APPENDIX A

EXCEPTION DRUG STATUS PROGRAM

NOTES REGARDING THE EXCEPTION DRUG STATUS (EDS) PROGRAM

- Duly licensed healthcare providers may apply for EDS.
- Requests can be submitted by telephone, by mail or by fax. A toll-free line with an electronic message system is available **exclusively** for requests on a 24-hour basis. The telephone number to access this line is **1-800-667-2549**; the Drug Plan EDS Unit fax number is **(306) 798-1089**.
- Patients are notified by letter if coverage has been approved and the time period for which coverage has been approved.
- If a request has been denied, letters are sent to the patient and prescriber notifying them of the reason for the denial. If the Drug Plan requires more information to determine the patient's eligibility for coverage, reconsideration of coverage will occur at such time as further information is received.
- If the drug requested is not a benefit under the Drug Plan, the patient and prescriber are notified. Payment for the medication is the responsibility of the patient in these cases. It is important to note that not all medications currently available on the market in Canada are benefits under the Saskatchewan Drug Plan or under the Exception Drug Status Program of the Drug Plan.
- The majority of EDS requests are approved from the date the Drug Plan receives the request, but backdating can be requested by a health professional. Patients are expected to meet EDS criteria within the dates requested. However, there is no provision for backdating further than one year from the current date.
- The Drug Plan policy does not allow a fee to be charged to clients for Exception Drug Status applications made to the Drug Plan on the client's behalf.
- Exception Drug Status approval will be limited to one immunosuppressive biologic agent at a time.

REQUIREMENTS FOR REVIEW OF DRUGS FOR NON-APPROVED INDICATIONS

On rare occasions drugs are required for non-approved indications on a case by case basis. In order to conduct a timely review of these requests the Drug Plan requests the following information be provided by the prescriber:

- the disease or problem being treated
- list of previous therapies tried and the response achieved
- other non-exception options available and why not appropriate
- name of the drug being requested
- clinical evidence to strongly support the use of the drug for the condition being treated
- outcome measures that will be followed to assess the effect of the drug
- dose of the drug and duration of treatment

ONLINE EDS ADJUDICATION (OEA)

Approval of certain medications may be available through online EDS adjudication or OEA. With OEA, the Drug Plan adjudication system will look for certain alternative medications, specific prescibers or age groups in order to generate an automatic EDS approval.

Please note: if a patient's computer profile is incomplete, OEA may not be possible and a traditional EDS request will be required. Drug Plan staff can provide further information on both EDS and OEA.

The following information is required to process all Exception Drug Status requests:

- **Patient name; patient Health Services Number (9 digits); name of drug; diagnosis or therapeutic indication relevant to use of drug; prescriber name and phone number.**
- **Pharmacists may initiate and EDS request on behalf of a patient when:**
    - **The necessary details, including diagnosis are obtained from the prescriber or prescribers' agent and documented, or**
    - **The prescribing pharmacist is an authorized prescriber of the drug product as outlined in medSask minor ailment prescribing guidelines or approved SCPP Level II prescribing.**

abacavir SO_4, oral solution, 20mg/mL (Ziagen); tablet, 300mg (listed generics) (possible OEA)
For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

abacavir SO_4/ dolutegravir/lamivudine, tablet, 600mg/50mg/300mg (Triumeq) (possible OEA)
For management of HIV disease in adult patients.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

abacavir SO_4/lamivudine, tablet, 600mg/300mg (listed generics) (possible OEA)
For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

abacavir SO_4/lamivudine/zidovudine, tablet, 300mg/150mg/300mg (listed generics) (possible OEA)
For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

abatacept, powder for solution, 125mg/mL pre-filled syringe (Orencia); 250mg/vial (Orencia)

Indication	Criteria
Rheumatoid arthritis (125 mg/mL & 250mg/vial)	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. Coverage will not be provided when used in combination with tumor necrosis factor inhibitors**.** **Note:** This product should be used in consultation with a specialist in this area.
Juvenile idiopathic arthritis (250 mg/vial only)	For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have not had an adequate response from etanercept. Initial coverage for treatment induction will be limited to a maximum of 16 weeks. Coverage of retreatment will only be considered for children who had an adequate initial treatment response and subsequently experience a disease flare.

Abilify Asimtufii – see aripiprazole
Abilify Maintena – see aripiprazole

abobotulinumtoxinA, powder for solution for injection, 300 units/vial, 500 units/vial (Dysport Therapeutic)
For treatment of:
(a) Cervical dystonia (torticollis);
(b) Focal spasticity affecting the upper limbs in adults; and
(c) Lower limb spasticity in patients 2 years of age and older.

Abrilada-see adalimumab

abrocitinib, tablet, 50mg, 100mg, 200mg (Cibinqo)
For the treatment of refractory moderate to severe[1] atopic dermatitis in patients 12 years and older who:
- Have had an adequate trial, or who were intolerant, or are ineligible for EACH of the following therapies:
  - Maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy[2] (where available), and
  - Maximally tolerated medical topical therapies for atopic dermatitis combined with at least one of the four systemic immunomodulators (methotrexate[2], cyclosporine[2], mycophenolate mofetil[2], or azathioprine[2]).

Requests must include documentation of the Eczema Area and Severity Index (EASI) score.
Initial approval: 20 weeks

Renewal Criteria:
Renewal requests will be considered for patients where there has been a 75% or greater improvement from baseline in the EASI score (EASI-75) after initiation and where this response is subsequently maintained thereafter every six months.

Renewal requests must include a recent EASI score.

Renewal approval: Six (6) months.

Both initial and renewal coverage requests for this indication must be made by, or in consultation with a specialist in this area.

Abrocitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other janus kinase (JAK) inhibitor treatment for moderate to severe atopic dermatitis.

[1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points.
[2]Adequate trials are defined as:
- Phototherapy – three times a week for 12 weeks.
- Methotrexate – 10 to 20mg per week for 12 weeks.
- Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.
- Mycophenolate mofetil – 1g twice daily for 12 weeks.
- Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.

Accel-Sevelamer - see sevelamer carbonate

acitretin, capsule, 10mg, (Soriatane, and listed generics); 25mg (Soriatane, and listed generics) (possible OEA)
For treatment of:
(a) Severe intractable psoriasis
(b) Darier's disease
(c) Ichthyosiform dermatoses
(d) Palmoplantar pustulosis
and other disorders of keratization.

Aclasta - see zoledronic acid

aclidinium bromide/formoterol fumarate dihydrate, powder for inhalation, 400ug/12ug (Duaklir Genuair) (possible OEA)
For the treatment of chronic obstructive pulmonary disease COPD:
- In patients with inadequate response to a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD) risk[1]; OR
- For patients initiated on LAMA/LABA combination therapy in hospital.

[1] Patients are considered low risk of AECOPD if they have experienced ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) **and** did not require a hospital admission or emergency department (ED) visit.

Actonel - see risedronate sodium
Actos - see pioglitazone HCl

adalimumab, 20mg/0.4mL PFS; 40mg/0.8mL PFS; 40 mg/0.8mL PF-pen (Abrilada)
adalimumab, 20mg/0.4mL PFS; 40mg/0.8mL PFS; 40 mg/0.8mL auto-injector (Amgevita)
adalimumab, 40mg/0.4mL PFS (Hadlima); 40mg/0.4mL auto-injector (Hadlima PushTouch); 40mg/0.8mL PFS; 40mg/0.8mL auto-injector (Hadlima PushTouch)
adalimumab, 20mg/0.4mL PFS; 40mg/0.8mL PFS; 40 mg/0.8mL PF-pen (Hulio)
adalimumab, 20mg/0.2mL PFS; 20mg/0.4mL PFS; 40mg/0.4mL auto-injector; 40mg/0.4mL PFS; 40mg/0.8mL PFS; 40mg/0.8mL auto-injector; 80mg/0.8mL auto-injector; 80mg/0.8mL PFS (Hyrimoz)
adalimumab, 40mg/0.8mL PFS; 40 mg/0.8mL auto-injector (Idacio)
adalimumab, 40mg/0.4mL PFS; 40mg/0.4mL auto-injector; 80mg/0.8mL PFS (Simlandi)
adalimumab, 40mg/0.4mL PFP; 40mg/0.4mL PFS; 80mg/0.8mL PFP;80mg/0.8mL PFS (Yuflyma)

Note: These products are not interchangeable. When requesting coverage, please state which specific adalimumab product is being prescribed to avoid administrative and assessment delays.

Indication	Criteria
Rheumatoid arthritis	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. **Note:** This product should be used in consultation with a specialist in this area.
Psoriatic arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.
Ankylosing Spondylitis	**Initial:** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration:12 weeks **First Renewal:** Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval Duration: One Year **Note:** Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed,or are intolerant to methotrexate **OR** cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. *Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.* **Note:** This product should be used in consultation with a specialist in this area.
Juvenile idiopathic arthritis	For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs). **Note:** This product should be used in consultation with a specialist in this area.
Crohn's disease	For the treatment of moderate to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy. Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders, and for doses not exceeding 40mg every two weeks. **Note**: This product should be used in consultation with a specialist in this area.
Ulcerative Colitis	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after three months of therapy. Ongoing coverage will only be provided for those who respond to therapy. **Note:** This product should be used in consultation with a specialist in this area.
Hidradenitis suppurativa	For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy (including systemic antibiotics) and who have met the following: o A total abscess and nodule count of 3 or greater; o Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III; o An inadequate response to a 90 day trial of oral antibiotics; o Prescribed by a specialist with expertise in the management of patients with HS. **Note:** Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.
Uveitis	For the treatment of moderate to severe non-infectious uveitis in patients unresponsive to,

	unable to take, systemic corticosteroids (or topical corticosteroid) and a non-biologic immunosuppressant. **Note:** This product should be used in consultation with a specialist in this area.

Adcirca - see tadalafil

adefovir dipivoxil, tablet, 10mg (Hepsera, and listed generics) (possible OEA)
For management of hepatitis B.
Note: This product should be used in consultation with a specialist in this area.

Adempas - see riociguat
Advagraf - see tacrolimus
Advair - see salmeterol xinafoate/fluticasone propionate
Advair Diskus - see salmeterol xinafoate/fluticasone propionate

aflibercept, pre-filled syringe, 8mg/0.07mL (Eylea HD) (possible OEA)

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	For the treatment of neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections. [1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease. The interval between doses should be no shorter than eight weeks (following the first three initiation doses that are given every four weeks). Treatment with aflibercept should be continued only in people who maintain adequate response to therapy. Aflibercept should be permanently discontinued if any one of the following occurs: (a) Reduction in best corrected visual acuity (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. (b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both. (c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment cannot be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after five consecutive treatments. (e) The interval between doses should be no shorter than eight weeks (following the first three initiation doses that are given every four weeks). (f) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness. (g) Injection will be by a qualified ophthalmologist with experience in intravitreal injections. **Note:** Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage and should also be considered if the patient is not responding to treatment as expected.

aflibercept, injection, 40mg (Eylea) (possible OEA)

Indication	**Criteria**
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	For the treatment of neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections. [1] Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease.

	The interval between the doses should be no shorter than one month for aflibercept. Treatment with aflibercept should be continued only in people who maintain adequate response to therapy. Aflibercept should be permanently discontinued if any one of the following occurs: (a) Reduction in best corrected visual acuity (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. (b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both. (c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment cannot be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after five consecutive treatments. (e) The interval between two doses should not be shorter than one month. (f) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness. (g) Injection will be by a qualified ophthalmologist with experience in intravitreal injections. Note: • Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.
Retinal Vein Occlusion (RVO)	For the treatment of visual impairment due to clinically significant macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) for patients meeting all of the following: (a) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less. (b) The interval between two doses should not be shorter than one month. (c) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity. (d) Treatment should be discontinued if there is no improvement after 6 months of initial treatment; and (e) Injection will be by a qualified ophthalmologist with experience in administering intravitreal injections. Note: • Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.

Ajovy – see fremanezumab
Aldara – see imiquimod
Alyftrek – see vanzacaftor/tezacaftor/deutivacaftor

alemtuzumab, solution for IV infusion, 12mg/1.2mL (Lemtrada)
See Appendix D

alendronate sodium, tablet, 10mg tablet, (listed generics) 70mg tablet, (Fosamax, and listed generics) (possible OEA)
a) For treatment of osteoporosis ***in patients*** with a 20% or greater 10-year fracture risk;
Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table.
The links to the tools are available at:
http://www.shef.ac.uk/FRAX/tool.jsp?country=19
http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf

The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.

b) For treatment of osteoporosis in patients with:
   - Pre-existing and/or recent fragility fractures; or
   - Glucocorticoid treatment for a duration of 3 months or longer; or
   - Men on androgen deprivation therapy for prostate cancer; or
   - Women on aromatase inhibitor therapy for breast cancer.

c) For treatment of osteogenesis imperfecta.

alendronate sodium/vitamin D3 (cholecalciferol), tablet, 70mg/5600IU (Fosavance, and listed generics) (possible OEA)

For the treatment of osteoporosis with a 20% or greater 10-year fracture risk.
Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table.

The links to the tools are available at:
http://www.shef.ac.uk/FRAX/tool.jsp?country=19
http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf

The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.

Alertec - see modafinil

alfacalcidol, capsule, 0.25ug, 1ug (One-Alpha and listed generics); oral drops, 2ug/mL (One-Alpha) (possible OEA)

For management of:
(a) Hypocalcemia in chronic renal disease patients prior to initiation of dialysis.
(b) Osteodystrophy in chronic renal disease patients prior to initiation of dialysis.
Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status coverage is not required for S.A.I.L. patients.

alglucosidase alfa, powder for solution, 50mg/vial (Myozyme)

For patients with infantile onset Pompe disease, as demonstrated by onset of symptoms and confirmed cardiomyopathy within the first 12 months of life.
The Committee approved the following monitoring and withdrawal criteria, which received approval from the Canadian Expert Drug Advisory Committee (CEDAC):
The *monitoring* of markers of disease severity and response to treatment must include at least:
- Weight, length and head circumference.
- Need for ventilatory assistance, including supplementary oxygen, CPAP, BiPAP, or endotracheal intubation and ventilation.
- Left ventricular mass index (LVMI) as determined by echocardiography (not ECG alone).
- Periodic consultation with cardiology.
- Periodic consultation with respirology.

Withdrawal of therapy:
- 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.
- The development of the need for continuing invasive ventilatory support after the initiation of enzyme-replacement therapy (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.
- 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, solution for injection, pre-filled pen, 75mg/mL, 150mg/mL, 300mg/2mL (Praluent)

For the treatment of patients with a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)[1] who are unable to reach Low Density Lipoprotein Cholesterol (LDL-C) target (i.e., LDL-C <2.0mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite either:

- A confirmed adherence to the maximally tolerated dose of at least two different statins, with one of the statins taken along with ezetimibe for at least a total of 3 months; OR,

- A confirmed adherence to a high dose statin (i.e., atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe for at least a total of 3 months.

Coverage will not be provided for use in combination with other proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.
LDL-C should be checked at least annually while on continued treatment with alirocumab.

[1]Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) is to be made using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

almotriptan malate, tablet, 6.25mg, 12.5mg (listed generics)
For treatment of migraine headaches in patients over 12 years of age.

The maximum quantity that can be claimed through the Drug plan is limited to 6 doses per 30 days within a 60-day period. Patients requiring more than 12 doses in a consecutive 60-day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.

ambrisentan, tablet, 5mg, 10mg (Volibris, and listed generics) (possible OEA)
For the treatment of pulmonary arterial hypertension, on the recommendation of a specialist.

Amgevita - see adalimumab

amifampridine, tablet, 10mg (Ruzurgi)
Initiation Criteria
For the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients who are 6 years of age and older, when initiated by a neurologist with expertise in managing LEMS.
A pre-amifampridine baseline Triple Timed Up and Go (3TUG) test result must be submitted with the initial coverage request.

Initial approval duration**:** 4 months

Renewal Criteria
Patients will be eligible for coverage renewal if attaining or maintaining a reduction of at least 30% on the 3TUG test, when compared to the pre-amifampridine baseline 3TUG test result.
For the initial renewal, the follow-up 3TUG test result should be obtained within 3 months of initiating amifampridine.
Patients should be under the care of a neurologist with expertise in managing LEMS.

Renewal duration**:** 12 months

amifampridine phosphate, tablet, 10mg (Firdapse)
Initiation Criteria
For the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients who are 18 years of age and older, when initiated by a neurologist with expertise in managing LEMS.
A pre-amifampridine baseline Triple Timed Up and Go (3TUG) test result must be submitted with the initial coverage request.

Initial approval duration: 4 months

Renewal Criteria
Patients will be eligible for coverage renewal if attaining or maintaining a reduction of at least 30% on the 3TUG test, when compared to the pre-amifampridine baseline 3TUG test result.
For the initial renewal, the follow-up 3TUG test result should be obtained within 3 months of initiating amifampridine.
Patients should be under the care of a neurologist with expertise in managing LEMS.

Renewal duration: 12 months

Amvuttra – see vutrisiran

anakinra, subcutaneous injection (pre-filled syringe), 100mg/0.67mL (Kineret)

Indication	Criteria
Rheumatoid arthritis	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.

	Coverage will not be provided when used in combination with tumor necrosis factor inhibitors. **Note:** This product should be used in consultation with a specialist in this area.

Andembry – see garadacimab

anifrolumab, solution for infusion, 150mg/mL (2mL vial) (mg) (Saphnelo)

For use in addition to standard therapy for the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) only if certain conditions are met:

Initiation:

Treatment with anifrolumab should be reimbursed when initiated in adult patients with moderate-severe SLE (defined as SLEDAI-2K [systemic lupus erythematosus disease activity index 2000] score of at least 6) and who are unable to control their disease while using oral corticosteroids (OCS) dose of at least 10 mg/day of prednisone or its equivalent in addition to standard of care.

Treatment with anifrolumab must not be reimbursed when initiated in patients with any of the following:

- severe or unstable neuropsychiatric SLE
- active severe SLE nephritis

The maximum duration of initial reimbursement is for 12 months.

Renewal:

Treatment with anifrolumab can be renewed as long as all of the following are met:

- OCS dose decreased to ≤ 7.5 mg/day of prednisone or its equivalent
- Reduction in disease activity measured by:
    - Reducing the SLEDAI-2K score to 5 or less, **OR**
    - BILAG (British Isles Lupus Activity Group) improvement in organ systems and no new worsening

For subsequent renewal, the physician must provide proof that the initial response achieved after the first 12 months of therapy with anifrolumab has been maintained. Subsequent renewals should be assessed annually.

Anifrolumab should not be reimbursed when used in combination with other biologic treatments.

Prescribing conditions:

- Patient should be under the care of a physician with expertise in the diagnosis and management of SLE.
- Anifrolumab should not be reimbursed when used in combination with other biologic treatments.

Anoro Ellipta - see umeclidinium bromide/vilanterol trifenatate
Aptiom – see eslicarbazepine acetate
Aranesp - see darbepoetin alfa
Arava - see leflunomide
Aricept - see donepezil HCl

aripiprazole, long acting injection, 300mg, 400mg (Abilify Maintena)

For patients:
a) With a history of non-adherence, as evidenced by outcomes such as repeated hospitalizations,
OR
b) Who have been on a first generation long-acting injectable antipsychotic agent but can no longer tolerate or have relapsed,
OR
c) Who were started on treatment in the hospital.

aripiprazole, pre-filled syringe, 720mg/2.4mL, 960mg/3.2mL (Abilify Asimtufii)

For patients:
a) With a history of non-adherence, as evidenced by outcomes such as repeated hospitalizations,
OR
b) Who have been on a first generation long-acting injectable antipsychotic agent but can no longer tolerate or have relapsed,
OR
c) Who were started on treatment in the hospital.

asenapine, sublingual tablet, 5mg, 10mg (Saphris)

(a) For the treatment of patients with bipolar disorder in combination with lithium or divalproex after trials of less expensive atypical antipsychotic agents (i.e. risperidone and quetiapine) have failed due to intolerance or lack of response.
(b) For the treatment of bipolar disorder as monotherapy for patients who have failed lithium or divalproex **AND** have failed trials of less expensive atypical antipsychotic agents (i.e. risperidone and quetiapine) due to intolerance or lack of response.

asfotase alfa, subcutaneous injection, 18mg/0.45mL vial, 28mg/0.7mL vial, 40mg/1mL vial, 80mg/0.8mL vial (mg) (Strensiq)

Coverage for asfotase alfa may be available through the Drug Plan for the treatment of patients with perinatal, infantile, or juvenile-onset hypophosphatasia (HPP), where:

- The HPP diagnosis has been confirmed by genetic testing; and
- The HPP diagnosis has occurred before the patient's 12th birthday, with documented onset of HPP signs/symptoms of HPP prior to their 12th birthday; and
- The patient is younger than 18 years of age at the time asfotase alfa is initiated; and
- The patient does not have odonto- or pseudo-HPP (i.e. craniosynostosis alone, premature loss of deciduous teeth alone, and vitamin D deficiency to be ruled out).

Asfotase alfa must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP.

Due to the unique nature of this condition and the cost of this treatment, Exception Drug Status (EDS) requests will require additional details to facilitate assessment of the application and accompanying clinical information. The initial coverage request must include information on the patient's diagnostic confirmation, clinical manifestations, radiologic findings, pain severity, respiratory findings, and treatment monitoring plan associated with HPP. (Please refer to the asfotase alfa Exception Drug Status Request form). In addition, patients who are approved will be required to undergo ongoing assessment to monitor for improvement over time and must meet renewal parameters for continuation of treatment.

Eligibility for asfotase alfa for the treatment of HPP is determined by the Canadian HPP Clinical Expert Committee. Please contact the Drug Plan at 1-800-667-7581 for more information regarding coverage availability and the EDS application process for this product.

<u>Renewal Considerations</u>

Renewal requests for asfotase alfa coverage must include confirmation that:

- The patient continues to be under the care of a metabolic specialist; and
- The patient has demonstrated compliance to the asfotase alfa treatment and monitoring schedule; and
- The goals of therapy determined at initiation of asfotase alfa treatment are being met; and
- The patient is demonstrating continued benefit from asfotase alfa treatment.

atazanavir SO4, capsule, 150mg, 200mg, 300mg (Reyataz, and listed generics) (possible OEA)

For management of HIV disease.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Atectura Breezhaler- see indacterol/mometasone furoate

atogepant, tablets, 10mg, 30mg, 60mg (Qulipta)

For patients who have a confirmed diagnosis of either:
1) Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months; **OR**
2) Chronic migraine: Headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:

• The patient must have experienced an inadequate response[1], intolerance or contraindication to at least two oral prophylactic migraine medications[2] of different classes, **AND**;
• The patient must be under the care of a prescriber who has appropriate experience in the management of migraine headaches, **AND**;
• The prescriber must provide the number of migraine days per month with the EDS application.

Initial approval duration = Six (6) months

Initial Renewal criteria:

Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Renewal duration = Six (6) months

Subsequent Renewals:
Maintenance of 50% reduction in the average number of migraine days per month from baseline.

EDS approval will not be provided if used in combination with alternative anti-calcitonin gene-related peptide therapies.
[1] Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.
[2] Oral prophylactic medication alternatives include:

- beta blockers or candesartan
- pregabalin or gabapentin
- serotonin and norepinephrine reuptake inhibitors (SNRIs)
- sodium valproate or divalproex sodium
- topiramate
- tricyclic antidepressants (TCAs)
- verapamil or flunarizine

atomoxetine HCl, capsule, 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg (listed generics)
For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who meet all of the following criteria:

- Has failed or is intolerant to treatment with methylphenidate and an amphetamine.
- Treatment with atomoxetine must be recommended by or in consultation with a specialist in psychiatry, pediatrics or a general practitioner with expertise in ADHD.

atovaquone, suspension, 150mg/mL (Mepron, and listed generics) (possible OEA)
(a) For treatment of Pneumocystis jirovecii Pneumonia (PJP) in patients intolerant to trimethoprim/sulfamethoxazole.
(b) For prophylaxis of Pneumocystis jirovecii Pneumonia (PJP) in patients intolerant to trimethoprim/sulfamethoxazole.

Avelox - see moxifloxacin HCl
Avonex - see Appendix D
Avonex PS - see Appendix D
Avtozma – see tocilizumab
Axberi – see enoxaparin
Axert - see almotriptan malate

azithromycin, tablet, 600mg (listed generics) (possible OEA)
For treatment and prophylaxis in patients with non-tuberculous Mycobacterium.

aztreonam, inhalation powder for solution, 75mg/vial (Cayston)
For the treatment of Pseudomonas aeruginosa infections when used as cyclic treatment (28 days of treatment, followed by a 28 days without aztreonam) in patients with moderate to severe cystic fibrosis (CF) and deteriorating clinical condition despite treatment with inhaled tobramycin.
Notes: This product has not been studied in patients under the age of six.

- Previous EDS approvals for inhaled tobramycin will be discontinued prior to authorizing EDS approval of Cayston
- This product should not be used in mild CF disease.

baclofen, injection, 0.05mg/mL, 2mg/mL (listed generics) (possible OEA)
For treatment of:
(a) Severe spastic conditions in patients unresponsive to oral baclofen.
(b) Severe spastic conditions in patients intolerant to oral baclofen.

Banzel – see rufinamide
Baraclude - see entecavir

baricitinib, tablet, 2mg, 4mg (Olumiant)

Indication	Criteria
Alopecia Areata (AA) **(2mg tablet AND 4mg tablet)**	For the treatment of patients with severe alopecia areata (AA) who: • Have a current episode of AA more than 6 months, and less than 8 years; AND, • Have a severity of alopecia (SALT) score of 50 or above. Baricitinib must be prescribed by a dermatologist with expertise managing patients with severe AA.

	Baricitinib should not be used in combination with other janus kinase (JAK) inhibitors, biologic immunomodulators, or systemic immunosuppressants. Initial Approval Duration: 9 months **Renewal Criteria:** Renewal of baricitinib coverage will be considered in individuals who: • Show a beneficial clinical effect to baricitinib therapy, defined as SALT score of 20 or less; AND, • Baricitinib continues to not be used in combination with other JAK inhibitors, biologic immunomodulators, or systemic immunosuppressants.
Rheumatoid Arthritis (RA) **(2mg tablet only**)	For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide. • Maximum daily dose is 2 mg per day. • This product should be used in consultation with a specialist in this area. • Patients should be assessed within the first 12 weeks to determine if the American College of Rheumatology (ACR) improvement criteria of at least 20% has been achieved. • Olumiant (baricitinib) should not be used in combination with Xeljanz (tofacitinib) OR with other janus kinase (JAK) inhibitors, OR with other biologics for rheumatoid arthritis.

belimumab, lyophilized powder for intravenous infusion, 24mg/mL (5m vial), 20mg/mL (20mL vial) (mg); solution for subcutaneous injection, 200mg/mL (mg) (Benlysta)

For the treatment of active lupus nephritis (LN) in adult patients who meet all of the following:

- Have International Society of Nephrology/Renal Pathology Society class III (with or without class V), class IV (with or without class V), or class V (i.e., pure class V),
- Started standard induction therapy within the previous 60 days,
- Have not previously failed both cyclophosphamide and mycophenolate mofetil induction therapies,
- Have not had an eGFR that is less than 30mL/min/1.73m^2, and
- Are under the care of a rheumatologist or nephrologist experienced in the management of LN.

Initial approval is for 12 months.

Renewal criteria:

Renewal requests that provide proof of beneficial clinical effect, including ALL of the following, may be considered:

- Reduction in glucocorticoids to less than or equal to 7.5mg/day after 12 months of therapy (consideration may also be given to those whose oral corticosteroid dose remains over 7.5mg/day of prednisone or its equivalent IF there has been a 50% or more decrease from baseline),
- Estimated eGFR that is no more than 20% less than the value before the renal flare (i.e., the preflare value) or greater than or equal to 60mL/min/1.73m^2,
- Improved proteinuria defined as:
  - No greater than 0.7g/24 hours after 12 months of therapy if baseline proteinuria is less than 3.5g/24 hours, OR
  - No greater than 0.7 g/24 hours after 18 to 24 months of therapy if baseline proteinuria is in the nephrotic range (i.e., > 3.5 g/24 hours)
- Have not had an eGFR that is less than 30mL/min/1.73m^2,
- Have not had the addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti-tumour necrosis factor therapy (such as, adalimumab, etanercept, infliximab), or other biologics (such as rituximab, abatacept), and
- Are under the care of a rheumatologist or nephrologist experienced in the management of LN.

In addition, requests for subsequent years will be considered if the initial response in the first 12 months is maintained.

Renewal approval is for 12 months.

belumosudil, tablet, 200mg (Rezurock)

For the treatment of adult and pediatric patients (12 years of age and older) with chronic graft-versus-host disease (cGvHD) who:

- Are experiencing cGvHD following a non-oncology transplant; AND,
- Have moderate to severe disease (based on the National Institutes of Health (NIH) consensus criteria); AND,
- Have had inadequate response to at least 2 prior lines of systemic therapy[1].

Patients must be under the care of a clinician with experience in the diagnosis and management of cGvHD.

Initial approval duration: 24 weeks

Coverage renewal of belumosudil may be requested in patients who do not meet the discontinuation criteria below and have achieved an overall response (i.e., complete response, partial response, or stable disease with significant reduction in steroid doses) according to the NIH criteria after approximately six months.

Discontinuation Criteria:
Coverage of belumosudil may be discontinued if:

- There is progression of cGvHD (new or worsening symptoms); OR,
- The corticosteroid dose remains at or above baseline for more than six weeks; OR,
- The patient experiences more than two GvHD flares which require increased corticosteroid therapy in a six month period of belumosudil treatment; OR,
- The patient has needed to start an additional therapy to treat GvHD which was not already initiated at baseline; OR,
- The patient is no longer under the care of a clinician with experience in the management of GvHD.

NOTE:

[1] Lines of systemic therapy:

- First line: corticosteroid with or without a calcineurin inhibitor (baseline corticosteroid dose must be submitted with the initial belumosudil coverage request);
- Second line: one other Formulary-listed treatment for cGvHD.

Inadequate response is considered corticosteroid-refractory or corticosteroid -dependent cGvHD and is defined as one or more of the following:

- A lack of response or disease progression after administration of prednisone at a dose of ≥1 mg/kg/day (or equivalent) for at least one week; OR
- Disease persistence without improvement despite continued treatment with prednisone at doses of ≥ 0.5 mg/kg/day or 1 mg/kg every other day (or equivalent) for at least four weeks; OR
- Increased prednisone dose to > 0.25 mg/kg/day (or equivalent) after two unsuccessful attempts to taper the dose.

Note: Coverage for belumosudil for cGvHD following an oncology related stem cell transplant is provided under the Saskatchewan Cancer Agency. Refer to the Saskatchewan Cancer Agency Formulary for details and criteria for coverage.

Benlysta – see belimumab

benralizumab, subcutaneous solution, 30mg/mL, prefilled syringe (Fasenra); prefilled pen (Fasenra pen)

For add-on maintenance treatment of adult patients with severe eosinophilic asthma[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]), and:

- Blood eosinophil count of ≥ 300 cells/μL within the past 12 months AND has experienced two or more clinically significant asthma exacerbations[3] in the past 12 months,
  OR
- Blood eosinophil count of ≥ 150cells/μL AND is receiving maintenance treatment with oral corticosteroids[4].

In addition:

- Benralizumab should not be used in combination with other biologics used to treat asthma.
- A baseline[5] assessment of asthma symptom control using a validated asthma control questionnaire[6] must be completed prior to initiation of benralizumab treatment and submitted with the application.
- Baseline[5] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications.
- Patients should be managed by a specialist in the treatment of asthma.

[1]Patients must have a documented diagnosis of asthma.
[2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily.
[3]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization.

[4]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day.
[5]Baseline refers to results achieved prior to initiation of the requested therapy.
[6]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT.

Discontinuation Criteria:
Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if:

- **First Renewal** (based on first 12 months of therapy)
  - The asthma control questionnaire score has not improved from baseline[5], **OR**
  - The number of clinically significant exacerbations has increased, **OR**
  - The oral corticosteroid maintenance dose has not decreased.
- **Subsequent Renewals** (after 2 years of therapy)
  - The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, **OR**
  - The number of clinically significant exacerbations has increased within the previous 12 months, **OR**
- The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently.

Beovu-see brolucizumab

berotralstat HCl, capsule, 150mg (Orladeyo)
For the routine prevention of attacks of hereditary angioedema (HAE) in patients 12 years of age or older with HAE type I or II[1] diagnosed by a specialist physician experienced in the diagnosis and management of HAE, who:

- Have experienced at least three HAE attacks within any four week period before initiating berotralstat therapy that required the use of an acute injectable treatment.
  - Applications must include the baseline number of attacks requiring acute injectable treatment in the three months prior to initiation of berotralstat[2].
- Will not be using berotralstat in combination with other medications used for long-term prophylactic treatment of angioedema[3] (e.g., C1 esterase inhibitors or lanadelumab); A**ND**
- Will not use a dose of berotralstat that is more than 150mg once daily.

Initial approval duration: 3 months

Renewal criteria
Renewal requests[4] may be considered:

- After treatment with berotralstat for three months if there has been a 50% or more reduction[2] in the number of HAE attacks where acute injectable treatment was received in the first three months of treatment with berotralstat compared to the rate of attacks observed before starting berotralstat; **OR**
- For patients with continued response[2] defined as maintenance of 50% or more reduction from baseline with no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to starting treatment with berotralstat;
  AND

Patients must continue to:

- Be under the care of a specialist experienced in the diagnosis and management of angioedema; **AND**
- Not use berotralstat in combination with other long-term prophylactic angioedema treatments (e.g., C1 esterase inhibitors or lanadelumab); **AND**
- Not use a dose of berotralstat that is more than 150mg once daily even in cases of inadequate response or loss of response.

Renewal duration: 6 months

Notes:
[1] A definitive diagnosis of HAE type I and II requires testing C1 esterase level and activity, as well as C1q levels (to rule out acquired angioedema for which berotralstat is not indicated).

[2] To determine which patients would be eligible for reimbursement of berotralstat, the current attack rate may be used for patients who are not receiving long-term prophylactic treatment and a historical attack rate may be used for those who are already receiving long-term prophylactic treatment and intend to transition to berotralstat.
[3] Patients on long-term prophylactic treatment will continue to require access to on-demand treatments that are used in the management of acute attacks.
[4] Coverage will be discontinued for patients who no longer meet the renewal criteria.

Betaseron - see Appendix D

bezafibrate, tablet, sustained release tablet, 400mg (Bezalip SR, and listed generics) (possible OEA)
For treatment of:
(a) Hyperlipidemia in patients unresponsive to gemfibrozil or fenofibrate.
(b) Hyperlipidemia in patients who have experienced side effects with gemfibrozil or fenofibrate.

Bezalip SR - see bezafibrate
Bicillin L-A - see penicillin G (benzathine)

bictegravir/emtricitabine/tenoforvir alafenamide, tablet, 50mg/200mg/25mg (Biktarvy) (possible OEA)
For the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with no known substitution associated with resistance to the individual tablet components.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Biktarvy - see bictegravir/emtricitabine/tenofovir alafenamide

bimekizumab, subcutaneous injection, prefilled syringe, autoinjector, 160mg/mL, 320mg/2mL (mg) (Bimzelx)

Indication	Criteria
Plaque Psoriasis (PsO) 160mg/mL prefilled syringe, autoinjector 320mg/2 mL prefilled syringe, autoinjector	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to, methotrexate OR cyclosporine AND have failed, are intolerant to, or are unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy. **Note:** This product should be used in consultation with a specialist in this area.
Ankylosing Spondylitis (AS) 160mg/mL prefilled syringe, autoinjector only	Initial: For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration: 16 weeks First Renewal: Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year Subsequent renewal: Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval Duration: One Year **Note:** Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.

Psoriatic Arthritis (PsA) 160mg/mL prefilled syringe, autoinjector only	For the treatment of adult patients with active psoriatic arthritis (PsA) who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). Note: This product should be used in consultation with a specialist in this area. Bimekizumab should not be used in combination with other biologic disease modifying anti-rheumatic drugs (bDMARDs), or target specific DMARDs (tsDMARDs) (such as janus kinase (JAK) inhibitors, phosphodiesterase 4 (PDE4) inhibitors, etc.).

Bimzelx- see bimekizumab
Biphentin - see methylphenidate HCl
Bildyos – see denosumab

bosentan, tablet, 62.5mg, 125mg (Tracleer, and listed generics) (possible OEA)
For treatment of pulmonary arterial hypertension on the recommendation of a specialist.

Botox - see onabotulinumtoxin A
Brenzys - see etanercept
Breo Ellipta - see vilanterol/fluticasone furoate

brexpiprazole, tablet, 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg (Rexulti)
For the treatment of schizophrenia and schizoaffective disorders.

Breztri Aerosphere- see budesonide/glycopyrronium/formoterol fumarate dihydrate
Brilinta - see ticagrelor

brivaracetam, tablet, 10mg, 25mg, 50mg, 75mg, 100mg (Brivlera and listed generics)
For adjunctive therapy in the management of partial-onset seizures (POS) in patients who meet all of the following:
- Are currently receiving two or more antiepileptic drugs; AND
- Are not receiving concurrent therapy with levetiracetam; AND
- Less costly antiepileptic drugs are ineffective or not clinically appropriate; AND
- Are under the care of a neurologist in the treatment of epilepsy.

Note: Patients should have tried and failed at least two less costly antiepileptic drugs.

Brivlera - see brivaracetam

brodalumab, pre-filled syringe, 210mg/1.5mL (Siliq)

Indication	Criteria
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to, methotrexate OR cyclosporine AND have failed, are intolerant to, or are unable to access phototherapy. *Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.* **Note:** This product should be used in consultation with a specialist in this area.

brolucizumab, solution for intravitreal injection, 6mg/0.05mL (Beovu)

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	For the treatment of mild to moderate neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections. [1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease. The interval between doses should be no shorter than eight weeks (following the first three initiation doses that are given every four weeks). Treatment with brolucizumab should be continued only in people who maintain adequate response to therapy. Brolucizumab should be permanently discontinued if any one of the following occurs: (a) Reduction in best corrected visual acuity (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.

