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* relevant to use of drug; prescriber name and phone number.**

*For pharmacist-initiated EDS requests:
The diagnosis, which must be obtained from the physician or physician's agent, is to be consistently documented within the pharmacy, whether the documentation is on the original prescription, computer file, or EDS fax form.

abacavir SO_4, oral solution, 20mg/mL (Ziagen) tablet; 300mg (Ziagen, 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.

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 (Kivexa, 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.

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 - 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.

acamprosate calcium, delayed release tablet, 333mg (Campral)
For alcohol use disorder in patients who have been abstinent from alcohol for at least four days and when the medication is being used as a component of an alcohol counselling program. Coverage will be reviewed every six months.

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, powder for inhalation, 400ug (Tudorza Genuair) (possible OEA)
For treatment of COPD.

aclidinium bromide/formoterol fumarate dihydrate, powder for inhalation, 400ug/12ug (Duaklir Genuair)
For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

Actemra - see tocilizumab
Actonel - see risedronate sodium
Actos - see pioglitazone HCl

acyclovir, oral suspension, 40mg/mL (Zovirax)
For patients unable to swallow the listed tablet formulation

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 autoinjector (Amgevita)
adalimumab, 40mg/0.4mL PFS (Hadlima); 40mg/0.4mL autoinjector (Hadlima PushTouch); 40mg/0.8mL PFS; 40 mg/0.8mL autoinjector (Hadlima PushTouch)
adalimumab, 20mg/0.4mL PFS; 40mg/0.8mL PFS; 40 mg/0.8mL autoinjector (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 autoinjector; 80mg/0.8mL auto-injector; 80mg/0.8mL PFS (Hyrimoz)

adalimumab, 40mg/0.8mL PFS; 40 mg/0.8mL autoinjector (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	For the treatment of ankylosing spondylitis (AS) according to the following criteria: **Initial Application (for a 12-week medication trial):** o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; AND o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment. **Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):** o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS. **Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):** o 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. **Notes:** o Requests for coverage for this indication must be made by a rheumatologist. o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.
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.

As announced on October 20, 2022, new and existing patients using adalimumab will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

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, 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

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, 75mg/mL, 150mg/mL (Praluent)

Initial Criteria

For the treatment of patients with 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) or (B):

(A) Confirmed adherence to high dose statin (e.g., atorvastatin 80mg or rosuvastatin 40mg) along with confirmed adherence to ezetimibe for at least a total of 3 months.
OR
(B) Unable to tolerate high dose statin defined as **all** of the following:

- Inability to tolerate at least 2 statins with at least one started at the lowest starting daily dose.
- For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether.
- For each statin (two statins in total), intolerable symptom (myopathy) or abnormal biomarkers (creatine kinase (CK) > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate.
- One of either:

i. Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out; OR

ii. Developed confirmed and documented rhabdomyolysis; OR

iii. Statin use is contraindicated i.e., active liver disease, unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.

- Confirmed adherence to ezetimibe for at least a total of 3 months

Quantity limits

- Patients prescribed Praluent 75mg every two weeks are limited to 26 prefilled syringes (PFS) or pre-filled pens (PFP) per year.
- Patients prescribed Praluent 150mg every two weeks or 300mg every four weeks must use the 150mg/mL dosage strength and are limited to 26 PFS or PFP per year.

Discontinuation criteria

Treatment with Praluent should be discontinued if the patient does not meet all of the following:

- Adherent to therapy.
- Achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of Praluent).
- Continues to have a significant reduction in LDL-C (with continuation of Praluent) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months).

[1] Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) is to be made by 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

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.

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

apomorphine HCl, soluble film, 10mg, 15mg, 20mg, 25mg, 30mg (Kynmobi)

For the adjunctive treatment of Parkinson's disease (PD) patients experiencing "off"[1] episodes despite receiving optimized therapy[1].

This medication should be prescribed in consultation with a specialist in this area.

[1] Optimized PD therapy is treatment with levodopa and derivatives and adjunctive therapy such as dopaminergic agonists (such as bromocriptine, pramipexole, ropinirole, rotigotine), MOA-B inhibitors (such as rasagiline and selegiline) or amantadine derivatives.

Approval Duration: Twelve months

Discontinuation Criteria:
Patients who do not improve by at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of sublingual apomorphine will not be eligible for renewal.

