in nursing home patients (regular benefit for Plan V).
- For the treatment of CAP in patients;
  - with co-morbidity upon radiographic confirmation of pneumonia,
  OR
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment of AECB in complicated patients who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

Clinical Notes:
1. If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
2. Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDS, smoking, malnutrition or acute weight loss.
3. Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea AND
   - FEV1 < 50% predicted
   OR
   - FEV1 50-65% and one of the following:
     - ≥ 4 exacerbations per year
     - Ischemic heart disease
     - Chronic oral steroid use
     - Antibiotic use in the past 3 months
Claim Notes:
- Prescriptions written by New Brunswick infectious disease specialists, medical microbiologists, medical oncologists, respirologists and internal medicine specialists will not require special authorization.
- Moxifloxacin is a regular benefit for Plan V.

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)
Prefilled syringes
NADROPARIN (FRAXIPARIN FORTE)
Prefilled syringes
See criteria under [Low Molecular Weight Heparins](#).

NALTREXONE (REVIA and generic brands)
50 mg film-coated tablet
- For the treatment of alcohol dependence, as an adjunct to a comprehensive program to support abstinence, and reduce the risk of relapse.
- For the maintenance of opioid-free state in individuals who were previously opioid-dependent but have successfully completed detoxification. Treatment should not be attempted until the patient has remained opioid-free for 7 - 10 days. Requests will be considered only when used as an adjunct to psychosocial intervention. In the event that a patient participates in a program other than those offered by New Brunswick Addiction Services, details on the type of counselling/supportive program the patient will be involved in will be requested.

Continued coverage will require information on the outcome of therapy as well as patient's compliance with treatment programs.

Claim Note:
- Coverage will be approved initially for 12 weeks.

NARATRIPTAN (AMERGE and 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:
- 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 with experience in the treatment of multiple sclerosis
- 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-HT3 antagonist and dexamethasone in a previous cycle.

Claim Note:
- Prescription claims for up to a maximum of 2 capsules will be reimbursed every 28 days when the prescription is written by an oncologist, an oncology clinical associate, or a general practitioner in oncology.

**NICOTINE (generic brands)**

- 2 mg gum
- 7 mg, 14 mg and 21 mg patches
- 1 mg, 2 mg, 3 mg and 4 mg mini-lozenges

For smoking cessation.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine prescription smoking cessation drug (varenicline or bupropion).

Claim Note:
- A maximum of 84 patches and 960 pieces of nicotine gum or nicotine lozenges will be reimbursed annually without special authorization.
- Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for up to 84 additional patches.
- Individuals being treated within a program or clinic that participates in the Ottawa Model will qualify for additional reimbursement based on degree of dependence (e.g. number of cigarettes smoked prior to initiating cessation therapy). All special authorization requests for additional nicotine replacement therapy will require confirmation that the individual has agreed, or is already registered with, Go Smoke-Free NB (1-866-366-3667) or is participating in another form of smoking cessation counselling to be specified.

For additional information on quitting smoking or to obtain the appropriate NB Drug Plans special authorization request form, visit our website [Smoking Cessation Therapies](#).

**NILOTINIB (TASIGNA)**

- 150 mg capsule

For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.

**NILOTINIB (TASIGNA)**

- 200 mg capsule

For the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in adult patients who:
- are resistant or intolerant to imatinib,
- OR
- intolerant to dasatinib

**NINTEDANIB (OFEV)**

- 100 mg and 150 mg capsules

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 ≥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 ≥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 ≥ 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.

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 (HFMSE).
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.
- 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 ≥ 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 Note:
- Requests will be considered for individuals enrolled in Plans ADEFGV.

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:
• Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
• Requests will be considered for individuals enrolled in Plans ADEFGV.

OCRIPLASMIN (JETREA)
2.5 mg/mL intravitreal injection

For the treatment of symptomatic vitreomacular adhesion (VMA) if the following clinical criteria and conditions are met:
• Diagnosis of VMA has been confirmed through optical coherence tomography.
• Patients do not have any of the following: large diameter macular holes (greater than 400 micrometres), high myopia (greater than 8 dioptre spherical correction or axial length greater than 28 millimetres), aphakia, history of retinal detachment, lens zonule instability, recent ocular surgery or intraocular injection (including laser therapy), proliferative diabetic retinopathy, ischemic retinopathies, retinal vein occlusions, exudative age-related macular degeneration, or vitreous hemorrhage.

Clinical Notes:
• Ocriplasmin should be administered by an ophthalmologist experienced in intravitreal injections.
• Treatment with ocriplasmin should be limited to a single injection per eye (i.e. retreatments are not covered).

OFLOXACIN (OCUFLOX)
0.3% ophthalmic solution

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

Claim Note:
• Prescriptions written by New Brunswick ophthalmologists and prescribing optometrists do not require special authorization.

OLAPARIB (LYNPARZA)
50 mg capsule, 100 mg and 150 mg tablet

As monotherapy maintenance treatment for patients with platinum-sensitive relapsed BRCA-mutated (germline or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
• Completed at least two previous lines of platinum-based chemotherapy
• Received at least four cycles of the most recent platinum-based chemotherapy regimen
• Radiologic response (complete or partial) to the most recent platinum-based chemotherapy regimen

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

Clinical Notes:
3. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
4. Maintenance therapy should begin within 8 weeks of the last dose of platinum-based chemotherapy.
5. Patients must have a good performance status.
6. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

OLODATEROL AND TIOTROPIUM BROMIDE (INSPIOLTO RESPIMAT)
2.5 mcg / 2.5 mcg solution for inhalation

See criteria under Long-acting beta-2 agonist/Long-acting anticholinergic (LABA/LAAC) combinations.
OMALIZUMAB (XOLAIR)
150 mg/1.2 mL single-use vial

For the treatment of patients ≥ 12 years of age with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H₁ antihistamines.