	(b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both. (c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment cannot be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment should be given every 6 weeks for the first five doses. Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after five consecutive treatments. (e) After the initial five doses, the interval between two doses should not be shorter than every 8 weeks (2 months). (f) Patients responding to treatment should be monitored at regular intervals to assess visual acuity AND retinal thickness. (g) Injection will be by a qualified ophthalmologist with experience in intravitreal injections. **Note:** • Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.

budesonide, controlled ileal release capsule, 3mg (Entocort)

(a) For treatment of mild to moderate Crohn's Disease affecting the ileum and/or ascending colon. *Coverage will be provided for up to 8 weeks.*
(b) Maintenance treatment in Crohn's Disease will be approved for patients unresponsive or intolerant to other agents.

budesonide/glycopyrronium/formoterol fumarate dihydrate, metered dose inhaler, 160ug/7.2ug/5ug (Breztri Aerosphere) (possible OEA)

For the treatment of chronic obstructive pulmonary disease (COPD):

- In patients who are not controlled on optimal dual inhaled therapy (i.e., long-acting muscarinic antagonist [LAMA]/long-acting beta-2 agonist [LABA] or inhaled corticosteroid [ICS]/LABA); OR
- To replace existing triple therapy regimens currently achieved with more than one inhaler; OR
- In patients initiated on single agent inhaled triple therapy (SITT) while in hospital; OR
- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a high risk of acute exacerbation of COPD (AECOPD)[1].

[1]Patients are considered high risk of AECOPD if they have ≥2 moderate AECOPD (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids), or ≥1 severe AECOPD in the last year (severe AECOPD is an event requiring hospitalization or an emergency department [ED] visit).

bumetanide, tablet, 1mg, , 5mg (Burinex) (possible OEA)

For treatment of patients intolerant to furosemide.

Burinex - see bumetanide

burosumab, solution for injection, 10mg/mL, 20 mg/mL, 30mg/mL (mg) (Crysvita)

A) <u>Initiation Pre-Epiphyseal Closure</u>

For treatment of X-linked hypophosphatemia (XLH) for pediatric patients who are at least one year of age and in whom epiphyseal closure has not yet occurred, who have ALL of the following:

- A clinical presentation consistent with XLH, including:
    - Fasting hypophosphatemia, and
    - Normal renal function (defined as fasting serum creatinine below the age-adjusted upper limit of normal), and
- Radiographic evidence of rickets with a rickets severity score (RSS) total score of two or greater, and
- A confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance.

Burosumab should be prescribed by a physician working in a comprehensive team of health care providers who are experienced in the diagnosis and management of XLH.

Initial approval duration = 13 months.

Renewal criteria:
In pediatric patients in whom epiphyseal closure has not yet occurred, coverage of burosumab may be renewed if:

- At initial renewal, the 12-month RSS total score has improved from baseline, where baseline represents the initiation of treatment.
- At subsequent renewal (at 24 months and beyond), the RSS total score achieved after the first 12 months of therapy continues to be maintained.

In adolescent or adult patients continuing burosumab treatment (after previous coverage according to the above pediatric criteria), burosumab coverage may be renewed if none of the following are present or have occurred:

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

Renewal approval duration = 12 months

B) <u>Initiation Post-Epiphyseal Closure</u>

For the treatment of X-linked hypophosphatemia (XLH) when initiated in patients who have ALL of the following:

- Age of 18 years or older, or younger than 18 years with epiphyseal closure, who have not previously received treatment with burosumab; AND
- A diagnosis of XLH supported by:
  - Classic clinical features of adult XLH (such as, but not limited to, short stature or bowed legs); AND
  - A confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in the patient. If a PHEX gene variant is not confirmed, diagnosis may be confirmed using serum intact fibroblast growth factor 23 (FGF23) level[1]; AND
- Estimated glomerular filtration rate (eGFR) of 60 mL/min or greater; or eGFR ranging from 45 mL/min to less than 60 mL/min with confirmation that the renal insufficiency is not due to nephrocalcinosis; AND
- Presence of skeletal pain that the treating physician attributes to XLH and/or osteomalacia; AND
- Insufficient response or refractory to conventional therapy with active vitamin D and oral phosphate supplementation, as shown by:
  - Presence of either radiographic evidence of osteomalacia, nonhealing complete fractures, or nonhealing incomplete fractures after 1 year of conventional therapy, OR
  - The development of hyperparathyroidism or nephrocalcinosis on conventional therapy.

[1] Examples of serum intact FGF23 level confirming XLH may include a level > 30 pg/mL by Kainos Assay or equivalent level through an alternative validated assay, as determined by the diagnosing specialist.

Burosumab should be prescribed by a physician working in a comprehensive team of health care providers who are experienced in the diagnosis and management of XLH.

Initial approval duration = 13 months

Renewal Criteria:

- Coverage of burosumab may be renewed if NONE of the following develop or progress while on treatment:
  - Hyperparathyroidism
  - Nephrocalcinosis
  - Evidence of fracture or pseudofracture based on radiographic assessment
  - Fasting hypophosphatemia.

Renewal approval duration = 12 months

buserelin acetate, injection, 1.05mg/mL (Suprefact)

For treatment of:
(a) Endometriosis. *(Coverage may be repeated after a six month lapse, for another 6 month course)*
(b) Menorrhagia in preparation for endometrial ablation, and:
(c) For pre-treatment of uterine fibroids prior to surgical removal.

Bylvay – see odevixibat

cabergoline, tablet, 0.5mg (Dostinex, and listed generics) (possible OEA)

For treatment of:

(d) Hyperprolactinemic disorders in patients unresponsive to bromocriptine.

(e) Hyperprolactinemic disorders in patients intolerant to bromocriptine.

Cabenuva – see cabotegravir & rilpivirine

cabotegravir, tablet, 30mg (Vocabria) (possible OEA)

For the treatment of human immunodeficiency virus-1 (HIV-1) infection in combination with rilpivirine tablets as follows, in adults with virologic suppression:

- Prior to initiation of injectable cabotegravir and rilpivirine, or
- To accommodate bridging therapy for patients previously established on injectable cabotegravir and rilpivirine who have experienced treatment interruption.

Note: Virologic suppression is defined as an HIV-1 ribonucleic acid (RNA) level (viral load) less than the lower limit of quantification (typically 50 copies/mL).

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

cabotegravir & rilpivirine, extended release injectable suspension, 200mg/mL & 300mg/mL, 2mL&2mL, 4mL kit (mL); 3mL&3mL, 6mL kit (mL) (Cabenuva) (possible OEA)

For the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with virologic suppression who have tolerated a trial of oral cabotegravir and rilpivirine.

Note: Virologic suppression is defined as an HIV-1 ribonucleic acid (RNA) level (viral load) less than the lower limit of quantification (typically 50 copies/mL).

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

calcitonin salmon, injection, 200IU/mL

For treatment of:

(a) Osteoporosis with bone pain due to crush fracture.

(b) For symptomatic treatment of Paget's disease of the bone.
Coverage will be provided for both indications for a maximum of three months.

(c) For the treatment of non-malignant hypercalcemia.

Note: Requests for the treatment of hypercalcemia of malignancy should be referred to the Saskatchewan Cancer Agency.

calcitriol, capsule, 0.25ug, 0.5ug (Rocaltrol, and listed generics) (possible OEA)

(a) For management of hypocalcemia and osteodystrophy in patients with chronic renal failure undergoing renal dialysis.
Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (SAIL) Program. Exception Drug Status coverage is NOT required for SAIL patients.

(b) For management of hypocalcemia and clinical manifestations associated with post-surgical hypoparathyroidism, idiopathic hypoparathyroidism, pseudohypoparathyroidism, or vitamin D resistant rickets.

Camzyos- see mavacamten

cannabidiol, oral solution, 100mg/mL (mL) (Epidiolex)

Indication	Criteria
Dravet Syndrome (DS)	For adjunctive treatment of seizures associated with Dravet Syndrome (DS) in patients 2 years of age or older who: • Have at least 4 convulsive seizures per month; AND, • Have inadequate seizure control despite the use of 2 or more antiseizure medications. Patients must be under the care of a specialist with experience in the diagnosis and management of patients with DS. Cannabidiol will not be reimbursed for individuals concurrently using cannabis products (recreational or medicinal) or other cannabinoid-based medication. Initial approval duration: Six (6) months

	Renewal Criteria: • The patients continue to be under the care of a physician with experience in the diagnosis and management of patients with DS; AND, • The physician can provide proof of a beneficial clinical effect.
Lennox-Gastaut Syndrome (LGS)	For adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older who: • Have failed at least 2 anti-seizure medications; AND, • Have been taking 1 or more anti-seizure medication(s) at a stable dose for at least 4 weeks; AND, • Have experienced at least 2 drop seizures per week over the past 28-day period. Patients must be under the care of a specialist with experience in the diagnosis and management of LGS. Cannabidiol will not be reimbursed for individuals concurrently using cannabis products (recreational or medicinal) or other cannabinoid-based medication. Initial approval duration: Six (6) months Renewal Criteria: • The patient continues to be under the care of a physician with experience in the diagnosis and management of LGS; AND, • The physician can provide proof of beneficial clinical effect.
Tuberous Sclerosis Complex (TSC)	For adjunctive treatment of seizures associated with Tuberous Sclerosis Complex (TSC) in patients 2 years of age or older who: • Have been taking 1 or more anti-seizure medication(s) at a stable dose for at least 4 weeks; AND, • Have inadequately controlled seizures despite previous or current treatment with at least 2 anti-seizure medications; AND, • Have experienced at least 8 seizures in the past 28-day period. Patients must be under the care of a specialist with experience in the diagnosis and management of TSC. Cannabidiol will not be reimbursed for individuals concurrently using mammalian target of rapamycin (mTOR) inhibitors, cannabis products (recreational or medicinal) or other cannabinoid-based medication. Initial approval duration: Six (6) months Renewal Criteria: • The patient must continue to be under the care of a specialist with experience in the diagnosis and management of TSC; AND, • The physician can provide proof of beneficial clinical effect.

cariprazine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Vraylar)
For the treatment of schizophrenia

Cayston - see aztreonam
Celsentri - see maraviroc
CellCept - see mycophenolate mofetil

certolizumab pegol, solution for injection, 200mg/mL, pre-filled syringe; 200mg/mL, autoinjector (Cimzia)

Indication	Criteria
Rheumatoid arthritis	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. **Note:** This product should be used in consultation with a specialist in this area.
Psoriatic arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.
Ankylosing Spondylitis	**Initial:** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control.

	This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration: 12 weeks **First Renewal:** Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval Duration: One Year **Note:** Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.

cenobamate, tablet, 12.5mg, 25mg, 50mg, 100mg, 150mg, 200mg; tablet 28-day starter (kit), 12.5mg & 25mg, 50mg & 100mg, 150mg & 200mg (Xcopri)

For the adjunctive treatment of refractory partial-onset seizures (POS) seizures in patients who meet all of the following criteria:

a) Are currently receiving two or more antiepileptic drugs; **AND**
b) less costly antiepileptic drugs are ineffective or inappropriate; **AND**
c) the medication is being used under the direction of a neurologist.

Note: Patients should have tried and failed at least two less costly antiepileptic drugs.

Cesamet - see nabilone
Cibinqo - see abrocitinib
Ciloxan - see ciprofloxacin
Cimzia - see certolizumab pegol
Cipro - see ciprofloxacin tablet

ciprofloxacin, ophthalmic solution, 0.3% (Ciloxan, and listed generics); ophthalmic ointment, 0.3% (Ciloxan) (possible OEA)

For treatment of:
(a) Ophthalmic infections caused by gram-negative organisms.
(b) Ophthalmic infections unresponsive to alternative agents.

ciprofloxacin, tablet, 250mg, 500mg, 750mg (Cipro, and listed generics); oral suspension100mg/mL (Cipro)

For treatment of:
(a) Infections caused by *Pseudomonas aeruginosa*.
(b) Infections in patients allergic to two or more alternative antibiotics.
(c) Infections known to be resistant to alternative antibiotics. Resistance must be determined by culture and sensitivity testing (C&S).
(d) Patients with severe diabetic foot infections in combination with other antibiotics.
(e) Infection (and prophylaxis) in patients with prolonged neutropenia.
(f) Genitourinary tract infections in patients allergic or unresponsive to alternative antibiotics.
(g) Patients with bronchiectasis or cystic fibrosis.
(h) Gonorrhea, and:
(i) For completion of antibiotic treatment initiated in hospital when alternatives are not appropriate.

ciprofloxacin, extended release tablet, 500mg (listed generic)

For treatment of **uncomplicated** *urinary tract infections* in **females** unresponsive or allergic to first-line agents.

cladribine, tablet, 10mg (Mavenclad)

See Appendix D

clonidine HCl, tablet, 0.025mg (listed generics)

For treatment of:
(a) Menopausal flushing.
(b) Attention Deficit Hyperactivity Disorder.

clozapine, orally disintegrating tablet, 12.5mg, 25mg, 50mg, 100mg, 200mg (listed generics) (possible OEA)
clozapine, tablet, 25mg, 50mg, 100mg, 200mg (Clozaril, and listed generics) (possible OEA)

For treatment of schizophrenia in patients who are either treatment resistant or treatment intolerant and have no other medical contraindications.

Clozaril - see clozapine

codeine, controlled release tablet, 50mg, 100mg, 150mg, 200mg (Codeine Contin)

For treatment of:

(a) Palliative and chronic pain patients as an alternative to ASA/codeine combination products or acetaminophen/codeine combination products.
(b) Palliative and chronic pain patients as an alternative to regular release tablet when large doses are required.

In non-palliative patients, coverage will only be approved for a 6 month course of therapy, subject to review.

Codeine Contin - see codeine
Complera – see emtricitabine/rilpivirine/tenofivir DF
Cosentyx – see secukinumab
Cresemba - see isavuconazole

crovalimab, solution for injection, 340mg/2mL (mg) (Piasky)

Initiation Criteria

For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) in patients diagnosed based on both of the following confirmatory results:

- Flow cytometry/FLAER exam with granulocyte or monocyte clone size ≥ 10%; AND,
- Lactate dehydrogenase (LDH) > 1.5 x upper limit of normal (ULN); AND,
- The patient is exhibiting at least ONE of the following features attributed to PNH:
    - A thrombotic or embolic event which required the initiation of therapeutic anticoagulant therapy; AND/OR,
    - Transfusion requirement of ≥ 4 units of red blood cells in the previous 12 months; AND/OR,
    - Chronic or recurrent anemia where causes other than hemolysis have been excluded, and demonstrated by more than one hemoglobin measure of ≤ 70g/L or more than one hemoglobin measure of ≤ 100 g/L with concurrent symptoms of anemia; AND/OR,
    - Pulmonary insufficiency, as defined by debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; AND/OR,
    - Renal insufficiency, demonstrated by an eGFR ≤ 60mL/min/1.73m^2, where causes other than PNH have been excluded; AND/OR,
    - Smooth muscle spasm, as defined by recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded; AND,
- Crovalimab is being prescribed by or in consultation with a hematologist or nephrologist with experience managing PNH.

Initial approval duration: 6 months

Renewal Criteria:

After the initial approval period, a patient may receive approval for further coverage of crovalimab where:

- There has been relief in the PNH symptoms that had qualified the patient for their initial approval; AND,
- There is demonstrated clinical improvement in the patient, or stabilization of the patient's condition, while receiving treatment with crovalimab; AND,
- The patient and treating physician have been adequately adherent to treatment and to measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; AND,
- Crovalimab is being prescribed by or in consultation with a hematologist or nephrologist with experience in managing PNH.

Requests for renewal must be accompanied by current confirmation of granulocyte and monocyte clone size (by flow cytometry), in accordance with the Exclusion Criteria below.

Renewal duration: 12 months

Exclusion Criteria (for initial and renewal requests):

Patients meeting **any** of the following criteria will not be eligible for crovalimab coverage:

- Prior treatment failure with crovalimab, ravulizumab or eculizumab;
- Receiving concurrent treatment with another C5 inhibitor drug (e.g. eculizumab or ravulizumab);
- Granulocyte and monocyte clone size both below 10%;
- Presence of aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Presence of another life threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (for example, acute myeloid leukemia or high-risk myelodysplastic syndrome); OR,
- Presence of another medical condition that might reasonably be expected to compromise a response to crovalimab therapy.

Crysvita – see burosumab

cyclobenzaprine HCl, tablet, 10mg (listed generics)

As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions in patients unresponsive to alternative therapy or who are experiencing severe adverse reactions to alternative therapy.

Coverage will be provided for up to a 3 week period. Coverage can be renewed for a 3 week period every 3 months.

cyclophosphamide, tablet, 50mg (Procytox)

For non-oncology conditions

cyclosporine, capsule, 10mg, 25mg, 50mg, 100mg; liquid, 100mg/mL (Neoral)

(a) For treatment of nephrotic syndrome.
(b) For treatment of severe active rheumatoid arthritis in patients for whom classical slow-acting anti-rheumatic agents are inappropriate or ineffective.
(c) For induction and maintenance of remission of severe psoriasis in patients for whom conventional therapy is ineffective or inappropriate.
(d) For treatment of patients with atopic dermatitis who have not responded, or are intolerant, to topical treatment (such as steroids, tacrolimus, pimecrolimus). Treatment should be initiated in consultation with a specialist in this area.
(e) For the treatment of mild to moderate chronic non-infectious uveitis in patients unresponsive to, or unable to take, systemic corticosteroids and a non-biologic conventional immunosuppressant.

Note: This medication should be used in consultation with an ophthalmologist experienced in the management of chronic non-infections uveitis.

(f) For patients with dermatomyositis or polymyositis where azathioprine and methotrexate are inappropriate or not effective.
(g) For treatment of chronic idiopathic urticaria in patients refractory or intolerant to antihistamines.
(h) For the treatment of pyoderma gangrenosum.

For the above indications prescriptions are subject to deductible (where applicable) and co-payment as for other drugs covered under the Drug Plan. **Pharmacies note: claims on behalf of these patients must use the following identifying numbers (not the DIN):**

10mg - 00950792	100mg - 00950815
25mg - 00950793	100mg/mL - 00950823
50mg – 00950807	

cyclosporine, capsule, 10mg, 25mg, 50mg, 100mg; liquid, 100mg/mL (Neoral)

For prophylaxis of graft rejection following solid organ transplant and in bone marrow transplant procedures.

In such cases, the cost is covered at 100% and the deductible (where applicable) does not apply.

cyclosporine, ophthalmic emulsion, 0.1% (Verkazia)

For the treatment of severe vernal keratoconjunctivitis (VKC) in children 4 to 18 years of age who are under the care of an ophthalmologist or other specialist physician with experience in the diagnosis and management of VKC.

Notes:

- Severe VKC is defined as either grade 3 (severe) or 4 (very severe) on the Bonini scale, OR grade 4 (marked) or 5 (severe) on the modified Oxford scale.
- Treatment with Verkazia should be discontinued once signs and symptoms of VKC have been resolved, or if there is no improvement after 4 months of treatment.

Initial approval duration: 4 months.

cysteamine bitartrate, delayed release capsule, 25mg, 75mg (Procysbi)

For the treatment of infantile nephropathic cystinosis with documented cystinosin, lysosomal cysteine transporter gene mutation.

Note*: This product should be used in consultation with a specialist in this area.*

dalteparin sodium, pre-filled syringe, 2500IU (0.2mL), 3500IU (0.28mL), 5000IU (0.2mL), 7500IU (0.3mL), 10,000IU (0.4mL), 12,500IU(0.5mL), 15,000IU(0.6mL), 16,500IU (0.66mL), 18,000IU (0.72mL): injection solution, 10,000IU/mL (1mL), 25,000IU/mL (3.8mL) (Fragmin)

(a) For treatment of venous thromboembolism for up to 10 days.
(b) For prophylaxis following total knee arthroplasty for up to 35 days.
(c) For major orthopedic trauma for up to10 days (treatment duration may be reassessed).
(d) For long-term outpatient prophylaxis in patients who are pregnant.
(e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
(f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
(g) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
(h) For extracorporeal anticoagulation in home hemodialysis patients.
(i) For prophylaxis following abdominal, thoracic, esophageal or pelvic surgery for up to 28 days.

darbepoetin alfa, pre-filled syringe, 10mcg/0.4mL, 20mcg/0.5mL, 30mcg/0.3mL, 40mcg/0.4mL, 50mcg/0.5mL, 60mcg/0.3mL, 80mcg/0.4mL, 100mcg/0.5mL, 130mcg/0.65mL, 150mcg/0.3mL, 200mcg/0.4mL (Aranesp-AMG)

For treatment of anemia in chronic renal disease patients prior to initiation of dialysis.
Note*: Coverage for dialysis patients is provided under the S.A.I.L. Program. EDS coverage is not required for S.A.I.L. patients.*

darifenacin, extended release tablet, 7.5mg, 15mg (Enablex, and listed generics)
(possible OEA)

For treatment of patients intolerant to oxybutynin chloride, solifenacin succinate or tolterodine l-tartrate.

darunavir, tablet, 600mg, 800mg (listed generics) (possible OEA)

a) For management of HIV disease. This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

darunavir/cobicistat, tablet, 800mg/150mg (Prezcobix) (possible OEA)

For treatment of human immunodeficiency virus (HIV) infection in treatment-naïve and treatment-experienced patients without darunavir (DRV) resistance-associated mutations (RAMS).
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

DDAVP - see desmopressin

deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade, and listed generics)

For treatment of chronic iron overload in patients with transfusion dependent anemias.
Note: Should not be used in combination with deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu).

deferasirox, film coated tablet, 90mg, 180mg, 360mg (Jadenu, and listed generics)

For treatment of chronic iron overload in patients with transfusion dependent anemias.
Note: Should not be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade) or deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox).

deferiprone, modified release tablet, 1000mg (Ferriprox MR)

For the treatment of chronic iron overload in patients with transfusion dependent anemias.
Note*:* Should NOT be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

deferiprone, tablet, 1000 mg; solution, 100 mg/mL (Ferriprox and listed generics)

For treatment of chronic iron overload in patients with transfusion dependent anemias.
Note: Should not be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

deferoxamine mesylate, powder for solution, 500mg/vial (Desferal, and listed generics) , 2g/vial (listed generics)

For treatment of iron overload in patients with transfusion-dependent anemias.

delgocitinib, topical cream, 20mg/g (Anzupgo)

For the treatment of moderate-to-severe[1] chronic hand eczema (CHE) in adult patients who have had an adequate trial[2], intolerance to, or ineligible for high-potency topical corticosteroids (TCS).

Delgocitinib must be prescribed by a dermatologist or clinician with experience in the management of chronic hand eczema (CHE).

Initial clinical response should be assessed after 12 weeks of treatment.

Renewal of delgocitinib coverage will be considered in patients who demonstrate either:

- a ≥ 2-step improvement in the Investigator Global Assessment for Chronic Hand Eczema (IGA-CHE) or the Physician Global Assessment (PGA) score, OR
- an IGA-CHE or PGA score of 0 to 1 (clear or almost clear).

Note: IGA-CHE or PGA scores must be provided with initial renewal applications.

[1]Moderate to severe chronic hand eczema is defined by a PGA or IGA-CHE score of 3 to 4.
[2]An adequate trial of a high-potency TCS requires a minimum 8-week duration.

denosumab, pre-filled syringe, 60mg/mL (Prolia)

Effective December 1, 2025, new patients (i.e., patients without previous EDS approval for Prolia) will only be eligible for a listed biosimilar formulation of denosumab.

a) To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
   - High fracture risk defined as either:
     - Moderate 10-year fracture risk (10% to 20%) as defined by either 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 either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool

   AND
   - Contraindication to oral bisphosphonates.

   Notes:
   - Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
   - Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g., esophageal stricture or achalasia).
   - Prescribers are reminded to consult the product monograph regarding use in patients with severe renal impairment.

b) For treatment of osteoporosis in patients with a moderate – high 10-year fracture risk (10% or more) and one of the following:
   - Men on androgen deprivation therapy for prostate cancer; or
   - Women on aromatase inhibitor therapy for breast cancer.

   Note:
   - Prescribers are reminded to consult the product monograph regarding use in patients with severe renal impairment.

denosumab, prefilled syringe, 60mg/mL (Bildyos) (Denoza) (Jubbonti) (Stoboclo)

a) To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
   - High fracture risk defined as either:
     - Moderate 10-year fracture risk (10% to 20%) as defined by either 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 either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool

AND

- Contraindication to oral bisphosphonates

Notes:
- Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
- Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g., esophageal stricture or achalasia).
- Prescribers are reminded to consult the product monograph regarding use in patients with severe renal impairment.

b) For treatment of osteoporosis in patients with a moderate – high 10-year fracture risk (10% or more) and one of the following:
- Men on androgen deprivation therapy for prostate cancer; or
- Women on aromatase inhibitor therapy for breast cancer.

Note:
- Prescribers are reminded to consult the product monograph regarding use in patients with severe renal impairment.

Denoza – see denosumab
Desferal - see deferoxamine mesylate

desmopressin, tablet, 0.1mg, 0.2mg; (listed generics); orally disintegrating tablet, 60ug, 120ug (DDAVP MELT)
For treatment of:
(a) Diabetes insipidus.
(b) Enuresis in children over 5 years of age refractory to bed-wetting alarms or alternative agents listed in the Formulary.
(c) Nocturia in patients with a recognized neurologic disorder which causes detrusor over-activity confirmed by cystogram in the absence of obstruction, who have not responded or are intolerant to at least two anticholinergic drugs.

desmopressin, intranasal solution, 10ug/dose (listed generics)
For treatment of diabetes insipidus.

desmopressin, injection, 4ug/mL (listed generics)
For prophylaxis and/or treatment of bleeding as a result of a bleeding disorder.

Diacomit - see stiripental

dienogest, tablet, 2mg (Visanne, and listed generic) (possible OEA)
For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options (oral contraceptives and medroxyprogesterone acetate depot injection suspensions) are either ineffective or cannot be used.
Note: An adequate trial with oral contraceptives or medroxyprogesterone acetate depot injection suspensions shall be defined as a six month interval.

Dificid - see fidaxomicin

dimethyl fumarate, delayed release capsule, 120mg, 240mg (Tecfidera, and listed generics)
See Appendix D

dipyridamole/acetylsalicylic acid, capsule, 200mg/25mg (listed generics) (possible OEA)
For treatment of patients who have had a:
(a) Stroke while on acetylsalicylic acid.
(b) Transient ischemic attack while on acetylsalicylic acid.

Dojolvi- see triheptanoin

dolutegravir/lamivudine, tablet, 50mg/300mg (Dovato) (possible OEA)
For use as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in patients 12 years of age and older who are naïve to any antiretroviral therapy (ART) and have an HIV-1 viral load of 500,000 copies/mL or less.

Note: Dovato is not recommended for patients weighing less than 40kg.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

dolutegravir/rilpivirine, tablet, 50mg/25mg (Juluca) (possible OEA)
For treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult patients who are virologically stable and suppressed (i.e. fewer than 50 copies per mL of HIV-1 ribonucleic acid [RNA]).
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

donepezil HCl, tablet, 5mg, 10mg (Aricept, and listed generics)
For the treatment of Alzheimer's disease in patients with:

- a Mini Mental State Exam (MMSE) score between 10-26; AND/OR,
- a Montreal Cognitive Assessment (MoCA) score between 4-16.

Initial Approval Duration: 6 months

NOTE: Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and MOCA are administered. Drugs with anticholinergic activity are not to be used concurrently with donepezil therapy.

Renewal Criteria:

To qualify for renewal of donepezil patients must continue to have an MMSE score ≥10 and/or MoCA score ≥4.
Renewal Duration: 2 years

doravirine, tablet, 100mg (Pifeltro) (possible OEA)
For management of HIV disease in adult patients without past or present evidence of viral resistance to doravirine.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

doravirine/lamivudine/tenofovir disoproxil fumarate, tablet, 100mg/300mg/300mg (Delstrigo) (possible OEA)
For management of HIV disease in adult patients without past or present evidence of viral resistance to each of the components.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

dornase alfa, inhalation solution, 1mg/mL (Pulmozyme) (possible OEA)
For treatment of cystic fibrosis patients who meet the following criteria:
(a) At least 5 years of age.
(b) Lung function greater than 40% (as measured by FVC).
(c) Physicians will be requested to provide evidence of the beneficial effect of this drug in their patients after 1 year of therapy before additional coverage is granted.

Renewal of coverage will be provided for a 1 year period if any of the following criteria are met:
(a) FEV1 has improved by 10% from pre-treatment value.
(b) Decreased antibiotic utilization.
(c) Decreased hospitalizations.
(d) Decreased absenteeism from school or work.
(e) If the individual deteriorates upon discontinuation of Pulmozyme therapy.

Physicians must provide appropriate documentation to establish benefit.

Dostinex - see cabergoline
Duaklir Genuair - see aclidinium bromide/formoterol fumarate dihydrate
Duodopa - see levodopa/carbidopa

dupilumab, solution for injection, 200mg/1.14mL (mg) pre-filled syringe, pre-filled pen; 300mg/2mL (mg) pre-filled syringe, pre-filled pen (Dupixent)

Indication	Criteria
Atopic Dermatitis	For the treatment of refractory moderate to severe[1] atopic dermatitis in patients 12 years and older who: • Have had an adequate trial, or who were intolerant, or are ineligible for EACH of the following therapies: o Maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy[2] (where available), and o Maximally tolerated medical topical therapies for atopic dermatitis combined with at least one of the four systemic immunomodulators (methotrexate[2], cyclosporine[2], mycophenolate mofetil[2], or azathioprine[2]). Requests must include documentation of the Eczema Area and Severity Index (EASI) score. Initial approval: Six (6) months. **Renewal Criteria** Renewal requests will be considered for patients where there has been a 75% or greater improvement from baseline in the EASI score (EASI-75) after initiation and where this response is subsequently maintained thereafter every six months. Renewal requests must include a recent EASI score. Renewal approval: Six (6) months. Both initial and renewal coverage requests for this indication must be made by, or in consultation with a specialist in this area. Dupilumab should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other janus kinase (JAK) inhibitor treatment for moderate to severe atopic dermatitis. [1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher. [2]Adequate trials are defined as: o Phototherapy – three times a week for 12 weeks. o Methotrexate – 10 to 20mg per week for 12 weeks. o Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks. o Mycophenolate mofetil – 1g twice daily for 12 weeks. o Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.
Asthma for patients 12 and over	For add-on maintenance treatment of patients age 12 years and older with a type 2/severe eosinophilic phenotype asthma[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), and • Blood eosinophil count of ≥ 300 cells/ µL (0.3×10^9) AND has experienced two or more clinically significant asthma exacerbations[3] in the in the past 12 months, OR • Blood eosinophil count of ≥ 150cells/µL (0.15×10^9) **AND** is receiving maintenance treatment with oral corticosteroids[4]. In addition: o Dupilumab should not be used in combination with other biologics used to treat asthma. o A baseline[5] assessment of asthma symptom control using a validated asthma control questionnaire[6] must be completed prior to initiation of dupilumab treatment and submitted with the application. o Baseline[5] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications. o Patients should be managed by a specialist in the treatment of asthma. [1]Patients must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype [2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily.

	[3] Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization. [4]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day. [5]Baseline refers to results achieved prior to initiation of the requested therapy. [6]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT. **Discontinuation Criteria** Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if: • First Renewal (based on first 12 months of therapy) o The asthma control questionnaire score has not improved from baseline[4,5,6], OR o The number of clinically significant exacerbations has increased[3], OR o The oral corticosteroid maintenance dose has not decreased. • Subsequent Renewals (after 2 years of therapy) o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, OR o The number of clinically significant exacerbations has increased within the previous 12 months, OR o The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently.
Asthma for patients 6-11 years of age	For add-on maintenance treatment of patients age 6 to 11 years of age with a type 2/severe eosinophilic phenotype asthma[1], who are inadequately controlled with medium to high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), and: • Blood eosinophil count of ≥ 150 cells/μL (0.15 × 109 /L) within the past 12 months AND • Has uncontrolled asthma with at least one clinically significant asthma exacerbation[3] in the past 12 months. In addition: o Dupilumab should not be used in combination with other biologics used to treat asthma. o A baseline[4] assessment of asthma symptom control using a validated asthma control questionnaire[5] must be completed prior to initiation of dupilumab treatment and submitted with the application. o Baseline[4] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications. o Patients should be managed by a specialist in the treatment of asthma. [1]Patients must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype. [2]High dose inhaled corticosteroids is defined as greater or equal to 400mcg of fluticasone propionate or equivalent daily. Medium dose inhaled corticosteroid is defined as greater than 100 mcg-400 mcg of fluticasone propionate or equivalent daily. [3]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in hospitalization, an emergency care visit, or treatment with systemic corticosteroids. [4]Baseline refers to results achieved prior to initiation of the requested therapy. [5]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a

	decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT. **Discontinuation Criteria** Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if: • First Renewal (based on first 12 months of therapy) o The asthma control questionnaire score has not improved from baseline[4,5], OR o The number of clinically significant exacerbations has increased. • Subsequent Renewals (after 2 years of therapy) o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, OR o The number of clinically significant exacerbations has increased within the previous 12 months.

Dupixent - see dupilumab
Duragesic - see fentanyl
Duragesic Mat - see fentanyl
Dysport Therapeutic - see abobotulinumtixinA

eculizumab, intravenous solution, 10mg/mL (30mL vial) (mL) (Soliris)

INDICATION*:* Atypical Hemolytic Uremic Syndrome (aHUS):

Initiation Criteria

For the treatment of atypical hemolytic uremic syndrome (aHUS), when prescribed by or in consultation with a nephrologist or hematologist, in patients meeting ALL of the following:

1. Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA) as follows:
   - ADAMTS-13* activity ≥ 10% on blood samples taken before plasma exchange or plasma infusion (PE/PI); and
   - Shiga toxin–producing Escherichia coli (STEC) test negative, in patients with a history of bloody diarrhea in the preceding 2 weeks; and
   - TMA must be unexplained (i.e., not attributed to any secondary cause).

   AND
2. Evidence of ongoing active TMA that is progressing (despite use of plasmapheresis, if appropriate), as demonstrated by the following:
   - Unexplained thrombocytopenia (platelet count < 150 × 10^9/L and not a secondary TMA); and hemolysis as indicated by the documentation of 2 of the following: schistocytes on the blood film, low or absent haptoglobin, or lactate dehydrogenase (LDH) above normal; or
   - TMA confirmed by tissue biopsy, in patients who do not have evidence of platelet consumption and hemolysis.

   AND
3. Evidence of at least ONE of the following documented clinical features of active organ damage or impairment:
   - Kidney impairment, as demonstrated by one of the following:

Patient Characteristics	Kidney Impairment Level
Adult, preexisting renal impairment	eGFR decline of > 20%
Adult, no history of preexisting renal impairment (including patients with no baseline eGFR measurement)	SCr > ULN for age, or eGFR < 60mL/min and renal function deteriorating despite prior PE/PI
Pediatric patients	SCr > the age-appropriate ULN (as determined by or in consultation with a pediatric nephrologist)

eGFR = estimated glomerular filtration rate
SCr = serum creatinine
ULN = upper limit of normal

and/or

- The onset of neurological impairment related to TMA; and/or
- Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, and retinal vein occlusion.

Initial coverage duration: 6 months

*__Notes__: ADAMTS-13 = A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13.

Initiation Criteria for Kidney Transplant Patients
Transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS-13 activity ≥ 10%) may be eligible for eculizumab coverage, when prescribed by or in consultation with a nephrologist or hematologist, if ANY of the following occur:

- Development of TMA immediately (within hours to 1 month) following a kidney transplant; or
- Experiencing aHUS recurrence after previous loss of a native or transplanted kidney due to the development of TMA; or
- The patient will be receiving a kidney transplant and requires prophylaxis with eculizumab at the time of the transplant.

Initial coverage duration: 6 months

Exclusion Criteria (for initial and renewal requests)
Patients with a history of eculizumab treatment failure (i.e., treated with eculizumab for a previous aHUS occurrence/recurrence) will not be eligible for coverage.

Treatment failure is defined as ANY of the following occurring while receiving eculizumab:

- Dialysis dependence at 6 months of eculizumab treatment, and failure to demonstrate resolution or stabilization of neurological or extrarenal aHUS complications (if these were originally present); or
- On dialysis for ≥ 4 of the previous 6 months of eculizumab treatment, and failure to demonstrate resolution or stabilization of neurological or extrarenal aHUS complications (if these were originally present); or
- Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline at the start of eculizumab treatment.

Patients will not be eligible for eculizumab coverage if receiving concurrent treatment with another C5 inhibitor drug (e.g., ravulizumab, etc.).

Initial Renewal Criteria (at 6 months)
After the initial 6 months of eculizumab treatment, coverage may be renewed if ALL of the following are met:

- The patient has demonstrated response to treatment, defined as, but not limited to:
  - Hematological normalization (e.g., platelet count, LDH); and
  - Stabilization of aHUS-related end-organ damage (such as acute kidney injury and brain ischemia); and
  - Transplant graft survival in susceptible individuals; and
  - Dialysis avoidance, in patients who are pre-end stage kidney disease (ESKD); and
- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above; and
- Eculizumab therapy continues to be managed by or in consultation with a nephrologist or hematologist.