Aptiom – see eslicarbazepine acetate
Aptivus - see tipranavir
Aranesp - see darbepoetin alfa
Arava - see leflunomide
Aricept - see donepezil HCl

aripiprazole, tablet, 2mg, 5mg, 10mg, 15mg, 20mg, 30mg (Abilify, and listed generics)
For the treatment of schizophrenia and schizoaffective disorders.

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.

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.

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 episodic migraine (migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months).
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 = 6 months

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

Subsequent renewal criteria:

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 alternative 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 (atenolol, bisoprolol, carvedilol, metoprolol, labetalol) or candesartan
tricyclic antidepressants (amitriptyline, clomipramine, imipramine, trimipramine, nortriptyline)
verapamil or flunarizine
sodium valproate or divalproex sodium
topiramate
gabapentin
venlafaxine

atomoxetine HCl, capsule, 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg (Strattera, and 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 generic) (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.

Aubagio - see teriflunomide
Avelox - see moxifloxacin HCl
Avonex - see Appendix D
Avonex PS - see Appendix D
Axert - see almotriptan malate

azithromycin, tablet, 600mg (Zithromax, and 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 (Olumiant)

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) (mg), 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.

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

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/emticitabine/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, 160mg/mL (mg) prefilled syringe, autoinjector (Bimzelx)
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.

Bimzelx - see bimekizumab
Biphentin - see methylphenidate HCl

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)
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, 170ug/7.7ug/5.3ug (Breztri Aerosphere)

For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not controlled on optimal dual inhaled therapy (i.e., LAMA/LABA or LABA/ICS) or to replace existing triple therapy regimens currently achieved with more than one inhaler.
Patients should not be started on triple inhaled therapy as initial therapy for COPD.

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

For treatment of patients intolerant to furosemide.

buprenorphine hydrochloride, subcutaneous implant, 80mg (Probuphine)

For the management of opioid dependence in patients clinically stabilized on no more than 8mg of sublingual buprenorphine for the preceding 90 days.

Patients should be under the care of a prescriber with expertise in the management of opioid use disorder.

Notes:

- Probuphine implants are inserted subdermally in the upper arm by trained health care professionals for a six month duration. Each implantation procedure will be for one (1) set of implants (i.e. four (4) 80mg implants providing a total of 320mg of buprenorphine).
- The product monograph indicates that dosing beyond 24 months cannot be recommended at this time. As a result, the maximum lifetime quantity that can be claimed through the Drug Plan is four (4) implant cycles per patient (i.e., two (2) years of the drug product) at this time.

Burinex - see bumetanide

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

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 in the 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 following are present or have occurred:

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

Renewal approval duration = 12 months

Please refer to the form Exception Drug Status Request Crysvita (burosumab)

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.

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 (Calcimar)

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.

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.

Campral – see acamprosate calcium

canagliflozin, tablet, 100mg, 300mg (Invokana) (possible OEA)

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

Cayston - see aztreonam

cefixime, tablet, 400mg(Suprax, and listed generics); suspension, 20mg/mL (Suprax)

For treatment of:

(a) For treatment of infections in patients allergic to alternative antibiotics. (Note: patients who have had an anaphylactic reaction to penicillin should not receive cephalosporins.)

(b) For Infections caused by organisms known to be:

- Resistant to alternative antibiotics.
- Unresponsive to alternative antibiotics.

(c) Uncomplicated gonorrhea.

(d) For completion of antibiotic treatment initiated in hospital.

(e) For prophylaxis of infection in immunocompromised patients. Should be prescribed in consultation with an infectious diseases specialist.

cefprozil, tablet, 250mg, 500mg; oral suspension, 25mg/mL, 50mg/mL (listed generics)

For treatment of:

(a) Upper and lower respiratory tract infections in patients unresponsive to first-line antibiotics.

(b) Infections caused by organisms known to be resistant or unresponsive to alternative antibiotics.

(c) Infections in patients allergic to alternative antibiotics. *(Note: patients who have had an anaphylactic reaction to penicillin should not receive cephalosporins.)*

(d) Respiratory tract infections in nursing home patients.

(e) Pneumonia in patients in the community with comorbidity e.g. chronic underlying lung disease (excluding asthma), diabetes mellitus, renal insufficiency, heart failure, stroke, and:

(f) For completion of antibiotic treatment initiated in hospital.