Requirement for Initial Requests:
- Documentation of the most recent Urticaria Activity Score over 7 days (UAS7) must be provided on the submitted request.

Renewal Criteria:
- Requests for renewal will be considered if the patient has achieved:
  - complete symptom control for less than 12 consecutive weeks; or
  - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline UAS7.

Clinical Notes:
1. Moderate to severe CIU is defined as a UAS7 ≥16.
2. 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.
3. In patients who discontinue treatment due to temporary symptom control, re-initiation can be considered if CIU symptoms reappear.

Claim Notes:
- Approvals will be for a maximum dose of 300mg every four weeks.
- Initial approval period: 24 weeks.

ONABOTULINUMTOXINA (BOTOX)
50 Allergan units per vial (PIN 00903741) and 100 Allergan units per vial

7. For the treatment of equinus foot deformity in cerebral palsy in patients 2 years of age and older.
8. To reduce the subjective symptoms and objective signs of cervical dystonia (spasmodic torticollis) in adults.
9. For the treatment of blepharospasm, hemifacial spasm (VII nerve disorder) and strabismus in patients 12 years of age and older.
10. For the treatment of upper and lower limb (at or below the knee) focal spasticity following stroke in adults. Initial approval period for focal spasticity following stroke will be 6 months.

Renewal criteria:
- Continued approval will require documented benefit of improved passive and/or active range of motion, muscle tone, or improved gait (in the case of lower limb spasticity).

5. For the treatment of overactive bladder (OAB) 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.

Exclusion Criteria:
The following conditions are excluded from coverage:
- Chronic migraine
- Chronic pain
- Hyperhidrosis
- Muscle contracture for support of perineal care

ONABOTULINUMTOXINA (BOTOX)
200 Allergan units per vial (PIN 00999505)

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.

April 7, 2020
ONDANSETRON (ZOFRAN, ZOFRAN ODT and generic brands)
4 mg and 8 mg tablets
4 mg and 8 mg orally disintegrating tablets
4 mg/5 mL oral solution

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 claims for tablets and orally disintegrating tablets written by an oncologist, an oncology clinical associate, or a general practitioner in oncology do not require special authorization.

OSELTAMIVIR (TAMIFLU and generic brand)
30 mg, 45 mg and 75 mg capsules

For beneficiaries residing in long-term care facilities* during an influenza outbreak situation and further to the recommendation of a Medical Officer of Health:
- For treatment of long-term care 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 facility or surrounding community.
- For prophylaxis of long-term care residents where the facility has 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 facility.

Clinical note:
- In these criteria, long-term care facility refers to a licensed nursing home and does not include special care homes.

OSIMERTINIB (TAGRISSO)
40 mg and 80 mg tablet

1. For the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
2. For the treatment of patients with locally advanced (not amenable to curative therapy) or metastatic EGFR T790M mutation-positive NSCLC who have progressed on EGFR tyrosine kinase inhibitor therapy.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment.

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

Claim Notes:
- Requests for first line therapy will be considered for patients with de novo EGFR T790M mutation-positive NSCLC.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

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.

OXYBUTYNIN (DITROPAN XL)
5 mg and 10 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 insufficient response to an adequate trial of immediate-release oxybutynin.

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.
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.

PALBOCICLIB (IBRANCE)
75 mg, 100 mg, and 125 mg capsules
In combination with an aromatase inhibitor for the treatment of hormone receptor positive, HER2 negative advanced or metastatic breast cancer in postmenopausal women or men who:
- have not received prior therapy for advanced or metastatic disease, and
- are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, 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:
23. For patients who received (neo)adjuvant NSAI therapy, a minimum disease-free interval of twelve months after stopping therapy is required
24. Patients must have a good performance status.
25. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for women with chemically-induced menopause will be considered.
- Patients with disease progression on palbociclib are not eligible for reimbursement of further CDK4/6 inhibitor therapy or everolimus.
- Initial approval period: 1 year.
- Renewal 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.

PALIPERIDONE PALMITATE (INVEGA TRINZA)
175 mg/0.875 mL, 263 mg/1.315 mL, 350 mg/1.75 mL, 525 mg/2.625 mL prefilled syringe
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.

PAZOPANIB (VOTRIENT)
200 mg tablet
1. As a first-line treatment for patients with advanced or metastatic clear cell renal carcinoma and good performance status.
2. For the treatment of advanced or metastatic renal cell (clear cell) carcinoma (mRCC) in patients who are unable to tolerate sunitinib and who have an ECOG performance status of 0 or 1.

Renewal Criteria:
- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

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

PEGFILGRASTIM (LAPELGA)
6 mg/0.6 mL prefilled syringe
For the prevention of febrile neutropenia in patients with non-myeloid malignancies 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, 94mcg /0.5 mL, and 125 mcg/0.5 mL prefilled syringe and pen

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations and slow the progression of disability who meet the following criteria:
• Two disabling attacks/relapses of MS in the previous two years, and
• Ambulatory with or without aid (EDSS of less than or equal to 6.5)

Clinical Note:
• An attack/relapse is defined as the appearance of new or recurring 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:
• Requests will be considered for individuals enrolled in Plans ADEFGV.
• Prescriptions written by New Brunswick neurologists do not require special authorization.

PERAMAPANEL (FYCOMPA)
2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 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 Notes:
• 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.

PIOGLITAZONE (generic brands)
15 mg, 30 mg and 45 mg tablets

For patients with type 2 diabetes who are not adequately controlled by diet, exercise and drug therapy. Drug therapy should include a trial of a sulfonylurea and metformin, alone and in combination, unless one of these agents is not tolerated or is contraindicated.