Initial Renewal coverage duration: 6 months

Subsequent Renewal Criteria (at 12 months and thereafter)
For patients requiring ongoing eculizumab treatment, coverage may be renewed if ALL of the following are met:

- The patient continues to demonstrate response to treatment, as defined in the Initial Renewal Criteria above; and
- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above; and
- The patient has limited organ reserve, or a high-risk genetic mutation (e.g., Factor H deficiency) associated with aHUS recurrence.
  - Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Stage 4 or 5 chronic kidney disease (eGFR < 30mL/min).

AND

- Eculizumab therapy continues to be managed by or in consultation with a nephrologist or hematologist.

Subsequent Renewal coverage duration: 12 months

Reinitiation Criteria

Patients previously diagnosed with aHUS who responded to treatment with eculizumab (without treatment failure, as defined in the Exclusion Criteria above) may be eligible for coverage to restart eculizumab, if a TMA related to aHUS redevelops and ALL of the following are present:

- Significant hemolysis, as evidenced by presence of schistocytes on the blood film, low or absent haptoglobin, or LDH above normal;

AND

- At least ONE of the following:
  - Platelet consumption, as measured by either ≥ 25% decline in platelet count from patient baseline or thrombocytopenia (platelet count < 150 × 10^9/L); or
  - TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin), including evidence of TMA on recent biopsy;

AND

- Eculizumab therapy is being prescribed by or in consultation with a nephrologist or hematologist.

Reinitiation Coverage duration: 6 months, with renewal considered according to Initial Renewal Criteria and Subsequent Renewal Criteria above.

INDICATION*:* Paroxysmal Nocturnal Hemoglobinuria (PNH):

Initiation Criteria

For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) in patients diagnosed based on both of the following confirmatory results:

- Flow cytometry/FLAER exam with granulocyte or monocyte clone size ≥ 10%; and
- Lactate dehydrogenase (LDH) > 1.5 x upper limit of normal (ULN);

AND

the patient is exhibiting at least ONE of the following features attributed to PNH:

- A thrombotic or embolic event which required the initiation of therapeutic anticoagulant therapy; and/or
- Transfusion requirement of ≥ 4 units of red blood cells in the previous 12 months; and/or
- Chronic or recurrent anemia where causes other than hemolysis have been excluded, and demonstrated by more than one hemoglobin measure of ≤ 70g/L or more than one hemoglobin measure of ≤ 100 g/L with concurrent symptoms of anemia; and/or
- Pulmonary insufficiency, as defined by debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; and/or
- Renal insufficiency, demonstrated by an eGFR ≤ 60mL/min/1.73m^2, where causes other than PNH have been excluded; and/or
- Smooth muscle spasm, as defined by recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded;

AND

eculizumab is being prescribed by or in consultation with a hematologist or nephrologist with experience managing PNH.

Initial approval duration: 6 months

Renewal Criteria

After the initial approval period, a patient may receive approval for further coverage of eculizumab where:

- There has been relief in the PNH symptoms that had qualified the patient for their initial eculizumab approval; and
- There is demonstrated clinical improvement in the patient, or stabilization of the patient's condition, while receiving treatment with eculizumab; and
- The patient and treating physician have been adequately adherent to treatment and to measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; and
- Eculizumab is being prescribed by or in consultation with a hematologist or nephrologist with experience in managing PNH.

Requests for renewal must be accompanied by current confirmation of granulocyte and monocyte clone size (by flow cytometry), in accordance with the Exclusion Criteria below.

Renewal duration: 1 year

Exclusion Criteria (for initial and renewal requests)

Patients meeting any of the following criteria will not be eligible for eculizumab coverage:

- Prior treatment failure with a C5 inhibitor (e.g., eculizumab, ravulizumab, etc.);
- Receiving concurrent treatment with another C5 inhibitor drug (e.g. ravulizumab);
- Granulocyte and monocyte clone size both below 10%;
- Presence of aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Presence of another life threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (for example, acute myeloid leukemia or high-risk myelodysplastic syndrome); or
- Presence of another medical condition that might reasonably be expected to compromise a response to eculizumab therapy.

edaravone, oral suspension, 21mg/mL (mL) (Radicava)

Initiation Criteria

For the treatment of amyotrophic lateral sclerosis (ALS) when initiated by a neurologist with expertise in the management of ALS, when the patient has ALL of the following:

- A probable or definite diagnosis of ALS; and
- Scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R); and
- Forced vital capacity ≥ 80% of predicted value; and
- Has had ALS symptoms for two years or less; and
- Not currently requiring permanent non-invasive or invasive ventilation.

Coverage will be reviewed every six months.

Coverage cannot be renewed once the patient meets ANY of the following:

- Becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); or
- Requires permanent non-invasive or invasive ventilation.

Note: Please submit the patient's updated ALSFRS-R scores (items 5a/5b and 8) AND current ventilation status every 6 months to request renewal of coverage.

Edecrin - see ethacrynic acid
Edurant – see rilpivirine

efavirenz, tablet, 600mg (listed generics) (possible OEA)

For management of HIV disease.
This drug, as with other antivirals in treatment of HIV, should be used under the direction of an infectious disease specialist.

efavirenz/emtricitabine/tenofovir disoproxil fumarate, tablet, 600mg/200mg/300mg (listed generics) (possible OEA)

For treatment of HIV-1 infection where the virus is susceptible to each of tenofovir and emtricitabine and efavirenz and:

(a) Atripla is used to replace existing therapy with its component drugs, or
(b) The patient is treatment naive, or
(c) The patient has established viral suppression but requires antiretroviral therapy modification due to intolerance or adverse effects.

This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

efgartigimod alfa, solution for infusion, 400mg/20mL (20mg/mL) (mg) (Vyvgart)

Initiation Criteria

For the treatment of adult patients with generalized myasthenia gravis (gMG) who:

- Have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; AND,
- Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥5; AND,
- Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
- Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
- Will not have efgartigimod alfa initiated during a gMG exacerbation or crisis, or within 3 months of a thymectomy; AND,
- Will not be using efgartigimod alfa concomitantly with rituximab, a complement inhibitor, or another neonatal Fc receptor (FcRn) antagonist; AND,
- Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

Initial Coverage Duration: 9 months

- Extension of initial coverage may be considered for individuals who have not yet completed 3 treatment cycles in the initial 9-month period.

Initial Renewal Criteria
After 3 treatment cycles, renewal of efgartigimod alfa coverage will be considered in individuals who:

- Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
- Will not be using efgartigimod alfa concomitantly with rituximab, a complement inhibitor, or another neonatal Fc receptor (FcRn) antagonist; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Subsequent Renewal Criteria:
Ongoing coverage of efgartigimod alfa will be considered in individuals who:

- Have maintained the improvement in MG-ADL score[2] demonstrated at the initial renewal; AND,
- Will not be using efgartigimod alfa concomitantly with rituximab, a complement inhibitor, or another neonatal Fc receptor (FcRn) antagonist; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Renewal duration: 12 months

[1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.

[2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

Eldepryl - see selegiline HCl

elexacaftor/tezacaftor/ivacaftor, granules, 100mg/50mg/75mg co-packaged with ivacaftor, granules, 75mg; 80mg/40mg/60mg, granules co-packaged with ivacaftor, granules 59.5mg (Trikafta) (possible OEA)
elexacaftor/tezacaftor/ivacaftor, tablet, 100mg/50mg/75mg co-packaged with ivacaftor, tablet, 150mg; 50 mg/25mg/37.5 mg co-packaged with ivacaftor, tablet, 75 mg (Trikafta) (possible OEA)

For treatment of cystic fibrosis (CF) in patients who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor/tezacaftor/ivacaftor.

Initiation criteria:

- Patient is two (2) years of age or older; AND
- Confirmed diagnosis of CF; AND
- The patient is receiving treatment for CF at the time of initiation; AND
- The patient has demonstrated adherence to their prescribed CF therapeutic regimen.

Non-eligibility/discontinuation criteria:

- Patient has undergone lung transplant.

Administration criteria:

- Coverage will only be provided when prescribed by a clinical specialist affiliated with a Canadian CF centre.
- Patients will only be eligible for coverage of **ONE** CFTR modulator at a time.

The following assessments should be made prior to initiating treatment:

- Weight, height, and BMI (BMI z-scores for pediatric patients);
- Baseline measurement of FEV1 in litres and % predicted (within the past 3 months)[1];
- Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months OR number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months;
- Number of CF-related hospitalizations in the previous 6 months; AND
- Cystic Fibrosis Questionnaire Respiratory (CFQ-R) Domain score.[1]

Renewal criteria:
At the time of first renewal:

- The patient must continue to demonstrate adherence to their prescribed CF therapeutic regimen; AND
- The patient must demonstrate at least ONE of the following after six months of treatment:

- Improvement of FEV1 by 5% predicted or more, relative to baseline[1]; OR
- A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six-month period prior to initiating treatment; OR
- A decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six-month period prior to initiating treatment; OR
- Decreased number of CF related hospitalizations compared with the six-month period prior to initiating treatment; OR
- No decline in BMI (or BMI z-score for pediatrics) at six months compared with the baseline BMI assessment; OR
- Improvement by 4 points or more in the CFQ-R Respiratory Domain Score.[1]

- Additionally, for patients aged 2-5 years, renewal will be considered if the physician has determined clinical benefit from treatment with elexacaftor/tezacaftor/ivacaftor.

[1]Only required for patients six years of age and older.

Continuation criteria (subsequent renewal criteria):

- Patient is continuing to benefit from therapy with elexacaftor/tezacaftor/ivacaftor.

Renewal criteria for patients switching from alternative CFTR modulator:
For patients who switched from a different CFTR modulator after the first renewal (following at least six months of prior therapy), the patient must demonstrate at least ONE of the following after six months of treatment with elexacaftor/tezacaftor/ivacaftor:

- No decline in FEV1, relative to baseline prior to the switch to elexacaftor/tezacaftor/ivacaftor[1]; OR
- No increase in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six-month period prior to initiating treatment with elexacaftor/tezacaftor/ivacaftor; OR
- No increase in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six-month period prior to initiating treatment with elexacaftor/tezacaftor/ivacaftor; OR
- No increase in the number of CF related hospitalizations compared with the six-month period prior to initiating treatment with elexacaftor/tezacaftor/ivacaftor; OR
- No decline in BMI (or BMI z-score for pediatrics) at six months compared with the baseline BMI assessment; OR
- No reduction in the CFQ-R Respiratory Domain Score compared with baseline measurement prior to initiating treatment with elexacaftor/tezacaftor/ivacaftor.[1]

- Additionally, for patients aged 2-5 years, renewal will be considered if the physician has determined clinical benefit from treatment with elexacaftor/tezacaftor/ivacaftor.

[1] Only required for patients six years of age and older.

Continuation criteria (subsequent renewal criteria):

- Patient is continuing to benefit from therapy with elexacaftor/tezacaftor/ivacaftor.

Elidel - see pimecrolimus
Eligard – see leuprolide acetate
Elmiron - see pentosan polysulfate sodium
Elonox- see enoxaparin

eltrombopag olamine, tablet, 25mg, 50mg (Revolade and listed generic)
For the treatment of persistent or chronic immune thrombocytopenia (ITP) in patients who:

- Have a confirmed diagnosis of persistent or chronic ITP for 3 or more months; AND,
- Are under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP; AND,
- Have failed first-line therapy with corticosteroids and/or IVIG[1]; AND,
- Have an ongoing need for therapy with a platelet count of:
  - Adults: $<30 \times 10^9$/L; OR,
  - Adults: $<50 \times 10^9$/L at high-risk of bleeding; OR,
  - Pediatrics: $<50 \times 10^9$/L.

Initial approval duration: 6 months

Notes: Dosage: 50 mg once daily to a maximum of 75 mg once daily.

Renewal:

Ongoing coverage of eltrombopag will be considered for individuals who remain under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP AND have:

- A clinically meaningful elevation in platelet count above baseline; AND,
- Documented clinical benefit, as demonstrated by outcomes such as fewer rescue treatments, reduced emergency visits, or reduced clinically significant bleeding episodes; AND,
- EITHER:
  - A platelet count of ≥30 x 10^9/L; OR,
  - A doubling of baseline platelet count

[1]Failure of first-line therapy is defined as no platelet count response or transient response only, or a contraindication or intolerance to first-line therapy.

elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, tablet, 150mg/150mg/200mg/300mg (Stribild) (possible OEA)

As a complete regimen for antiretroviral treatment-naïve HIV-1 infected patients.
This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, tablet, 150mg/150mg/200mg/10mg (Genvoya) (possible OEA)

For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 12 years of age and older (and weighing ≥ 35kg) with no known mutations associated with resistance to the individual components.
This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Emgality - see galcanezumab

empagliflozin, tablet, 10mg, 25mg (Jardiance) (possible OEA)

a) For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.
b) To reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes who meet the following criteria:
   - Inadequate glycemic control despite an adequate trial of metformin; AND
   - Established cardiovascular disease defined as one of the following:
     - History of myocardial infarction;
     - 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 either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection;
     - Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease;
     - History of ischemic or hemorrhagic stroke;
     - Occlusive peripheral artery disease.

empagliflozin/metformin HCl, tablet, 5mg/500mg, 5mg/850mg, 5mg/1000mg. 12.5mg/500mg, 12.5mg/850mg, 12.5mg/1000mg (Synjardy) (possible OEA)

For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

a) To reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes who meet the following criteria:
   - Inadequate glycemic control despite an adequate trial of metformin; AND
   - Established cardiovascular disease defined as one of the following:
     - History of myocardial infarction;
     - 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 either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection;
     - Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease;
     - History of ischemic or hemorrhagic stroke;
     - Occlusive peripheral artery disease.

Empaveli - see pegcetacoplan

emtricitabine/rilpivirine/tenofovir disoproxil fumarate, tablet, 200mg/25mg/300mg (Complera) (possible OEA)

For the treatment of human immunodeficiency virus type 1 (HIV-1) in antiretroviral treatment-naïve patients, or to replace the three components given as dual or triple therapy.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

emtricitabine/rilpivirine/tenofovir alafenamide, tablet, 200mg/25mg/25mg (Odefsey) (possible OEA)

As a complete regimen for the treatment of adults infected with HIV-1 with no known mutations associated with resistance to the non-nucleoside reverse-transcriptase inhibitor (NNRTI) class, tenofovir or FTC, and with a viral load < 100,000 copies/mL.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Enablex - see darifenacin
Enerzair Breezhaler- see indacaterol/glycopyrronium/mometasone furoate

enfuvirtide, powder for solution, 108mg/vial (vial) (Fuzeon) (possible OEA)

For management of HIV disease.

This drug should be used under the direction of an HIV specialist.

enoxaparin, solution for injection (pre-filled syringe), 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Axberi); 120mg/0.8mL, 150mg/1mL (Axberi HP);
enoxaparin, solution for injection, pre-filled syringe 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/1.0mL (Elonox); enoxaparin, solution for injection, pre-filled syringe 120mg/0.8 mL, 150mg/1mL (Elonox HP);
enoxaparin, solution for injection (pre-filled syringe), 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Inclunox); 120mg/0.8mL, 150mg/1mL (Inclunox HP);
enoxaparin, solution for injection (pre-filled syringe), 20mg/0.2mL, 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Noromby); 120mg/0.8mL, 150mg/mL (Noromby HP);
enoxaparin sodium, solution for injection (pre-filled syringe), 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Redesca); solution for injection (multiple dose vial), 300mg/3mL; solution for injection (pre-filled syringe), 120mg/0.8mL, 150mg/mL (Redesca HP)

(a) For treatment of venous thromboembolism for up to 10 days.
(b) For prophylaxis following total knee arthroplasty for up to 35 days.
(c) For major orthopedic trauma for up to 10 days (treatment duration may be reassessed).
(d) For long-term outpatient prophylaxis in patients who are pregnant.
(e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
(f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
(g) For treatment of pediatric patients where anticoagulant therapy is required and warfarin therapy cannot be administered.
(h) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
(i) For prophylaxis following abdominal, thoracic, esophageal or pelvic surgery for up to 28 days.

Enspryng- see satralizumab

entecavir, tablet, 0.5mg (Baraclude, and listed generics) (possible OEA)

For management of hepatitis B.

Note: This product should be used in consultation with a specialist in this area.

Entocort - see budesonide
Entresto - see sacubitril/valsartan
Entyvio - see vedolizumab
Envarsus PA - see tacrolimus
Epclusa –see sofosbuvir/velpatasvir
Epidiolex – see cannabidiol

eplerenone, tablet, 25mg, 50mg (Inspra, and listed generics)

For treatment of chronic heart failure in patients who have previously tried spironolactone.

Patients should be on optimal therapy with an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB) or an angiotensin receptor-neprilysin inhibitor (ARNI), as well as a beta blocker.

eplontersen, pre-filled autoinjector, 45mg/0.8mL (100mcg) (Wainua)

For the treatment of adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:

- Polyneuropathy disability [PND][1] stage I to ≤ IIIB, or
- Familial amyloidotic polyneuropathy [FAP][2] stage I or II.

Patients must be under the care of a specialist with experience in the diagnosis and management of hATTR-PN.

Exclusion Criteria (at therapy initiation):

- Patients exhibiting severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV); or
- Patients who have previously undergone a liver transplant; or
- Patients receiving other interfering ribonucleic acid drugs (such as patisiran or vutrisiran) or transthyretin stabilizers (such as tafamidis); or
- Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care[3].

Initial approval duration: Nine (9) months

Discontinuation Criteria:

Treatment with eplontersen should be reviewed nine months after the initial approval, and then at least every six months thereafter, to determine the continued clinical benefit for the patient.

Coverage will be discontinued if the patient is:

- Permanently bedridden and dependent on assistance for basic activities of daily living, or
- Receiving end-of-life care[3].

After the initial nine (9) month approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:

[1]PND is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Sensory disturbances but preserved walking capability
- Stage II – Impaired walking capacity but ability to walk without a stick or crutches
- Stage IIIA – Walking with the help of one stick or crutch
- Stage IIIB – Walking with the help of two sticks or crutches
- Stage IV – Confined to a wheelchair or bedridden.

[2]FAP is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Unimpaired ambulation; mostly mild sensor, motor, and autonomic neuropathy in the lower limbs
- Stage II – Assistance with ambulation required, mostly moderate impairment progression to the lower limbs, upper limbs, and trunk
- Stage III – Wheelchair bound or bedridden; severe sensory, motor, and autonomic involvement of all limbs.

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g., management of symptoms such as pain, nausea and stress).

epoetin alfa, pre-filled syringe, 1,000 IU/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/0.5mL, 30,000IU/0.75mL, 40,000IU/mL (Eprex)

For treatment of:

(a) Anemia in chronic renal disease patients prior to initiation of dialysis.
Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status coverage is not required for S.A.I.L. patients.
(b) Anemia in AIDS patients.
(c) Anemia in transplant patients.

The following products are not interchangeable. When requesting coverage, please state which specific epoprostenol product is being prescribed to avoid administrative and assessment delays.

- **epoprostenol, powder for solution, 0.5mg/vial, 1.5mg/vial (Flolan)**
- **epoprostenol, powder for solution, 0.5mg/vial, 1.5mg/vial (Caripul)**

For treatment of pulmonary hypertension on the recommendation of a specialist.
Please contact the Drug Plan for billing information.

Eprex - see epoetin alfa

eptinezumab, solution for intravenous infusion, 100mg/1mL; 1mL vial, 3mL vial (mg) (Vyepti)
For patients who have a confirmed diagnosis of either:
1) Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months; OR
2) Chronic migraine: Headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:
• The patient must have experienced an inadequate response[1], intolerance or contraindication to at least two oral prophylactic migraine medications[2] of different classes, and;
• The patient must be under the care of a prescriber who has appropriate experience in the management of migraine headaches, and;
• The prescriber must provide the number of migraine days per month with the EDS application.
Initial approval duration = Six (6) months

Initial Renewal criteria:
Reduction of at least 50% in the average number of migraine days per month compared to baseline.
Renewal duration = Six (6) months

Subsequent Renewals:
Maintenance of 50% reduction in the average number of migraine days per month from baseline.
EDS approval will not be provided if used in combination with alternative anti-calcitonin gene-related peptide therapies.

[1] Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.
[2] Oral prophylactic medication alternatives include:
- beta blockers or candesartan
- pregabalin or gabapentin
- serotonin and norepinephrine reuptake inhibitors (SNRIs)
- sodium valproate or divalproex sodium
- topiramate
- tricyclic antidepressants (TCAs)
- verapamil or flunarizine

Please contact the Drug Plan for billing information.

Erelzi - see etanercept
Esbriet - see pirfenidone
eslicarbazepine acetate, tablet, 200mg, 400mg, 600mg, 800mg (Aptiom and listed generics)
For the adjunctive treatment of refractory partial-onset seizures in patients who meet all of the following:
a) Are currently receiving two or more antiepileptic drugs; AND
b) Less costly antiepileptic drugs are ineffective or inappropriate; AND
c) The medication is being used under the direction of a neurologist.
Note: *Patients should have tried and failed at least two less costly antiepileptic drugs.*

esomeprazole magnesium trihydrate, delayed release tablet, 20mg, 40mg (Nexium, and listed generics)
(a) For a maximum of 8 weeks in treatment of peptic ulcer disease, which includes gastric and duodenal ulcers, in patients not responding or experiencing unusual or severe adverse reactions to a reasonable trial with H_2 blockers, sucralfate or misoprostol. *Coverage for a repeat treatment will be approved only after a 3-6 month period of no treatment or prophylaxis with an H_2 blocker, sucralfate or misoprostol.*
(b) For treatment of symptoms of gastroesophageal reflux disease (GERD). *It was noted that patients with non-erosive GERD could potentially be reduced to stop-down therapy with an H_2 antagonist depending on symptom resolution.*
(c) For treatment of severe erosive esophagitis and Zollinger-Ellison Syndrome.
(d) For 14-day eradication of H. pylori-related infections in individuals with peptic ulcer disease. *Provision will be made for additional coverage in treatment failures.*

(e) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*
(f) For a maximum of 8 weeks in patients discharged from hospital, on a proton pump inhibitor, following a gastroduodenal bleed.

etanercept, 50mg/mL, pre-filled syringe; pre-filled autoinjector (Brenzys)
etanercept, 25mg/0.5mL, pre-filled syringe, 50mg/mL, pre-filled syringe; pre-filled autoinjector (Erelzi)
etanercept, 50mg/mL, pre-filled syringe; pre-filled autoinjector (Rymti)

Note: These products are not interchangeable. When requesting coverage, please state which specific etanercept product is being prescribed to avoid administrative and assessment delays.

Indication	Criteria
Rheumatoid arthritis	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. **Note:** This product should be used in consultation with a specialist in this area.
Psoriatic arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.
Juvenile idiopathic arthritis	For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs). **Note:** This product should be used in consultation with a specialist in this area.
Ankylosing Spondylitis	**Initial:** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration: 12 weeks **First Renewal:** Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval Duration: One Year **Note:** Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. *Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.* **Note:** This product should be used in consultation with a specialist in this area.

ethacrynic acid, tablet, 25mg (Edecrin) (possible OEA)
For treatment of patients intolerant to furosemide.

Etibi – see ethambutol

ethambutol, tablet, 100mg, 400mg (Etibi)
For treatment of non-TB mycobacterium infection (NTMI), when prescribed in consultation with an infectious disease specialist.

Note: Contact TB Prevention and Control Saskatchewan if these medications are being prescribed for treatment of tuberculosis.

etravirine, tablet, 100mg, 200mg (Intelence) (possible OEA)

For use in combination with other antiretroviral agents for the treatment of HIV-1 strains resistant to multiple antiretroviral agents, including non-nucleoside reverse transcriptase inhibitors. *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*

etrasimod, tablet, 2mg (Velsipity)

For the treatment of ulcerative colitis in patients unresponsive to high dose steroids.
Initial clinical response should be assessed after 12 weeks of therapy.

Ongoing coverage will only be provided for those who respond to therapy.

Note: This product should be used in consultation with a specialist in this area.
This product will not be reimbursed for combination use with other escalated ulcerative colitis treatments (such as biologics and janus kinase inhibitors).

evinacumab, solution for infusion, 150mg/mL (2.3mL vial) (mg) (Evkeeza)

Initiation Criteria:

For the treatment of adult and pediatric patients (5 years of age and older) with a clinically[1] or genetically[2] confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) who:

- Have elevated low density lipoprotein cholesterol (LDL-C)[3] despite receiving an adequate trial of other accessible lipid-lowering therapies[4]; AND,
- Are under the care of a specialist with experience in the diagnosis and management of HoFH.

[1] Clinical Diagnostic Criteria:
A clinically confirmed diagnosis of HoFH is defined as:

- Untreated total cholesterol > 12.93 mmol/L and triglycerides < 3.39 mmol/L; AND,
  - Both parents have documented total cholesterol > 6.47 mmol/L, indicative of heterozygous familial hypercholesterolemia (HeFH); OR,
  - Cutaneous or tendinous xanthoma before the age of 10 years.

[2] Genetic Diagnostic Criteria:
A genetically confirmed diagnosis of HoFH is defined as:

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

[3] Elevated LDL-C levels are defined as:

- Adult patients: LDL-C > 1.8 mmol/L
- Pediatric patients: LDL-C > 3.4 mmol/L

[4] Accessible lipid-lowering therapies may include a maximally tolerated statin, ezetimibe, and/or a PCSK9 inhibitor.

Initial Approval Duration: 7 months

Renewal Criteria:

Ongoing coverage of evinacumab will be considered for individuals who:

- Experience a reduction in LDL-C that is considered clinically beneficial by the treating physician; AND,
- Remain under the care of a specialist with experience in the diagnosis and management of HoFH.

Renewal Duration: 12 months

NOTE: The patient's LDL-C must be provided at baseline and with each renewal request.

Evenity - see romosozumab
Evista - see raloxifene HCl
Evkeeza- see evinacumab

evolocumab, solution for injection, 140mg/mL (Repatha)

Indication	Criteria

Heterozygous Familial Hypercholesterolemia (HeFH)	For the treatment of patients with a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)[1] who are unable to reach Low Density Lipoprotein Cholesterol (LDL-C) target (i.e., LDL-C <2.0mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite either: • A confirmed adherence to the maximally tolerated dose of at least two different statins, with one of the statins taken along with ezetimibe for at least a total of 3 months; OR, • A confirmed adherence to a high dose statin (i.e., atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe for at least a total of 3 months. Coverage will not be provided for use in combination with other proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors. LDL-C should be checked at least annually while on continued treatment with evolocumab. [1]Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) is to be made using the Simon Broome or Dutch Lipid Network criteria or genetic testing.
Atherosclerotic Cardiovascular Disease	For the treatment of adult patients with a recent acute coronary syndrome (ACS) event who continue to have elevated cholesterol levels (as defined in the criteria) despite either: A) A confirmed adherence to an adequate trial of maximally tolerated dose of statin[1] **with or without** ezetimibe, with the following cholesterol levels: • LDL-C > 2.2 mmol/L; AND/OR • non-HDL-C > 2.9 mmol/L; AND/OR • ApoB > 0.8 g/L. [1]An adequate trial of statin will be defined as a moderate-to-high dose statin (e.g., atorvastatin 20mg or greater; or rosuvastatin 10mg or greater) for at least 4 weeks. B) A confirmed adherence to an adequate trial of maximally tolerated dose of statin **and** ezetimibe[2], with the following cholesterol levels: • LDL-C level between 1.8 mmol/L and 2.2 mmol/L; AND/OR, • non-HDL-C between 2.6 mmol/L and 2.9 mmol/L; AND/OR, • ApoB between 0.7g/L and 0.8 g/L. [2]An adequate trial of statin **and** ezetimibe will be defined as a moderate-to-high dose statin (e.g., atorvastatin 20mg or greater; or rosuvastatin 10mg or greater) in combination with ezetimibe for at least 4 weeks.

Evrysdi- see risdiplam
Exelon - see rivastigmine
Exjade - see deferasirox
Eylea - see aflibercept
Eylea HD – see aflibercept

faricimab, pre-filled syringe, 6mg/0.5mL (mg) (Vabysmo) (possible OEA)

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	For the treatment of mild to moderate neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections. [1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease. The interval between doses should be no shorter than eight weeks (following the first four initiation doses that are given every four weeks). Treatment with faricimab should be continued only in people who maintain adequate response to therapy.

	Faricimab should be permanently discontinued if any one of the following occurs: (a) Reduction in best corrected visual acuity (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. (b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both. (c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment cannot be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Initiation of treatment is to begin with either 6 loading doses every 4 weeks followed by injections every 8 weeks, or every 4 weeks for at least the first 4 doses followed by a dosing treat and extend approach of up to every 16 weeks based on patient outcomes. Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after five consecutive treatments. (e) After the macular edema is resolved, the interval between two doses should not be shorter than every 8 weeks. (f) Patients responding to treatment should be monitored at regular intervals to assess visual acuity AND retinal thickness. (g) Injection will be by a qualified ophthalmologist with experience in intravitreal injections. **Note:** Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.
Retinal Vein Occlusion (RVO)	For the treatment of visual impairment due to clinically significant macular edema secondary to retinal vein occlusion for patients meeting all of the following: (a) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less. (b) The interval between two doses should not be shorter than 4 weeks. (c) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity. (d) Treatment should be discontinued if there is no improvement after 6 months of initial treatment; and (e) Injection will be by a qualified ophthalmologist with experience in administering intravitreal injections. **Note:** Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected**.**

Fasenra - see benralizumab

febuxostat, tablet, 80mg (listed generics)

For the treatment of symptomatic gout in patients with a documented hypersensitivity to allopurinol.

Hypersensitivity to allopurinol is a rare condition that is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy and hematological abnormalities (eosinophilia, atypical lymphocytes). *NOTE: Intolerance or lack of response to allopurinol will not be covered by this criteria.*

fentanyl, transdermal system, 12ug/hr, 25ug/hr, 37ug/hr, 50ug/hr, 75ug/hr, 100ug/hr (listed generics) (possible OEA)

For treatment of patients:

(a) Intolerant to, or unable to take, oral sustained-release strong opioids; or

(b) As an alternative to subcutaneous narcotic infusion therapy.

Pharmacists are not required to call the Drug Plan if a prescription has been filled for an oral sustained release or injectable opioid, such as hydromorphone, morphine, or oxycodone in the past 6 months.

Ferrlecit - see iron ferric sodium gluconate complex
Ferriprox - see deferiprone
Ferriprox MR – see deferiprone

fesoterodine fumerate, extended release tablet, 4mg, 8mg (Toviaz, and listed generics) (possible OEA)
For treatment of patients intolerant to oxybutynin chloride, solifenacin succinate or tolterodine l-tartrate.

fidaxomicin, film-coated tablet, 200mg (Dificid)
For the treatment of patients with a confirmed diagnosis of Clostridioides difficile infection (CDI) who:
- Have failed oral vancomycin; OR,
- Are experiencing a recurrence of CDI following treatment with oral vancomycin; OR,
- Are allergic to, or intolerant of oral vancomycin; OR,
- Have initiated fidaxomicin while hospitalized.

filgrastim, injection solution, pre-filled syringe 300ug/0.5mL, 480ug/0.8mL (Grastofil)
filgrastim, injection solution, pre-filled syringe 300ug/0.5mL, 480ug/0.8mL; injection solution vial, 300ug/1mL, 480ug/1.6mL (Nivestym)
filgrastim, injection solution, pre-filled syringe 300ug/0.5mL, 480ug/0.8mL (Nypozi)
For patients requiring filgrastim for the treatment of:
(a) Congenital, cyclic or idiopathic neutropenia in patients with absolute neutrophil counts of less than or equal to 500.
(b) Non-cancer patients who have undergone bone marrow transplantation.
(c) HIV patients with absolute neutrophil counts of less than 500.
Note: All EDS requests for filgrastim will be assessed for coverage of a listed filgrastim biosimilar option.

finerenone, tablet, 10mg, 20mg (Kerendia)
Initiation Criteria
As an adjunct to standard of care therapy[1] in adults with chronic kidney disease (CKD) **AND** type 2 diabetes (T2D) who have:
- an estimated glomerular filtration rate (eGFR) level **of at least** 25mL/min/1.73m^2, and;
- albuminuria level **of at least** 30mg/g (or 3 mg/mmol).

In addition, patients **must not**:
- have chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV, and;
- be receiving an alternative mineralocorticoid receptor antagonist (MRA).

Finerenone must be prescribed in consultation with a nephrologist, or by other prescribers who have experience in the diagnosis and management of patients with CKD and T2D.
Initial approval duration: 6 months

Renewal Criteria
Patients may be considered for renewal if:
- The eGFR is maintained at or above 15mL/min/1.73m^2, and
- The urinary albumin to creatinine ratio (UACR) has NOT increased from baseline level while receiving finerenone, and
- The medication continues to be prescribed in consultation with a nephrologist, or by other prescriber with experience in the diagnosis and management of patients with CKD and T2D.

Renewal approval duration: 1 year

[1] Standard of care is defined as maximally tolerated doses of angiotensin converting enzyme inhibitor (ACE) or an angiotensin receptor blocker (ARB), in combination with a sodium glucose cotransporter 2 inhibitor (SGLT2), unless SGLT2 inhibitors are contraindicated or not tolerated

fingolimod hydrochloride, capsule, 0.5mg (Gilenya, and listed generics)
See Appendix D

Firazyr – see icatibant acetate
Firdapse – see amifampridine phosphate
Flexitec - see cyclobenzaprine HCl

Flolan - see epoprostenol

flunarizine HCl, capsule, 5mg (listed generics)

For prophylaxis of migraines in cases where alternative prophylactic agents have not been effective.

fluticasone furoate/umeclidinium/vilanterol, inhalation powder, 100mcg/62.5mcg/25mcg (Trelegy Ellipta) (possible OEA)

For the treatment of chronic obstructive pulmonary disease (COPD):

- In patients who are not controlled on optimal dual inhaled therapy (i.e., long-acting muscarinic antagonist [LAMA]/long-acting beta-2 agonist [LABA] or inhaled corticosteroid [ICS]/LABA); OR
- To replace existing triple therapy regimens currently achieved with more than one inhaler; OR
- In patients initiated on single agent inhaled triple therapy (SITT) while in hospital; OR
- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a high risk of acute exacerbation of COPD (AECOPD)[1].

[1]Patients are considered high risk of AECOPD if they have ≥2 moderate AECOPD (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids), or ≥1 severe AECOPD in the last year (severe AECOPD is an event requiring hospitalization or an emergency department [ED] visit).

formoterol fumarate, powder for inhalation (package), 6ug/dose, 12ug/dose (Oxeze Turbuhaler) (possible OEA)

For treatment of:
(a) Asthma uncontrolled on concurrent inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
(b) For treatment of COPD

formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ug/200ug (Symbicort Turbuhaler) (possible OEA)

For the treatment of:
(a) Asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
(b) Chronic obstructive pulmonary disease (COPD):

- In patients with concurrent or past use of long-acting beta-2 agonist (LABA) or long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients initiated on inhaled corticosteroid (ICS)/LABA combination therapy in hospital; OR
- In patients with concomitant asthma and moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD)[1] risk.

[1]Patients are considered low risk of AECOPD if they have ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) and did not require a hospital admission or emergency department (ED) visit.

Foquest- see methylphenidate HCl
Fosamax - see alendronate sodium
Fosavance - see alendronate sodium/vitamin D_3 (cholcalciferol)

foslevodopa/foscarbidopa, solution for subcutaneous infusion, 240mg/12mg per mL (10mL vial) (Vyalev)

For the treatment of patients with advanced levodopa-responsive Parkinson's disease (PD) who do not have satisfactory control of severe, debilitating motor fluctuations and hyperkinesia or dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products, and meet the following:

Initiation Criteria:

1. The patient experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day).[1]
2. The patient has received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
3. The patient has failed adequate trials of each of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgement of the prescriber: a catechol-O-methyltransferase (COMT) inhibitor, a dopamine agonist, a monoamine oxidase (MAO-B) inhibitor, and amantadine.
4. The patient and/or caregiver are able to demonstrate correct understanding and use of the delivery system.
5. The patient does not have severe psychosis or dementia.
6. Vyalev is being prescribed by a neurologist who is a movement disorder subspecialist or who has expertise in managing advanced PD.

Initial approval duration = 12 months

Renewal Criteria:

- The patient continues to benefit from treatment. The patient should continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing, bothersome levodopa-induced dyskinesias, along with an improvement in the related disability.
- The patient's care continues to be managed by, or in, consultation with, a neurologist who is a movement disorder subspecialist or who has expertise in managing advanced PD.

Renewal duration = 1 year

Note:

This product is administered with a Vyafuser infusion pump.
The product manufacturer will provide patients with the necessary equipment needed for product administration.

[1]Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a neurologist who is a movement disorder subspecialist or who has expertise in managing advanced PD and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.

Fragmin - see dalteparin sodium
Fraxiparine - see nadroparin calcium
Fraxiparine Forte - see nadroparin calcium

fremanezumab, pre-filled syringe; pre-filled autoinjector, 225 mg/1.5 mL, (Ajovy)

For patients who have a confirmed diagnosis of either:

1) Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months; OR
2) Chronic migraine: Headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:

- The patient must have experienced an inadequate response[1], intolerance or contraindication to at least two oral prophylactic migraine medications[2] of different classes, and;
- The patient must be under the care of a prescriber who has appropriate experience in the management of migraine headaches, and;
- The prescriber must provide the number of migraine days per month with the EDS application.

Initial approval duration = Six (6) months

Initial Renewal criteria:

Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Renewal duration = Six (6) months

Subsequent Renewals:

Maintenance of 50% reduction in the average number of migraine days per month from baseline.
EDS approval will not be provided if used in combination with alternative anti-calcitonin gene-related peptide therapies.