Ceftin - see cefuroxime axetil

cefuroxime axetil, suspension, 25mg/mL (Ceftin) tablet, 250mg, 500mg (listed generics)

For treatment of:

(a) Upper and lower respiratory tract infections in patients unresponsive to first-line antibiotics.

(b) Infections caused by organisms known to be resistant or unresponsive to alternative antibiotics.

(c) Infections in patients allergic to alternative antibiotics. *(Note: patients who have had an anaphylactic reaction to penicillin should not receive cephalosporins.)*

(d) Respiratory tract infections in nursing home patients.

(e) Pneumonia in patients in the community with comorbidity i.e. chronic underlying lung disease (excluding asthma), diabetes mellitus, renal insufficiency, heart failure, stroke, and:

(f) For completion of antibiotic treatment initiated in hospital.

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	For the treatment of ankylosing spondylitis (AS) according to the following criteria: **Initial Application (for a 12-week medication trial):** o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; AND o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment. **Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):** o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS. **Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):** o 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. **Notes:** o Requests for coverage for this indication must be made by a rheumatologist. o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.

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

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 (Cipro XL, and listed generics)
For treatment of **uncomplicated** *urinary tract infections* in **females** unresponsive or allergic to first-line agents.

ciprofloxacin, extended release tablet, 1000mg (Cipro XL)
For treatment of **complicated** *urinary tract infections* in patients unresponsive or allergic to first-line agents.

cladribine, tablet, 10mg (Mavenclad)
See Appendix D

Climara - see estradiol

clonidine HCl, tablet, 0.025mg (listed generics)
For treatment of:
(a) Menopausal flushing.
(b) Attention Deficit Hyperactivity Disorder.

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
Combivir - see lamivudine/zidovudine
Complera – see emtricitabine/rilpivirine/tenofivir DF
Cosentyx – see secukinumab
Cresemba - see isavconazole
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, 25mg, 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
25mg - 00950793
50mg – 00950807
100mg - 00950815
100mg/mL - 00950823

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, 75mg, 150mg (Prezista-JAN); 600mg, 800mg (Prezista, and 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, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox)

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 deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu).

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.

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

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).

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.

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.

Divigel - see estradiol
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)
(a) A diagnosis of probable Alzheimer's disease as per DSM-V criteria.
(b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60-days prior to application for coverage by a clinician or nurse practitioner.
(c) A Functional Activities Questionnaire (FAQ) must be completed within 60-days prior to initial application for coverage by a clinician or nurse practitioner.

(d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with donepezil therapy. List all current medications patient was taking at the time of assessment.
(e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

- **Eligible patients currently taking donepezil** would require assessment at 6 month intervals. To continue receiving donepezil, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.
- **Eligible new patients** will enter a 3 month treatment period with donepezil. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with donepezil. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving donepezil, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.
- The MMSE score must remain at 10 or greater at all times to be eligible for coverage.
- Patients who do not meet criteria to continue donepezil can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.

- Donepezil does not need to be discontinued prior to MMSE or FAQ testing.

- A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such.

- Coverage will not be considered for patients who have failed on other drugs in this class.

Initial EDS applications for donepezil (Aricept) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available online at **http://formulary.drugplan.health.gov.sk.ca** *or by calling the Drug Plan. EDS renewals can be submitted either by telephone, mail or fax.*

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 pre-filled syringe, 200mg/1.14mL pre-filled pen, 300mg/2mL pre-filled syringe, 300mg/2mL
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 x 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 x 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.*

	○ *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[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* ○ *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: ○ Dupilumab 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 dupilumab treatment and submitted with the application. ○ Baseline[4] 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 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) ○ The asthma control questionnaire score has not improved from baseline[4,5], OR ○ The number of clinically significant exacerbations has increased. • 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.

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

edaravone, intravenous solution, 30mg/100mL (mg) (Radicava)
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.

Patients will only be eligible for coverage of one edaravone formulation at a time (i.e. either edaravone oral suspension or edaravone IV solution). Please specify the requested formulation with the EDS application.

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.