PIRFENIDONE (ESBRINET)
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 ≥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 ≥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 ≥ 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)
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:
- PBBD34+ count of less than 10 cells/μL 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 Note:
- Reimbursement is limited to a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.

POMALIDOMIDE (POMALYST)
1 mg, 2 mg, 3 mg and 4 mg capsules
For the treatment of patients with relapsed and/or refractory multiple myeloma who:
- Have previously failed at least two treatments including both bortezomib and lenalidomide, and
- Demonstrated disease progression on the last treatment.

Clinical Note:
- Requests for pomalidomide will be considered in rare instances where bortezomib is contraindicated or when patients are intolerant to it; however, in all cases patients should have failed lenalidomide which they may have received in the maintenance setting.

Claim Note:
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

PONATINIB (ICLUSIG)
15 mg and 45 mg film-coated tablets
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:
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

PRASUGREL (EFFIENT)
10 mg tablet
In combination with ASA for patients with:
- ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab. Treatment must be initiated in hospital.
• Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis1, or recurrent STEMI, or NSTEMI or UA after prior revascularization via PCI.

Clinical Notes:
1. 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. Definite stent thrombosis must be confirmed by angiography or by pathologic evidence of acute thrombosis.
2. As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as gastrointestinal bleeding or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).
3. As per the product monograph, prasugrel is not recommended in patients ≥ 75 years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight < 60 kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

Claim Notes:
• Approval will be for a maximum of 12 months.
• Prescriptions written by invasive (interventional) cardiologists do not require special authorization.

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

QUINAGOLIDE (NORPROLAC)
0.075 mg, 0.15 mg tablets
For the treatment of patients with hyperprolactinemia who have failed or are intolerant to bromocriptine.

RANIBIZUMAB (LUCENTIS)
10 mg/mL solution for intravitreal injection
1. Neovascular (wet) age-related macular degeneration (AMD)

Initial Coverage:
For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply to the eye to be treated:
• Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
• The lesion size is less than or equal to 12 disc areas in greatest linear dimension
• There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT))
• Administration is to be done by a qualified ophthalmologist experienced in intravitreal injections.
• The interval between doses should not be shorter than 1 month.

Continued Coverage:
Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy.

Clinical Notes:
1. Coverage will not be approved for patients:
   • With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines
   • Receiving concurrent treatment with verteporfin.
2. Ranibizumab should be permanently discontinued if any one of the following occurs:
   • Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
   • Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
   • There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.
Claim Notes:
- An initial claim of up to two vials of ranibizumab (one vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If additional medication is required, a request should be made through special authorization.
- The NB Drug Plans will limit reimbursement to a maximum of 1 vial of ranibizumab per eye treated every 30 days. Claims submitted for greater than 1 vial, or submitted within 30 days of a previous claim will not be reimbursed.

2. Diabetic macular edema (DME)

Initial coverage:
For the treatment of visual impairment due to diabetic macular edema (DME) in patients who meet all of the following criteria:
- clinically significant centre-involving macular edema for whom laser photocoagulation is also indicated
- hemoglobin A1c test in the past 6 months with a value of less than or equal to 11%
- best corrected visual acuity of 20/32 to 20/400
- central retinal thickness greater than or equal to 250 micrometers

Renewal Criteria:
- confirm that a hemoglobin A1c test in the past 6 months had a value of less than or equal to 11%
- date of last visit and results of best corrected visual acuity at that visit
- date of last OCT and central retinal thickness on that examination
- if ranibizumab is being administered monthly, please provide details on the rationale

Clinical Note:
- Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on ranibizumab). Thereafter, the patient's visual acuity should be monitored monthly. Treatment should be resumed when monitoring indicates a loss of visual acuity due to DME until stable visual acuity is reached again for three consecutive months.

Claim Notes:
- Approval Period: 1 year.

REGORAFENIB (STIVARGA)
40 mg film-coated tablet

Advanced Hepatocellular Carcinoma
For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have had disease progression on sorafenib and meet all of the following criteria:
- ECOG performance status of 0 or 1
- Child-Pugh class status of A
- Tolerated sorafenib at a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment

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:
- Initial approval period: 4 months.
- Renewal approval period: 6 months.

Gastrointestinal Stromal Tumor
For the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib, and who have an 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:
- Initial approval period: 6 months.
- Renewal approval period: 6 months.
RIBOCOCLIB (KISQALI)
200 mg tablet

In combination with an aromatase inhibitor for the treatment of hormone receptor positive, HER2 negative advanced or metastatic breast cancer in postmenopausal women or men who:
- have not received prior therapy for advanced or metastatic disease, and
- are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, 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. For patients who received (neo)adjuvant NSAI therapy, a minimum disease-free interval of twelve months after stopping therapy is required.
2. Patients must have a good performance status.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for women with chemically-induced menopause will be considered.
- Patients with disease progression on ribociclib are not eligible for reimbursement of further CDK4/6 inhibitor therapy or everolimus.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

RIFABUTIN (MYCOBUTIN)
150 mg capsule

Mycobacterium Avium Complex (MAC)
For the prevention of disseminated Mycobacterium avium complex (MAC) disease in patients with advanced HIV infection.

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.

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.

RILUZOLE (RILUTEK and generic brands)
50 mg tablet

For the treatment of probable or definite amyotrophic lateral sclerosis.