[1] Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.
[2] Oral prophylactic medication alternatives include:

- beta blockers or candesartan
- pregabalin or gabapentin
- serotonin and norepinephrine reuptake inhibitors (SNRIs)
- sodium valproate or divalproex sodium
- topiramate
- tricyclic antidepressants (TCAs)

- verapamil or flunarizine

Fuzeon - see enfuvirtide
Fycompa - see perampanel

galantamine hydrobromide, extended release capsule, 8mg, 16mg, 24mg (listed generics)

For the treatment of Alzheimer's disease in patients with:

- a Mini Mental State Exam (MMSE) score between 10-26; AND/OR,
- a Montreal Cognitive Assessment (MoCA) score between 4-16.

Initial Approval Duration**:** 6 months

NOTE: Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and MOCA are administered. Drugs with anticholinergic activity are not to be used concurrently with galantamine therapy.

Renewal Criteria:

To qualify for renewal of galantamine patients must continue to have an MMSE score ≥10 and/or MoCA score ≥4.

Renewal Duration**:** 2 years

galcanezumab, solution for subcutaneous injection, 120 mg/mL, pre-filled syringe, pre-filled pen (Emgality)

For patients who have a confirmed diagnosis of either:

1) Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months; **OR**
2) Chronic migraine: Headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

Initiation criteria:

• The patient must have experienced an inadequate response[1], intolerance or contraindication to at least two oral prophylactic migraine medications[2] of different classes, **AND**;
• The patient must be under the care of a prescriber who has appropriate experience in the management of migraine headaches, **AND**;
• The prescriber must provide the number of migraine days per month with the EDS application.

Initial approval duration = Six (6) months

Initial Renewal criteria:
Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Renewal duration = Six (6) months

Subsequent Renewals:

Maintenance of 50% reduction in the average number of migraine days per month from baseline.
EDS approval will not be provided if used in combination with alternative anti-calcitonin gene-related peptide therapies.

[1] Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.
[2] Oral prophylactic medication alternatives include:

- beta blockers or candesartan
- pregabalin or gabapentin
- serotonin and norepinephrine reuptake inhibitors (SNRIs)
- sodium valproate or divalproex sodium
- topiramate
- tricyclic antidepressants (TCAs)
- verapamil or flunarizine

garadacimab, pre-filled pen, 200mg/1.2mL (mg) Andembry

For the routine prevention of attacks of hereditary angioedema (HAE) in patients 12 years of age or older with HAE type I or II[1] diagnosed by a specialist physician experienced in the diagnosis and management of HAE, who:

- Have experienced at least three HAE attacks within any four-week period before initiating garadacimab therapy that required the use of an acute injectable treatment.

- Applications must include the baseline number of attacks requiring acute injectable treatment in the three months prior to initiation of garadacimab [2].

- Will not be using garadacimab in combination with other medications used for long-term prophylactic treatment of angioedema[3] (e.g., C1 esterase inhibitors, lanadelumab, or berotralstat); AND

- Will not use a dose of garadacimab that is more than 200mg once monthly (following the loading dose).

Initial approval duration: 3 months

Renewal criteria

Renewal requests[4] may be considered:

- After treatment with garadacimab for three months if there has been a 50% or more reduction[2] in the number of HAE attacks where acute injectable treatment was received in the first three months of treatment with garadacimab compared to the rate of attacks observed before starting garadacimab; OR

- For patients with continued response[2] defined as maintenance of 50% or more reduction from baseline with no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to starting treatment with garadacimab; AND

- Patients must continue to:
  - Be under the care of a specialist experienced in the diagnosis and management of angioedema; AND
  - Not use garadacimab in combination with other long-term prophylactic angioedema treatments (e.g., C1 esterase inhibitors, lanadelumab, or berotralstat); AND
  - Not use a dose of garadacimab that is more than 200mg once monthly even in cases of inadequate response or loss of response.

Renewal duration: 6 months

Notes:

[1]A definitive diagnosis of HAE type I and II requires testing C1 esterase level and activity, as well as C1q levels (to rule out acquired angioedema for which garadacimab is not indicated).

[2]To determine which patients would be eligible for reimbursement of garadacimab, the current attack rate may be used for patients who are not receiving long-term prophylactic treatment and a historical attack rate may be used for those who are already receiving long-term prophylactic treatment and intend to transition to garadacimab.

[3]Patients on long-term prophylactic treatment will continue to require access to on-demand treatments that are used in the management of acute attacks.

[4]Coverage will be discontinued for patients who no longer meet the renewal criteria.

gatifloxacin, ophthalmic solution, 0.3% (Zymar and listed generics) (possible OEA)

For treatment of:

(a) Ophthalmic infections caused by gram-negative organisms.

(b) Ophthalmic infections unresponsive to alternative agents.

Genotropin - see somatropin

Genvoya – see elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide

Gilenya - see Appendix D

Givlaari- see givosiran

givosiran, 1mL vial for subcutaneous injection, 189mg/mL (mg) (Givlaari)

Initiation Criteria

For the treatment of adult patients with acute hepatic porphyria (AHP) where ALL of the following have been met:

- In the 12 months prior to givosiran initiation, the patient has experienced 4 or more AHP attacks requiring either hospitalization, an urgent health care visit (including an emergency department or infusion centre), or administration of intravenous hemin for acute management; AND
- Givosiran will be prescribed by a specialist experienced in the management of AHP; AND
- Givosiran will not be used in combination with prophylactic hemin.

Requests must include the baseline number of attacks requiring medical attention (as defined above) in the 12 months prior to initiation of givosiran.

Approval duration: 13 months

Renewal Criteria

- For consideration of coverage renewal, patients must experience a reduction in their annualized attack rate compared to the rate observed in the 12 months prior to givosiran initiation.

Renewal duration**:** 12 months

glatiramer acetate, injection, 20mg (pre-filled syringe) [Glatect and Glatiramer Acetate Injection (non interchangeable)] - See Appendix D

glecaprevir/pibrentasvir, tablet, 100mg/40mg; granules, 50mg/20mg (sachet) (Maviret) (possible OEA)

For the treatment of hepatitis C virus (HCV) infection in individuals who:

- Have laboratory confirmed quantitative HCV RNA value with the last 12 months; AND
- Treatment is prescribed by a hepatologist, gastroenterologist, or an infectious disease specialist or other prescriber experienced in the treatment of hepatitis C as determined by the Drug Plan.

The following treatment regimens will be reimbursed:

Treatment Naïve (Acute or Chronic HCV):

Genotype	Treatment Regimen and Duration
1, 2, 3, 4, 5 or 6	8 weeks

Treatment Experienced[1] Chronic HCV:

Genotype	Previous Treatment Received	Treatment Regimen and Duration	
Genotype 1, 2, 4, 5 or 6	PRS (peg)interferon, ribavirin, and/or sofosbuvir: - (peg)interferon/ribavirin, - sofosbuvir + (peg)interferon/ribavirin, - sofosbuvir + ribavirin	8 weeks without cirrhosis	12 weeks with cirrhosis[2]
Genotype 1	NS3/4A PI (NS5A inhibitor-naïve) - simeprevir + sofosbuvir, or - simeprevir + (peg)interferon/ribavirin, or - boceprevir + (peg)interferon/ribavirin, or - telaprevir + (peg)interferon/ribavirin	12 weeks	
Genotype 1	NS5A (NS3/4A inhibitor naïve) - daclatasvir + sofosbuvir, or - daclatasvir + (peg)interferon/ribavirin, or - ledipasvir + sofosbuvir	16 weeks	
Genotype 3	PRS (peg)interferon, ribavirin, and/or sofosbuvir: - (peg)interferon/ribavirin, - sofosbuvir + (peg)interferon/ribavirin, - sofosbuvir + ribavirin	16 weeks[2]	

[1]Treatment experienced is defined by the Health Canada Product Monograph based on the genotype treated and the scenario in which the previous drug(s) have been used.

[2]See product monograph for dosing recommendations in patients with a liver or kidney transplant.

Exceptional case-by-case consideration:

- Retreatment for direct acting antiviral failures will be considered on a case-by-case basis. Funding considerations will be based on recommendations from approved clinical practice guidelines. The specific drug regimen may include combination therapy involving a different company's products.

glycerol phenylbutyrate, oral liquid, 1.1g/mL (Ravicti)

For the chronic management of urea cycle disorders (UCDs).

Medication should be prescribed in consultation with a specialist in this area.

golimumab, 50mg/0.5mL, pre-filled syringe; autoinjector (mg) (Simponi)

(a) For treatment of ankylosing spondylitis (AS) according to the following criteria:

Initial:

For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control.

This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS.

Approval Duration: 12 weeks

First Renewal:

Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units.

Approval Duration: One Year

Subsequent renewal:

Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score.

Approval Duration: One Year

Note: Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination

(b) For the treatment of psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

(c) For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in the area. (Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated).

golimumab, 50mg/0.5mL, 100mg/1.0mL, pre-filled syringe; autoinjector (mg) (Simponi)

For treatment of ulcerative colitis in patients unresponsive to high dose steroids.

Note: Clinical response should be assessed after three months of therapy. Ongoing coverage will only be provided for those who respond to therapy.

Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

golimumab, 50mg/4.0mL solution for infusion (mg) (Simponi I.V.)

For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in the area. (Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated)

goserelin acetate, 3.6mg/syringe (Zoladex)

For treatment of:

(a) Endometriosis. (*Coverage may be repeated after a six month lapse, for another 6 month course).*

(b) Menorrhagia in preparation for endometrial ablation, and:

(c) For pre-treatment of uterine fibroids prior to surgical removal.

Coverage will be provided for a maximum of 6 months.

Grastofil - see filgrastim

guanfacine, extended release tablet, 1mg, 2mg, 3mg, 4mg (listed generics)

For the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 years to 17 years who:

- Will be using guanfacine monotherapy following significant/intolerable adverse events to an amphetamine-based psychostimulant AND a methylphenidate-based psychostimulant, or have a contraindication to these agents; OR,
- Have demonstrated suboptimal response to psychostimulants and will be using guanfacine as adjunctive therapy to a psychostimulant.

guselkumab, autoinjector, pre-filled pen, pre-filled syringe, 100mg/mL (mg); pre-filled pen, 200mg/2mL (mg) (Tremfya); solution for I.V. infusion, 10mg/mL vial (mg) (Tremfya I.V.)

Indication	Criteria
Crohn's Disease (solution for I.V. infusion 10mg/mL vial) (100mg/mL autoinjector, 100mg/mL pre-filled pen, 100mg/mL pre-filled syringe) (200mg/2 mL pre-filled pen)	For the treatment of moderate to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy. Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and janus kinase inhibitors, etc.) for Crohn's disease. Note: This product should be used in consultation with a specialist in this area.
Plaque Psoriasis (100mg autoinjector, 100mg/mL pre-filled pen, 100mg/mL pre-filled syringe only)	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy. **Note**: This product should be used in consultation with a specialist in this area. • Guselkumab should not be used in combination with other biologic disease modifying anti-rheumatic drugs (bDMARDs), or phosphodiesterase 4 (PDE4) inhibitors, etc.).
Psoriatic Arthritis (100mg/mL autoinjector, 100mg/mL pre-filled pen, 100mg/mL pre-filled syringe only)	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note**: This product should be used in consultation with a specialist in this area. • Guselkumab should not be used in combination with other biologic disease modifying anti-rheumatic drugs (bDMARDs), or target specific DMARDS (tsDMARDS) (such as janus kinase (JAK) inhibitors, phosphodiesterase 4 (PDE4) inhibitors, etc.).
Ulcerative Colitis (solution for I.V. infusion 10mg/mL vial) (100mg/mL autoinjector, 100mg/mL pre-filled pen, 100mg/mL pre-filled syringe) (200mg/2 mL pre-filled pen)	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after the induction regimen. Ongoing coverage will only be provided for those who respond to therapy. **Note:** This product should be used in consultation with a specialist in this area.

Hadlima - see adalimumab
Harvoni - see ledipasvir/sofosbuvir
Hemangiol - see propanolol
Hepsera - see adefovir dipivoxil
Holkira Pak - see ombitasvir/paritaprevir/ritonavir and dasabuvir
Hulio - see adalimumab
Humatrope - see somatropin
Hydrea - see hydroxyurea
Hyrimoz - see adalimumab

hydroxyurea, capsule, 500mg (Hydrea, and listed generics)
For non-oncology conditions.

icatibant acetate, subcutaneous injection, 10mg/mL (Firazyr and listed generics)

For the treatment of acute attacks of hereditary angioedema (HAE) in adults with lab confirmed C1-esterase inhibitor deficiency (type I or type II) if the following conditions are met:

- Treatment of non-laryngeal attacks of at least moderate severity, OR
- Treatment of acute laryngeal attacks

Notes:

- Limited to a single dose for self-administration per attack
- Prescribed by physicians with experience in the treatment of HAE
- Maximum quantity dispensed at one time is two (2) doses

Icosapent ethyl, capsule, 1g (Vascepa) (possible OEA)

For patients aged 45 years or older, have established cardiovascular disease (CVD) (secondary prevention), and who are concomitantly treated and maintained on a statin.

Eligible patients should have all of the following:

- A fasting triglyceride level of 1.7 mmol/L or greater and lower than 5.6 mmol/L at baseline, measured within the preceding three months before starting treatment with icosapent ethyl; AND
- A low-density lipoprotein cholesterol (LDL-c) greater than 1.0 mmol/L and lower than 2.6 mmol/L at baseline; AND
- Patient must be receiving a maximally tolerated statin dose, targeted to achieve an LDL-c lower than 2 mmol/L, for a minimum of four weeks.

Idacio - see adalimumab
Ilumya - see tildrakizumab
Imcivree – see setmelanotide

imiquimod, topical cream, 5% (Aldara, and listed generics)

For treatment of:

(a) Genital warts.

(b) Biopsy-confirmed primary superficial basal cell carcinoma (sBCC) in patients meeting the following criteria:

- Tumour diameter of ≤ 2 cm, AND
- Tumour location on the trunk, neck or extremities (excluding hands and feet), AND
- Surgery or irradiation therapy is not medically indicated (e.g. recurrent lesions in previously irradiated area, number of lesions too numerous to irradiate or remove surgically).

Notes for the sBCC criteria:

- Renewals for the same tumour will not be considered.
- Requests approved for sBCC will be approved for six weeks.
- Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

c) For treatment of actinic keratosis in patients who are intolerant or have not responded to 5-fluorouracil.

d) For treatment of squamous cell carcinoma in situ (Bowen's disease) in patients who are intolerant or have not responded to 5-fluorouracil.

e) For the management of molluscum contagiosum in immunosuppressed patients where conventional treatment options[1] are ineffective, intolerable, or cannot be used due to:

- Widespread distribution, or large number of lesions; or
- Lesions located in difficult-to-treat areas, such as the genital area.

[1]Examples of conventional treatment include surgical removal, cryosurgery (liquid nitrogen/freezing), laser therapy, podofilox, tretinoin, tazarotene.

Imitrex - see sumatriptan

inclisiran, solution for subcutaneous injection, pre-filled syringe, 284mg/1.5mL (mg) (Leqvio)

For the treatment of patients with a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)[1] who are unable to reach Low Density Lipoprotein Cholesterol (LDL-C) target (i.e., LDL-C <2.0mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite either:

- A confirmed adherence to the maximally tolerated dose of at least two different statins, with one of the statins taken along with ezetimibe for at least a total of 3 months; OR,
- A confirmed adherence to a high dose statin (i.e., atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe for at least a total of 3 months.

Coverage will not be provided for use in combination with other proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.
LDL-C should be checked at least annually while on continued treatment with inclisiran.

[1]Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) is to be made using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

Inclunox - see enoxaparin

incobotulinumtoxin A, powder for solution, 50U/vial, 100U/vial (Xeomin)
(a) For treatment of blepharospasm.
(b) For treatment of cervical dystonia, that is spasmodic torticollis.

Increlex - see mecasermin

indacaterol/glycopyrronium, inhalation powder capsule, 110ug/50ug (Ultibro Breezhaler) (possible OEA)
For the treatment of chronic obstructive pulmonary disease COPD:
- In patients with inadequate response to a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD) risk[1]; OR
- For patients initiated on LAMA/LABA combination therapy in hospital.

[1] Patients are considered low risk of AECOPD if they have experienced ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) **and** did not require a hospital admission or emergency department (ED) visit.

indacaterol/glycopyrronium/mometasone furoate, inhalation powder capsule, 150ug/50ug/160ug (Enerzair Breezhaler)
For the treatment of asthma in patients uncontrolled on inhaled steroid therapy in conjunction with a long acting beta-2 agonist (LABA) who experienced one or more asthma exacerbations in the previous 12 months.
It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

indacaterol/mometasone furoate, inhalation powder capsule, 150ug/80ug, 150ug/160ug, 150ug/320ug (Atectura Breezhaler)
For the treatment of asthma in patients uncontrolled on inhaled steroid therapy.
It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

inebilizumab, solution for infusion, 10mg/mL vial (mg) (Uplizna)
For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who meet ALL of the following:
- The patient is anti–aquaporin 4 (AQP4) seropositive; and
- The patient has had one or more NMOSD attacks in the previous 12 months, or two or more NMOSD attacks in the previous 2 years; and
- The patient has experienced an inadequate response or intolerance following a trial of rituximab, or has a contraindication to rituximab; and
- The patient has an Expanded Disability Status Scale (EDSS) score of 8 points or less; and
- Inebilizumab is being prescribed by a neurologist with expertise in treating NMOSD; and
- Inebilizumab will not be used in combination with rituximab, satralizumab, eculizumab, or ravulizumab.

Initial Approval Duration**:** 12 months

Note: Inebilizumab should not be initiated during a NMOSD relapse episode.
Renewal
To be eligible for ongoing coverage of inebilizumab, the patient must:
- Maintain an EDSS score of 8 points or less (measured annually); and
- Remain under the care of a neurologist with expertise in treating NMOSD; and
- Not be using inebilizumab in combination with rituximab, satralizumab, eculizumab, or ravulizumab.

Renewal Duration: 12 months

Infliximab, pre-filled pen, pre-filled syringe, 120mg/mL (pen, syringe) (Remsima SC)

Indication	Criteria
Crohn's Disease	For the maintenance treatment of moderate to severely active Crohn's Disease (CD) in patients who have achieved a clinical response to induction therapy with intravenous (IV) infliximab at week 10 of treatment. ***Note****:* -This product should only be used in consultation with a specialist in this area. -To be eligible for funding, individuals must have met the Exception Drug Status (EDS) criteria for infliximab IV. -This product will not be reimbursed in combination with other biologic or janus kinase inhibitor treatments for CD.
Rheumatoid Arthritis	For the maintenance treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to methotrexate and leflunomide. *Note:* This product should be used in consultation with a specialist in this area.
Ulcerative Colitis	For the maintenance treatment of ulcerative colitis in patients who have achieved a clinical response to induction therapy with intravenous (IV) infliximab at week 10 of treatment. ***Note:*** -This product should be used in consultation with a specialist in this area. -To be eligible for funding, individuals must have met the Exception Drug Status (EDS) criteria for infliximab IV. -This product will not be reimbursed in combination with other advanced treatments for ulcerative colitis, such as biologics, sphingosine 1-phosphate (S1P) receptor modulators or janus kinase inhibitors.

infliximab, vial (mg), 100mg/vial (Avsola)
infliximab, vial (mg), 100mg/vial (Ixifi)
infliximab, vial (mg),100mg/vial (Remdantry)
infliximab, vial (mg),100mg/vial (Renflexis)

Note: These products are not interchangeable. When requesting coverage, please state which specific infliximab product is being prescribed to avoid administrative and assessment delays.

Indication	Criteria
Rheumatoid arthritis	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. **Note:** This product should be used in consultation with a specialist in this area.
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. *Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.* **Note:** This product should be used in consultation with a specialist in this area.
Psoriatic arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.
Ankylosing Spondylitis	**Initial:** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration: 12 weeks **First Renewal:** Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score.

	Approval Duration: One Year **Note:** Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.
Crohn's Disease	For the treatment of moderate to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy. Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders. **Note:** This product should only be used in consultation with a specialist in this area.
Fistulizing Crohn's Disease	For the treatment of patients with fistulizing Crohn's Disease including but not limited to, symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae. Clinical response should be assessed after the induction regimen. *Ongoing coverage of maintenance therapy will only be provided for those who respond to treatment.* **Note:** This product should be used in consultation with a specialist in this area.
Ulcerative Colitis	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after the induction regimen. *Ongoing coverage will only be provided for those who respond to therapy.* **Note:** This product should be used in consultation with a specialist in this area.

Innohep - see tinzaparin sodium.
Inspiolto Respimat - see tiotropium bromide monohydrate/olodaterol HCl
Inspra - see eplerenone

insulin aspart, injection solution, 100U/mL (10mL) (NovoRapid)
Note: Effective February 1st, 2022, new patients (i.e., patients without previous approval for NovoRapid) will only be eligible for a listed biosimilar formulation of insulin aspart.
For patients requiring an insulin aspart vial for use in an insulin pump.

Insulin glargine, injection solution, 100U/mL (5x3mL) (Lantus)
For pediatric patients who require a half-unit pen device to administer insulin glargine (possible OEA)

insulin glargine/lixisenatide, solution for injection, 100IU/33mcg/mL (Soliqua) (possible OEA)
For the treatment of type 2 diabetes in patients who have been unable to achieve adequate glycemic control on, or are intolerant, to metformin and a basal insulin (less than 60 units per day).

insulin pump supplies
For eligibility criteria and coverage information for insulin pump supplies, please see:
http://www.saskatchewan.ca/residents/health/accessing-health-care-services/insulin-pump-program

Intelence - see etravirine

interferon beta-1a, powder for IM injection, 30ug (Avonex); pre-filled syringe, 30ug (Avonex PS)
See Appendix D

interferon beta-1a, pre-filled syringe, 8.8ug/0.2mL (6)/22ug/0.5mL (6) (Rebif Initiation Pack)
See Appendix D

interferon beta-1a, pre-filled syringe,8.8 ug/0.2mL (6), 22ug (6 million IU), 44ug (12 million IU); pre-filled cartridge, 66ug/1.5mL (3 doses of 22ug), 132ug/1.5mL (3 doses of 44ug) (Rebif)
See Appendix D

interferon beta-1b, powder for injection, 0.3mg (vial) (Betaseron)
See Appendix D

Invega Sustenna - see paliperidone palmitate

iron ferric derisomaltose, elemental iron injection, 100mg/mL (1mL,5mL,10mL vial) (mL) (Monoferric)
For patients with end stage renal disease who are receiving supplemental therapy with erythropoietin stimulating agents (ESAs).

Patients undergoing hemodialysis will ***not be*** candidates for coverage of ferric derisomaltose.

Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status approval is not required for S.A.I.L. patients.

For treatment of iron deficiency anemia - ***refer to Saskatchewan Health Authority (SHA) Drug Formulary Criteria for parenteral irons:***

For treatment of iron deficiency anemia in patients:

- intolerant to or inadequate response to oral iron; OR
- requiring urgent iron replacement.

Definitions

Iron Deficiency Anemia (IDA) - Adult:

- Hemoglobin (Hgb) less than 130 g/L
  AND
- Ferritin less than 30 mcg/L OR transferrin saturation (TSAT) less than 30% OR blood loss greater than 1,000 mL within 7 days

Intolerant

- Persistence of gastrointestinal side-effects despite having tried tolerability strategies:
  - oral iron has been titrated up from low-dose,
  - utilizing alternate day dosing regimen of oral iron,
  - an adequate trial of at least two different oral iron formulations (e.g., iron salts, polysaccharide iron, heme iron),
  - taking oral iron with small amounts of food,
  - taking oral iron at bedtime.

Inadequate response

- Hgb continues to decline while on oral iron, or
- a trial of oral iron equivalent to at least ferrous gluconate 300 mg orally every second day for a minimum of three months resulting in a Hgb increase of less than 10 g/L, or
- anticipated to have inadequate response due to clinical malabsorption (e.g., history of bariatric surgery, clinically active inflammatory bowel disease (IBD), celiac disease, chronic kidney disease, short bowel syndrome), or
- chronic blood loss in which the pace of iron loss exceeds ability to replete from oral iron intake.

Urgent iron replacement

- Hgb less than 90 g/L OR ferritin less than 15 mcg/L OR short duration to high risk blood loss surgery/time to achieve adequate Hgb levels OR ongoing blood loss.
- **Ferric derisomaltose** must be ordered via SHA order set (except those excluded from the order set i.e., pediatric less than 17 years of age, 1st trimester pregnancy).
- Must be administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided.

iron (sucroferric oxyhydroxide), chewable tablet, 500mg (Velphoro) (possible OEA)

For treatment of:

a) End-stage renal disease in patients intolerant to aluminum or calcium containing phosphate-binding agents.
b) End-stage renal disease in patients where aluminum or calcium containing phosphate-binding agents are inappropriate.

iron sodium ferric gluconate complex, injection solution, 12.5mg/mL (Ferrlecit)

1. For patients with end stage renal disease who are receiving supplemental therapy with erythropoietin stimulating agents (ESAs).
   Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status approval is not required for S.A.I.L. patients.

2. For treatment of iron deficiency anemia - ***refer to Saskatchewan Health Authority (SHA) Drug Formulary Criteria for parenteral irons:***
   For treatment of iron deficiency anemia in patients:
   o intolerant to or inadequate response to oral iron; OR
   o requiring urgent iron replacement.

   Definitions
   Iron Deficiency Anemia (IDA) - Adult:
   • Hemoglobin (Hgb) less than 130 g/L
   AND
   • Ferritin less than 30 mcg/L OR transferrin saturation (TSAT) less than 30% OR blood loss greater than 1,000 mL within 7 days

Intolerant

- Persistence of gastrointestinal side-effects despite having tried tolerability strategies:
  - oral iron has been titrated up from low-dose,
  - utilizing alternate day dosing regimen of oral iron,
  - an adequate trial of at least two different oral iron formulations (e.g., iron salts, polysaccharide iron, heme iron),
  - taking oral iron with small amounts of food,
  - taking oral iron at bedtime.

Inadequate response

• Hgb continues to decline while on oral iron, or
• a trial of oral iron equivalent to at least ferrous gluconate 300 mg orally every second day for a minimum of three months resulting in a Hgb increase of less than 10 g/L, or
• anticipated to have inadequate response due to clinical malabsorption (e.g., history of bariatric surgery, clinically active inflammatory bowel disease (IBD), celiac disease, chronic kidney disease, short bowel syndrome), or
• chronic blood loss in which the pace of iron loss exceeds ability to replete from oral iron intake.

Urgent iron replacement

• Hgb less than 90 g/L OR ferritin less than 15 mcg/L OR short duration to high risk blood loss surgery/time to achieve adequate Hgb levels OR ongoing blood loss.
• iron sodium ferric gluconate complex injection must be ordered via SHA order set (except those excluded from the order set i.e., pediatric less than 17 years of age, 1st trimester pregnancy).
• Must be administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided.

iron sucrose, injection, 20mg/mL (Venofer and listed generic)

1. For patients with end stage renal disease who are receiving supplemental therapy with erythropoietin stimulating agents (ESAs).
   Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status approval is not required for S.A.I.L. patients.

2. For treatment of iron deficiency anemia - ***refer to Saskatchewan Health Authority (SHA) Drug Formulary Criteria for parenteral irons:***
   For treatment of iron deficiency anemia in patients:
   o intolerant to or inadequate response to oral iron;
   OR
   o requiring urgent iron replacement.

Definitions
Iron Deficiency Anemia (IDA) - Adult:
• Hemoglobin (Hgb) less than 130 g/L
AND
• Ferritin less than 30 mcg/L OR transferrin saturation (TSAT) less than 30% OR blood loss greater than 1,000 mL within 7 days

Intolerant

- Persistence of gastrointestinal side-effects despite having tried tolerability strategies:
  - oral iron has been titrated up from low-dose,
  - utilizing alternate day dosing regimen of oral iron,
  - an adequate trial of at least two different oral iron formulations (e.g., iron salts, polysaccharide iron, heme iron),
  - taking oral iron with small amounts of food,
  - taking oral iron at bedtime.

Inadequate response

• Hgb continues to decline while on oral iron, or
• a trial of oral iron equivalent to at least ferrous gluconate 300 mg orally every second day for a minimum of three months resulting in a Hgb increase of less than 10 g/L, or
• anticipated to have inadequate response due to clinical malabsorption (e.g., history of bariatric surgery, clinically active inflammatory bowel disease (IBD), celiac disease, chronic kidney disease, short bowel syndrome), or
• chronic blood loss in which the pace of iron loss exceeds ability to replete from oral iron intake.

Urgent iron replacement

• Hgb less than 90 g/L OR ferritin less than 15 mcg/L OR short duration to high risk blood loss surgery/time to achieve adequate Hgb levels OR ongoing blood loss.

• iron sucrose injection must be ordered via SHA order set (except those excluded from the order set i.e., pediatric less than 17 years of age, 1st trimester pregnancy).

• Must be administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided.

isavuconazole, capsule, 100mg (Cresemba)

a) For the treatment of invasive aspergillosis when oral voriconazole is contraindicated, not tolerated, or failed. This medication should be prescribed in consultation with an infectious disease specialist.

b) For the treatment of invasive mucormycosis when prescribed in consultation with an infectious disease specialist.

Isentress - see raltegravir

isoniazid, tablet, 100mg, 300mg; oral solution, 10mg/mL (PDP-Isoniazid)

For treatment of non-TB mycobacterium infection (NTMI), when prescribed in consultation with an infectious disease specialist.

Note: Contact TB Prevention and Control Saskatchewan if these medications are being prescribed for treatment of tuberculosis.

itraconazole, capsule, 100mg; oral solution, 10mg/mL (listed generic)

For treatment of:

(a) Severe or life-threatening fungal infections.

(b) Severe dermatophytoses unresponsive to other forms of therapy.

(c) Onychomycosis.

ivabradine hydrochloride, film-coated tablets, 5mg, 7.5mg (Lancora) (possible OEA)

For the treatment of stable chronic heart failure with reduced left ventricular ejection fraction (LVEF) ($\leq$35%) in adult patients with New York Heart Association (NYHA) classes II or III who are in sinus rhythm with a resting heart rate $\geq$77 beats per minute (bpm) if the following are met:

- Patients with NYHA class II to III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) in combination with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA).
- Patients with at least one hospitalization due to heart failure in the last year.
- 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.

Patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up and monitoring.

ivacaftor, tablet, 150mg (Kalydeco)

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

Note: Initial requests should provide baseline sweat chloride and FEV1 scores along with the corresponding testing dates

Renewal Criteria:

The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

When the baseline sweat chloride level is over 60mmol/litre, the patient will be considered to have responded to treatment if either:

a) The patient's sweat chloride test falls below 60mmol/litre; OR

b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmol/litre, the patient will be considered to have responded to treatment if either:

c) The patient's sweat chloride test falls by at least 30%; OR

d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pretreatment level one month and three months after starting treatment.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria.

Note: Coverage may be approved for up to 150mg every 12 hours according to the following time frame:

- Initial approval: Six (6) months
- First Renewal: Six (6) months
- Subsequent renewals (second and later): One year

Patients will be limited to receiving a one month supply per prescription.

ixekizumab, subcutaneous injection, 80mg/mL pre-filled autoinjector; 80mg/mL pre-filled syringe (Taltz)

Indication	Criteria
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 12 weeks. Coverage can be renewed in patients who have responded to therapy. **Note**: This product should be used in consultation with a specialist in this area.
Psoriatic Arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.

Ixifi - see infliximab
Jadenu – see deferasirox
Jakavi – see ruxolitinib
Jamteki – see ustekinumab
Janumet - see sitagliptin and metformin hydrochloride
Janumet XR - see sitagliptin and metformin hydrochloride
Januvia - see sitagliptin
Jardiance - see empagliflozin
Jentadueto - see linagliptin/metformin
Jubbonti – see denosumab
Juluca - see dolutegravir/rilpivirine
Kaletra - see lopinavir/ritonavir
Kalydeco - see ivacaftor
Kerendia – see finerenone
Kesimpta – see ofatumumab

ketoconazole, tablet, 200mg (**listed generics)**

For treatment of:
(a) Severe or life-threatening fungal infections.
(b) Severe dermatophytoses.
(c) Dermatophytoses unresponsive to other forms of therapy.

ketotifen fumarate, tablet, 1mg (Zaditen)

For treatment of pediatric patients with asthma who are unresponsive to or unable to administer alternative prophylactic agents listed in the Formulary.

Kevzara - see sarilumab
Kineret - see anakinra
Komboglyze - see saxagliptin HCl/metformin HCl
Koselugo – see selumetinib
Kuvan - see sapropterin dihydrochloride

lacosamide, tablet, 50mg, 100mg, 150mg, 200mg (Vimpat, and listed generics)

For the adjunctive treatment of refractory partial-onset seizures in patients who meet all of the following criteria:

- Are currently receiving two or more antiepileptic drugs; **AND**
- Less costly antiepileptic drugs are ineffective or not appropriate; **AND**
- The medication is being used under the direction of a neurologist.

Note: Patients should have tried and failed at least two less costly antiepileptic drugs.

lactulose, solution, 667mg/mL (listed generics) (possible OEA)

For treatment of portal systemic encephalopathy.

lamivudine, tablet, 100mg (listed generics) (possible OEA)

For management of hepatitis B.

Note: This product should be used in consultation with a specialist in this area.

lamivudine, tablet, 150mg, 300mg; oral solution, 10mg/mL (3TC, and listed generics) (possible OEA)

For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

lamivudine/zidovudine, tablet, 150mg/300mg (listed generics) (possible OEA)

a) For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

lanadelumab, solution for injection, 300mg/2mL vial (mg); 300mg/2mL pre-filled pen (mg), 300mg/2mL pre-filled syringe (mg) (Takhzyro)

For the routine prevention of attacks of hereditary angioedema (HAE) in patients 12 years of age or older with HAE type I or II[1] diagnosed by a specialist physician experienced in the diagnosis and management of HAE, who:

- Have experienced at least three HAE attacks within any four week period before initiating lanadelumab therapy that required the use of an acute injectable treatment.
  - Applications must include the baseline number of attacks requiring acute injectable treatment in the three months prior to initiation of lanadelumab[2].
- Will not be using lanadelumab in combination with other medications used for long-term prophylactic treatment of angioedema[3] (e.g., C1 esterase inhibitors); and
- Will not use a dose of lanadelumab that is more than 300mg every two weeks.

Initial approval duration: 3 months.

Renewal criteria – approval duration 6 months

Renewal requests[4] may be considered:

- After treatment with lanadelumab for three months if there has been a 50% or more reduction[2] in the number of HAE attacks where acute injectable treatment was received in the first three months of treatment with lanadelumab compared to the rate of attacks observed before starting lanadelumab, OR
- For patients with continued response[2] defined as maintenance of 50% or more reduction from baseline with no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to starting treatment with lanadelumab,

AND

- Patients must continue to:
  - Be under the care of a specialist experienced in the diagnosis and management of angioedema, and
  - Not use lanadelumab in combination with other long-term prophylactic angioedema treatments (e.g., C1 esterase inhibitors), and
  - Not use a dose larger than 300mg every two weeks even in cases of inadequate response or loss of response.

Notes:

[1]A definitive diagnosis of HAE type I and II requires testing C1 esterase level and activity, as well as C1q levels (to rule out acquired angioedema for which lanadelumab is not indicated).

[2]To determine which patients would be eligible for reimbursement of lanadelumab, the current attack rate may be used for patients who are not receiving long-term prophylactic treatment and a historical attack rate may be used for those who are already receiving long-term prophylactic treatment and intend to transition to lanadelumab.

[3]Patients on long-term prophylactic treatment will continue to require access to on-demand treatments that are used in the management of acute attacks.

[4]Coverage will be discontinued for patients who no longer meet the renewal criteria.

Lancora - see ivabradine HCl

lanreotide acetate, injection, 60mg, 90mg, 120mg (Somatuline Autogel and listed generics)

For treatment of acromegaly.

lansoprazole, orally disintegrating tablet, 15mg, 30mg (Prevacid FasTab)

For patients who require treatment with a proton pump inhibitor, but who are unable to swallow or who are tube fed.

lansoprazole/clarithromycin/amoxicillin, 7day package, 30mg/500mg/500mg (listed generic)

For 14-day eradication of H. pylori-related infections in individuals with peptic ulcer disease. *Provision will be made for additional coverage in treatment failures.*

Latuda - see lurasidone

ledipasvir/sofosbuvir, tablet, 90mg/400mg (Harvoni) (possible OEA)

For use as monotherapy for treatment-naïve or treatment-experienced[1] adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND

(ii) Laboratory-confirmed hepatitis C genotype 1; AND

(iii) Laboratory-confirmed quantitative HCV RNA value within the last 12 months.

Treatment regimens reimbursed*:

Patient Population		Treatment Regimen and Duration
Genotype 1	Treatment-naïve, non-cirrhotic, viral load < 6M IU/mL	8 weeks OR 12 weeks*
	Treatment-naïve, non-cirrhotic, viral load ≥ 6M IU/mL OR Treatment-naïve, cirrhotic[2] OR Treatment-experienced[1], non-cirrhotic	12 weeks
	Treatment-naïve or treatment-experienced(1) with decompensated cirrhosis[2]	24 weeks Harvoni
	Treatment-naïve or treatment-experienced[1] liver transplant recipients without cirrhosis, or with compensated cirrhosis[2]	12 weeks Harvoni
	Treatment-experienced[1], cirrhotic[2]	24 weeks

**For this population cohort, evidence has shown that the SVR rates for the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have borderline or severe fibrosis or if they are co-infected with HIV.*

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:

- Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.
- Genotype is not required to be submitted with the EDS application

[1]Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.

[2]Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

***leflunomide, tablet, 10mg, 20mg (Arava, and listed generics)**

For treatment of:

a) Active rheumatoid arthritis in patients who have failed methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine or hydroxychloroquine).

b) Active rheumatoid arthritis in patients intolerant to methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine or hydroxychloroquine).

c) For psoriatic arthritis patients who fail, or are intolerant, to methotrexate and one other DMARD.

d) For pediatric arthritis patients who fail, or are intolerant, to one DMARD.

e) For transplant patients with BK virus nephropathy.