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)
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)

For treatment of cystic fibrosis (CF) in patients who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Initiation criteria:
• Patient is two (2) years of age or older; AND
• Confirmed diagnosis of CF with at least one F508del mutation in the CFTR gene; AND
• The patient is receiving treatment for their CF at the time of initiation; AND
• The patient has demonstrated adherence to their prescribed CF therapeutic regimen.
Initial approval duration = 7 months

Non-eligibility/discontinuation criteria:
• Patient has undergone lung transplant.

Administration criteria:
• May only be 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 FEV_1* in litres and % predicted (within the last 30 days);
• 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 for patients 6 years of age and older.

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:
    - o Improvement of FEV_1* by 5% of predicted or more, relative to baseline; OR
    - o 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
    - o Decreased number of CF related hospitalizations compared with the six-month period prior to initiating treatment; OR
    - o No decline in BMI (or BMI z-score for pediatrics) at six months compared with the baseline BMI assessment; OR
    - o Improvement by 4 points or more in the CFQ-R Respiratory Domain Score for patients 6 years of age and older.
- Additionally, for patients aged 2-5 years, renewal will be considered if the physician can provide evidence of clinical benefit from treatment with elexacaftor/tezacaftor/ivacaftor.

Renewal Duration = 1 year

Continuation criteria (subsequent renewal criteria)
• Patient is continuing to benefit from therapy with Trikafta.

Renewal Duration = 1 year
***** Submission of FEV_1 values is not required for patients 2-5 years of age.

Elidel - see pimecrolimus
Elmiron - see pentosan polysulfate sodium
Elonox- see enoxaparin

eltrombopag olamine, tablet, 25mg, 50mg (Revolade and listed generic)

For the treatment of refractory chronic idiopathic thrombocytopenic purpura ("ITP") with bleeding complications in patients who meet the following conditions:

a) have undergone a splenectomy[1]; and
b) have tried and are unresponsive to other treatment modalities[2].

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

Renewal of requests for eltrombopag will be assessed on a case-by-case basis.

Note: After 1 year of continuous treatment, therapeutic options should be reassessed.

1. Where surgery is contraindicated, the requesting physician must provide a rationale for why a splenectomy cannot be considered, and where possible, include both a preoperative/surgical evaluation of the patient's risks and a consideration of risks of laparoscopic and open surgical interventions if these are available. The requesting physician's rationale must be evaluated by an independent physician.

2. Patients must be refractory to two of the following first line treatment modalities:
    - Corticosteroids
    - IV anti-D
    - Intravenous immune globulin (IVIG)

    In addition, patients must be refractory to two of the following second-line treatment modalities:
    - Azathioprine
    - Cyclosporine
    - Cyclophosphamide
    - Mycophenolate
    - Rituximab
    - Danazol
    - Dapsone

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)

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.

Empaveli - see pegcetacoplan

emtrictabine/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 (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)
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)

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

(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.

As announced on October 20, 2022, new and existing patients using enoxaparin will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

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

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.

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 (mg), 100mg/1mL (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
♣ tricyclic antidepressants
♣ verapamil or flunarizine
♣ sodium valproate or divalproex sodium
♣ topiramate
♣ gabapentin

Erelzi - see etanercept
Esbriet - see pirfenidone

eslicarbazepine acetate, tablet, 200mg, 400mg, 600mg, 800mg (Aptiom)

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.

Estalis - see estradiol/norethindrone acetate

estradiol, transdermal gel (metered dose pump), 0.06% (Estrogel); transdermal gel, 0.1% (Divigel); +transdermal therapeutic system, 25ug, 50ug, 75ug (Climara), 25ug, 37.5ug, 50ug, 75ug, 100ug (Estradot, and listed generics) (possible OEA)

For treatment of patients:
(a) Intolerant to oral estrogen.
(b) With a fasting plasma triglyceride level of 4.5 mmol/L or more.

estradiol/norethindrone acetate, transdermal therapeutic system (8), 50ug/140ug; 50ug/250ug (Estalis) (possible OEA)

For treatment of patients:
(a) Intolerant to oral hormone replacement therapy (either estrogen or progesterone).
(b) With a fasting plasma triglyceride level of 4.5 mmol/L or more.