RIOCIQUIT (ADEMPAS)
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.
RISANKIZUMAB (SKYRIZI)  
75 mg/0.83 mL prefilled syringe

For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria:
- Psoriasis Area Severity Index (PASI) > 10 and Dermatology Life Quality Index (DLQI) > 10, or major involvement of visible areas, scalp, genitals, or nails
- Refractory, intolerant or unable to access phototherapy
- Refractory, intolerant or have contraindications to one of the following:
  - Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥ 15 mg if patient is ≥ 65 years of age) for a minimum of 12 weeks
  - Cyclosporine for a minimum of 6 weeks

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

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- 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.

RISEDRONATE (generic brand)  
30 mg film-coated tablet

For the treatment of Paget’s disease.

Claim Notes:
- A maximum of 60 tablets will be reimbursed annually without special authorization.
- Requests for re-treatment may be considered through special authorization following a two month post-treatment observation period.

RISPERIDONE (RISPERDAL CONSTA)  
Prolonged release suspension for injection 12.5 mg, 25 mg, 37.5 mg and 50 mg vials

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.

RISPERIDONE (generic brands)  
0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg oral disintegrating tablets

For patients requiring an oral antipsychotic who are unable to be treated with regular oral tablets.

Claim Note:
- Prescriptions written by New Brunswick psychiatrists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

RITUXIMAB (RITUXAN)  
10 mg/mL single-use vial

1. Rheumatoid Arthritis
   - For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent.

Clinical Notes:
- Rituximab will not be reimbursed concomitantly with anti-TNF agents.
- Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose.
2. Polyangiitis
   - For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

RIVAROXABAN (XARELTO)
10 mg tablet
Venous thromboembolic event prophylaxis following total knee or total hip replacement surgery
   - For the prevention of venous thromboembolic events in patients who have undergone elective total knee replacement (TKR) surgery or total hip replacement (THR) surgery.

Clinical Note:
   - The total duration of therapy includes the period during which doses are administered post-operatively in an acute care (hospital) setting, and the approval period is for the balance of the total duration after discharge.

Claim Notes:
   - Maximum reimbursement without special authorization will be limited to 14 days of therapy (14 tablets) for TKR or 35 days of therapy (35 tablets) for THR, within a 6 month period.
   - Subsequent reimbursement for prophylaxis within a 6 month period (i.e. second joint replacement procedure within the 6 month period) will require special authorization.

RIVAROXABAN (XARELTO)
15 mg and 20 mg tablets
Atrial fibrillation
For the prevention of stroke and systemic embolism in at-risk patients (CHADS2 score ≥ 1) with non-valvular atrial fibrillation for whom:
   - Anticoagulation is inadequate following at least a two month trial on warfarin; or
   - Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Clinical Note:
   - Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period.

Venous thromboembolic events treatment
For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

Clinical Note:
   - When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Claim Note:
   - Approval Period: Up to 6 months.

RIVASTIGMINE (EXELON and generic brands)
1.5 mg, 3 mg, 4.5 mg and 6 mg capsules
2 mg/mL oral solution
See criteria under Cholinesterase Inhibitors.

ROTIGOTINE (NEUPRO)
2 mg, 4 mg, 6 mg, 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)
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, 20 mg tablets

Myelofibrosis
For the treatment of patients with intermediate to high risk symptomatic myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status ≤3 and be either previously untreated or refractory to other treatment.

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 10^9/L and white blood cell count > 10 x 10^9/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 10^9/L, platelet count < 100 x 10^9/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 10^9/L, white blood cell count ≤ 10 x 10^9/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)
24 mg / 26 mg, 49 mg / 51 mg and 97 mg / 103 mg film-coated tablet

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 < 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 an aldosterone antagonist.
- Plasma B-type natriuretic peptide (BNP) ≥ 150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP) ≥ 600 pg/mL.

Clinical Notes:
1. A plasma BNP ≥ 100 pg/mL or NT-proBNP ≥ 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 aldosterone antagonist due to an intolerance or contraindication, details must be provided.

SALMETEROL (SEREVENT DISKUS)
50 mcg diskus

See criteria under Long-acting beta-2 agonists (LABA)
SALMETEROL AND FLUTICASONE (ADVAIR)
25 mcg / 125 mcg and 25 mcg / 250 mcg metered-dose inhalers
SALMETEROL AND FLUTICASONE (ADVAIR DISKUS)
50 mcg / 100 mcg, 50 mcg / 250 mcg and 50 mcg / 500 mcg diskus

See criteria under Long-acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) combinations

SARILUMAB (KEVZARA)
150 mg / 1.14 mL and 200 mg / 1.14 mL prefilled syringe and prefilled pen

For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- 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.

SAXAGLIPTIN (ONGLYZA)
2.5 mg and 5 mg tablets

For the treatment of type 2 diabetes mellitus as a third drug 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.

SECUKINUMAB (COSENTYS)
150 mg/mL prefilled syringe and 150 mg/mL SensoReady pen

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

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

Claim Notes:
- Must be prescribed by a rheumatologist or internist.
Combined use of more than one biologic DMARD will not be reimbursed.
Approvals will be for 150 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
Initial approval period: 6 months.
Renewal approval period: 1 year.

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

Clinical Notes:
26. 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.
27. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
28. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a dermatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 300 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- 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 ≥ 20 mg weekly (≥15 mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
  - leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- 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.
SEMAGLUTIDE (OZEMPIC)
2 mg / 1.5 mL and 4 mg / 3 mL prefilled pens

For the treatment of type 2 diabetes mellitus as a:
- second drug added to metformin for patients who have inadequate glycemic control on metformin; or
- third drug added to metformin and a sulfonylurea for patients who have inadequate glycemic control on metformin and a sulfonylurea.

Clinical Note:
- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.