Note: Leflunomide is contraindicated in patients with pre-existing impairment of liver function.

Lemtrada - see alemtuzumab

Leqvio – see inclisiran

letermovir, tablet, 240mg, 480mg (Prevymis and listed generics)

For the prophylaxis therapy of cytomegalovirus (CMV) infection in patients meeting the following criteria:

- Patient is an adult CMV-seropositive recipient [R+] of an allogeneic hematopoietic stem cell transplant (HSCT); and
    - Patient has undetectable CMV viremia at baseline; and

- Prevymis is being prescribed by a clinician with expertise in the management of HSCT (such as a medical oncologist, hematologist, or infectious disease specialist); and
- Patient has at least ONE of the following characteristics:
    - Received stem cells sourced from umbilical cord blood; or
    - Is a haploidentical recipient, or
    - Is a recipient of T-cell depleted grafts, or
    - Was treated with antithymocyte globulin (ATG) for conditioning, or
    - Requires high-dose steroids (defined as the use of ≥1mg/kg/day of prednisone or equivalent dose of another corticosteroid) or other immunosuppression for acute graft versus host disease (GVHD), or
    - Was treated with ATG for steroid-refractory acute GVHD treatment, or
    - Has documented history of CMV disease prior to transplantation.

The maximum Prevymis dosage approved will not exceed 480mg administered orally or intravenously per day.

The approved duration of treatment will not exceed 100 days, per patient, per HSCT procedure. Requesting health professionals are asked to indicate the date of treatment initiation in hospital on the request.

Leucovorin - see leucovorin calcium

leucovorin calcium, tablet, 5mg (Leucovorin) (possible OEA)
For folic acid deficiency in non-oncology indications.

leuprolide acetate, injection, 3.75mg/mL, 7.5mg/mL; depot injection, 11.25mg (3-month SR) (Lupron Depot)
For treatment of:

a) Endometriosis. (Coverage may be repeated after a six month lapse, for another 6 month course).
b) Menorrhagia in preparation for endometrial ablation, and:
c) For pre-treatment of uterine fibroids prior to surgical removal.

*Coverage **for the above indications** will be provided for a maximum of 6 months.*

d)Central precocious puberty**.**

leuprolide acetate, prefilled syringe, 45mg (mg) (Eligard)
For the treatment of central precocious puberty.

levodopa/carbidopa, intraintestinal gel, 20mg/mL/5mg/mL (Duodopa)
For the treatment of patients with advanced levodopa-responsive Parkinson's disease:

- who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products,
- and for whom the benefit of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration.

Initiation Criteria:

1. The patient experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). 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 from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
2. The patient has received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
3. The patient has failed adequate trials of each of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgement of the prescriber: a catechol-O-methyl transferase (COMT) inhibitor, a dopamine agonist, a monoamine oxidase (MAO-B) inhibitor, and amantadine.
4. The patient is able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.
5. The patient does not have a contraindication to the insertion of a percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube.
6. The patient does not have severe psychosis or dementia.

Renewal Criteria:

1. The duration of approval is one year.
2. The patient continues to benefit from treatment. The patient should continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing, bothersome levodopa-induced dyskinesias, along with an improvement in the related disability.

Discontinuation Criteria:

It is expected that physicians will continue to monitor their patients and discontinue Duodopa if the patient is no longer benefiting from treatment, as described for renewal criteria, or if Duodopa is no longer appropriate.

Administration Criteria:

Requests for Duodopa initiation will be limited to movement disorder subspecialists who have appropriate training in the use of Duodopa and are practicing in movement disorder clinics that provide ongoing management and support for patients receiving treatment with Duodopa.

levofloxacin, tablet, 250mg (listed generics); 500mg (listed generics)

For treatment of:

(a) Pneumonia in patients with underlying lung disease (excluding asthma).
(b) Pneumonia in nursing home patients.
(c) Infections in patients allergic to two or more alternative antibiotics.
(d) Infections known to be resistant to alternative antibiotics. Resistance must be determined by culture and sensitivity testing (C&S). Where C&S cannot be obtained coverage will be approved when a patient has failed at least 2 other classes of antibiotics, and:
(e) For completion of antibiotic treatment initiated in hospital when alternatives are not appropriate.
(f) For treatment of pelvic inflammatory disease.
(g) Infection (and prophylaxis) in patients with prolonged neutropenia.

levofloxacin, tablet, 750mg (listed generics)

EDS will only be approved for five days.

For treatment of:

(a) Pneumonia in patients with underlying lung disease (excluding asthma)
(b) Pneumonia in patients in a nursing home.
(c) Pneumonia in patients allergic to two or more alternative antibiotics.
(d) Pneumonia known to be resistant to alternative antibiotics. Resistance must be determined by culture and sensitivity testing (C&S). Where C & S cannot be obtained coverage will be approved when a patient has failed at least 2 other classes of antibiotics, and:
(e) For completion of antibiotic treatment of pneumonia initiated in hospital when alternatives are not appropriate.

levofloxacin, solution for inhalation, 240mg/2.4mL (ampoules) (Quinsair)

For the treatment of chronic *Pseudomonas aeruginosa* infections in adult patients with cystic fibrosis according to the following criteria:

- Treatment is prescribed in consultation with a specialist in this area; and
- Treatment should not be used in combination with another inhaled antibiotic to treat pulmonary *Pseudomonas aeruginosa* infections, either concurrently or for antibiotic cycling during off-treatment periods.

linagliptin, tablet, 5mg (Trajenta) (possible OEA)

For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

linagliptin/metformin, tablet, 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (Jentadueto) (possible OEA)

For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

linezolid, tablet, 600mg (listed generics); oral suspension, 100mg/5mL (Zyvoxam)

Following consultation with an infectious disease specialist

For treatment *of:*

(a) Gram-positive infections in patients resistant to vancomycin.
(b) Gram positive infections in patients intolerant to or experiencing severe adverse effects from vancomycin, and:
(c) For completion of therapy initiated in hospital with intravenous vancomycin, quinupristin/dalfopristin or linezolid for patients who can be discharged on oral therapy.

lisdexamfetamine dimesylate, capsule, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg; chewable tablet, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg (Vyvanse and listed generics)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients:

(a) Where the use of methylphenidate (short or long-acting formulations) or the use of dexamphetamine has not properly controlled the symptoms of the disease;

OR

(b) Who cannot swallow tablets/capsules whole and require a dissolvable form of a long-acting ADHD medication.

Livmarli – see maralixibat
Livtencity- see maribavir

lopinavir/ritonavir, tablet, 100mg/25mg; 200mg/50mg; oral solution, 80mg/20mg (mL) (Kaletra-) (possible OEA)

a) For management of HIV disease.
This drug, as with other antivirals in the treatment of HIV, should be prescribed by an Infectious Disease specialist.
b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

Losec - see omeprazole
Lucentis - see ranibizumab

lumacaftor/ivacaftor, tablet, 100mg/125mg, 200mg/125mg (Orkambi); granules, 100mg/125mg, 150mg/188mg (Orkambi)

Coverage may be available for Orkambi through the Drug Plan for the treatment of cystic fibrosis patients who meet certain medical criteria. Please contact the Drug Plan at 1-800-667-7581 for more information regarding coverage availability and the EDS application process for this product.

lumasiran, solution for subcutaneous injection, 94.5mg/0.5mL (100mcg) Oxlumo

For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients if **all** the following criteria are met:

Initiation Criteria

- Patients must have a genetically confirmed diagnosis of PH1; **AND**
- Patients must be unable to normalize oxalate excretion (while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months), based on one of the following levels:
  - 24-hour urinary oxalate (level must be at least 1.5 times the upper limit of normal [ULN]), in patients in whom urinary oxalate can be measured; **OR**
  - Spot urine oxalate: creatinine ratio, in patients who are not continent; **OR**
  - Plasma oxalate, in patients with end-stage kidney disease (ESKD) or who are on dialysis. Levels must be measured pre-dialysis in applicable patients.

AND

- The patient has not received a liver transplant (with or without a kidney transplant); **AND**
- Lumasiran is being initially prescribed by a nephrologist or metabolic diseases specialist with experience in the diagnosis and management of PH1.

Initial approval duration: 1 year

Discontinuation Criteria

Lumasiran coverage will be discontinued if **any** of the following occur:

- The patient has received a liver transplant (with or without a kidney transplant); **AND/OR**
- There is evidence of no response, or loss of response, to lumasiran treatment.
  Response is defined as:
  - For patients in whom urinary oxalate can be measured: Lowering 24-hour urine oxalate to less than 1.5 times the ULN; **OR**
  - For patients who are not continent: 30% reduction in spot urine oxalate: creatinine ratio compared to baseline; **OR**
  - For patients with ESKD or who are on dialysis: 15% reduction in plasma oxalate level compared to baseline. Levels must be measured pre-dialysis in applicable patients.

Subsequent prescribing may occur through a specialist in pediatrics, nephrology, or metabolic diseases.

Renewal duration, if discontinuation criteria are not met: 1 year

Please contact the Drug Plan for billing information.

Lupron Depot - see leuprolide acetate

lurasidone HCl, tablet, 20mg, 40mg, 60mg, 80mg,120mg (Latuda, and listed generics)

For manifestations of schizophrenia.

luspatercept, powder for solution, 25mg/vial, 75mg/vial (Reblozyl)

Initiation Criteria

For the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with beta-thalassemia. Patients must be receiving regular transfusions, as defined by ALL of the following occurring within the 24 weeks prior to initiating treatment with luspatercept:

- The patient has received between 6 and 20 RBC units, AND
- The patient has not experienced a transfusion-free period of greater than 35 days.

Patients should be under the care of a specialist with experience in managing beta-thalassemia.

The maximum funded dose of luspatercept will not exceed 1.25 mg/kg (or 120 mg) per dose administered once every three weeks.

Initial approval duration: 7 months

Exclusion Criteria

- Patients with a diagnosis of Hemoglobin S/beta-thalassemia.
- Patients with a diagnosis of alpha-thalassemia.

First Renewal

Patients will be eligible for coverage renewal if a transfusion burden reduction of 33% or greater is achieved (measured as the number of RBC units required in the initial 24 weeks of luspatercept treatment compared to the 24 weeks prior to luspatercept initiation).

First renewal duration: 7 months

Subsequent Renewals

Patients will be eligible for coverage renewal if continued response is demonstrated, defined as a maintained transfusion burden reduction of 33% or greater (measured as the number of RBC units required in the past 24 weeks compared to the 24 weeks prior to luspatercept initiation).

Renewal duration: 7 months

Notes:

- *In accordance with the product monograph, luspatercept should be discontinued in patients who have not achieved a reduction in RBC transfusion burden after using 3 consecutive escalated doses (9 weeks) at 1.25 mg/kg. Subsequently, patients should be assessed for ongoing response to luspatercept every 6 months.*
- *Coverage for luspatercept for the indication of myelodysplastic syndrome is determined by the Saskatchewan Cancer Agency according to their policies.*

macitentan, tablet, 10mg (Opsumit) (possible OEA)

For the treatment of pulmonary arterial hypertension, on the recommendation of a specialist.

maralixibat, oral solution, 9.5mg/mL (mg) (Livmarli)

For the treatment of cholestatic pruritus in patients 12 months of age or older with Alagille syndrome (ALGS) who:

- Have moderate to severe itch defined as an average daily score of 2 or more on the Itch Reported Outcome (ItchRO) or Clinician Scratch Scale (CSS) for 2 consecutive weeks; AND,
- Are currently treated with, or have received an adequate trial of systemic treatment for pruritus[1] prior to initiating maralixibat; AND,
- Have evidence of cholestasis, defined as at least one of the following:
  - Total serum bile acid (sBA) >3 x upper limit normal (ULN) for age; OR,
  - Conjugated bilirubin >1 mg/dL; OR,
  - Fat-soluble vitamin deficiency otherwise unexplainable; OR,
  - Gamma glutamyltransferase (GGT) >3 x ULN for age; OR,
  - Intractable pruritus explainable only by liver disease.

Patients must be under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS.

Exclusion Criteria:

Individuals who have ANY of the following will not be eligible for initiation of maralixibat coverage:

- Biliary diversion; OR,
- Previous liver transplant; OR,

- Decompensated cirrhosis; OR,
- History or presence of other concomitant liver disease.

[1] Systemic treatment may include a trial of at least one month with one of the following:
- Ursodeoxycholic acid (UDCA)
- Rifampin
- Sertraline
- Naltrexone
- Cholestyramine

Initial approval duration: Six (6) months

Initial Renewal Criteria:
Renewal of maralixibat coverage will be considered in individuals who:
- Remain under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS; AND,
- Have not received a liver transplant or biliary diversion surgery; AND,
- Experience either:
  - An improvement in pruritus to minimal or no itch (a score of 1 or less on the ItchRO or CSS); OR,
  - An improvement (decrease) in ItchRO or CSS by 1 point in patients with a baseline score of 4.

Subsequent Renewal Criteria:
Ongoing coverage of maralixibat coverage will be considered in individuals who:
- Remain under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS; AND,
- Have not received a liver transplant or biliary diversion surgery; AND,
- Maintains the improvement in ItchRO or CSS demonstrated at the initial renewal.

Renewal duration: Six (6) months

maraviroc, tablet, 150mg, 300mg (Celsentri and listed generics) (possible OEA)
For treatment of HIV-1 disease (in combination with other antiretroviral agents) in patients:
(a) Who have CCR5 tropic viruses **AND**
(b) Who have documented resistance to at least one agent from each of the three major classes of antiretroviral agents (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors).

Note: Testing for CCR5 tropic viruses is required for use of this agent. This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

maribavir, tablet, 200mg (Livtencity) (possible OEA)
Initial Criteria:
For the treatment of post-transplant cytomegalovirus (CMV) infection when all of the following are met:
- The patient is an adult refractory to one or more of the following antiviral drugs:
  - valganciclovir, ganciclovir, foscarnet, or cidofovir,

AND
- The patient is being prescribed maribavir by a clinician with experience and expertise in transplant medicine, transplant infectious disease, or infectious disease.

Maribavir treatment is to be discontinued if either of the following occurs:
- There is no change, or an increase, in CMV viral load after at least 2 weeks of maribavir treatment, OR
- There is confirmation of CMV genetic mutation associated with resistance to maribavir.

Renewal/Retreatment Criteria:
Subsequent coverage approval may be considered if all of the following are met:
- The patient had a recurrence of CMV viremia after a previous successful treatment course with maribavir, AND
- The patient continues to be prescribed maribavir by a clinician with experience and expertise in transplant medicine, transplant infectious disease, or infectious disease.

Maribavir treatment is to be discontinued if either of the following occurs:
- There is no change, or an increase, in CMV viral load after at least 2 weeks of maribavir treatment, OR
- There is confirmation of CMV genetic mutation associated with resistance to maribavir.

Mar-Trientine – see trientine HCl

mavacamten, capsule, 2.5mg, 5mg, 10mg, 15mg (Camzyos)

For the treatment of symptomatic obstructive hypertrophic cardiomyopathy (HCM) of New York Heart Association (NYHA) class II to III in adult patients, if **all of** the following are met:

- Documented left ventricular ejection fraction (LVEF) ≥ 55% at rest determined by echocardiography, and
- Left ventricular (LV) wall thickness ≥ 15 mm (or ≥ 13 mm with a family history of HCM), and
- Left ventricular outflow tract (LVOT) peak gradient ≥ 50 mm Hg at rest, after Valsalva maneuver, or postexercise, as confirmed by echocardiography, and
- Receiving a beta-blocker (BB) or calcium channel blocker (CCB) therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments, and;
- The patient is under the care of a cardiologist, or the medication is prescribed in consultation with a cardiologist.

Discontinuation criteria:

Mavacamten should be permanently discontinued if the patient has either:

- Left ventricular ejection fraction (LVEF) ≤ 30%, or
- Received septal reduction therapy.

Note: Continuing patients should still be under the care of a cardiologist.

Mavenclad - see Appendix D
Maviret - see glecaprevir/pibrentasvir
Maxalt - see rizatriptan benzoate
Maxalt RPD - see rizatriptan benzoate
Mayzen- see siponimod

mecasermin, solution for injection, 10mg/mL (4mL vial) (mg) (Increlex)

Initiation Criteria

For the treatment of growth failure in children and adolescents age 2 to 18 years with confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) in whom:

- Epiphyseal closure has not yet occurred;

AND

- The confirmed diagnosis of SPIGFD has been made according to at least ONE of the following:
  - The patient has a known genetic mutation recognized as a cause of SPIGFD; and/or
  - The patient has clinical and biochemical features of SPIGFD.

AND

- Mecasermin treatment is being initiated by a pediatric endocrinologist;

AND

- Mecasermin is not being prescribed concomitantly with recombinant growth hormone treatment.

Approval duration: 1 year

Coverage renewal may be requested for patients who do not meet the discontinuation criteria below.

Discontinuation Criteria

Patients will be not be eligible for coverage initiation or renewal if any of the following are met:

- The patient has reached their 18th birthday; or
- The patient's height velocity is less than 1 cm per 6 months or less than 2 cm per year; or
- The patient's bone age is more than 16 years in boys or 14 years in girls.

megestrol acetate, tablet, 40mg, 160mg (listed generics)

For treatment of anorexia, cachexia, or unexplained weight loss in patients with a diagnosis of acquired immunodeficiency (AIDS).

meloxicam, tablet, 7.5mg, 15mg (listed generics) (possible OEA)

For treatment of patients intolerant to other NSAIDs listed in the formulary.

mepolizumab, powder for injection; prefilled autoinjector; prefilled syringe 100mg/mL (mg) (Nucala)

Indication	Criteria
Severe eosinophilic asthma	For add-on maintenance treatment of adult patients with severe eosinophilic asthma[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting betaagonist [LABA]), and: • Blood eosinophil count of ≥ 300 cells/μL AND has experienced two or more clinically significant asthma exacerbations[3] in the past 12 months, OR

	• Blood eosinophil count of ≥ 150cells/μL AND is receiving maintenance treatment with oral corticosteroids[4]. In addition: • Mepolizumab should not be used in combination with other biologics used to treat asthma. • A baseline[5] assessment of asthma symptom control using a validated asthma control questionnaire[6] must be completed prior to initiation of mepolizumab treatment and submitted with the application. • Baseline[5] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications. • Patients should be managed by a specialist in the treatment of asthma. [1]Patients must have a documented diagnosis of asthma. [2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily. [3]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization. [4]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day. [5]Baseline refers to results achieved prior to initiation of the requested therapy. [6]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT. **Discontinuation Criteria** Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if: • First Renewal (based on first 12 months of therapy) o The asthma control questionnaire score has not improved from baseline[5], OR o The number of clinically significant exacerbations has increased, OR o The oral corticosteroid maintenance dose has not decreased. • Subsequent Renewals (after 2 years of therapy) o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, OR o The number of clinically significant exacerbations has increased within the previous 12 months, OR o The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently
Severe chronic rhinosinusitis with nasal polyps	For maintenance treatment of severe chronic rhinosinusitis with nasal polyps, as an add-on to intranasal corticosteroids, in patients who are inadequately controlled on intranasal corticosteroids alone, where ALL of the following clinical criteria are met: • Endoscopically or CT-documented bilateral nasal polyps, • Have undergone a surgical intervention for nasal polyps, or have a contraindication to surgery, and • Experience refractory symptoms despite use of intranasal corticosteroids for 3 months at maximally tolerated doses, AND use of intranasal corticosteroids will continue with mepolizumab. In addition: A baseline assessment of symptoms using a SNOT-22 (Sino-Nasal Outcome Test-22) OR endoscopic Nasal Polyp Score (NPS) must be completed prior to initiation of mepolizumab. The result(s) must be included with the initial EDS application. Mepolizumab should be prescribed by a specialist with experience in managing severe chronic rhinosinusitis with nasal polyps (such as otolaryngologists, allergists, and respirologists). Mepolizumab should not be used in combination with other similar biologics. Initial approval duration: 1 year

	Renewal Patients must demonstrate a decrease from the baseline SNOT-22 score of at least 8.9 points OR a decrease in baseline NPS of at least 1 point. Renewal requests will be compared to baseline scores received with the initial EDS application. Renewal duration: 1 year

Mepron - see atovaquone

mercaptopurine, tablet, 50mg (Purinethol) (Mercaptopurine Tablets)

For treatment of:
(a) Crohn's disease.
(b) Rheumatoid arthritis

Metadol - see methadone

methadone HCl, tablet, 1mg, 5mg, 10mg, 25mg (Metadol PC and listed generic); oral suspension, 1mg/mL, 10mg/mL (Metadol (PC))

(a) Coverage restricted to Drug Plan registered palliative care patients only. An Exception Drug Status request is not required for these patients.
(b) For management of moderate to severe chronic pain in non-palliative patients, under the care of a chronic pain specialist (or where it is prescribed in consultation with a chronic pain specialist), when the patient has at least one of the following:
- Moderate to severe renal impairment; or
- Has failed or is intolerant to other opioid therapies.

methylphenidate HCl, controlled release capsule, 25mg, 35mg, 45mg, 55mg, 70mg, 85mg, 100mg (Foquest)

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

methylphenidate HCl, extended release capsule, 10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg, 80mg (Biphentin, and listed generics)

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients:
(a) Where the use of an another (short or long-acting) formulation has not properly controlled the symptoms of the disease; or
(b) Who cannot swallow tablets/capsules whole and require a long-acting ADHD medication.

metreleptin, solution for subcutaneous injection vial, 3mg, 5.8mg, 11.3mg (100mcg) (Myalepta)

For the treatment of complications of leptin deficiency in patients with lipodystrophy (LD) who have a confirmed diagnosis of generalized LD (GL or Berardinelli-Seip syndrome), acquired generalized LD (Lawrence syndrome), familial partial LD (PL), or acquired PL (Barraquer-Simons syndrome) as determined following genetic testing. In individuals whose genetic testing does not confirm a diagnosis of LD, a confirmed clinical diagnosis[1] may be accepted.

Initiation Criteria:

1. For patients with GL or acquired generalized LD, individuals must:
   - Be 2 years of age or older; AND,
   - Have at least 1 metabolic abnormality (diabetes mellitus, insulin resistance, or hypertriglyceridemia); AND,
   - Be under the care of an endocrinologist with experience in the diagnosis and management of LD.

2. For patients with familial PL or acquired PL, individuals must:
   - Be 12 years of age or older; AND,
   - Have persistent significant metabolic disease (hemoglobin A1C ≥6.5% and/or fasting triglycerides (TGs) ≥5.65 mmol/L) despite a 12-month trial of standard treatments[2]; AND,
   - Be under the care of an endocrinologist with experience in the diagnosis and management of LD.

[1] A confirmed clinical diagnosis of LD should consist of a comprehensive clinician assessment and a fasting leptin level as follows:
- *<12.0 ng/mL in females older than 5 years of age; OR,*
- *<8.0 ng/mL in males older than 5 years of age; OR,*
- *<6.0 ng/mL in children 6 months to 5 years of age.*

[2] Standard treatments are defined as optimized diet and exercise, as well as:

- *Antihyperglycemics (in individuals with elevated A1C); AND/OR,*
- *Lipid-lowering medications (in individuals with elevated TGs).*

NOTE: Individuals who are pregnant or lactating, or who have human immunodeficiency virus- (HIV-) associated LD will not be eligible for coverage of metreleptin.

Initial Approval Duration: 12 months

Renewal:
Renewal of metreleptin coverage will be considered in individuals who remain under the care of an endocrinologist with expertise in the management of LD, and have a beneficial metabolic effect, defined as:

- Actual hemoglobin A1C reduction of at least 0.5% from baseline; AND/OR,
- Percent fasting TG reduction of at least 15% from baseline.

Mictoryl Pediatric - see propiverine HCl

mirabegron, extended release tablet, 25mg, 50mg (Myrbetriq and listed generics) (possible OEA)
For treatment of overactive bladder (OAB) for patients intolerant to, or with an inadequate response to oxybutynin, solifenacin succinate or tolterodine l-tartrate.
Note: Should not be used in combination with other pharmacologic treatments for OAB.

mirikizumab, solution for I.V. infusion, 20mg/mL vial (mg); pre-filled pen, 100mg/mL, 200mg/2mL, 100mg/mL+200mg/2mL (mg); pre-filled syringe, 100mg/mL, 200mg/2mL, 100mg/mL+200mg/2mL (mg) (Omvoh)

Indication	Criteria
Crohn's Disease (solution for I.V. infusion) vial 20mg/mL) (pre-filled pens, 100mg/mL+ 200mg/2mL) (pre-filled syringes, 100mg/mL+ 200mg/2mL)	For the treatment of moderately to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroid or other immunosuppressive therapy. Clinical response should be assessed after the induction regimen (i.e., IV infusion at weeks 0, 4 and 8). **Initial approval**: 12 weeks Ongoing coverage of the maintenance subcutaneous injections will only be provided for patients who have responded to a course of IV induction therapy. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and janus kinase inhibitors, etc.) for Crohn's disease. **Note**: This product should be used in consultation with a specialist in this area.
Ulcerative Colitis (solution for I.V. infusion 20mg/mL vial) (pre-filled pen, 100mg/mL) (pre-filled syringe 100mg/mL)	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after six months of therapy. Ongoing coverage will only be provided for those who respond to therapy. Coverage will not be provided for use in combination with other biologic therapies or janus kinase (JAK) inhibitors for ulcerative colitis. **Note**: this product should be used in consultation with a specialist in this area.

modafinil, tablet, 100mg (Alertec, and listed generics)
For treatment of:
(a) Patients with sleep laboratory-confirmed diagnosis of narcolepsy.
(b) Patients with sleep laboratory-confirmed diagnosis of idiopathic CNS hypersomnia.

mometasone furoate/ formoterol fumarate dihydrate, inhalation aerosol, 100ug/5ug, 200ug/5ug (Zenhale)
For treatment of asthma in patients uncontrolled on inhaled steroid therapy.

Monoferric - see iron ferric derisomaltose

montelukast sodium, chewable tablet, 4mg, 5mg; tablet, 10mg (Singulair, and listed generics); oral granules, 4mg (listed generic)
(a) For treatment of asthma patients under the age of six years.

(b) For asthma patients who cannot manage the use of an inhalation device despite assistance with a spacer (eg. physically or mentally challenged patients or pediatric patients).
(c) For adjunctive treatment in patients up to the age of 18 concurrently on an inhaled steroid who have failed a long acting beta-2 agonist (LABA).

Movapo - see apomorphine HCl

moxifloxacin HCl, tablet, 400mg (listed generics)
For treatment of:
(a) Pneumonia in patients with underlying lung disease (excluding asthma) or pneumonia in nursing home patients.
(b) Infections in patients allergic to two or more alternative antibiotics.
(c) Infections known to be resistant to alternative antibiotics. Resistance must be determined by culture and sensitivity testing (C&S). Where a C & S cannot be obtained coverage will be approved when a patient has failed at least 2 other classes of antibiotics.
(d) For completion of antibiotic treatment initiated in hospital when alternatives are not appropriate.
(e) For management of adults with febrile neutropenia.
(f) For treatment of suspected mycoplasma genitalium infections in patients unresponsive or intolerant to azithromycin.

moxifloxacin HCl, ophthalmic solution, 0.5% (Vigamox, and listed generics) (possible OEA)
For treatment of ophthalmic infections unresponsive to alternative agents.

Myalepta – see metreleptin
Mycobutin - see rifabutin

mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept, and listed generics); powder for oral suspension, 200mg/mL (CellCept, and listed generics)
(a) For treatment of autoimmune conditions.

For the above indication prescriptions are subject to deductible (where applicable) and co-payment as for other drugs covered under the Drug Plan. **Pharmacies note: claims on behalf of these patients must use the following identifying numbers (not the DIN):**

250mg Capsule:	500mg tablet:
00951169- Sandoz Mycophenolate	00951172- Mycophenolate Mofetil (Accord)
00951167- Teva-Mycophenolate	00951164- Apo-Mycophenolate
00951163- Apo-Mycophenolate	00951170- Sandoz Mycophenolate
00951174- Mycophenolate Mofetil (Accord)	00951168- Teva-Mycophenolate
00951175- Jamp-Mycophenolate	00951176- Jamp-Mycophenolate
00951359- Mycophenolate (Sanis)	00951360- Mycophenolate (Sanis)
00950887 Cellcept	00950888 Cellcept
200mg/mL powder for oral suspension:	
00951560- Mar-Mycophenolate Mofetil	
00950937-Cellcept	

mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept, and listed generics); powder for oral suspension, 200mg/mL (CellCept, and listed generics)
(a) For prevention of acute rejection in transplant patients.
(b) For treatment of nephrotic syndrome in cases of biopsy-proven evidence of severe proliferative lesions or sclerosis, which have not responded after a 6 month course of cyclophosphamide, or in patients unable to tolerate cyclophosphamide.

mycophenolate sodium, enteric coated tablet, 180mg, 360mg (Myfortic, and listed generics)
For prevention of acute rejection in renal transplant patients.

Myfembree – see relugolix/estradiol/norethindrone acetate
Myfortic - see mycophenolate sodium
Myozyme - see alglucosidase alfa
Myrbetriq - see mirabegron

nabilone, capsule, 0.5mg, 1mg (Cesamet, and listed generics)
For treatment of nausea and anorexia in AIDS patients.

nabumetone, tablet, 500mg (listed generics) (possible OEA)
For treatment of patients intolerant to other NSAIDs listed in the Formulary.

nadroparin calcium, syringe, 9,500IU/mL (0.3mL, 0.4mL, 0.6mL, 0.8mL, 1.0mL) (Fraxiparine); syringe, 19,000IU/mL (0.6mL, 0.8mL, 1mL) (Fraxiparine Forte)

(a) For treatment of venous thromboembolism for up to 10 days.
(b) For prophylaxis following total knee arthroplasty for up to 35 days.
(c) For major orthopedic trauma for up to 10 days (treatment duration may be reassessed).
(d) For long-term outpatient prophylaxis in patients who are pregnant.
(e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
(f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
(g) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
(h) For prophylaxis following abdominal, thoracic, esophageal or pelvic surgery for up to 28 days.

nafarelin acetate, intranasal solution, 2mg/mL (Synarel)

For treatment of:
(a) Endometriosis. *(Coverage may be repeated after a six month lapse, for another 6 month course).*
(b) Menorrhagia in preparation for endometrial ablation, and:
(c) For pre-treatment of uterine fibroids prior to surgical removal. *Coverage will be provided for a maximum of 6 months*

naratriptan HCl, tablet, 1mg, 2.5mg (listed generics)

For treatment of migraine headaches in patients over 18 years of age.

The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60-day period. *Patients requiring more than 12 doses in a consecutive 60-day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.*

natalizumab, solution for IV infusion, 20mg/mL (Tysabri)

See Appendix D

Neoral - see cyclosporine
Neupro - see rotigotine

nevirapine, tablet, 200mg (Viramune, and listed generics); extended release tablet, 400mg (listed generics) (possible OEA)

For management of HIV disease.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Nexium - see esomeprazole magnesium trihydrate
Ngenla - see somatrogon

nintedanib, capsule, 100mg, 150mg (OFEV and listed generics)

Indication	Criteria
Idiopathic pulmonary fibrosis (IPF)	**Initial approval criteria:** • The patient is an adult diagnosed with mild to moderate idiopathic pulmonary fibrosis (IPF), confirmed by a respirologist and a high-resolution CT scan within the previous 24 months. • All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded. • The patient has a forced vital capacity (FVC) greater than or equal to 50% of predicted. • Patient is under the care of a physician with experience in the diagnosis and management of IPF. Initial approval period: Seven months (allow four weeks for repeat pulmonary function tests) **Initial renewal criteria (at six months):** Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial six 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 four weeks later. Approval period: 6 months

	Second and subsequent renewals (at twelve months and thereafter): • 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 four weeks later. Approval period: 12 months **Exclusion Criteria:** Combination use of nintedanib and pirfenidone will not be funded. **Notes:** Patients with IPF who have experienced intolerance or failure to nintedanib or pirfenidone will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.
Chronic fibrosing interstitial lung diseases with a progressive phenotype	**Initial approval criteria:** • The patient is diagnosed with chronic fibrosing interstitial lung disease with a progressive phenotype confirmed by a specialist in interstitial lung diseases; and • The patient has a forced vital capacity (FVC) greater than or equal to 45% of predicted. • Patient is under the care of a physician with experience in the diagnosis and management of interstitial lung diseases. **Initial approval period: 12 months** Renewal Criteria: • Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy during the preceding year of treatment with nintedanib. • If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later. **Exclusion Criteria:** Combination use of nintedanib and pirfenidone will not be funded.

Nipozi- see filgrastim

nirmatrelvir and ritonavir, 4 x 150mg and 2 x 100mg tablet (daily dose blister card) (Paxlovid)

For the treatment of moderately or severely immunosuppressed adult patients diagnosed with COVID-19 infection. Paxlovid MUST be initiated within 5 days of symptom onset.

Examples of severe immunosuppression may include:
- Solid organ transplant recipients
- Treatment for malignant hematologic conditions
- Bone marrow, stem cell transplant, or transplant-related immunosuppressant use
- Receipt of anti-CD20 agents or B-cell depleting agents (such as rituximab) in the previous 2 years
- Severe primary immunodeficiencies[a]

Examples of moderate immunosuppression may include:
- Treatment for cancer including solid tumors
- Treatment with significant immunosuppressing drugs[b]
- Advanced HIV infection (treated or untreated)
- Moderate primary immunodeficiencies[c]
- Renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis and dispensing of a steroid, eGFR < 15 mL/min/1.73m2).

a) Severe immunodeficiencies include combined immunodeficiencies affecting T cells, immune dysregulation (particularly familial hemophagocytic lymphohistiocytosis), or type 1 interferon defects (caused by a genetic primary immunodeficiency disorder or secondary to anti-interferon autoantibodies).

b) Immunosuppressing drugs such as a biologic in the past 3 months, oral immune-suppressing medication in the past months, oral steroid (20 mg/day of prednisone equivalent on an ongoing basis) in the past month, or immune-suppressing infusion or injection in the past 3 months.
c) Includes a primary immunodeficiency with a genetic cause at any time or a primary immunodeficiency due to immunoglobulin replacement therapy in the past year.

Nivestym - see filgrastim
Nizoral - see ketoconazole
Norditropin FlexPro – see somatropin

norfloxacin, tablet, 400mg (listed generics)

For treatment of:

(a) Genitourinary tract infections caused by *Pseudomonas aeruginosa*.
(b) Genitourinary tract infections in patients allergic to alternative agents.
(c) Genitourinary tract infections in patients with organisms known to be resistant to alternative antibiotics, and:
(d) For adults with gonococcal urethritis or cervicitis.
(e) For secondary prophylaxis in patients who have had an episode of spontaneous bacterial peritonitis and are intolerant or unresponsive to sulfamethoxazole/trimethoprim
(f) For primary prophylaxis for patients with cirrhosis considered high risk for spontaneous bacterial peritonitis who are intolerant to sulfamethoxazole/trimethoprim.

Note: High risk is defined as cirrhosis with ascities with an ascitic protein concentration less than 15g/L

Noromby- see enoxaparin
Norvir - see ritonavir
NovoRapid - see insulin aspart
Nplate - see romiplostim
Nucala - see mepolizumab

nusinersen, solution for intrathecal injection, 12mg/5mL (Spinraza)

Coverage may be available for this product through the Drug Plan for the treatment of spinal muscular atrophy. Due to the unique nature of this condition and the cost of this treatment, Exception Drug Status (EDS) requests will require additional details to facilitate assessment of the application and accompanying clinical information. In addition, patients who are approved will be required to undergo ongoing assessment to monitor for improvement over time and must meet renewal criteria for continuation of treatment. Please contact the Drug Plan at 1-800-667-7581 for more information regarding coverage availability and the EDS application process for this product.

obeticholic acid, tablets, 5mg, 10mg (Ocaliva)

For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:

- A confirmed diagnosis of PBC, defined as:
  - Positive antimitochondrial antibodies (AMA); or
  - Liver biopsy results consistent with PBC.

  AND
- The patient has received ursodeoxycholic acid (UDCA) for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:
  - alkaline phosphatase (ALP) ≥ 1.67 x upper limit of normal (ULN) **and/or**
  - bilirubin > ULN and < 2 x ULN **and/or**
  - compensated cirrhosis.

  OR
- The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

  AND
- Patients should be under the care of a specialist experienced in the diagnosis and management of primary biliary cholangitis.