Estradot - see estradiol
Estrogel - see estradiol

etanercept, pre-filled syringe/pre-filled pen, 50mg/mL (Brenzys)
etanercept, 25mg/0.5mL pre-filled syringe, 50mg/mL pre-filled syringe, 50mg/mL pre-filled autoinjector (Erelzi)
etanercept, pre-filled syringe 50mg/mL, pre-filled autoinjector 50mg/mL (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	For the treatment of ankylosing spondylitis (AS) according to the following criteria: **Initial Application (for a 12-week medication trial):**

	o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; AND o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment. **Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):** o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS. **Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):** o 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. **Notes:** o Requests for coverage for this indication must be made by a rheumatologist. o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.
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.

As announced on October 20, 2022, new and existing patients using etanercept will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

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.*

Evenity - see romosozumab
Evista - see raloxifene HCl

evolocumab, solution for injection, 120mg/mL, 140mg/mL (Repatha)
Initial Criteria

For the treatment of patients with 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 despite either (A) **or** (B):

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

OR

(B) Unable to tolerate high dose statin defined as **all** of the following:

- Inability to tolerate at least 2 statins with at least one started at the lowest starting daily dose.
- For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether.
- For each statin (two statins in total), intolerable symptom (myopathy) or abnormal biomarkers (creatine kinase (CK) > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate.
- One of either:
  i. Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out; OR
  ii. Developed confirmed and documented rhabdomyolysis; OR
  iii. Statin use is contraindicated i.e., active liver disease, unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.
- Confirmed adherence to ezetimibe for at least a total of 3 months.

Quantity limits

- Patients prescribed Repatha 140mg every two weeks are limited to 26 prefilled syringes (PFS) per year.
- Patients prescribed Repatha 420mg every month must use the automated mini doser (AMD) and are limited to 12 AMD per year.

Discontinuation criteria

Treatment with Repatha should be discontinued if the patient does **not** meet all of the following:

- Adherent to therapy.
- Achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of Repatha).
- Continues to have a significant reduction in LDL-C (with continuation of Repatha) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months).

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

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

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 Clostridium difficile infection (CDI) in patients who:

- Have confirmed Clostridium difficile infection not improving after a course of metronidazole, and are allergic to, or are intolerant of oral vancomycin;

OR

- Patients with prior history of CDI after failure on other treatments* who are experiencing a recurrence of CDI**.

Notes:
(i) A course of metronidazole is defined as at least 7 days of oral metronidazole therapy with a dose of at least 500 mg 3 times daily without acceptable clinical improvement.
(ii) Fidaxomicin should not be used as add-on to existing therapy (metronidazole or vancomycin)
**Other treatments include metronidazole, vancomycin and vancomycin tapering regimen.*

** A recurrence of CDI is defined as less than 56 days since last medication dose for a previous CDI.

This medication should be prescribed in consultation with an infectious disease specialist.

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.
As announced on October 20, 2022, new and existing patients using filgrastim will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

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)
For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not controlled on optimal dual inhaled therapy (i.e., LAMA/LABA or LABA/ICS) or to replace existing triple therapy regimens currently achieved with more than one inhaler.

Patients should not be started on triple inhaled therapy as initial therapy for COPD.

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 treatment of:
(a) Asthma in patients uncontrolled on inhaled steroid therapy
(b) COPD in patients where there has been concurrent or past use of a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta-2 agonist (LABA).

Foquest- see methylphenidate HCl
Fosamax - see alendronate sodium

fosamprenavir calcium, tablet, 700mg; oral suspension, 50mg/mL (Telzir) (possible OEA)
For the 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.

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.

Fosrenol - see lanthanum carbonate hydrate
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
- tricyclic antidepressants
- verapamil or flunarizine
- sodium valproate or divalproex sodium
- topiramate
- gabapentin

Fuzeon - see enfuvirtide
Fycompa - see perampanel

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

(a) A diagnosis of probable Alzheimer's disease as per DSM-V criteria.
(b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60-days prior to application for coverage by a clinician.
(c) A Functional Activities Questionnaire (FAQ) must be completed within 60-days prior to initiation for coverage by a clinician.
(d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with nticholinergic activity are not to be used concurrently with galantamine hydrobromide therapy. List all current medications patient was taking at the time of assessment.
(e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

- **Eligible patients currently taking galantamine hydrobromide** would require assessment at 6 month intervals. To continue receiving galantamine hydrobromide, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.
- **Eligible new patients** will enter a 3 month treatment period with galantamine hydrobromide. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with galantamine hydrobromide. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving galantamine hydrobromide, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

- The MMSE score must remain at 10 or greater at all times to be eligible for coverage.