SILDENAFIL (REVATIO and generic brands)
20 mg film-coated tablet

- For the treatment of patients with World Health Organization (WHO) functional class III idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers.
- For the treatment of patients with World Health Organization (WHO) functional class III pulmonary arterial hypertension (PAH) associated with connective tissue diseases who do not respond to conventional therapy.
- Diagnosis of PAH should be confirmed by cardiac catheterization.

Claim Note:
- The maximum dose of sildenafil that will be reimbursed is 20mg three times daily.

SITAGLIPTIN (JANUVIA)
25 mg, 50 mg and 100 mg tablets

For the treatment of type 2 diabetes mellitus as a third drug 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.

SITAGLIPTIN AND METFORMIN (JANUMET)
50 mg / 500 mg, 50 mg / 850 mg and 50 mg / 1000 mg tablets
SITAGLIPTIN AND METFORMIN (JANUMET XR)
50 mg / 1000 mg extended-release tablet

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

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$_2$) < 22mmol/L.

SODIUM FERRIC GLUCONATE COMPLEX (FERRLECIT)
12.5 mg/mL ampoule and vial

For the treatment of iron deficiency anemia in patients who
- are intolerant to oral iron replacement products, OR
- have not responded to adequate therapy with oral iron.

SODIUM PHENYLIBUTRATE (PEBURANE)
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 Note:
- Must be prescribed by, or in consultation with, a physician experienced in the treatment of UCDs.
SOFOSBUVIR (SOVALDI)
400 mg tablet

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without cirrhosis</td>
<td>12 weeks in combination with ribavirin (RBV)</td>
</tr>
<tr>
<td>With compensated cirrhosis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without cirrhosis</td>
<td>24 weeks in combination with RBV</td>
</tr>
<tr>
<td>With compensated cirrhosis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without cirrhosis</td>
<td>12 weeks in combination with daclatasvir</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>With compensated or decompensated cirrhosis</td>
<td>12 weeks in combination with daclatasvir and ribavirin</td>
</tr>
<tr>
<td>Post-liver transplant without cirrhosis or with compensated cirrhosis</td>
<td></td>
</tr>
</tbody>
</table>

The following information is also required:
1. Lab-confirmed hepatitis C genotype 2 and 3
2. Quantitative HCV RNA value within the last 6 months
3. Fibrosis stage

**Clinical Notes:**
1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen and has not experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as a 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:**
1. Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
2. Requests will be considered for individuals enrolled in Plans ADEFGV.
3. Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.
**SOFOSBUVIR AND LEDIPASVIR (HARVONI)**

400 mg / 90 mg tablet

For treatment-naive or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genotype 1</strong></td>
</tr>
<tr>
<td>- Treatment-naive without cirrhosis, who have pre-treatment HCV RNA level &lt; 6 million IU/mL and mono-HCV infected only</td>
</tr>
<tr>
<td><strong>Genotype 1</strong></td>
</tr>
<tr>
<td>- Treatment-naive without cirrhosis, who have pre-treatment HCV RNA level ≥ 6 million IU/mL</td>
</tr>
<tr>
<td>- Treatment-naive with compensated cirrhosis</td>
</tr>
<tr>
<td>- Treatment-naive with advanced liver fibrosis (Fibrosis stage F3-F4)</td>
</tr>
<tr>
<td>- Treatment-experienced without cirrhosis</td>
</tr>
<tr>
<td>- HCV/HIV co-infected without cirrhosis or with compensated cirrhosis</td>
</tr>
<tr>
<td><strong>Genotype 1</strong></td>
</tr>
<tr>
<td>- Treatment-experienced with compensated cirrhosis</td>
</tr>
<tr>
<td><strong>Genotype 1</strong></td>
</tr>
<tr>
<td>- Decompensated cirrhosis</td>
</tr>
<tr>
<td>- Liver transplant recipients without cirrhosis or with compensated cirrhosis</td>
</tr>
</tbody>
</table>

The following information is also required:
1. Lab-confirmed hepatitis C genotype 1
2. Quantitative HCV RNA value within the last 6 months
3. Fibrosis stage

**Clinical Notes:**
1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen, including regimens containing HCV protease inhibitors and who has not experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as a 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:**
1. Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
2. Requests will be considered for individuals enrolled in Plans ADEFGV.
3. Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

**SOFOSBUVIR AND VELPATASVIR (EPCLUSA)**

400 mg / 100 mg tablet

For treatment-naive or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Approval Period and Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</strong></td>
</tr>
<tr>
<td>- Patients with compensated cirrhosis</td>
</tr>
<tr>
<td>- Patients without cirrhosis</td>
</tr>
<tr>
<td><strong>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</strong></td>
</tr>
<tr>
<td>- Patients with decompensated cirrhosis</td>
</tr>
</tbody>
</table>
The following information is also required:
1. Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
2. Quantitative HCV RNA value within the last 6 months
3. Fibrosis stage

Clinical Notes:
1. Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen, including regimens containing HCV protease inhibitors and who has not experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as a 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:
1. Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
2. Requests will be considered for individuals enrolled in Plans ADEFGV.
3. Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

SOFOSBUVIR, VELPATASVIR AND VOXILAPREVIR (VOSEVI)
400 mg / 100 mg / 100 mg tablet

For treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table>
<thead>
<tr>
<th>Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes</th>
<th>Approval Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with compensated cirrhosis</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Patients without cirrhosis</td>
<td></td>
</tr>
</tbody>
</table>

The following information is also required:
1. Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes.
2. Quantitative HCV RNA value within the last 6 months.

Clinical Notes:
1. Treatment experienced is defined as a patient who has been previously treated with an NS5A inhibitor for genotype 1, 2, 3, 4, 5 or 6 or sofosbuvir without an NS5A inhibitor for genotype 1, 2, 3 or 4 and who has not experienced an adequate response.
2. Compensated cirrhosis is defined as a CTP score of 5 to 6 (Class A).