  Duration of approval: 12 months

Renewal Criteria:

The patient continues to benefit from treatment with obeticholic acid as evidenced by:

- A reduction in the ALP level to less than 1.67 x ULN; **or**
- A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Duration of approval: 12 months

Ocaliva - see obeticholic acid
Ocphyl - see octreotide
Ocrevus - see ocrelizumab

ocrelizumab, solution for infusion, 30mg/mL (Ocrevus)
See Appendix D

octreotide, injection, 50ug/mL (1mL), 100ug/mL (1mL); 200ug/mL (5mL); 500ug/mL (1mL) (listed generics); powder for injection, 10mg/vial (mg), 20mg/vial (mg), 30mg/vial (mg) (Sandostatin LAR, and listed generics)
(a) For management of terminal malignant bowel obstruction in palliative patients.
(b) For treatment of acromegaly.
***Note**: Coverage for federally approved cancer indications is provided under the Saskatchewan Cancer Agency according to their guidelines.*

Ocuflox - see ofloxacin ophthalmic solution
Odefsey - see emtricitabine/rilpivirine/tenofovir alafenamide

odevixibat, capsule, 200mcg, 400mcg, 600mcg, 1200mcg (100mcg) (Bylvay)

Indication	Criteria
Progressive Familial Intrahepatic Cholestasis (PFIC)	For the treatment of pruritus in patients 6 months of age or older with progressive familial intrahepatic cholestasis (PFIC) who: • Have a genetic diagnosis of PFIC1 or PFIC2; AND, • Have severe pruritus, defined as an observer-reported outcome (ObsRO) scratching score ≥ 2; AND, • Are receiving at least 1 systemic treatment[1] used for symptomatic relief of pruritus prior to initiating odevixibat; AND, • Have a serum bile acid (sBA) level ≥ 100 umol/L; AND, • Have not received a liver transplant. Patients must be under the care of a gastroenterologist or other specialist with experience in the diagnosis and management of PFIC. Eligible dose: 40 mcg/kg/day for the first three months, with an increase in patients not responding after three months to up to 120 mcg/kg/day (maximum of 7,200 mcg/day). [1]Systemic treatment may include a trial of at least one month with one of the following: • Ursodeoxycholic acid (UDCA) • Rifampin • Sertraline • Naltrexone • Cholestyramine **Initial approval duration**: Six (6) months **Initial Renewal Criteria**: Renewal of odevixibat coverage will be considered in individuals who: • Remain under the care of a gastroenterologist or other specialist with experience in the diagnosis and management of PFIC; AND, • Have not received a liver transplant; AND, • Demonstrate a reduction in pruritus, defined as either: o An ObsRO scratching score of ≤ 1; OR, o A decrease of at least 1 point in the ObsRO scratching score from baseline. **Subsequent Renewal Criteria**: Ongoing coverage of odevixibat will be considered in individuals who: • Remain under the care of a gastroenterologist or other specialist with experience in the diagnosis and management of PFIC; AND, • Have not received a liver transplant; AND, • Maintain the improvement in ObsRO scratching score demonstrated at the initial renewal. Patients meeting initial or subsequent renewal criteria will be eligible for renewal of coverage for their lowest effective dose of odevixibat. Renewal duration: Six (6) months
Alagille Syndrome (ALGS)	For the treatment of cholestatic pruritus in patients 12 months of age or older with Alagille syndrome (ALGS) who:

	• Have significant pruritus, defined as an itching or scratching score of 2 or higher on the PRUCISION patient-reported (PRO) or observer-reported outcome (ObsRO) scale; AND, • Are currently treated with, or have received an adequate trial of systemic treatment for pruritus[1] prior to initiating odevixibat; AND, • Have a serum bile acid (sBA) level greater than the upper limit normal (ULN) for age. Patients must be under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS. **Exclusion Criteria**: Individuals who have ANY of the following will not be eligible for initiation of odevixibat coverage: • Previous biliary diversion surgery; OR, • Previous liver transplant; OR, • Decompensated liver disease; OR, • History or presence of other concomitant liver disease. [1] Systemic treatment for pruritus may include a trial of at least one month with one of the following: • Ursodeoxycholic acid (UDCA) • Rifampin • Sertraline • Naltrexone • Cholestyramine **Initial approval duration**: Six (6) months **Initial Renewal Criteria**: Renewal of odevixibat coverage will be considered in individuals who: • Remain under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS; AND, • Have not received a liver transplant or biliary diversion surgery; AND, • Experience either: o An improvement in pruritus to minimal or no itch (defined as a score of 1 or less on the PRUCISION PRO or ObsRO scale); OR, o An improvement (decrease) in PRUCISION PRO or ObsRO by 1 point. **Subsequent Renewal Criteria**: Ongoing coverage of odevixibat will be considered in individuals who: • Remain under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS; AND, • Have not received a liver transplant or biliary diversion surgery; AND, • Maintain the improvement (decrease) in PRUCISION PRO or ObsRO scale demonstrated at the initial renewal. Renewal duration**:** Six (6) months

ofatumumab, 20mg/0.4mL pre-filled pen (mg) (Kesimpta)
See Appendix D

OFEV – see nintedanib

ofloxacin, ophthalmic solution, 0.3% (Ocuflox, and listed generics) (possible OEA)
For the treatment of:
(a) Ophthalmic infections caused by gram-negative organisms.
(b) Ophthalmic infections unresponsive to alternative agents, and:
(c) Infiltrative corneal infections.

Okedi – see risperidone
Olumiant - see baricitinib

omalizumab, prefilled syringe; prefilled pen; 75mg/0.5mL, 150mg/mL (Omlyclo)

Indication	Criteria
Allergic Asthma	For add-on maintenance treatment of adult and pediatric patients (6 years of age and above) with moderate to severe persistent asthma[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), and: • The patient consistently adheres to daily use of both ICS and LABA as prescribed and demonstrates correct inhaler technique, AND • Has experienced two or more clinically significant asthma exacerbations[3] in the past 12 months, OR is receiving maintenance treatment with oral corticosteroids[4] for asthma, AND • The patient has a documented positive skin test or in vitro reactivity to a perennial aeroallergen. Requester will be required to provide baseline IgE level and patient weight with the EDS application. In addition: • Omalizumab should not be used in combination with other biologics used to treat asthma. • A baseline[5] assessment of asthma symptom control using a validated asthma control questionnaire[6] must be completed prior to initiation of omalizumab treatment and submitted with the application. • Baseline[5] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications. • Patients should be managed by a specialist in the treatment of asthma. [1]Patients must have a documented diagnosis of asthma. [2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily for patients 12 years and older; OR greater or equal to 400 mcg of fluticasone propionate or equivalent daily for patients aged 6 to 11 years of age. [3]Clinically significant asthma exacerbations are defined as hospitalization for asthma OR two or more urgent visits for asthma to a physician or an emergency department OR two or more courses of high-dose oral corticosteroids. [4]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day. [5]Baseline refers to results achieved prior to initiation of the requested therapy. [6]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT. **Discontinuation Criteria:** Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if: • At First Renewal (based on first 12 months of therapy): o The asthma control questionnaire score has not improved from baseline[5], OR o The number of clinically significant exacerbations has increased, OR o The oral corticosteroid maintenance dose has not decreased. • At Subsequent Renewals (after 2 years of therapy): o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, OR o The number of clinically significant exacerbations has increased within the previous 12 months, OR • The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently.
Chronic Idiopathic Urticaria (CIU)	For the treatment of adults and adolescents (12 years of age or older) with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimal management with H1 antihistamines. Notes:

	• Document the baseline urticaria activity score over seven days (UAS7) on the initial request. • Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment. • Initial approval will be granted for a period of 24 weeks at a maximum dose of 300mg every 4 weeks. • 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. Extension requests: • Continued coverage may be authorized if the patient has achieved: o complete symptom control for less than 12 consecutive weeks; or o partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7) Re-initiation requests: • In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation may be considered should CIU symptoms reappear.
Chronic Rhinosinusitis with nasal polyposis (CRSwNP)	As an add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by intranasal corticosteroids alone, where ALL of the following clinical criteria are met: • Endoscopically or CT-documented bilateral nasal polyps, • Have undergone a surgical intervention for nasal polyps, or have a contraindication to surgery, and • Experience refractory symptoms despite use of intranasal corticosteroids for 3 months at maximally tolerated doses, AND use of intranasal corticosteroids will continue with omalizumab. In addition: • A baseline assessment of symptoms using a SNOT-22 (Sino-Nasal Outcome Test-22) OR endoscopic Nasal Polyp Score (NPS) must be completed prior to initiation of omalizumab. The result(s) must be included with the initial EDS application. • Omalizumab should be prescribed by a specialist with experience in managing severe chronic rhinosinusitis with nasal polyps (such as otolaryngologists, allergists, and respirologists). Omalizumab should not be used in combination with other similar biologics. Requester will be required to provide baseline IgE level and patient weight with the EDS application. **Initial approval duration**: 1 year **Renewal** Patients must demonstrate a decrease from the baseline SNOT-22 score of at least 8.9 points OR a decrease in baseline NPS of at least 1 point. Renewal requests will be compared to baseline scores received with the initial EDS application. Renewal duration: 1 year

omeprazole, capsule/tablet 10mg (Losec, and listed generics)
For pediatric patients requiring treatment with a proton pump inhibitor where the full Formulary options are not appropriate.

Omlyclo – see omalizumab
Omnitrope - see somatropin
Omvoh – see mirikizumab

onabotulinumtoxin A, injection, 50IU/vial, 100IU/vial, 200IU/vial (Botox)
For treatment of:
(a) Eye dystonias, that is, blepharospasm and strabismus.
(b) Cervical dystonia, that is, torticollis.
(c) For the treatment of patients with upper or lower limb spasticity associated with cerebral palsy or stroke.
(d) Hyperhidrosis of the axilla.
(e) Children with non-neurologic functional outflow obstruction due to external sphincter over-activity who are not candidates for or who have not responded to other options.
(f) Spinal cord injury patients with chronic urinary retention who are not candidates for or who have not responded to other options.
Note: This criteria does not apply to patients with multiple sclerosis.

(g) Severe neurogenic bladder dysfunction in patients who have failed treatment with two anticholinergic drugs, who are unable to take these drugs because of adverse effects, who have definite evidence of detrusor hyperactivity on cystometrogram done by a qualified urodynamicist.
(h) For the treatment of overactive bladder (OAB), in adult patients who have had an inadequate trial response, or are intolerant to two alternative pharmacologic agents for OAB.

Notes:Adequate trial response to alternative pharmacologic agents would be considered a total of 6 months on two other pharmacologic treatments for OAB. For clarity, this means 3 months on each of the pharmacologic treatment for OAB for a total of 6 months.

- Prescribing and administration is restricted to urologists or gynecologists
- Prescribers should discontinue treatment after one dose if a patient is considered a non-responder (i.e., those who fail to achieve a reduction of at least 50% in the frequency of urinary incontinence episodes with one dose). Initial EDS approval will be for one dose of 100U in the first 12 weeks.
- Maximum of three doses per year in responders, at a frequency of no more than once every 12 weeks.

ondansetron, orally disintegrating tablet/film, 4mg, 8mg (Ondissolve and listed generics)
For the treatment of:
a) Severe nausea in patients refractory to dexamethasone, dimenhydrinate, metoclopramide OR prochlorperazine.
b) Hyperemesis gravidarum.

ondansetron HCl dihydrate, oral solution, 4mg/5mL (listed generics)
For treatment of severe nausea in patients refractory to dexamethasone, dimenhydrinate, metoclopramide or prochlorperazine, who cannot tolerate or use the ondansetron orally disintegrating tablets (ODTs).

ondansetron HCl dihydrate, solution for injection, 2mg/mL (mL) (listed generics)
For the treatment of:
a) Severe nausea in patients uncontrolled on, or who cannot tolerate or use ondansetron oral liquid, AND orally disintegrating tablets (ODTs).
b) Hyperemesis gravidarum in patients who are uncontrolled on, OR who cannot tolerate or use available ondansetron oral formulations.

One-Alpha - see alfacalcidol
Onglyza - see saxagliptin
Onpattro - see patisiran
Opsumit - see macitentan
Orencia - see abatacept
Orkambi - see lumacaftor/ivacaftor
Orladeyo – see berotralstat HCl
Otulfi – see ustekinumab
Otulfi I.V.- see ustekinumab

oxcarbazepine, tablet, 150mg, 300mg, 600mg (Trileptal, and listed generics); oral suspension, 60mg/mL (Trileptal) (Possible OEA)
For treatment of partial seizures in patients intolerant to carbamazepine.
Oxeze Turbuhaler - see formoterol fumarate
Oxlumo- see lumasiran
Oxsoralen - see methoxsalen

oxycodone HCl, controlled release tablet, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg (Oxyneo)
For the treatment of pain in palliative and cancer patients.

Oxyneo - see oxycodone HCl

ozanimod, capsule, 0.23mg & 0.46mg initiation kit; capsule, 0.92mg (Zeposia)
For the treatment of ulcerative colitis in patients unresponsive to high dose steroids.
Initial clinical response should be assessed after 10 weeks of therapy.
Ongoing coverage will only be provided for those who respond to therapy.
Note: This product should be used in consultation with a specialist in this area.
This product will not be reimbursed for combination use with other escalated ulcerative colitis treatments (such as biologics and janus kinase inhibitors).

Ozempic - see semaglutide

paliperidone palmitate, pre-filled syringe, 50mg, 75mg, 100mg, 150mg (Invega Sustenna); prolonged release pre-filled syringe, 175mg/0.875mL, 263mg/1.315mL, 350mg/1.75mL, 525mg/2.625mL (Invega Trinza)

For patients:

a) With a history of non-adherence, as evidenced by outcomes such as repeated hospitalizations,
OR
b) Who have been on a first generation long acting injectable antipsychotic agent but can no longer tolerate or have relapsed,
OR
c) Who were started on treamtment in the hospital.

palovarotene, capsule, 1mg, 1.5mg, 2.5mg, 5mg, 10mg (mg) (Sohonos)

Initial Requests

For the treatment of adults and children (aged 8 years and older for females and 10 years and older for males) who:

- Have a confirmed clinical diagnosis of fibrodysplasia (myositis) ossificans progressiva (FOP); **AND**
- Have completed genetic testing confirming presence of the R206H ACVR1 mutation; **AND**
- Do not have complete ankylosis of the whole body; **AND**
- Are under the care of a specialist with experience in the diagnosis and management of FOP.

A description of the patient's baseline assessments and individualized treatment goals for palovarotene treatment must be submitted with the initial coverage request. Baseline assessments should address the following:

- Ability to eat and feed
- Ability to perform activities of daily living
- Pain
- Mobility
- Joint range of motion
- Pulmonary function

Initial Approval Duration:12 months

Renewal Requests

Patients who demonstrate continued benefit with palovarotene will be considered for renewal. Requesters must include a description of the patient's current response to palovarotene therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

The response update should address the following:

- Ability to eat and feed
- Ability to perform activities of daily living
- Pain
- Mobility
- Joint range of motion
- Pulmonary function
- Current extent of ankylosis
  - Note: Coverage will be discontinued in patients where complete ankylosis of the whole body has occurred.
- Summary of individual benefit/risk assessment for the patient and the rationale for continuing treatment with palovarotene.

Patients must continue to be under the care of a specialist with experience in the diagnosis and management of FOP.
Renewal duration: Up to 12 months

patisiran, solution for injection, 2mg/mL (Onpattro)

For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:

- Polyneuropathy disability [PND][1] stage I to ≤ IIIB, or
- Familial amyloidotic polyneuropathy [FAP][2] stage I or II.

Patients must be under the care of a specialist with experience in the diagnosis and management of hATTR.

Exclusion Criteria (at therapy initiation):

- Patients exhibiting severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV); or
- Patients who have previously undergone a liver transplant; or

- Patients receiving other interfering ribonucleic acid drugs (such as Tegsedi (inotersen)]) or transthyretin stabilizers (such as Vyndaqel [tafamidis meglumine]); or
- Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care.

Initial approval duration: Nine (9) months.

Discontinuation Criteria:

Treatment with Onpattro (patisiran) should be reviewed nine months after the initial approval, and then at least every six months thereafter, to determine the continued clinical benefit for the patient.
Treatment should be discontinued if the patient is:

- Permanently bedridden and dependent on assistance for basic activities of daily living, or
- Receiving end-of-life care[3].

After the initial nine (9) month approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:
[1]PND is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Sensory disturbances but preserved walking capability
- Stage II – Impaired walking capacity but ability to walk without a stick or crutches
- Stage IIIA – Walking with the help of one stick or crutch
- Stage IIIB – Walking with the help of two sticks or crutches
- Stage IV – Confined to a wheelchair or bedridden

[2]FAP is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Unimpaired ambulation; mostly mild sensor, motor, and autonomic neuropathy in the lower limbs
- Stage II – Assistance with ambulation required, mostly moderate impairment progression to the lower limbs, upper limbs, and trunk
- Stage III – Wheelchair bound or bedridden; severe sensory, motor, and autonomic involvement of all limbs.

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g. management of symptoms such as pain, nausea and stress).

Please contact the Drug Plan for billing information.

Paxlovid – see nirmatrelvir and ritonavir
Paxlovid Renal – see nirmatrelvir and ritonavir
PDP-Isoniazid – see isoniazid
Pegasys - peginterferon alfa-2a

pegcetacoplan, subcutaneous infusion, 54mg/mL, 20mL vial (mL) (Empaveli)

Initiation Criteria

For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) in patients with ALL of the following:

- The patient has qualified for EDS approval for C5 inhibitor treatment (e.g., ravulizumab or eculizumab); **and**
- Pegcetacoplan is being prescribed by or in consultation with a hematologist or nephrologist with experience managing PNH; **and**
- The patient is experiencing at least ONE of the following:
    - Persistent anemia with hemoglobin levels less than 105 g/L despite six months of treatment with a stable dose of a C5 inhibitor, and where causes other than extravascular hemolysis have been excluded; **or**
    - Intolerable adverse events from C5 inhibitor treatment.

Initial approval duration: 6 months

Renewal Criteria

After the initial approval period, a patient may receive approval for further coverage of pegcetacoplan where:

- There has been relief in the PNH symptoms that had qualified the patient for their initial C5 inhibitor coverage approval; **and**
- There is demonstrated clinical improvement in the patient, or stabilization of the patient's condition, while receiving treatment with pegcetacoplan; **and**

- The patient and treating physician have been adequately adherent to treatment and to measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; **and**
- Pegcetacoplan is being prescribed by or in consultation with a hematologist or nephrologist with experience in managing PNH.

Requests for renewal must be accompanied by current confirmation of granulocyte and monocyte clone size (by flow cytometry), in accordance with the Exclusion Criteria below.

Renewal duration: 1 year

Exclusion Criteria (for initial and renewal requests)

Patients meeting **any** of the following criteria will not be eligible for pegcetacoplan coverage:

- Receiving concurrent treatment with other complement inhibitors (e.g., ravulizumab or eculizumab, aside from the first 4 weeks of the pegcetacoplan initiation period);
- Granulocyte and monocyte clone size both below 10%;
- Presence of aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Presence of another life threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (for example, acute myeloid leukemia or high-risk myelodysplastic syndrome); or
- Presence of another medical condition that might reasonably be expected to compromise a response to pegcetacoplan therapy.

peginterferon alfa-2a, injection (pre-filled syringe), 180ug/0.5mL (Pegasys Proclick)

For the management of hepatitis B for up to 48 weeks.

Note: This product should be used in consultation with a specialist in this area.

peginterferon beta-1a, prefilled syringe/pen, 63mcg/94mcg/0.5mL (starter pack), 125mcg/0.5mL (Plegridy)

See Appendix D

penicillin G (bezathine), suspension for injection, 1,200,000IU/2mL (Bicillin L-A)

For prophylaxis of recurrent rheumatic fever and its associated complications.

Note: This drug is supplied by local public health offices when used in the treatment of sexually transmitted infections.

pentosan polysulfate sodium, capsule, 100mg (Elmiron)

For treatment of interstitial cystitis where other treatments have failed.

perampanel, tablet, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg (Fycompa and listed generic)

For the adjunctive treatment of refractory partial-onset seizures (POS) or of primary generalized tonic-clonic (PGTC) seizures in patients who meet all of the following criteria:

a) Are currently receiving two or more antiepileptic drugs; AND
b) less costly antiepileptic drugs are ineffective or inappropriate; AND
c) the medication is being used under the direction of a neurologist.

Note: Patients should have tried and failed at least two less costly antiepileptic drugs.

Persantine - see dipyridamole
Pheburane - see sodium phenylbutyrate
Piasky – see crovalimab
Pifeltro - see doravirine

pilocarpine HCl, tablet, 5mg (Salagen)

For the treatment of:

(a) Symptoms of xerostomia (dry mouth) due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck; or
(b) Symptoms of xerostomia (dry mouth) and xerophthalmia (dry eyes) in patients with Sjogren's syndrome.

pimecrolimus, topical cream, 1% (Elidel) (possible OEA)

For treatment of:

(a) Atopic dermatitis in patients unresponsive to topical steroids tried within the last 3 months.
(b) Atopic dermatitis in patients intolerant to topical steroids tried within the last 3 months.
(c) For the treatment of prurigo nodularis (PN) in patients where topical corticosteroids (TCS) are not advisable, or not effective.

*__pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Actos, and listed generics) (possible OEA)__

For treatment of patients with Type 2 diabetes who have had previous prescriptions for metformin **and** a sulfonylurea.

Note: *These products should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin **and** a sulfonylurea.*

pirfenidone, capsule, 267mg (listed generics); tablet, 267mg, 801mg (Esbriet, and listed generics)

Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Prescribers may be asked to provide documentation to support confirmation of diagnosis.

Initial approval period: seven months (allow four weeks for repeat pulmonary function tests)

Initial renewal criteria (at six months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial six 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 four weeks later.

Approval period: six months

Second and subsequent renewals (at 12 months and thereafter):

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 four weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.

Notes: Patients who have experienced intolerance or failure to Esbriet (pirfenidone) or Ofev (nintedanib) will be considered for the alternate agent provided the patient continues to meet the above coverage criteria.

Plegridy - see Appendix D
Praluent –see alirocumab
Prevacid - see lansoprazole
Prevacid FasTab - see lansoprazole
Prevymis - see letermovir
Precobix - see darunivir/cobicistat
Probuphine - see buprenorphine hydrochloride
Procysbi - see cysteamine bitartrate
Procytox - see cyclophosphamide
Prograf - see tacrolimus
Prolia - see denosumab

propranolol, oral solution, 3.75mg/mL (Hemangiol)

For the treatment of proliferating infantile hemangioma in patients requiring systemic therapy and meeting at least one of the following:

- life- or function-threatening hemangioma, OR
- ulcerated hemangioma with pain and/or lack of response to simple wound care measures, OR
- hemangioma with a risk of permanent scarring or disfigurement.

propiverine HCl, tablet, 5mg (Mictoryl Pediatric)

For the symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency in pediatric patients with overactive bladder.

Protopic - see tacrolimus
Pulmozyme - see dornase alfa
Purinethol - see mercaptopurine
Pyzchiva – see ustekinumab

Quinsair- see levofloxacin
Qulipta - see atogepant
Radicava - see edaravone

raloxifene HCl, tablet, 60mg (Evista, and listed generics)
For treatment of osteoporosis in postmenopausal women who do not tolerate listed bisphosphonates.

raltegravir, tablet, 400mg, (Isentress) (possible OEA)
a) For the treatment of HIV-1 infection in treatment-experienced patients who have evidence of viral replication and HIV-1 strains resistant to three classes of HIV agents. *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*
b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

ranibizumab, injection solution, 10mg/mL (mcg) (Lucentis) (possible OEA)

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	For the treatment of neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections. [1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease. The interval between the doses should be no shorter than one month. Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy. Ranibizumab should be permanently discontinued if any one of the following occurs: (a) Reduction in best corrected visual acuity (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. (b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both. (c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment can not be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment to be given monthly for three consecutive treatments. Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after three consecutive treatments. (e) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness. (f) Treatment should be resumed with monthly injections when monitoring indicates a loss in visual acuity and increase in retinal thickness and continued until stable visual acuity and improvement in retinal thickness is reached again for three consecutive monthly assessments. (g) Treatment should be discontinued if there is no improvement of retinal thickness or visual acuity after three consecutive treatments. (h) Injection will be by a qualified ophthalmologist with experience in intravitreal injections. Note: • Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.
Retinal Vein Occlusion (RVO)	For the treatment of visual impairment due to clinically significant macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) for patients meeting all of the following:

	(a) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less. (b) Treatment is to be given monthly until edema is resolved or there is no further improvement with three consecutive treatments. (c) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity. (d) Treatment should be resumed if there is a recurrence of macular edema with macular thickness greater than 300 microns or loss of visual acuity, and continued until stable visual acuity and improvement in retinal thickness is reached again for three consecutive assessments. (e) Treatment should be discontinued if there is no improvement after 6 months of initial treatment. (f) Injection will be by a qualified ophthalmologist with experience in administering intravitreal injections.
Choroidal Neovascularization	For treatment of visual impairment due to choroidal neovascularization secondary to pathologic myopia. Must be administered by a qualified ophthalmologist with experience in intravitreal injections. Note: • Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected. • Grid Laser photocoagulation can also be considered for BRVO at the discretion of the treating ophthalmologist.

Rapamune - see sirolimus
Ravicti - see glycerol phenylbutyrate

ravulizumab, intravenous solution, 10mg/mL (30mL vial), 100mg/mL (3mL vial), 100mg/mL (11mL vial) (mg) (Ultomiris)

INDICATION: Atypical Hemolytic Uremic Syndrome (aHUS)

Initiation Criteria

For the treatment of atypical hemolytic uremic syndrome (aHUS), when prescribed by or in consultation with a nephrologist or hematologist, in patients meeting **ALL** of the following:

1. Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA) as follows:
   - ADAMTS-13* activity ≥ 10% on blood samples taken before plasma exchange or plasma infusion (PE/PI); **and**
   - Shiga toxin–producing *Escherichia coli* (STEC) test negative, in patients with a history of bloody diarrhea in the preceding 2 weeks; **and**
   - TMA must be unexplained (i.e. not attributed to any secondary cause).

AND

2. Evidence of ongoing active TMA that is progressing (despite use of plasmapheresis, if appropriate), as demonstrated by the following:
   - Unexplained thrombocytopenia (platelet count < 150 × 10^9/L and not a secondary TMA); **and** hemolysis as indicated by the documentation of 2 of the following: schistocytes on the blood film, low or absent haptoglobin, or lactate dehydrogenase (LDH) above normal;
     or
   - TMA confirmed by tissue biopsy, in patients who do not have evidence of platelet consumption and hemolysis.

AND

3. Evidence of **at least ONE** of the following documented clinical features of active organ damage or impairment:
   - Kidney impairment, as demonstrated by one of the following:

Patient Characteristic	Kidney Impairment Level
Adult, preexisting renal impairment	eGFR decline of > 20%
Adult, no history of preexisting renal impairment (including patients with no baseline eGFR measurement)	SCr > ULN for age, or eGFR < 60mL/min and renal function deteriorating despite prior PE/PI
Pediatric patients	SCr > the age-appropriate ULN (as determined by or in consultation with a pediatric nephrologist)

eGFR = estimated glomerular filtration rate
SCr = serum creatinine
ULN = upper limit of normal

and/or

- The onset of neurological impairment related to TMA; **and/or**
- Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, and retinal vein occlusion.

Initial coverage duration: 6 months
**Notes:*
ADAMTS-13 = A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13.

Initiation Criteria for Kidney Transplant Patients
Transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS-13 activity ≥ 10%) may be eligible for ravulizumab coverage, when prescribed by or in consultation with a nephrologist or hematologist, if **ANY** of the following occur:

- Development of TMA immediately (within hours to 1 month) following a kidney transplant; **or**
- Experiencing aHUS recurrence after previous loss of a native or transplanted kidney due to the development of TMA; **or**
- The patient will be receiving a kidney transplant and requires prophylaxis with ravulizumab at the time of the transplant.

Initial coverage duration: 6 months

Exclusion Criteria (for initial and renewal requests)
Patients with a history of ravulizumab treatment failure (i.e. treated with ravulizumab for a previous aHUS occurrence/recurrence) will not be eligible for coverage.

Treatment failure is defined as **ANY** of the following occurring while receiving ravulizumab:

- Dialysis dependence at 6 months of ravulizumab treatment, and failure to demonstrate resolution or stabilization of neurological or extrarenal aHUS complications (if these were originally present); **or**
- On dialysis for ≥ 4 of the previous 6 months of ravulizumab treatment, and failure to demonstrate resolution or stabilization of neurological or extrarenal aHUS complications (if these were originally present); **or**
- Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline at the start of ravulizumab treatment.

Patients will not be eligible for ravulizumab coverage if receiving concurrent treatment with another C5 inhibitor drug (e.g. eculizumab).

Initial Renewal Criteria (at 6 months)
After the initial 6 months of ravulizumab treatment, coverage may be renewed if ALL of the following are met:

- The patient has demonstrated response to treatment, defined as, but not limited to:
    - Hematological normalization (e.g., platelet count, LDH); **and**
    - Stabilization of aHUS-related end-organ damage (such as acute kidney injury and brain ischemia); **and**
    - Transplant graft survival in susceptible individuals; **and**
    - Dialysis avoidance, in patients who are pre-end stage kidney disease (ESKD); **and**
- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above; **and**
- Ravulizumab therapy continues to be managed by or in consultation with a nephrologist or hematologist.

Initial Renewal coverage duration: 6 months

Subsequent Renewal Criteria (at 12 months and thereafter)
For patients requiring ongoing ravulizumab treatment, coverage may be renewed if **ALL** of the following are met:

- The patient continues to demonstrate response to treatment, as defined in the Initial Renewal Criteria above; **and**
- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above; **and**
- The patient has limited organ reserve, or a high-risk genetic mutation (e.g. Factor H deficiency) associated with aHUS recurrence.
    - Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Stage 4 or 5 chronic kidney disease (eGFR < 30mL/min).

and

- Ravulizumab therapy continues to be managed by or in consultation with a nephrologist or hematologist.

Subsequent Renewal coverage duration: 12 months

Reinitiation Criteria

Patients previously diagnosed with aHUS who responded to treatment with ravulizumab (without treatment failure, as defined in the Exclusion Criteria above) may be eligible for coverage to restart ravulizumab, if a TMA related to aHUS redevelops and **ALL** of the following are present:

- Significant hemolysis, as evidenced by presence of schistocytes on the blood film, low or absent haptoglobin, or LDH above normal; **and**
- **At least ONE** of the following:
    - Platelet consumption, as measured by either ≥ 25% decline in platelet count from patient baseline or thrombocytopenia (platelet count < 150 × 10^9/L); **or**
    - TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin), including evidence of TMA on recent biopsy;

    and
- Ravulizumab therapy is being prescribed by or in consultation with a nephrologist or hematologist.

Reinitiation Coverage duration: 6 months, with renewal considered according to Initial Renewal Criteria and Subsequent Renewal Criteria above.

INDICATION: Generalized Myasthenia Gravis (gMG):

Initiation Criteria:

For the treatment of adult patients with generalized myasthenia gravis (gMG) who:

- Have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; AND,
- Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥6; AND,
- Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
- Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
- Will not have ravulizumab initiated during a gMG exacerbation or crisis, or within 12 months of a thymectomy; AND,
- Will not be using ravulizumab concomitantly with rituximab, a neonatal Fc receptor antagonist, or another complement inhibitor; AND,
- Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

Initial Coverage Duration: 6 months

Initial Renewal Criteria:

Renewal of ravulizumab coverage will be considered in individuals who:

- Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
- Will not be using ravulizumab concomitantly with rituximab, a neonatal Fc receptor antagonist, or another complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Subsequent Renewal Criteria:

Ongoing coverage of ravulizumab will be considered in individuals who:

- Have maintained the improvement in MG-ADL score[1] demonstrated at the initial renewal; AND,
- Will not be using ravulizumab concomitantly with rituximab, a neonatal Fc receptor antagonist, or another complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Renewal Duration: 12 months

[1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.

[2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

INDICATION*:* Neuromyelitis Optica Spectrum Disorder (NMOSD):

For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who meet ALL of the following:

- The patient is anti–aquaporin 4 (AQP4) seropositive; and

- The patient has had at least one NMOSD attack or relapse in the previous 12 months; and
- The patient has experienced an inadequate response or intolerance following a trial of rituximab, or has a contraindication to rituximab; and
- The patient has an Expanded Disability Status Scale (EDSS) score of 7 points or less; and
- Ravulizumab is being prescribed by a neurologist with expertise in treating NMOSD; and
- Ravulizumab will not be used in combination with rituximab, satralizumab, eculizumab, or inebilizumab.

Initial approval duration: 12 months

Note: Ravulizumab should not be initiated during a NMOSD relapse episode.

Renewal
To be eligible for ongoing coverage of ravulizumab, the patient must:
- Maintain an EDSS score of 8 points or less (measured annually); and
- Remain under the care of a neurologist with expertise in treating NMOSD; and
- Not be using ravulizumab in combination with rituximab, satralizumab, eculizumab, or inebilizumab.

Renewal duration: 12 months

INDICATION: Paroxysmal Nocturnal Hemoglobinuria (PNH)
Initiation Criteria
For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) in patients diagnosed based on both of the following confirmatory results:
- Flow cytometry/FLAER exam with granulocyte or monocyte clone size ≥ 10%; **and**
- Lactate dehydrogenase (LDH) > 1.5 x upper limit of normal (ULN);

AND the patient is exhibiting at least one of the following features attributed to PNH:
- A thrombotic or embolic event which required the initiation of therapeutic anticoagulant therapy; **and/or**
- Transfusion requirement of ≥ 4 units of red blood cells in the previous 12 months; **and/or**
- Chronic or recurrent anemia where causes other than hemolysis have been excluded, and demonstrated by more than one hemoglobin measure of ≤ 70g/L or more than one hemoglobin measure of ≤ 100 g/L with concurrent symptoms of anemia; **and/or**
- Pulmonary insufficiency, as defined by debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **and/or**
- Renal insufficiency, demonstrated by an eGFR ≤ 60mL/min/1.73m^2, where causes other than PNH have been excluded; **and/or**
- Smooth muscle spasm, as defined by recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded;

AND ravulizumab is being prescribed by or in consultation with a hematologist or nephrologist with experience managing PNH.
Initial approval duration: 6 months

Renewal Criteria
After the initial approval period, a patient may receive approval for further coverage of ravulizmuab where:
- There has been relief in the PNH symptoms that had qualified the patient for their initial ravulizumab approval; **and**
- There is demonstrated clinical improvement in the patient, or stabilization of the patient's condition, while receiving treatment with ravulizumab; **and**
- The patient and treating physician have been adequately adherent to treatment and to measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; **and**
- Ravulizumab is being prescribed by or in consultation with a hematologist or nephrologist with experience in managing PNH.

Requests for renewal must be accompanied by current confirmation of granulocyte and monocyte clone size (by flow cytometry), in accordance with the Exclusion Criteria below.
Renewal duration: 1 year

Exclusion Criteria (for initial and renewal requests)
Patients meeting **any** of the following criteria will not be eligible for ravulizumab coverage:
- Prior treatment failure with ravulizumab or eculizumab;
- Receiving concurrent treatment with another C5 inhibitor drug (e.g. eculizumab);

- Granulocyte and monocyte clone size both below 10%;
- Presence of aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Presence of another life threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (for example, acute myeloid leukemia or high-risk myelodysplastic syndrome); or
- Presence of another medical condition that might reasonably be expected to compromise a response to ravulizumab therapy.

Rebif - see Appendix D
Rebif Initiation Pack - see Appendix D
Reblozyl – see luspatercept
Redesca - see enoxaparin

relugolix/estradiol/norethindrone acetate, tablet, 40mg/1mg/0.5mg (Myfembree)

For the treatment of premenopausal individuals 18 years of age or older with heavy menstrual bleeding due to uterine fibroids.

Note: relugolix/estradiol/norethindrone acetate should not be used in combination with another gonadotropin releasing hormone (GnRH) agonist or antagonist.

Approval Duration: Twenty-four (24) months

Discontinuation Criteria:
Relugolix/estradiol/norethindrone acetate should be discontinued:
- Following a successful surgical procedure; OR,
- If there is a plan to become pregnant; OR,
- Menopause occurs; OR,
- There is a meaningful decline in Bone Mineral Density.

remdesivir, powder for solution for infusion, 100mg/vial (Veklury)

For the treatment of moderately or severely immunosuppressed adult patients diagnosed with COVID-19 infection.
Remdesivir MUST be initiated within 7 days of symptom onset.
Refer to Saskatchewan Health Authority (SHA) Pre-Printed Order set for further details on eligibility.

Remodulin - see Treprostinil
Remsima SC – see Infliximab
Renagel - see sevelamer HCl
Renflexis - see infliximab
Renvela - see sevelamer carbonate
Repatha – see evolocumab
Retrovir - see zidovudine
Revatio - see sildenafil citrate
Revestive - see teduglutide
Revolade - see eltrombopag olamine
Rexulti - see brexpiprazole
Reyataz - see atazanavir SO4
Rezurock – see belumosudil

rifabutin, capsule, 150mg (Mycobutin)

a) For prevention of disseminated *Mycobacterium avium complex* (MAC) in patients with advanced human immunodeficiency virus (HIV) infection.

b) For treatment of non-TB mycobacterium infection (NTMI), when prescribed in consultation with an infectious disease specialist.

Note: Contact TB Prevention and Control Saskatchewan if these medications are being prescribed for treatment of tuberculosis.

rifampin, capsule, 150mg, 300mg (Rofact)

(a) For treatment of non-tuberculosis (TB) mycobacterium infection, when prescribed in consultation with an infectious disease specialist.
(b) For treatment of cholestatic pruritis.
(c) For treatment of non-tuberculosis infections when:
- the organism is susceptible to rifampin, AND

- alternative agents are not appropriate, OR
- the patient does not respond or is intolerant to other recommended agents, OR
- rifampin treatment is being completed following initiation in hospital.

Organism susceptibility should be determined.
This medication should be prescribed in consultation with an infectious diseases specialist.
Note: Contact TB Prevention and Control Saskatchewan if rifampin is being prescribed for treatment of tuberculosis.

rifaximin, tablet, 550mg (Zaxine)
For recurrence of overt hepatic encephalopathy (HE), for patients who are unable to achieve adequate control of HE with maximal tolerated doses of lactulose alone.
***Note**: To be used in combination with maximal tolerated dose of lactulose.*

rilpivirine, tablet, 25mg (Edurant) (possible OEA)
For management of HIV disease.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Rilutek – see riluzole

riluzole, tablet, 50mg (Rilutek, and listed generics)
For the treatment of amyotrophic lateral sclerosis (ALS) when initiated by a neurologist with expertise in the management of ALS, when the patient has:
- Probable or definite diagnosis of ALS;
- ALS symptoms for less than five years;
- FVC > 60% predicted upon initiation of therapy; and
- No tracheostomy for invasive ventilation.