Claim Notes:
1. Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
2. Requests will be considered for individuals enrolled in Plans ADEFGV.
3. Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

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® prefilled pens

1. Growth Hormone Deficiency in Children
For the treatment of growth hormone deficiency in children under the age of 19.

Claim Notes:
1. Must be prescribed by, or in consultation with, an endocrinologist.
2. Somatropin is a regular benefit for Plan T

2. Turner Syndrome
For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

Claim Note:
1. Must be prescribed by, or in consultation with, an endocrinologist.
SOMATROPIN (HUMATROPE)
5 mg vial
6 mg, 12 mg and 24 mg cartridges

1. 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.

2. 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 prefilled pens

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

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

1. 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.

2. 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.

3. 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/1.73m² (75 mL/min/1.73m²)
- 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 3rd 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

**Metastatic Renal Cell Carcinoma (MRCC)**
As second-line therapy for patients with histologically confirmed metastatic clear cell renal cell carcinoma, who:
- have disease progression after prior cytokine therapy (e.g. interferon; aldesleukin) within the previous 8 months; **AND**
- have a performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria†; **AND**
- have a favourable or intermediate risk status, according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score.

Renewal criteria:
- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

**Clinical Note:**
- † Patients who are asymptomatic and those who are symptomatic but completely ambulant.

**Claim Notes:**
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

**Advanced Hepatocellular Carcinoma (HCC)**
For patients with Child-Pugh Class A† who have:
- A performance status of 0, 1, or 2† on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria; **AND**
- Either progressed on trans-arterial chemoembolization (TACE) or not suitable for the TACE procedure.
- Coverage may be renewed for patients with documentation of radiography and/or scan results indicating no progression

**Clinical Notes:**
1. Sorafenib will not be reimbursed if used with induction or adjuvant intent along with other curative-intent treatments; for maintenance therapy after trans-arterial chemoembolization; or if patients have Child-Pugh B or Child-Pugh C cirrhosis.
2. A Child-Pugh score of 5-6 is considered class A (well-compensated disease); 7-9 is class B (significant functional compromise); and 10-15 is class C (decompensated disease).
3. † Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.
4. The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present: Favourable = none; Intermediate = one or two; Poor = three or more. Pre-treatment risk factors:
   - Low Karnofsky performance status (<80%)
   - Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
   - Hemoglobin level below the lower limit of normal
   - High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
   - Interval of less than 1 year between diagnosis and treatment

**Claim Notes:**
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

STIRIPENTOL (DIACOMIT)
250 mg and 500 mg capsules
250 mg and 500 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.

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)
12.5 mg, 25 mg and 50 mg capsules
1. Pancreatic Neuroendocrine Tumors (pNET)
For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) with an ECOG performance status of 0-2, until disease progression.

2. Gastrointestinal Stromal Tumour (GIST)
For the treatment of patients with c-KIT expressing (CD117+) unresectable or metastatic/recurrent gastrointestinal stromal tumour (GIST) who meet the criteria for imatinib and who have:
- Early progression (within 6 months) while on imatinib;
- Progression following treatment with optimum (escalated) doses of imatinib; OR
- Intolerance to imatinib

Clinical Notes:
- Response to sunitinib therapy should be assessed at least every six months and therapy should be discontinued when there is objective evidence of disease progression
- Sunitinib will not be reimbursed concomitantly with imatinib

Claim Note:
- The dose reimbursed will be 50mg per day (4 weeks on, 2 weeks off)

3. Metastatic Renal Cell Carcinoma (MRCC)
For patients with histologically confirmed metastatic renal cell carcinoma (MRCC), who require:
- First-line therapy for the treatment of MRCC, and the patient is either a favourable or intermediate risk according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score* OR
- Second-line therapy for the treatment of MRCC, provided that disease progression has occurred after prior cytokine therapy (e.g. interferon; aldesleukin).

Renewal criteria:
- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Clinical Notes:
- The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present: Favourable = none; Intermediate = one or two; Poor = three or more. Pre-treatment risk factors:
  - Low Karnofsky performance status (<80%)
  - Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
  - Hemoglobin level below the lower limit of normal
  - High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
  - Interval of less than 1 year between diagnosis and treatment


Claim Notes:
- The prescribed dosage is 50mg daily for four weeks, followed by two weeks off. This dosage is repeated in six week cycles.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.
TACROLIMUS (PROTOPIC)
0.03% ointment

For children over 2 years of age with refractory atopic dermatitis.

Claim Note:
- Approvals will be given for up to twelve months at a time.

TACROLIMUS (PROTOPIC)
0.1% ointment

For the treatment of adults with moderate to severe atopic dermatitis who have failed or are intolerant 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).

TALIGLUCERASE ALFA (ELELYSO)
200 units per vial

For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is not tolerated or contraindicated.

Clinical Notes:
1. Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy for GD1. Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be considered for coverage of velaglucerase alfa only.
2. 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.

TAZAROTENE (TAZORAC CREAM)
0.05% and 0.1% cream
TAZAROTENE (TAZORAC GEL)
0.05% and 0.1% gel

For the treatment of patients with plaque psoriasis in whom conventional therapies have been ineffective or are inappropriate.

TEDUGLUTIDE (REVESTIVE)
5 mg vial

For the ongoing treatment of adult patients with Short Bowel Syndrome (SBS) who have all of the following:
- SBS as a result of major intestinal resection (e.g. volvulus, vascular disease, cancer, Crohn’s disease, injury)
- dependency on parenteral nutrition (PN) for a least 12 months
- prior to initiating teduglutide, PN required at least three times weekly to meet caloric, fluid and electrolyte needs, due to ongoing malabsorption and stable PN 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 PN volume compared to baseline, while on teduglutide therapy.

Renewal Criteria:
- Has maintained at least a 20% reduction in PN volume from baseline at 12 months.

Clinical Note:
- PN is defined as the parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and 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 (AUBAGIO)
14 mg film-coated tablet
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 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 ADEFGV.

TESTOSTERONE (ANDRODERM)
2.5 mg/hr and 5 mg/hr transdermal patches
TESTOSTERONE (ANDROGEL, TESTIM and generic brand)
1% gel (2.5g and 5g packets)
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, orchietomy, and other established causes
- Secondary: Pituitary-hypothalamic injury due to tumors, trauma, radiation

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate free testosterone measurements before initiating any replacement therapy

Clinical Note:
- Older males with non-specific symptoms of fatigue, malaise, or depression who have low testosterone levels do not satisfy these criteria.

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 (≥ 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.

TICAGRELOL (BRILINTA)
90 mg tablet
To be taken in combination with ASA 75mg -150mg daily for patients with acute coronary syndrome (i.e. ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA), as follows:
STEMI\(^{b,c}\)
- STEMI patients undergoing primary PCI

NSTEMI or UA\(^{b,c}\)
- Presence of high risk features irrespective of intent to perform revascularization:
  - High GRACE risk score (>140)
  - High TIMI risk score (5-7)
  - Second ACS within 12 months
  - Complex or extensive coronary artery disease e.g. diffuse three vessel disease
  - Definite documented cerebrovascular or peripheral vascular disease
  - Previous CABG
  - OR
- Undergoing PCI + high risk angiographic anatomy\(^d\)

Clinical Notes:
1. \(^a\) Co-administration of ticagrelor with high maintenance dose ASA (>150mg daily) is not recommended.
2. \(^b\) In the PLATO study more patients on ticagrelor experienced non CABG related major bleeding than patients on clopidogrel, however, there was no difference between the rate of overall major bleeding, between patients treated with ticagrelor and those treated with clopidogrel. As with all other antiplatelet treatments the benefit/risk ratio of antithrombotic effect vs. bleeding complications should be evaluated.
3. \(^c\) Ticagrelor is contraindicated in patients with active pathological bleeding, in those with a history of intracranial hemorrhage and moderate to severe hepatic impairment.
4. \(^d\) High risk angiographic anatomy is defined as any of the following: left main stenting, high risk bifurcation stenting (i.e. two-stent techniques), long stents \(\geq 38\) mm or overlapping stents, small stents \(\leq 2.5\) mm in patients with diabetes.

Claim Notes:
- Approval will be for a maximum of 12 months.
- Prescriptions written by invasive (interventional) cardiologists do not require special authorization.

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)
10,000IU/mL multidose vials and prefilled syringes
20,000IU/mL multidose vials and prefilled syringes
See criteria under Low Molecular Weight Heparins

TIOTROPIUM BROMIDE (SPIRIVA)
18 mcg powder for inhalation
TIOtroPIUM BROMIDE (SPIRIVA RESPIMAT)
2.5 mcg solution for inhalation
See criteria under Long-acting anticholinergics (LAAC)

TIPRANAVIR (APTVUS)
250mg capsule
For the treatment of adult patients with HIV-1 infection who are treatment experienced, have demonstrated failure to multiple protease inhibitors and in whom no other protease inhibitor is a treatment option.

TOBRAMYCIN (TOBI PODHALER)
28 mg powder for inhalation
For the treatment of chronic pulmonary \textit{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 Note:
- 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 ABDEFGV

TOCILIZUMAB (ACTEMRA)
80 mg/4 mL, 200 mg/10 mL, and 400 mg/20 mL single-use vial and 162 mg/0.9 mL 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.
- Requests for renewal must include:
  - confirmation of response to treatment (e.g., absence of flares, normalization of C-reactive protein), and
  - description of attempts to taper or discontinue glucocorticoids, and
  - 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 ≥ 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 DMARD will not be reimbursed.
- Subcutaneous injection: Approvals will be for up to 162 mg every week.
- Approval period: 1 year

Polyarticular Juvenile Idiopathic Arthritis
For the treatment of children (age 2-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).

Claim Note:
- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Intravenous infusion: Approvals will be for 10mg/kg for patients <30kg or 8mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered 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 or intolerant to:
- methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
- methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Intravenous infusion: Initial approvals will be for 4mg/kg/dose every four weeks, with a maximum maintenance dose escalation up to 8mg/kg, to a maximum of 800mg per infusion for patients >100kg.
- Subcutaneous injection: Initial approvals will be for 162mg every other week for patients <100kg, with a maximum maintenance dose escalation to weekly dosing permitted. Patients ≥100kg will be approved for 162mg every week, with no dose escalation permitted.
- Initial approval period: 16 weeks
- Renewal approval period: 1 year. Confirmation of continued response is required.
Systemic Juvenile Idiopathic Arthritis (sJIA)
For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

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 DMARD will not be reimbursed.
• Intravenous infusion: Approvals will be for 12 mg/kg for patients < 30kg or 8 mg/kg for patients ≥ 30kg, to a maximum of 800mg, administered every two weeks.
• Initial approval period: 16 weeks.
• Renewal approval period: 1 year. Confirmation of continued response is required.