Coverage will be reviewed every six months.
Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation.

Rinvoq – see upadacitinib

riociguat, tablet, 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg (Adempas and listed generic)
For treatment of patients 18 years of age or older with chronic thromboembolic pulmonary hypertension (CTEPH) with World Health Organization (WHO) Functional Class 2 or 3 pulmonary hypertension, with;
a) inoperable chronic thromboembolic pulmonary hypertension (CTEPH), World Health Organization (WHO) Group 4, OR
b) persistent or recurrent CTEPH after surgical treatment.
Note: must be prescribed by clinicians experienced in the diagnosis and treatment of CTEPH.

risankizumab, solution for infusion, 60mg/mL (10mL vial) (mg); prefilled cartridge, 180mg/1.2mL, 360mg/2.4mL (mg); pre-filled pen, pre-filled syringe 150mg/mL (mg) (Skyrizi)

Indication	Criteria
Crohn's disease (solution for infusion, 60mg/mL (10mL vial); prefilled cartridge, 360mg/2.4mL only)	For the treatment of moderate to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy. **Initial approval: 12 weeks** Clinical response should be assessed after the induction regimen (i.e., IV infusion at weeks 0, 4 and 8). Ongoing coverage of the maintenance subcutaneous injections will only be provided for patients who have responded to a course of IV induction therapy. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and janus kinase inhibitors, etc) for Crohn's disease. **Note:** This product should be used in consultation with a specialist in this area.
Ulcerative Colitis	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after the induction regimen.

(solution for infusion, 60mg/mL (10mL vial); prefilled cartridge, 180mg/1.2mL, 360mg/2.4mL only)	Ongoing coverage will only be provided for those who respond to therapy. **Note:** This product should be used in consultation with a specialist in this area.
Plaque psoriasis (pre-filled pen, 150mg/mL; pre-filled syringe 150mg/mL only)	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to or unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy. **Note:** This product should be used in consultation with a specialist in this area.

risdiplam, powder for (oral) solution, 0.75mg/mL (mg); tablet, 5mg (mg) (Evrysdi)

Coverage may be available for this product through the Drug Plan for the treatment of spinal muscular atrophy. Due to the unique nature of this condition and the cost of this treatment, Exception Drug Status (EDS) requests will require additional details to facilitate assessment of the application and accompanying clinical information. In addition, patients who are approved will be required to undergo ongoing assessment to monitor for improvement over time and must meet renewal criteria for continuation of treatment. Please contact the Drug Plan at 1-800-667-7581 for more information regarding coverage availability and the EDS application process for this product.

risedronate sodium, tablet, 35mg (listed generics); 150mg (Actonel, and listed generics); delayed release tablet, 35mg (Actonel DR, and listed generics) (possible OEA)

a) For treatment of osteoporosis ***in patients*** with a 20% or greater 10-year fracture risk;
Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table. The links to the tools are available at:
http://www.shef.ac.uk/FRAX/tool.jsp?country=19
http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf
The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.

b) For treatment of osteoporosis in patients with:
- Pre-existing and/or recent fragility fractures; or
- Glucocorticoid treatment for a duration of 3 months or longer; or
- Men on androgen deprivation therapy for prostate cancer; or
- Women on aromatase inhibitor therapy for breast cancer.

c) For treatment of osteogenesis imperfecta.

risedronate sodium, tablet, 30mg (listed generics) (possible OEA)

For treatment of symptomatic Paget's disease of the bone.

Risperdal Consta - see risperidone

risperidone, powder for suspension sustained-release, 12.5mg/vial, 25mg/vial, 37.5mg/vial, 50mg/vial (Risperdal Consta)
risperidone, powder for suspension sustained-release, 75mg/prefilled syringe, 100mg/prefilled syringe (Okedi)

For patients:
a) With a history of non-adherence, as evidenced by outcomes such as repeated hospitalizations,
OR
b) Who have been on a first generation long acting injectable antipsychotic agent but can no longer tolerate or have relapsed,
OR
c) Who were started on treatment in the hospital.

ritonavir, oral solution, 80mg/mL (Norvir); tablet, 100mg (Norvir and listed generic) (possible OEA)

a) For management of HIV disease.
This drug, as with other antivirals in treatment of HIV, should be used under the direction of an infectious disease specialist.
b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

rituximab, injection solution, 10mg/mL (Riximyo)
rituximab, injection solution, 10mg/mL (Ruxience)
rituximab, injection solution, 10mg/mL (Truxima)

Note: These products are not interchangeable. When requesting coverage, please state which specific rituximab product is being prescribed to avoid administrative and assessment processing delays.

Indication	Criteria
Rheumatoid Arthritis	For treatment of severe rheumatoid arthritis when used in combination with methotrexate in adult patients who have failed to respond to an adequate trial of an anti-TNF agent, when prescribed in consultation with a specialist. *Rituximab should not be used in combination with biologics for rheumatoid arthritis, or other target specific DMARDS (tsDMARDS) (such as janus kinase (JAK) inhibitors, or phosphodiesterase 4 (PDE4) inhibitors, etc.).*
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA) Associated Vasculitis	For treatment of patients with severely active anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis (AAV), when prescribed in consultation with a specialist.
Antibody-mediated rejection	For treatment of antibody-mediated rejection in kidney, lung, heart or liver transplant patients.
Chronic Immune Thrombocytopenia	For the treatment of persistent or chronic immune thrombocytopenia (ITP) in patients who: • Have a confirmed diagnosis of persistent or chronic ITP for 3 or more months; AND, • Are under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP; AND, • Have failed first-line therapy with corticosteroids and/or IVIG[1]; AND, • Have an ongoing need for therapy with a platelet count of: o Adults: <30 x 10^9/L; OR, o Adults: <50 x 10^9/L at high-risk of bleeding; OR, o Pediatrics: <50 x 10^9/L. **Initial approval duration:** 6 months **Renewal:** Ongoing coverage of rituximab will be considered for individuals who remain under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP AND have: • A clinically meaningful elevation in platelet count above baseline; AND, • Documented clinical benefit, as demonstrated by outcomes such as fewer rescue treatments, reduced emergency visits, or reduced clinically significant bleeding episodes; AND, • EITHER: o A platelet count of ≥30 x 10^9/L; OR, o A doubling of baseline platelet count. [1]Failure of first-line therapy is defined as no platelet count response or transient response only, or a contraindication or intolerance to first-line therapy.
Neuromyelitis Optica Spectrum Disorder	For the management of neuromyelitis optica spectrum disorder, when prescribed in consultation with a specialist.
Myasthenia Gravis	For the treatment of patients with myasthenia gravis refractory to pyridostigmine and immunosuppressants, when prescribed in consultation with a specialist.
Prevention of Transplant Rejection	For prevention of antibody mediated rejection in individuals undergoing renal transplantation from an ABO-incompatible living donor, when prescribed in consultation with a specialist.
Primary Membranous Nephropathy	For patients 18 years and older at moderate to high risk of developing progressive kidney injury or complications of nephrotic syndrome, who meet one of the following criteria: • Proteinuria >5 g/day despite a minimum of 6 months of conservative therapy with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB). o An observation period of less than 6 months can be considered when proteinuria is > 8 g/day or high anti-PLA2R titres > than 50 or eGFR less than 60mL/min/1.73m^2. • Proteinuria >3.5 g/day with life- or organ-threatening complications of nephrotic syndrome (i.e., venous thrombosis, infection, or rapid decline in kidney function not otherwise explained).

	• Biopsy-proven or serology (anti-PLA2R)-proven recurrence in a patient who has received a kidney transplant and has proteinuria > 3.5 g/day. Notes: • Initial approval will allow for two doses to be administered on day 0 and day 15. **Renewal criteria:** Additional courses of rituximab may be approved 6 months after completion of initial treatment course for patients who: • After an initial course of therapy, proteinuria is reduced from baseline by at least 25%, but do not achieve complete remission[1]; or • Relapse[2]. Coverage will not be renewed for patients who demonstrate non-response.[3] [1] Complete Remission: proteinuria < 0.3 g/day or protein-creatinine ratio < 30 mg/mmol. [2] Relapse: Recurrence of proteinuria (as per the initiation criteria) accompanied by a decrease in serum albumin to less than 30g/L in patients who have achieved a complete or partial remission following prior rituximab treatment. [3]Non-response: Lower than 25% reduction in proteinuria by 6 months after initial course.
Dermatomyositis/Polymyositis	For patients with dermatomyositis or polymyositis where azathioprine and methotrexate are inappropriate or not effective, when prescribed in consultation with a specialist.
Refractory interstitial lung disease	For treatment of refractory interstitial lung disease associated with a connective tissue disease (or autoimmune disease), when prescribed in consultation with a specialist.
Systemic lupus erythematosus (SLE)	For patients with systemic lupus erythematosus (SLE) flares who have not responded to, or are unable to take, cyclophosphamide and mycophenolate, when prescribed by a specialist.
Thrombotic thrombocytopenic purpura (TTP)	For treatment of acute acquired thrombotic thrombocytopenic purpura (TTP) in patients who are refractory to or unable to tolerate plasma exchange as well as corticosteroids. For prevention of relapse of acquired thrombotic thrombocytopenic purpura in patients with a history of relapse and ADAMTS13 level <10%.
Multiple Sclerosis	See Appendix D.

rivaroxaban, granules for suspension, 51.7mg, 103.4mg (Xarelto Granules)

For the treatment and prevention of venous thromboembolism (VTE) in pediatric patients.

rivaroxaban, tablet, 2.5mg (Xarelto and listed generics)

For patients with concomitant coronary artery disease[1] (CAD) and peripheral artery disease[2] (PAD), when used in combination with acetylsalicylic acid (ASA) 75mg to 100mg daily. Patients who meet any one of the exclusion criteria below will not be eligible for coverage.

Exclusion Criteria: Rivaroxaban 2.5mg will not be reimbursed for patients who have CAD or PAD alone, or in patients with **any** one of the following characteristics:

- At high risk of bleeding;
- A history of stroke within one month of treatment initiation;
- Any history of hemorrhagic or lacunar stroke;
- Severe heart failure with a known ejection fraction < 30% or New York Heart Association class III or IV symptoms;
- An estimated glomerular filtration rate < 15 mL/min; or
- Require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy.

Notes:

1. Patients with CAD are defined as having **one or more** of the following:
   - Myocardial infarction within the last 20 years;
   - Multi-vessel coronary disease (i.e., stenosis of ≥ 50% in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina;
   - Multi-vessel percutaneous coronary intervention; **or**
   - Multi-vessel coronary and artery bypass graft surgery.

   and

   Meet **at least one** of the following criteria:

- Aged 65 years or older; or
- Aged younger than 65 years with either:
  - Documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular)

    or

  - **At least two** additional risk factors:
    - Current smoker;
    - Diabetes mellitus;
    - Estimated glomerular filtration rate <60 mL/min;
    - Heart failure; **or**
    - Non-lacunar ischemic stroke ≥ 1 month ago.
    -

2. Patients with PAD are defined as having **one or more** of the following:
   - Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries;
   - Previous limb or foot amputation for arterial vascular disease;
   - History of intermittent claudication **AND one or more** of the following:
     - An anklebrachial index less than 0.90; **or**
     - Significant peripheral artery stenosis (≥50%) documented by angiography or by duplex ultrasound; **or**
   - Previous carotid revascularization or asymptomatic carotid artery stenosis ≥ 50%, as diagnosed by duplex ultrasound or angiography.

rivaroxaban, tablet, 10mg (Xarelto and listed generics)

(a) For prophylaxis following total knee arthroplasty for up to 14 days following the procedure.
(b) For prophylaxis in patients undergoing total hip replacement for up to 35 days following the procedure.

rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon, and listed generics); oral solution, 2mg/mL (Exelon)

For the treatment of Alzheimer's disease in patients with:

- a Mini Mental State Exam (MMSE) score between 10-26; AND/OR,
- a Montreal Cognitive Assessment (MoCA) score between 4-16.

Initial Approval Duration: 6 months
NOTE: Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and MOCA are administered. Drugs with anticholinergic activity are not to be used concurrently with rivastigmine therapy.

Renewal Criteria:
To qualify for renewal of rivastigmine patients must continue to have an MMSE score ≥10 and/or MoCA score ≥4.
Renewal Duration: 2 years

Riximyo - see rituximab

rizatriptan benzoate, tablet, 5mg (listed generics); tablet, 10mg (Maxalt, and listed generics); orally disintegrating tablet, 5mg, 10mg (Maxalt RPD, and listed generics)

For treatment of migraine headaches in patients over 18 years of age.

The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60-day period. *Patients requiring more than 12 doses in a consecutive 60-day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.*

Rocaltrol - see calcitriol
Rofact – see rifampin

romiplostim, solution for injection, 250ug/0.5mL, 500ug/mL (Nplate)

For the treatment of persistent or chronic immune thrombocytopenia (ITP) in patients who:

- Have a confirmed diagnosis of persistent or chronic ITP for 3 or more months; AND,
- Are under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP; AND,
- Have failed first-line therapy with corticosteroids and/or IVIG[1]; AND,
- Have an ongoing need for therapy with a platelet count of:
  - Adults: <30 x 10^9/L; OR,
  - Adults: <50 x 10^9/L at high-risk of bleeding; OR,
  - Pediatrics: <50 x 10^9/L.

Initial approval duration: 6 months

Notes: Dosage: To a maximum of 10 mcg/kg once weekly.

Renewal:
Ongoing coverage of romiplostim will be considered for individuals who remain under the care of a hematologist or clinician with expertise in the diagnosis and management of ITP AND have:

- A clinically meaningful elevation in platelet count above baseline; AND,
- Documented clinical benefit, as demonstrated by outcomes such as fewer rescue treatments, reduced emergency visits, or reduced clinically significant bleeding episodes; AND,
- EITHER:
  - A platelet count of ≥30 x 10^9/L; OR,
  - A doubling of baseline platelet

[1]Failure of first-line therapy is defined as no platelet count response or transient response only, or a contraindication or intolerance to first-line therapy.

romosozumab, pre-filled syringe (syr), 105mg/1.17mL (Evenity)
For the treatment of osteoporosis in postmenopausal women:

- With a history of osteoporotic fracture and at high risk for future fracture (defined as a 10-year fracture risk ≥ 20% as defined by the FRAX tool), and
- Who are treatment naïve to osteoporosis medications and are not receiving concurrent osteoporosis medications except for calcium and/or vitamin D.

Treatment approval will be to a maximum of 12 months.

rosiglitazone maleate, tablet, 2mg, 4mg, 8mg (listed generics)
For the treatment of patients with Type 2 diabetes who are not adequately controlled on or are intolerant to metformin **and** a sulfonylurea.
Note: Precribers are reminded to ensure that the Patient Informed Consent form is completed prior to prescribing this medication.

rotigotine, transdermal system, 2mg/24hr, 4mg/24hr, 6mg/24hr, 8mg/24hr (Neupro)
For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

rozanolixizumab, solution for subcutaneous infusion, 140mg/mL (2mL vial) (mg) (Rystiggo)
For the treatment of adult patients with generalized myasthenia gravis (gMG) who:

- Have a positive serologic test for either anti-acetylcholine receptor (anti-AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; AND,
- Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥3 (with at least 3 points coming from nonocular symptoms); AND,
- Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
- Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
- Will not have rozanolixizumab initiated during a gMG exacerbation or crisis, or within 3 months of a thymectomy; AND,
- Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another neonatal Fc receptor (FcRn) antagonist; AND,
- Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

Initial Coverage Duration: 6 months

Initial Renewal Criteria:
Renewal of rozanolixizumab coverage will be considered in individuals who:

- Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
- Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another FcRn antagonist; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Subsequent Renewal Criteria:
Ongoing coverage of rozanolixizumab will be considered in individuals who:

- Have not had a worsening of (increase in) MG-ADL score[1] compared to the initial renewal score; AND,

- Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another FcRn antagonist; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

[1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.
[2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

rufinamide, tablet, 100mg, 200mg, 400mg (Banzel)

For the adjunctive treatment of patients with Lennox-Gastaut Syndrome who are under the care of a physician experienced in treating Lennox-Gastaut Syndrome associated seizures, and are currently receiving two or more antiepileptic drugs (one of which should be lamotrigine or topiramate).

Ruxience - see rituximab

ruxolitinib, tablet, 5mg, 10mg (Jakavi)

Acute GVHD:

For the treatment of adult and pediatric patients (12 years of age and older) with acute graft-versus-host disease (aGvHD) who:

- Are experiencing aGvHD following a **non-oncology transplant**; AND,
- Are clinically diagnosed with Grade II to IV disease according to the NIH Criteria; AND,
- Are confirmed to be corticosteroid refractory[1] or corticosteroid dependent[2].

Patients must be under the care of a clinician with experience in the diagnosis and management of GvHD.

Discontinuation Criteria:

Coverage of ruxolitinib may be discontinued if:

- The patient experiences progression of aGvHD (new or worsening symptoms); OR,
- The patient has needed to start an additional systemic therapy (other than a calcineurin inhibitor) to treat aGvHD after Day 28.

NOTES:

[1] Corticosteroid refractory is defined as having one or more of the following:

1. Progressing based on organ assessment after at least 3 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid +/- a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) for the treatment of grade II to IV aGvHD;
2. Failure to achieve, at a minimum, a partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid +/- a calcineurin inhibitor for the treatment of grade II to IV aGvHD;
3. Failure of a corticosteroid taper, defined as fulfilling either of the following criteria:
   i. requirement for an increase in the corticosteroid dose to methylprednisolone ≥ 2 mg/ kg/day (or equivalent prednisone dose of ≥ 2.5 mg/kg/day); or,
   ii. failure to taper the methylprednisolone dose to < 0.5 mg/kg/day (or equivalent prednisone dose of < 0.6 mg/kg/day) for a minimum of 7 days.

[2] Corticosteroid dependence is defined as the inability to taper prednisone under 2 mg/kg/day (or equivalent) after an initially successful treatment of at least 7 days or as the recurrence of aGvHD activity during the steroid taper.

Coverage for ruxolitinib for aGvHD following an oncology related stem cell transplant is provided under the Saskatchewan Cancer Agency. Refer to the Saskatchewan Cancer Agency Formulary for details and criteria for coverage.

Chronic GVHD:

For the treatment of adult and pediatric patients (12 years of age and older) with chronic graft-versus-host disease (cGvHD) who:

- Are experiencing cGvHD following a **non-oncology transplant**; and,
- Have moderate to severe disease (based on the NIH consensus criteria); and,

- Have had inadequate response to corticosteroids (corticosteroid refractory[1]) or other systemic therapy.

Patients must be under the care of a clinician with experience in the diagnosis and management of GvHD.
Initial approval duration: 24 weeks.
Coverage renewal may be requested for patients who do not meet the discontinuation criteria below.

Discontinuation Criteria:
Coverage of ruxolitinib may be discontinued if:

- The patient experiences progression of cGvHD (new or worsening symptoms).

NOTES:
[1] Corticosteroid refractory cGvHD is defined based on the NIH consensus criteria, including one or more of the following:

1. A lack of response or disease progression after administration of minimum prednisone 1mg/kg/day (or equivalent) for at least 1 week;
2. Disease persistence without improvement despite continued treatment with prednisone at 0.5mg/kg/day or 1mg/kg/every other day (or equivalent) for at least 4 weeks;
3. Increased prednisone dose to > 0.25mg/kg/day (or equivalent) after two unsuccessful attempts to taper the dose.

Coverage for ruxolitinib for cGvHD following an oncology related stem cell transplant is provided under the Saskatchewan Cancer Agency. Refer to the Saskatchewan Cancer Agency Formulary for details and criteria for coverage.

Ruzurgi - see amifampridine
Rymti – see etanercept
Rystiggo - rozanolixizumab

sacubitril/valsartan, tablet, 24.3mg/25.7mg, 48.6mg/51.4mg, 97.2mg/102.8mg (Entresto) (possible OEA)
For the treatment of heart failure (HF) with reduced ejection fraction in patients with New York Heart Association (NYHA) class II or III to reduce the incidence of cardiovascular (CV) death and HF hospitalization, if all of the following clinical criteria are met:

- Reduced left ventricular ejection fraction (LVEF) (<40%)
- Patient has NYHA class II-III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin-converting-enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB) in combination with a beta-blocker and other recommended therapies, including an aldosterone antagonist (if tolerated).
- Plasma B-type natriuretic peptide (BNP) ≥ 150 pg/mL or N-terminal prohormone-B-type natriuretic peptide (NT-proBNP) ≥ 600 pg/mL; or plasma BNP ≥ 100 pg/mL or NT-proBNP ≥ 400 pg/mL levels if the patient has been hospitalized for HF within the past 12 months.
- Patients should be under the care of a specialist experienced in the treatment of HF for patient selection, titration, follow-up and monitoring.

Saizen - see somatropin
Salagen - see pilocarpine HCl

salmeterol xinafoate, powder for inhalation (package), 50ug/dose (Serevent Diskus) (possible OEA)
For treatment of:
(a) Asthma uncontrolled on concurrent inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
(b) For treatment of COPD.

salmeterol xinafoate/fluticasone propionate, metered dose inhaler (package), 25ug/125ug, 25ug/250ug (Advair); powder for inhalation (package), 50ug/100ug, 50ug/250ug, 50ug/500ug (Advair Diskus, and listed generics) (possible OEA)
For the treatment of:
(a) Asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
(b) Chronic obstructive pulmonary disease (COPD):

- In patients with concurrent or past use of long-acting beta-2 agonist (LABA) or long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients initiated on inhaled corticosteroid (ICS)/LABA combination therapy in hospital; OR
- In patients with concomitant asthma and moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD)[1] risk.

[1]Patients are considered low risk of AECOPD if they have ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) and did not require a hospital admission or emergency department (ED) visit.

Sandostatin LAR - see octreotide
Saphnelo - see anifrolumab
Saphris - see asenapine

sapropterin dihydrochloride, tablet, 100mg; sachet, 100mg (Kuvan)
See Inherited Metabolic Disease Benefit List

sarilumab, pre-filled syringe, 150mg/1.14mL, 200mg/1.14mL; pre-filled pen, 150mg/1.14mL, 200mg/1.14mL (Kevzara)
For the treatment of moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease modifying antirheumatic drugs (DMARDs), in patients who have failed to respond to an adequate trial of DMARDs.
This product should not be used concomitantly with other biologic agents (such as TNF alpha inhibitors).
This product should be used in consultation with a specialist in this area.

satralizumab, pre-filled syringe, 120mg/mL (Enspryng)
For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult and adolescent patients (aged 12 years or older) who meet ALL of the following:
- The patient is anti–aquaporin 4 (AQP4) seropositive; and
- The patient has had at least one relapse of NMOSD in the previous 12 months; and
- The patient has experienced relapse or intolerance following an adequate trial of other accessible preventive treatments for NMOSD[1], and
- The patient has an Expanded Disability Status Scale (EDSS) score of 6.5 points or less; and
- Satralizumab is being prescribed by a neurologist with expertise in treating NMOSD.

[1]Other accessible preventative treatments should include consideration of monoclonal antibodies including rituximab, and may include other immunosuppressants.

Initial approval duration: 12 months

Note: Satralizumab should not be initiated during a NMOSD relapse episode. Satralizumab will not be eligible for coverage in combination with rituximab, inebilizumab, eculizumab, or ravulizumab.

Renewal
- The patient must maintain an EDSS score of less than 8 points to be eligible for ongoing coverage of satralizumab. The EDSS score must be measured every 12 months after the initial approval period.

Renewal duration: 12 months

saxagliptin, tablet, 2.5mg, 5mg (Onglyza and listed generics) (possible OEA)
For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

saxagliptin/metformin HCl, tablet, 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (Komboglyze) (possible OEA)
For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylureacalphyx – see sodium thiosulfate

secukinumab, pre-filled syringe, 75mg/0.5mL, 150mg/1.0mL, 300mg/2.0mL (mg); pre-filled pen, 150mg/1.0mL, 300mg/2.0mL (mg) (Cosentyx)

Indication	Criteria
Ankylosing Spondylitis	**Initial:** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval Duration: 16 weeks

	First Renewal: Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval Duration: One Year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval Duration: One Year **Note**: Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.
Hidradenitis Suppurativa	For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy (including systemic antibiotics) and who have met the following: • 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; • Prescribed by a specialist with expertise in the management of patients with HS. **Note**: Treatment with secukinumab should be discontinued if there is no improvement after 24 weeks of treatment. **Initial Approval Duration: 12 months** **Renewal Criteria:** Renewal of secukinumab may be considered for individuals who experience an HiSCR50 response at 12 months.
Psoriatic Arthritis	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). **Note:** This product should be used in consultation with a specialist in this area.
Plaque Psoriasis	For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 12 weeks. Coverage can be renewed in patients who have responded to therapy. **Note**: This product should be used in consultation with a specialist in this area. Coverage may be approved as follows: initial dosing of 300mg doses at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300mg doses starting at week 4.

selegiline HCl, tablet, 5mg (listed generics) (possible OEA)

a) For use as an adjunct in cases of Parkinson's disease being treated with levodopa, levodopa/benzerazide, levodopa/carbidopa, or bromocriptine.
b) For prophylaxis in early Parkinsonism.

selexipag, tablet, 200mcg, 400mcg, 600mcg, 800mcg, 1000mcg, 1200mcg, 1400mcg, 1600mcg (Uptravi)

For the long-term treatment of idiopathic pulmonary arterial hypertension (PAH), heritable PAH, PAH associated with connective tissue disorders, and PAH associated with congenital heart disease, in adult patients with World Health Organization (WHO) functional class (FC) II to III who have failed to control symptoms or are intolerant to a PDE5 inhibitor (such as sildenafil citrate or tadalafil) AND one other drug (such as bosentan) with or without a calcium channel blocker. This medication should be prescribed under the direction of a specialist in the area of PAH.

Note: Combination therapy with prostacyclin (such as epoprostenol) or prostacyclin analog therapies (such as treprostinil) will NOT be covered.

selumetinib, capsule, 10mg, 25mg (Koselugo)

Initiation Criteria:

For the treatment of pediatric patients aged 2 to 18 years with neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PNs), where:

- The PN is unable to be completely surgically removed without risk of substantial morbidity due to encasement of, or close proximity to, vital structures, or invasiveness or high vascularity of the PN; **OR,**
- Surgical PN removal did not result in improvement of symptoms.

Patients receiving selumetinib must be under the care of a neurooncologist or other specialist in oncology or neurology with expertise in the diagnosis and management of NF1.

The initial coverage request must include current baseline information on the patient's PN location(s) and size(s), PN-related pain, PN-related functional impairment, and description of overall NF1 disease activity.

Initial approval duration: 18 months

Renewal Consideration:
Renewal of coverage will be considered in patients who:
- Are demonstrating an improvement in or stabilization of clinical status as compared to baseline; AND,
- Continue to be under the care of a neurooncologist or other specialist in oncology or neurology with expertise in the diagnosis and management of NF1.

Renewal requests should include updated information on ALL of the following parameters, as determined through clinical assessment and/or imaging:
- Reduction in PN-related pain
- Improved function in PN-affected anatomical areas
- Reduction in PN size
- Achievements in NF1 disease stabilization

Renewal duration: 12 months

Discontinuation Criteria:
Patients will not be eligible for renewal of selumetinib coverage if they have experienced disease worsening or progression (e.g., worsening of motor function or pain) as compared to baseline.

semaglutide, solution, 0.68mg/mL (2mg/pen); 1.34mg/mL (2mg/pen, 4mg/pen) (Ozempic and listed generics) (possible OEA)

For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

setmelanotide, solution for injection, 10mg/mL (mg) (Imcivree)

Initiation Criteria:
For weight management of adult and pediatric patients (6 years of age and older) with obesity associated with clinically or genetically diagnosed Bardet-Biedl syndrome (BBS).

The patient must be under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity.

Initial Approval Duration: 7 months

Initial Renewal Criteria:
Renewal of setmelanotide coverage will be considered in individuals who:
- Remain under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity; AND,
- For individuals 12 year of age or older: have a 5% or greater reduction in body mass index (BMI) or total body weight; OR,
- For individuals 6 to 11 years of age: have a reduction of 0.20 or greater in BMI Z score.

Subsequent Renewal Criteria:
Ongoing coverage of setmelanotide coverage will be considered in individuals who:
- Remain under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity; AND,
- Maintain the response to setmelanotide as seen at the initial renewal.

NOTE: The patient's total body weight, as well as BMI or BMI Z score must be provided at baseline and with each renewal request.

Serevent - see salmeterol xinafoate

Serevent Diskus - see salmeterol xinafoate

sevelamer carbonate, tablet, 800mg (Renvela and listed generic) (possible OEA)

For treatment of:

(a) End-stage renal disease in patients intolerant to aluminum or calcium containing phosphate-binding agents.

(b) End-stage renal disease in patients where aluminum or calcium containing phosphate-binding agents are inappropriate.

sevelamer HCl, tablet, 800mg (Renagel) (possible OEA)

For treatment of:

(a) End-stage renal disease in patients intolerant to aluminum or calcium containing phosphate-binding agents.

(b) End-stage renal disease in patients where aluminum or calcium containing phosphate-binding agents are inappropriate.

Siliq - see brodalumab

sildenafil citrate, tablet, 20mg (Revatio, and listed generics) (possible OEA)

For treatment of pulmonary arterial hypertension on the recommendation of a specialist.

Note: The maximum dose that will be provided as a benefit is 20mg three times daily.

Simlandi- see adalimumab

Simponi - see golimumab

Singulair - see montelukast sodium

siponimod, tablet, 0.25mg, 2mg (Mayzent)

See Appendix D

sirolimus, tablet, 1mg; oral solution, 1mg/mL (Rapamune)

For prophylaxis of graft rejection in transplant patients.

sitagliptin and metformin hydrochloride, tablet, 50mg/500mg, 50mg/850mg, 50mg/1000mg (Janumet, and listed generics); modified release tablet, 50mg/500mg, 50mg/1000mg, 100mg/1000mg (Janumet XR, and listed generics) (possible OEA)

For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

sitagliptin, tablet, 25mg, 50mg (Januvia, and listed generics)

For the treatment of patients with Type 2 diabetes with reduced renal function who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

sitagliptin, tablet, 100mg (Januvia, and listed generics) (possible OEA)

For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

Skyrizi - see risankizumab

sodium phenylbutyrate, oral granules, 483mg/g (Pheburane)

For the chronic management of urea cycle disorders (UCDs).

Medication should be prescribed in consultation with a specialist in this area.

sodium thiosulfate, solution for injection, 250mg/mL (mL) (Seacalphyx)

For treatment of calciphylaxis in end-stage renal disease.

sofosbuvir, tablet, 400mg (Sovaldi) (possible OEA)

For use as combination therapy with ribavirin or daclatasvir or both for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND

(ii) Laboratory-confirmed hepatitis C genotype 2 or 3; AND

(iii) Laboratory-confirmed quantitative HCV RNA value within the last 12 months.

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) or sofosbuvir in combination with daclatasvir (Daklinza) as one of the preferred therapeutic options over sofosbuvir with ribavirin regimens for treatment of genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa

or Daklinza in combination with sofosbuvir offers advantages in some patient populations, including potentially higher SVR rates and a shorter course of therapy for genotype 3 infections.

Treatment regimens reimbursed*:

Patient Population		Treatment Regimen and Duration
Genotype 2	Treatment-naïve or treatment-experienced(1)	12 weeks in combination with ribavirin
Genotype 3	Treatment-naïve or treatment-experienced(1) without cirrhosis	12 weeks in combination with daclatasvir OR 24 weeks in combination with ribavirin
	Treatment-naïve or treatment-experienced(1) with compensated or decompensated cirrhosis(2)	12 weeks in combination with daclatasvir and ribavirin OR 24 weeks in combination with ribavirin
	Treatment-naïve or treatment-experienced(1) post liver transplant	12 weeks in combination with daclatasvir and ribavirin

**Combination therapy with elbasvir/grazoprevir (Zepatier) will not be considered for funding.*

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

sofosbuvir/velpatasvir, tablet, 400mg/100mg (Epclusa) (possible OEA)

For use as monotherapy for treatment-naïve or treatment-experienced[1] adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6, or mixed genotypes; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last 12 months.

Treatment regimens reimbursed:

Patient Population		Treatment Regimen and Duration
All HCV genotypes	Treatment-naïve or treatment-experienced[1] without cirrhosis, or with compensated cirrhosis[2]	12 weeks of Epclusa
	Treatment-naïve or treatment-experienced[1] with decompensated cirrhosis[2]	24 weeks of Epclusa

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
- Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.
- Genotype is not required to be submitted with the EDS application.

[1]Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
[2]Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

sofosbuvir/velpatasvir/voxilaprevir, tablet, 400mg/100mg/100mg (Vosevi) (possible OEA)

For use as monotherapy for treatment-experienced[1] adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6, or mixed genotypes; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last 12 months.

Treatment regimens reimbursed:

Patient Population		Treatment Regimen and Duration
All HCV genotypes	Treatment-experienced[1], non-cirrhotic or compensated cirrhosis[2]	12 weeks

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:

- Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.
- Genotype is not required to be submitted with the EDS application.

[1]Treatment-experienced is defined as those who have failed prior therapy with a HCV regimen containing:

- NS5A inhibitor (daclatasvir (Daklinza), elbasvir (part of Zepatier), ledipasvir (part of Harvoni), ombitasvir (part of Holkira Pak), velpatasvir (part of Epclusa)) for genotype 1, 2, 3, 4, 5, or 6;

OR

- Sofosbuvir (Sovaldi) without an NS5A inhibitor for genotype 1, 2, 3, or 4

[2]Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

Sohonos – see palovarotene
Soliris – see eculizumab
Soliqua - see insulin glargine/lixisenatide

somatrogon, pre-filled pen, 24mg/1.2mL, 60mg/1.2mL (Ngenla)

For the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency [GHD]) only if the following conditions are met:

Initiation:

- Pre-pubertal children who are at least 3 years of age, and who are diagnosed with either isolated GHD, or growth hormone insufficiency as part of multiple pituitary hormone deficiency.

Discontinuation:

- Treatment with somatrogon must be discontinued upon the occurrence of any of the following:
  - Height velocity is less than 2cm/year and bone age is more than 16 years in boys and 14 years in girls.
  - Closure of the epiphyseal growth plates.

This medication should be prescribed by, or in consultation with, a specialist in this treatment area (i.e., pediatric endocrinologists).

The following products are not interchangeable. When requesting coverage, please state which specific somatropin product is being prescribed to avoid administrative and assessment delays.

- **somatropin, injection 0.6mg/syr, 0.8mg/syr, 1.0mg/syr, 1.2mg/syr, 1.4mg/syr, 1.6mg/syr, 1.8mg/syr, 2.0mg/syr, 5.3mg/pen, 12mg/pen (Genotropin);**
- **somatropin, injection, cartridge, 6 mg, 12mg, 24 mg (Humatrope Cartridge);**
- **somatropin, pre-filled pen, 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL (pen) (Norditropin FlexPro);**
- **somatropin, injection, cartridge, 5mg/1.5mL, 10mg/1.5mL, 15mg/1.5 mL (Omnitrope);**

For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone. (Note: These products are not interchangeable)

The following products are not interchangeable. When requesting coverage, please state which specific somatropin product is being prescribed to avoid administrative and assessment delays.

- **somatropin, injection, vial, 5mg; cartridge, 6mg, 12mg, 20mg (Saizen)**
  For treatment of:
  (a) Children who have growth failure due to inadequate secretion of normal endogenous growth hormone.
  (b) Children who have growth failure associated with chronic renal insufficiency.
  Note Exception Drug Status coverage is not required for S.A.I.L. patients. Coverage is provided under Saskatchewan Aids to Independent Living (S.A.I.L.) Program.

Somatuline Autogel - see lanreotide acetate

Soriatane - see acitretin

sotatercept, solution for subcutaneous injection, 45mg/vial (1 vial kit), (2 vial kit) (mg); 60mg/vial (1 vial kit), (2 vial kit) (mg) (Winrevair)

- ***Note to Pharmacies: For billing purposes please use the assigned PINs (noted on the Formulary website) when dispensing the two vial kits.***

For the treatment of adult patients with a confirmed diagnosis[1] of World Health Organization (WHO) Group 1 Pulmonary Arterial Hypertension (PAH) who:

- Are not low risk[2]; AND,
- Are experiencing Functional Class (FC) II or III symptoms; AND,
- Have been receiving optimal background therapy[3] for PAH for at least 3 months; AND,
- Will use sotatercept in combination with their current PAH therapy; AND,
- Have NOT undergone a lung and/or heart transplant; AND,
- Are under the care of a clinician with expertise in the diagnosis and management of PAH.

[1.] A diagnosis of WHO Group 1 PAH should be confirmed based on guidelines-approved diagnostic procedure, including right heart catheterization.

[2.] Low risk is defined as:

- FC I or II; AND,
- 6-minute walk distance (6MWD) >440m; AND,
- N-terminal prohormone-B-type natriuretic peptide (NT-proBNP) <300ng/L or Plasma B-type natriuretic peptide (BNP) < 100ng/L.

[3.] Optimal background PAH therapy includes at least a 3-month trial at optimal dosing of:

- A Phosphodiesterase 5 inhibitor (PDE5i); AND,
- An Endothelin Receptor Antagonist (ERA); AND,
- A prostacyclin receptor agonist OR prostacyclin analogue.

Initial Approval Duration: 12 months

Renewal Criteria:
Renewal of sotatercept coverage will be considered in individuals who:

- Remain under the care of a clinician with expertise in the diagnosis and management of PAH; AND,
- Show a beneficial clinical effect to sotatercept therapy, defined as stability in or improvement in the patient's risk status; AND,
- Have NOT undergone a lung and/or heart transplant.