TOFACITINIB (XELJANZ and XELJANZ XR)
5 mg film-coated tablet
11 mg extended-release tablet

For the treatment of moderately to severely active rheumatoid arthritis, alone or in combination with methotrexate, in adult patients who are refractory or intolerant to:
• methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; and
• methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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

Claim Notes:
• Must be prescribed by a rheumatologist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• Approvals will be for a maximum dose of 5 mg twice daily (Xeljanz) or 11 mg once daily (Xeljanz XR).
• Initial approval period: 6 months.
• Renewal approval period: 1 year. Confirmation of continued response is required.

TOPIRAMATE (TOPAMAX)
15 mg and 25 mg sprinkle capsules

For the treatment of refractory epilepsy not well controlled with conventional therapy.
• To reduce the frequency of migraine headaches in adult patients who have failed an adequate trial of, or have contraindications to, beta blockers AND tricyclics for prophylaxis.

TRAMETINIB (MEKINIST)
0.5 mg and 2 mg tablets

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 and/or MEK inhibitor therapy.
• Initial approval period: 6 months.
• Renewal approval period: 6 months.
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 primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class III or IV disease who have both:
1. failed to respond to non-prostanoid therapies
   AND
2. who are not candidates for epoprostenol therapy because of:
   • prior recurrent complications with central line access (e.g. infection, thrombosis)
   OR:
   • inability to operate the complicated delivery system of epoprostenol
   OR:
   • they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol.

TROSPIUM (TROSEC and generic brand)
20 mg tablet
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.

ULIPRISTAL (FIBRISTAL)
5mg tablet
For the treatment of adult women of reproductive age with moderate to severe uterine fibroids as either:
• Pre-operative treatment in patients who are eligible for surgery; or
• Intermittent treatment in patients who are not eligible for surgery.

Clinical Note:
• Each course of treatment is three months in duration.

Claim Notes:
• The maximum quantity reimbursed is limited to four courses of treatment.
• The patient must be under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids.

UMECLIDINIUM BROMIDE (INCRUSE ELLIPTA)
62.5mcg powder for inhalation
See criteria under Long-acting anticholinergics (LAAC)

USTEKINUMAB (STELARA)
45 mg/0.5 mL and 90 mg/mL prefilled syringes
For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria:
• Psoriasis Area Severity Index (PASI) > 10 and Dermatology Life Quality Index (DLQI) > 10, or major involvement of visible areas, scalp, genitais, or nails
• Refractory, intolerant or unable to access phototherapy
• Refractory, intolerant or have contraindications to one of the following:
  – Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥ 15 mg if patient is ≥ 65 years of age) for a minimum of 12 weeks
  – Cyclosporine for a minimum of 6 weeks

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

Claim Notes:
• Must be prescribed by a dermatologist.
• Combined use of more than one biologic DMARD will not be reimbursed.
• Approvals will be for 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter
• Initial approval period: 16 weeks.
• Renewal approval period: 1 year. Confirmation of continued response is required.

VALGANCICLOVIR (VALCYTE)
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 Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

VARENICLINE (CHAMPIX and generic brands)
0.5 mg and 1 mg tablets
For smoking cessation in adults 18 years of age and older.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine prescription smoking cessation drug (varenicline or bupropion).

Claim Notes:
• A maximum of 168 tablets will be reimbursed annually without special authorization.
• Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for 168 additional tablets.
• All special authorization requests for additional tablets will require confirmation the individual has agreed, or is already registered with, Go Smoke-Free NB (1-866-366-3667) or is participating in another form of smoking cessation counselling to be specified.

For additional information on quitting smoking or to obtain the appropriate NB Drug Plans special authorization request form, visit our website Smoking Cessation Therapies.

VEDOLIZUMAB (ENTYVIO)
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 of more than one biologic DMARD will not be reimbursed.
• 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 > 4, and a rectal bleeding subscore ≥ 2 and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥ 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 > 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 of more than one biologic DMARD will not be reimbursed.
- Initial approval period: 10 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 and/or MEK inhibitor therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

**VENETOCLAX (VECLENXTA)**
10 mg, 50 mg, 100 mg film-coated tablets
As monotherapy for the treatment of patients with chronic lymphocytic leukemia/small lymphocytic lymphoma who have received at least one prior therapy which must include disease progression 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. Patient must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
Claim Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.

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.

VILANTEROL AND FLUTICASONE (BREO ELLIPTA)
25 mcg / 100 mcg and 25 mcg / 200 mcg powder for inhalation
See criteria under Long-acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) combinations

VILANTEROL AND UMECLIDINIUM BROMIDE (ANORO ELLIPTA)
25 mcg / 62.5 mcg powder for inhalation
See criteria under Long-acting beta-2 agonist/Long-acting anticholinergic (LABA/LAAC) combinations

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 AND inappropriate for radiotherapy
• Patient 18 years or age or older;
• Patient has ECOG ≤ 2
• Patient preference for oral therapy will not be considered

Information Required
• Physicians must provide rationale for why surgery AND radiation 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;
• 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:
• 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
  - Suboptimal outcomes expected due to size/location/invasiveness of BCC
• Dose: 150mg orally once daily taken until disease progression or unacceptable toxicity.

Claim Notes:
• Initial approval period: 1 year.
• Renewal approval period: 1 year.
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.

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.

ZOLEDRONIC ACID (ACLASTA and generic brands)
5 mg/100 mL bottle

Osteoporosis
For the treatment of osteoporosis in patients who are refractory, intolerant or have a contraindication to oral bisphosphonates.

Clinical Notes:
1. Intolerance is defined as esophageal ulceration, erosion or stricture, or lower gastrointestinal symptoms severe enough to cause discontinuation of oral bisphosphonates, or swallowing disorders that will increase the risk of esophageal ulceration from oral bisphosphonates.
2. Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline level, despite adherence to oral bisphosphonates for one year.

Paget's Disease
For the treatment of Paget’s disease of bone.

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.