Sovaldi - see sofosbuvir
Spinraza - see nusinersen
Steqeyma – see ustekinumab
Steqeyma IV – see ustekinumab
Strensiq- see Asfotase alfa

stiripental, capsule, 250mg 500mg; powder for suspension, 250mg (Diacomit)
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.

Note: The patient must be under the care of a neurologist or a pediatrician.

Stoboclo – see denosumab
Stribild - see elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

sumatriptan, tablet, 25mg (listed generics); 50mg (listed generics), 100mg; injection solution, 6mg/0.5mL (Imitrex, and listed generics); nasal spray, 5mg, 20mg (Imitrex)

For treatment of migraine headaches in patients over 18 years of age.
The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60-day period. *Patients requiring more than 12 doses in a consecutive 60-day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.*

Suprefact- see buserelin acetate
Symbicort Turbuhaler - see formoterol fumarate dihydrate/budesonide
Synarel - see nafarelin acetate
Synjardy - see empagliflozin/metformin HCl
3TC - see lamivudine

tacrolimus, extended release tablet, 0.75mg, 1mg, 4mg (Envarsus PA)

For prophylaxis of graft rejection following renal or liver transplant. This medication should be prescribed by a transplant physician.

tacrolimus, capsule, 0.5mg, 1mg, 5mg (Prograf); extended-release capsule, 0.5mg, 1mg, 3mg, 5mg; (Advagraf); ampoule, 5mg/mL (Prograf)

For prophylaxis of graft rejection and to prevent rejection in post bone marrow/stem cell transplant patients.

tacrolimus, topical ointment, 0.03%, 0.1% (Protopic) (possible OEA)

(a) For treatment of atopic dermatitis in patients unresponsive or intolerant to topical steroids tried within the last 3 months.
(b) For the treatment of pyoderma gangrenosum.
(c) For the treatment of prurigo nodularis (PN) in patients where topical corticosteroids (TCS) are not advisable, or not effective.

tadalafil, tablet, 20mg (Adcirca, and listed generics) (possible OEA)

For the treatment of:
a) Pulmonary arterial hypertension on the recommendation of a specialist.
b) Raynaud's phenomenon in patients with severe digital ischemia refractory to lifestyle management, calcium channel blockers and nitrate agents (unless contraindicated or not tolerated).
Note: The maximum dose that will be provided as a benefit is 40mg once daily.

tafamidis, capsule, 61mg (Vyndamax)
tafamidis meglumine, capsule, 20mg (Vyndaqel)

For the treatment of adult patients with documented cardiac disease due to transthyretin (TTR)-mediated amyloidosis cardiomyopathy (ATTR-CM), wild-type[1] or hereditary[2], who meet all of the following criteria:

- History of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic; and
- Heart failure symptoms classified as New York Heart Association (NYHA) Class I to III.

Patients must be under the care of a specialist with experience in the diagnosis and management of ATTR-CM.

Exclusion Criteria (at therapy initiation):

- Patients classified as NYHA class IV; or
- Patients who have received a heart or liver transplant; or
- Patients with an implanted cardiac mechanical assist device (CMAD); or
- Patients receiving other disease-modifying treatments for ATTR (including interfering ribonucleic acid drugs such as Tegsedi [inotersen] or Onpattro [patisiran]).

Initial approval duration: Nine (9) months

Discontinuation Criteria:
Patients should be regularly reassessed to determine ongoing treatment benefit of tafamidis. Treatment with tafamidis should be discontinued for patients who:

- Progress to NYHA class IV; or
- Receive a heart or liver transplant; or
- Receive an implanted CMAD; or
- Require end-of-life care[3].

After initial approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:

[1]Documented wild-type ATTR-CM consists of all of the following:

- absence of a variant TTR genotype; AND
- evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; AND
    - positive findings on technetium-99mm pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computerized tomography (SPECT) scanning; OR
    - presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac); and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.

[2]Documented hereditary ATTR-CM consists of all of the following:

- presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; AND
- evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; AND
    - positive findings on Tc-99m-PYP scintigraphy with SPECT scanning OR
    - presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac).

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g. management of symptoms such as pain, nausea and stress).

Takhzyro - see lanadelumab
Taltz - see ixekizumab
Tecfidera - see Appendix D

teduglutide, powder for injection, 5mg/vial (Revestive)

Adult Criteria

For the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral nutrition according to the following criteria:

- Initiation Criteria:
    - Age 18 years or greater.
    - SBS as a result of major intestinal resection (e.g. due to injury, volvulus, vascular disease, cancer, Crohn's disease).
    - Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months.
    - PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption.
    - PN frequency and volume have been stable for at least one month.

Initial approval duration: 6 months

- Renewal Criteria:
    - A positive response to treatment, defined as at least a 20% reduction in parenteral nutrition volume compared to the baseline volume, achieved within 52 weeks of teduglutide therapy.

Renewal approval duration: 6 months

Notes:

- *Parenteral support volume and percentage of total consumption should be documented at each clinic visit.*
- *Parenteral Support (PS) will represent parenteral nutrition (PN) which encompasses parenteral delivery of lipids, protein, and/or carbohydrates to address caloric needs, and intravenous (IV) fluids (IVF) which addresses fluid and electrolyte needs of patients.*
- *Initiation and assessment for continued treatment with teduglutide should be done only by physicians currently working within a specialized multi-disciplinary intestinal rehabilitation program.*
- *Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide.*

Pediatric Criteria

For the treatment of pediatric patients 1 year of age and above with short bowel syndrome (SBS) who are dependent on parenteral support according to the following criteria:
Initiation Criteria:

- Children between 1 and 17 years old.
- The cumulative lifetime duration of parenteral support therapy must be at least 12 months.
- Parenteral support (PS) must provide more than 30% of caloric and/or fluid/electrolyte needs within at least the preceding three months.
- PS requirements must be stable for at least the preceding three months, or there must have been no improvement in enteral feeding for at least the preceding three months.

Initial approval duration: 6 months
Renewal Criteria:

- A positive response to treatment, defined as at least a 20%reduction in weight adjusted parenteral support volume compared to the baseline volume.

Renewal approval duration: 6 months
Notes:

- *Parenteral support volume and percentage of total consumption should be documented at each clinic visit.*
- *Parenteral Support (PS) will represent parenteral nutrition (PN) which encompasses parenteral delivery of lipids, protein, and/or carbohydrates to address caloric needs, and intravenous (IV) fluids (IVF) which addresses fluid and electrolyte needs of the patients.*
- *Initiation and assessment for continued treatment with teduglutide should be done only by physicians currently working within a specialized multi-disciplinary intestinal rehabilitation program.*
- *Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide.*

tenofovir alafenamide, tablet, 25mg (Vemlidy) (possible OEA)
For management of hepatitis B.
Note: This product should be used in consultation with a specialist in this area.

tenofovir disoproxil fumarate, tablet, 300mg (Viread, and listed generics) (possible OEA)
For treatment of:
(a) HIV in patients who have failed an alternative nucleoside reverse transcriptase inhibitor.
(b) HIV in patients intolerant to an alternative nucleoside reverse transcriptase inhibitor.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
(c) For management of hepatitis B.

Note: This product should be used in consultation with a specialist in this area.

teriflunomide, tablet, 14mg (listed generics)
See Appendix D

tezepelumab, subcutaneous injection, 210mg/1.91mL, pre-filled syringe, pre-filled pen (mg) (Tezspire)
For add-on maintenance treatment of patients age 12 years and older[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), AND has experienced two or more clinically significant asthma exacerbations[3] in the past 12 months.
In addition:

- Tezepelumab should not be used in combination with other biologics used to treat asthma.
- A baseline[4] assessment of asthma symptom control using a validated asthma control questionnaire[5] must be completed prior to initiation of tezepelumab treatment and submitted with the application.
- Baseline[6] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications.
- Patients should be managed by a specialist in the treatment of asthma.

Discontinuation Criteria
Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if:
•First Renewal (based on first 12 months of therapy)

- The asthma control questionnaire score has not improved from baseline[4,5],
  OR
- The number of clinically significant exacerbations has increased[3],
  OR
- The oral corticosteroid maintenance dose has not decreased[6].

•Subsequent Renewals (after 2 years of therapy)
- The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently, OR
- The number of clinically significant exacerbations has increased within the previous 12 months, OR
- The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently.

[1]Patients must have a documented diagnosis of asthma.
[2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily.
[3] Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization.
[4]Baseline refers to results achieved prior to initiation of the requested therapy.
[5]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT.
[6]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day.

Tezspire - see tezepelumab

ticagrelor, tablet, 60mg (Brilinta and listed generics) (possible OEA)

For secondary prevention of atherothrombotic events in patients with a history of myocardial infarction (MI), when co-administered with low-dose (75 mg to 150 mg) acetylsaclicylic acid (ASA), for patients who are between 12 and 24 months from their most recent MI, and less than 12 months since dual antiplatelet therapy with ASA and an adenosine diphosphate (ADP) receptor inhibitor, with a high risk subsequent cardiovascular events, defined by at least one of:

1) Age 65 years or older
2) Diabetes requiring medication
3) Second prior spontaneous MI
4) Angiographic evidence of multivessel coronary artery disease
5) Chronic renal dysfunction (creatinine clearance <60mL/min)

When prescribed by a specialist in cardiology, cardiac surgery, or other physician with experience managing acute coronary syndrome as identified by the Drug Plan.
Total duration of coverage not to exceed 3 years.

ticagrelor, tablet, 90mg (Brilinta and listed generics)

A) Possible OEA

For treatment of Acute Coronary Syndrome (ACS), defined as unstable angina or myocardial infarction when initiated in hospital and prescribed by a specialist in cardiology, cardiac surgery, or other physician with experience managing ACS as identified by the Drug Plan.

Treatment must be in combination with low dose ASA.

Exclusions:

- Patients on triple-therapy (warfarin, ASA, antiplatelet)
- Patients on high dose ASA (doses greater than 150 mg)

Duration of approval: Requests meeting the above inclusion criteria will be eligible for an approval period of 12 months.

B) For secondary prevention of ischemic stroke when co-administered with low-dose (75mg to 150mg) acetylsalicylic acid (ASA) when initiated by, or in consultation with, a practitioner experienced in stroke management.

ticlopidine HCl, tablet, 250mg (listed generics) (possible OEA)

For treatment of patients who have experienced a:
(a) Transient ischemic attack, stroke, or myocardial infarction while on acetylsalicylic acid.
(b) Transient ischemic attack, stroke or myocardial infarction and have clearly demonstrated allergy to acetylsalicylic acid (manifested by asthma or nasal polyps).
(c) Transient ischemic attack, stroke or a myocardial infarction and are intolerant of acetylsalicylic acid (manifested by gastrointestinal hemorrhage).

tildrakizumab, injection, 100mg/mL pre-filled syringe (mg), pre-filled pen (mg) (Ilumya)

For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.

Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.

***Note**: This product should be used in consultation with a specialist in this area.*

tinzaparin sodium, syringe, 10,000IU/mL (0.25mL, 0.35mL, 0.45mL), 20,000IU/mL (0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL, 0.9mL); injection solution, 10,000IU/mL (2mL), 20,000IU/mL (2mL) (Innohep)

(a) For treatment of venous thromboembolism for up to 10 days.
(b) For prophylaxis following total knee arthroplasty for up to 35 days.
(c) For major orthopedic trauma for up to 10 days (treatment duration may be reassessed).
(d) For long-term outpatient prophylaxis in patients who are pregnant.
(e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
(f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
(g) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
(h) For prophylaxis following abdominal, thoracic, esophageal or pelvic surgery for up to 28 days.
(i) For extracorporeal anticoagulation in home hemodialysis patients.

tiotropium bromide monohydrate/olodaterol HCl, inhalation solution, 2.5ug/2.5ug (Inspiolto Respimat) (possible OEA)

For the treatment of chronic obstructive pulmonary disease COPD:

- In patients with inadequate response to a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD) risk[1]; OR
- For patients initiated on LAMA/LABA combination therapy in hospital.

[1] Patients are considered low risk of AECOPD if they have experienced ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) **and** did not require a hospital admission or emergency department (ED) visit.

tizanidine HCl, tablet, 4mg (listed generics) (possible OEA)

For treatment of:
(a) Severe spasticity in patients unresponsive to baclofen or benzodiazepines.
(b) Severe spasticity in patients intolerant to baclofen or benzodiazepines.

TOBI - see tobramycin inhalation solution
TOBI PODHALER - see tobramycin inhalation powder

tobramycin, inhalation powder capsule, 28mg (TOBI PODHALER)

For the treatment of chronic Pseudomonas aeruginosa infections in patients with cystic fibrosis where the Podhaler dosage form is required due to administration difficulties with the inhalation solution formulation.

tobramycin, inhalation solution, 60mg/mL (TOBI, and listed generics)

For the treatment of chronic Pseudomonas aeruginosa infections in patients with cystic fibrosis.

tocilizumab, autoinjector, 162mg/0.9mL; prefilled syringe, 162mg/0.9mL; solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial) (Tyenne)
tocilizumab, autoinjector, 162mg/0.9mL: prefilled syringe, 162mg/0.9mL; solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial) (Avtozma)

Indication	Criteria
Giant Cell Arteritis (GCA) (auto-injector and pre-filled syringe ONLY)	For the treatment of Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse. **Notes:** • Patients should be under the care of a prescriber with experience in the diagnosis and management of GCA. • Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.

Polyarticular Juvenile Idiopathic Arthritis (pJIA) (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). This product should be used in consultation with a specialist in this area.
Rheumatoid Arthritis (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs), in patients who have failed to respond to an adequate trial of DMARDs. Patients should be assessed after 16 weeks of treatment and therapy continued only if there is a clinical response to treatment. Tocilizumab should not be used concomitantly with tumor necrosis factor (TNF) alpha inhibitors. This product should be used in consultation with a specialist in this area.
Systemic Juvenile Idiopathic Arthritis (sJIA) (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy. Tocilizumab should not be used concomitantly with tumor necrosis factor (TNF) alpha inhibitors. This product should be used in consultation with a specialist in this area

tofacitinib, tablet, 5mg (Xeljanz and listed generics)

A) For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

Maximum daily dose of the 5mg tablets is 10mg per day. Maximum daily dose of the XR 11mg tablets is 11mg per day. This product should be used in consultation with a specialist in this area.

B) For treatment of ulcerative colitis in patients unresponsive to high dose steroids.

Note: Clinical response should be assessed after eight (8) weeks of therapy. Ongoing coverage will only be provided for those who respond to therapy. Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

C) For the treatment of patients with a confirmed diagnosis of juvenile idiopathic arthritis (JIA)[1] who have had an inadequate response to methotrexate or a tumor necrosis factor (TNF) inhibitor.

[1] Patients must have a confirmed diagnosis of JIA before 18 years of age by a clinician with expertise in the diagnosis of JIA, including any of the following subtypes:
- Polyarticular course JIA (rheumatoid factor- [RF-] positive polyarthritis, RF-negative polyarthritis, extended oligoarthritis, and systemic JIA without active systemic features);
- Psoriatic arthritis;
- Enthesitis-related arthritis.

tofacitinib, tablet, 10mg (Xeljanz and listed generics)

For treatment of ulcerative colitis in patients unresponsive to high dose steroids.
Note: Clinical response should be assessed after eight (8) weeks of therapy. Ongoing coverage will only be provided for those who respond to therapy. Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

tofacitinib, tablet, extended release tablet, 11mg (Xeljanz XR and listed generics)

For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide. Maximum daily dose of the 5mg tablets is 10mg per day. Maximum daily dose of the XR 11mg tablets is 11mg per day. This product should be used in consultation with a specialist in this area.

Toviaz - see fesoterodine fumerate
Tracleer - see bosentan
Trajenta - see linagliptin
Trelegy Ellipta - see fluticasone furoate/umeclidinium/vilanterol
Tremfya - see guselkumab

treprostinil, injection solution, 1mg, 2.5mg, 5mg, 10mg (Remodulin)

For treatment of patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart association class 111 or 1V disease who have both:

(a) failed to respond to non-prostanoid therapies (i.e. calcium channel blockers, vasodilators, bosentan) **and:**

(b) who are not candidates for epoprostenol therapy because of:
- prior recurrent complications with central line access (i.e. infection, thrombosis) or,
- they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol theapy.

Please contact the Drug Plan for billing information.

trientine HCl, capsule, 250mg (Mar-Trientine) (Waymade-Trientine)

For the treatment of Wilson's disease patients who are intolerant to penicillamine.

triheptanoin, oral liquid, 100% w/w (mL) (Dojolvi)
Initiation Criteria

For the treatment of patients with an acute life-threatening long-chain fatty acid oxidation disorder (LC-FAOD) in whom:
- Alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation is required; and
- Triheptanoin treatment will be prescribed and monitored by a clinician experienced in the management of LC-FAOD (i.e. metabolic or genetic specialist physician); and
- One of the following are met:
  - The patient has a confirmed diagnosis of LC-FAOD and is experiencing acute life-threatening events*; or
  - The patient lacks a confirmed diagnosis of LC-FAOD but is presenting with acute life-threatening events* consistent with LC-FAOD.

*Acute life-threatening events associated with LC-FAOD may include:
- A catastrophic presentation with acute or recurrent rhabdomyolysis with severe pain, compartment syndrome, acute renal failure requiring hospitalization and life-saving interventions including dialysis, treatment of hyperkalemia, and surgical treatment of compartment syndrome.
- Severe hypoglycemia, recurrent or acute, with or without seizures.
- Cardiomyopathy with or without arrhythmia.

A description of the patient's baseline acute life-threatening events, response to conventional even-chain MCT supplementation, and individualized treatment goals for triheptanoin treatment must be submitted with the initial coverage request.
Approval duration: 12 months

Renewal Requests

Patients who exhibit continued benefit with triheptanoin will be considered for renewal. Requesters must include a description of the patient's current response to triheptanoin therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

Renewal duration: up to 12 months

Trikafta - see elexacaftor/tezacaftor/ivacaftor/ivacaftor
Trileptal - see oxcarbazepine
Triumeq - see abacavir/dolutegravir/lamivudine
Trosec - see trospium chloride

trospium chloride, tablet, 20mg (Trosec) (possible OEA)

For treatment of patients intolerant to oxybutynin chloride, solifenacin succinate or tolterodine l-tartrate.

Truxima - see rituximab
Tysabri - see natalizumab
Ultibro Breezhaler - see indacaterol/glycopyrronium
Ultomiris – see ravulizumab

umeclidinium bromide/vilanterol trifenatate, powder for inhalation, 62.5ug/25ug (Anoro Ellipta) (possible OEA)

For the treatment of chronic obstructive pulmonary disease COPD:
- In patients with inadequate response to a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA) monotherapy; OR

- In patients with a moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD) risk[1]; OR
- For patients initiated on LAMA/LABA combination therapy in hospital.

[1] Patients are considered low risk of AECOPD if they have experienced ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) **and** did not require a hospital admission or emergency department (ED) visit.

upadacitinib, extended release tablets, 15mg, 30mg, 45mg (Rinvoq)

Indication	Criteria
Ankylosing Spondylitis (Only 15mg)	**Initial** For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4 who have had an inadequate response to a biologic disease modifying anti-rheumatic drug (bDMARD), are intolerant to, or have contraindications to a biologic DMARD. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS. Approval duration: 12 weeks **First renewal:** Coverage can be renewed in patients who have responded to therapy defined as at least 50% reduction in pre-treatment baseline BASDAI score or by ≥ 2 units. Approval duration: One year **Subsequent renewal:** Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e., remains within two units of the second assessment) and remains at least two units less than the initial application's BASDAI score. Approval duration: One year Note: Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination. Coverage provided up to a maximum daily dose of 15mg per day.
Atopic Dermatitis (15mg,30mg)	For the treatment of refractory moderate to severe[1] atopic dermatitis in patients 12 years and older who: • Have had an adequate trial, or who were intolerant, or are ineligible for EACH of the following therapies: o Maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy[2] (where available), and o Maximally tolerated medical topical therapies for atopic dermatitis combined with at least one of the four systemic immunomodulators (methotrexate[2], cyclosporine[2], mycophenolate mofetil[2], or azathioprine[2]). Requests must include documentation of the Eczema Area and Severity Index (EASI) score. Initial approval: 20 weeks Renewal Criteria: Renewal requests will be considered for patients where there has been a 75% or greater improvement from baseline in the EASI score (EASI-75) after initiation and where this response is subsequently maintained thereafter every six months. Renewal requests must include a recent EASI score. Renewal approval: Six (6) months. Both initial and renewal coverage requests for this indication must be made by, or in consultation with a specialist in this area. Upadacitinib should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other janus kinase (JAK) inhibitor treatment for moderate to severe atopic dermatitis. [1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points. [2]Adequate trials are defined as: o Phototherapy – three times a week for 12 weeks. o Methotrexate – 10 to 20mg per week for 12 weeks. o Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.

	o Mycophenolate mofetil – 1g twice daily for 12 weeks. o Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks.
Psoriatic Arthritis (Only 15mg)	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). • This product should be used in consultation with a specialist in this area. • Upadacitinib should not be used in combination with biologics, or other target specific DMARDs (tsDMARDs) (such as janus kinase (JAK) inhibitors, phosphodiesterase 4 (PDE4) inhibitors, etc.). • Coverage provided up to a maximum daily dose of 15mg per day.
Rheumatoid Arthritis (Only 15mg)	For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide. • This product should be used in consultation with a specialist in this area. • Patients should be assessed within the first 12 weeks to determine if the American College of Rheumatology (ACR) improvement criteria of at least 20% has been achieved. • Upadacitinib should not be used in combination with biologics for rheumatoid arthritis, or other target specific DMARDs (tsDMARDs) (such as janus kinase (JAK) inhibitors, or phosphodiesterase 4 (PDE4) inhibitors, etc.). • Coverage provided up to a maximum daily dose of 15mg per day.
Crohn's Disease (15mg,30mg,45mg)	For the treatment of moderately to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroid or other immunosuppressive therapy. Clinical response should be assessed after the 12-week induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and alternative janus kinase inhibitors, etc) for Crohn's disease. *Note: This product should be used in consultation with a specialist in this area.*
Ulcerative Colitis (15mg,30mg,45mg)	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after the 8 week induction regimen. Ongoing coverage will only be provided for responders. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and alternative janus kinase inhibitors, etc) for ulcerative colitis. *Note: This product should be used in consultation with a specialist in this area.*

Uplizna – see inebilizumab
Uptravi - see selexipag

ustekinumab, solution for subcutaneous injection (PFS/vial), 45mg/0.5mL (mg) (Jamteki)
ustekinumab, solution for subcutaneous injection (PFS), 45mg/0.5mL (mg) (Otulfi, Pyzchiva, Steqeyma, Wezlana)
ustekinumab, solution for subcutaneous injection (PFP), 45mg/0.5mL (mg) (Wezlana)
ustekinumab, solution for subcutaneous injection (vial), 45mg/0.5mL (mg) (Wezlana)
ustekinumab, solution for subcutaneous injection (PFS), 90mg/1.0mL (mg) (Jamteki, Otulfi, Pyzchiva, Steqeyma, Wezlana)
ustekinumab, solution for subcutaneous injection (PFP), 90mg/1.0mL (mg) (Wezlana)
ustekinumab, solution for IV infusion (vial),130mg/26mL (mg) (Otulfi I.V., Pyzchiva I.V., Steqeyma I.V., Wezlana I.V.)

Indication	Criteria
Plaque Psoriasis (solution for subcutaneous injection ONLY)	For the treatment of adult patients with severe plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy. Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy. **Note**: This product should be used in consultation with a specialist in this area.
Psoriatic arthritis (solution for subcutaneous injection ONLY)	For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic disease-modifying anti-rheumatic drug (DMARD). **Note**: This product should be used in consultation with a specialist in this area.
Crohn's Disease (ONLY BIOSIMILARS	For treatment of moderate to severely active Crohn's disease (CD) in adult patients who are refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy.

WITH AN AVAILABLE solution for IV infusion) (The 45mg/ 0.5mL solution for subcutaneous injection is not a benefit for this indication)	Clinical response should be assessed in the eight weeks following the single intravenous (IV) induction dose. Ongoing coverage will only be provided for those who respond to therapy. Therapy with ustekinumab subcutaneous should only be initiated in patients who have achieved clinical response after the single intravenous (IV) induction dose. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and janus kinase inhibitors, etc.) for Crohn's disease. **Note**: This product should be used in consultation with a specialist in this area.
Ulcerative Colitis (ONLY BIOSIMILARS WITH AN AVAILABLE solution for IV infusion) (The 45mg/ 0.5mL solution for subcutaneous injection is not a benefit for this indication)	For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed in the eight weeks following the single intravenous (IV) induction dose. Ongoing coverage will only be provided for those who respond to therapy. Therapy with ustekinumab subcutaneous should only be initiated in patients who have achieved clinical response after the single intravenous (IV) induction dose. Coverage will not be provided for use in combination with other escalated therapies (such as biologics and alternative janus kinase inhibitors, etc.) for ulcerative colitis. **Note**: This product should be used in consultation with a specialist in this area.

Vabysmo – see faricimab
Valcyte - see valganciclovir HCl

valganciclovir HCl, tablet, 450mg (Valcyte, and listed generics); powder for oral solution, 50mg/mL (Valcyte)

(a) For treatment of retinitis arising from CMV infection in patients with HIV infection.
(b) For treatment and prophylaxis of CMV infection in transplant patients. Coverage will be approved for a twelve month period for lung or heart/lung transplant patients, or for a six month period for other transplant patients.
(c) For the treatment of patients with symptomatic congenital CMV under the advice of an infectious disease specialist.
(d) For the treatment of CMV in immunocompromised patients under the advice of an infectious disease specialist.

Vancocin - see vancomycin HCl

vancomycin HCl, capsule, 125mg, 250mg (Vancocin, and listed generics); injection, 500mg, 1g (listed generics)

A) For the treatment of patients with a confirmed diagnosis of Clostridioides difficile infection (CDI).
Approval duration: 2 weeks.

B) For the treatment of patients with a recurrent Clostridioides difficile infection (CDI) who require a vancomycin tapering regimen.
Approval duration: up to 12 weeks.

vanzacaftor/tezacaftor/deutivacaftor, tablet, 4mg/20mg/50mg, 10mg/50mg/125mg (Alyftrek) (possible OEA)

For treatment of cystic fibrosis (CF) in patients who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to vanzacaftor/tezacaftor/deutivacaftor.

Initiation criteria:

- Patient is six (6) years of age or older; AND
- Confirmed diagnosis of CF; AND
- The patient is receiving treatment for CF at the time of initiation; AND
- The patient has demonstrated adherence to their prescribed CF therapeutic regimen.

Non-eligibility/discontinuation criteria:

- Patient has undergone lung transplant.

Administration criteria:

- Coverage will only be provided when prescribed by a clinical specialist affiliated with a Canadian CF centre.
- Patients will only be eligible for coverage of **ONE** CFTR modulator at a time.

The following assessments should be made prior to initiating treatment:

- Weight, height, and BMI (BMI z-scores for pediatric patients);
- Baseline measurement of FEV1 in litres and % predicted (within the past 3 months);
- Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months OR number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months;
- Number of CF-related hospitalizations in the previous 6 months; AND
- Cystic Fibrosis Questionnaire Respiratory (CFQ-R) Domain score.

Renewal criteria:

At the time of first renewal:

- The patient must continue to demonstrate adherence to their prescribed CF therapeutic regimen; AND
- The patient must demonstrate at least ONE of the following after six months of treatment:
    - Improvement of FEV1 by 5% predicted or more, relative to baseline; OR
    - A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six-month period prior to initiating treatment; OR
    - A decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six-month period prior to initiating treatment; OR
    - Decreased number of CF related hospitalizations compared with the six-month period prior to initiating treatment; OR
    - No decline in BMI (or BMI z-score for pediatrics) at six months compared with the baseline BMI assessment; OR
    - Improvement by 4 points or more in the CFQ-R Respiratory Domain Score.

Continuation criteria (subsequent renewal criteria):

- Patient is continuing to benefit from therapy with vanzacaftor/tezacaftor/deutivacaftor.

Renewal criteria for patients switching from alternative CFTR modulator:

- For patients who switched from a different CFTR modulator after the first renewal (following at least six months of prior therapy), the patient must demonstrate at least ONE of the following after six months of treatment with vanzacaftor/tezacaftor/deutivacaftor:
    - No decline in FEV1, relative to baseline prior to the switch to vanzacaftor/tezacaftor/deutivacaftor; OR
    - No increase in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the six-month period prior to initiating treatment with vanzacaftor/tezacaftor/deutivacaftor; OR
    - No increase in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the six-month period prior to initiating treatment with vanzacaftor/tezacaftor/deutivacaftor; OR
    - No increase in the number of CF related hospitalizations compared with the six-month period prior to initiating treatment with vanzacaftor/tezacaftor/deutivacaftor; OR
    - No decline in BMI (or BMI z-score for pediatrics) at six months compared with the baseline BMI assessment; OR
    - No reduction in the CFQ-R Respiratory Domain Score compared with baseline measurement prior to initiating treatment with vanzacaftor/tezacaftor/deutivacaftor.

Continuation criteria (subsequent renewal criteria):

- Patient is continuing to benefit from therapy with vanzacaftor/tezacaftor/deutivacaftor.

Vascepa – see icosapent ethyl

vedolizumab, solution for infusion, 300mg/vial; pre-filled pen, pre-filled syringe 108mg/0.68mL (Entyvio)

(a) For treatment of ulcerative colitis in patients unresponsive to high dose steroids.
Ongoing coverage will only be provided for those who respond to therapy.

Therapy with vedolizumab subcutaneous should only be initiated in patients who have achieved clinical response after induction therapy with vedolizumab IV.

Note: This product should be used in consultation with a specialist in this area

(b) For the treatment of moderate to severely active Crohn's Disease (CD) in patients refractory to, or with contraindications to, an adequate course of corticosteroids or other immunosuppressive therapy.
Ongoing coverage will only be provided for those who respond to therapy.
Therapy with vedolizumab subcutaneous should only be initiated inpatients who have achieved clinical response after induction therapy with vedolizumab IV.

Note: This product should be used in consultation with a specialist in this area.

Veklury – see remdesivir
Velphoro - see iron (sucroferric oxyhydroxide)
Velsipity – see etrasimod
Venofer - see iron sucrose
Vemlidy – see tenofovir alafenamide

vericiguat, tablet, 2.5mg, 5mg, 10mg (Verquvo) (possible OEA)

For the treatment of symptomatic chronic heart failure (HF) if all of the following are met:

- Heart failure decompensation event requiring hospitalization within the previous 6 months and/or IV diuretic therapy within the previous 3 months; **AND**
- Left ventricular ejection fraction below 45%; **AND**
- Prescribed in combination with standard of care heart failure therapy[1].

Notes:

[1] Standard of care therapy includes ALL of the following;

- angiotensin converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), **OR** angiotensin receptor/neprilysin inhibitor (ARNI); **AND**
- beta blocker; **AND**
- mineralocorticoid receptor antagonist (MRA); **AND**
- sodium glucose cotransporter-2 (SGLT2) inhibitor.

Consideration may be given to requests where these options are not tolerated or not appropriate.

verteporfin, injection solution, 15mg/vial (mg) (Visudyne)

For the treatment of:

a) Age related macular degeneration with predominantly classic subfoveal choroidal neovascularization (CNV)
b) Pathologic myopia
c) Ocular histoplasmosis

Note: The associated photodynamic therapy treatment is funded through Saskatchewan Health Authority.

Verkazia – see cyclosporine (ophthalmic emulsion)
Verquvo – see vericiguat
Vfend - see voriconazole
Videx EC - see didanosine
Vigamox - see moxifloxacin HCl

vilanterol/fluticasone furoate, powder for inhalation, 25mcg/100mcg (Breo Ellipta) (possible OEA)

For the treatment of:
(a) Asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
(b) Chronic obstructive pulmonary disease (COPD):

- In patients with concurrent or past use of long-acting beta-2 agonist (LABA) or long-acting muscarinic antagonist (LAMA) monotherapy; OR
- In patients initiated on inhaled corticosteroid (ICS)/LABA combination therapy in hospital; OR
- In patients with concomitant asthma and moderate to high symptom burden and/or health status impairment, as well as impaired lung function and a low acute exacerbation of COPD (AECOPD)[1] risk.

[1]Patients are considered low risk of AECOPD if they have ≤1 moderate AECOPD in the last year (moderate AECOPD is an event which required a prescribed antibiotic and/or oral corticosteroids) and did not require a hospital admission or emergency department (ED) visit.

vilanterol/fluticasone furoate, powder for inhalation, 25mcg/200mcg, (Breo Ellipta) (possible OEA)

For the treatment of asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

Vimpat - see lacosamide
Viramune - see nevirapine
Viread - see tenofovir disoproxil fumarate
Visanne - see dienogest
Visudyne – see verteporfin
Vocabria – see cabotegravir
Volibris - see ambrisentan

voriconazole, tablet, 50mg, 200mg; (Vfend, and listed generics)

For step-down treatment of patients treated in hospital for invasive aspergillosis or other serious fungal infections in consultation with an infectious disease specialist.

Vosevi - see sofosbuvir/velpatasvir/voxilaprevir
Vraylar – see cariprazine

vutrisiran, pre-filled syringe, 25mg/0.5mL (100mcg) (Amvuttra)

For the treatment of adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:

- Polyneuropathy disability [PND][1] stage I to ≤ IIIB, or
- Familial amyloidotic polyneuropathy [FAP][2] stage I or II.

Patients must be under the care of a specialist with experience in the diagnosis and management of hATTR-PN.

Exclusion Criteria (at therapy initiation):

- Patients exhibiting severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV); or
- Patients who have previously undergone a liver transplant; or
- Patients receiving other interfering ribonucleic acid drugs (such as patisiran) or transthyretin stabilizers (such as tafamidis); or
- Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care[3].

Initial approval duration: Nine (9) months

Discontinuation Criteria:
Treatment with vutrisiran should be reviewed nine months after the initial approval, and then at least every six months thereafter, to determine the continued clinical benefit for the patient.
Coverage will be discontinued if the patient is:

- Permanently bedridden and dependent on assistance for basic activities of daily living,
  Or
- Receiving end-of-life care[3].

After the initial nine (9) month approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:
[1]PND is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Sensory disturbances but preserved walking capability
- Stage II – Impaired walking capacity but ability to walk without a stick or crutches
- Stage IIIA – Walking with the help of one stick or crutch
- Stage IIIB – Walking with the help of two sticks or crutches
- Stage IV – Confined to a wheelchair or bedridden.

[2]FAP is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Unimpaired ambulation; mostly mild sensor, motor, and autonomic neuropathy in the lower limbs
- Stage II – Assistance with ambulation required, mostly moderate impairment progression to the lower limbs, upper limbs, and trunk

Please contact the Drug Plan for billing information.

Vyalev – see foslevodopa/foscarbidopa
Vyepti - see eptinezumab
Vyndamax- see tafamidis
Vyndaqel - see tafamidis meglumine
Vyvanse - see lisdexamfetamine dimesylate
Vyvgart- see efgartigimod alfa
Wainua – see eplontersen
Waymade-Trientine- see trientine
Wezlana – see ustekinumab

Wezlana I.V. – see ustekinumab
Winrevair – see sotatercept
Xarelto - see rivaroxaban
Xarelto Granules – see rivaroxaban
Xcopri – see cenobamate
Xeljanz - see tofacitinib
Yuflyma - see adalimumab
Zaditen - see ketotifen fumarate
Zaxine - see rifaxmin
Zenhale - see mometasone furoate/ formoteral fumarate dehydrate
Zeposia – see ozanimod
Ziagen - see abacavir SO_4

zidovudine, syrup, 10mg/mL; injection, 10mg/mL (Retrovir) capsule, 100mg (listed generic) (possible OEA)

For management of HIV disease.

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

zilucoplan (zilucoplan sodium), prefilled syringe, 16.6/0.416mL, 23mg/0.574mL, 32.4mg/0.81mL (100mcg) (Zilbrysq)

Initiation Criteria

For the treatment of adult patients with generalized myasthenia gravis (gMG) who:

- Have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; AND,
- Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥6; AND,
- Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
- Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
- Will not have zilucoplan initiated during a gMG exacerbation or crisis, or within 12 months of a thymectomy; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

Initial Coverage Duration: 6 months

Initial Renewal Criteria

Renewal of zilucoplan coverage will be considered in individuals who:

- Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Subsequent Renewal Criteria:

Ongoing coverage of zilucoplan will be considered in individuals who:

- Have not had a worsening of (increase in) MG-ADL score[1] compared to the initial renewal score; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

[1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.
[2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

Zithromax - see azithromycin
Zoladex - see goserelin acetate

zoledronic acid, solution, 5mg/100mL (Aclasta, and listed generics)

(a) For symptomatic treatment of Paget's disease of the bone.
(b) For the treatment of patients with osteoporosis who would otherwise meet the current EDS criteria for oral bisphosphonates, but are unable to take oral bisphosphonates due to abnormalities of the esophagus (e.g., esophageal stricture or achalasia) or the development of severe intolerance following at least a three month trial of an oral bisphosphonate.

AND have at least two of the following:

i) Age > 75 years;
ii) A prior fragility fracture;
iii) A bone mineral density (BMD) T-score ≤ -2.5

Note: Only one treatment per year is required.

zolmitriptan, tablet, 2.5mg (Zomig, and listed generics); orally dispersible tablet, 2.5mg (Zomig Rapimelt, and listed generics); nasal spray, 5mg (Zomig Nasal Spray)

For treatment of migraine headaches in patients over 18 years of age.

The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60-day period. *Patients requiring more than 12 doses in a consecutive 60-day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.*

Zomig - see zolmitriptan
Zomig Nasal Spray - see zolmitriptan
Zomig Rapimelt - see zolmitriptan
Zymar - see gatifloxacin
Zyvoxam - see linezolid