- Patients who do not meet criteria to continue galantamine hydrobromide can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.

- Galantamine hydrobromide does not need to be discontinued prior to MMSE or FAQ testing.

- A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such.

- Coverage will not be considered for patients who have failed on other drugs in this class.

Initial EDS applications for galantamine (Reminyl) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available online at http://formulary.drugplan.health.gov.sk.ca or *by calling the Drug Plan. EDS renewals can be submitted either by telephone, mail or fax.*

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
- tricyclic antidepressants
- verapamil or flunarizine
- sodium valproate or divalproex sodium
- topiramate
- gabapentin

gatifloxacin, ophthalmic solution, 0.3% (Zymar) (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

Glatect - see glatiramer acetate

glatiramer acetate, injection, 20mg (pre-filled syringe) (Glatect)
See Appendix D

As announced on October 20, 2022, new and existing patients using glatiramer will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

glecaprevir/pibrentasvir, tablet, 100mg/40mg; granules, 50mg/20mg (sachet) (Maviret) (possible OEA)
For treatment naïve and treatment experienced[1] patients with chronic hepatitis C infection (regardless of fibrosis stage) according to the following criteria:

- Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6; AND
- Laboratory confirmed quantitative HCV RNA value within 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.

Treatment regimens reimbursed:

Treatment Naïve

Genotype	Treatment Regimen and Duration
1, 2, 3, 4, 5 or 6	8 weeks with or without cirrhosis

Treatment Experienced[1] and previously treated with regimens containing:

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]	

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.

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 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.

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.

glycopyrronium bromide, inhalation powder capsule, 50ug/dose (Seebri Breezhaler) (possible OEA)
For treatment of COPD

golimumab, 50mg/0.5mL, pre-filled syringe; autoinjector (Simponi)
(a) For treatment of ankylosing spondylitis (AS) according to the following criteria:

Initial Application (for a 12-week medication trial):
- For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; **AND**
- Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.

Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):
- Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.

Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):
- 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.

Notes:
- Requests for coverage for this indication must be made by a rheumatologist.
- Applications for this indication must be submitted on the designated *EDS Application – Ankylosing Spondylitis Drugs* form found on the Formulary website.
- Coverage may be provided for one switch for patients transitioning to another biologic agent following an adequate trial of the first agent if the patient fails to respond, if there is a loss of response, or is intolerant, to the first agent. Approval will be subject to the published Exception Drug Status criteria for the requested biologic agent.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

(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 (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 (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

guselkumab, 100mg/ml, autoinjector (mg), pre-filled syringe (mg) (Tremfya)

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 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	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.).*

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.

Ibavyr - see ribavirin

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

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
Inclunox - see enoxaparin
Incruse Ellipta - see umeclidinium bromide

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)

For treatment of COPD in patients with an inadequate response to a long-acting beta-2 agonist (LABA), or a long-acting muscarinic antagonist (LAMA).

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.

infliximab, vial (mg), 100mg/vial (Avsola)
infliximab, vial (mg), 100mg/vial (Inflectra)
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	For the treatment of ankylosing spondylitis (AS) according to the following criteria: **Initial Application (for a 12-week medication trial):** o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; AND o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment. **Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):** o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.

	Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis): o 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. **Notes:** o Requests for coverage for this indication must be made by a rheumatologist. o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.
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.

As announced on October 20, 2022, new and existing patients using infliximab will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

Inflectra - see infliximab

inotersen, solution for injection, 284mg/1.5mL (Tegsedi)

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 Onpattro [patisiran]) 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 Tegsedi (inotersen) 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).

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 treatment of patients with type 2 diabetes who would be eligible for Adlyxine but will also be treated with a basal insulin (less than 60U/day) to achieve adequate glycemic control.

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
Invokana – see canagliflozin

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)

a) For treatment of iron deficiency when patients are intolerant or have inadequate response to oral iron replacement products.
b) For treatment of iron deficiency anemia in patients requiring loading regimens of IV iron therapy.
c) For management of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. Note: Coverage for dialysis patients is provided under the S.A.I.L. Program. Exception Drug Status coverage is not required for S.A.I.L. patients
d) For treatment of iron deficiency anemia in patients with inflammatory bowel disease.
e) For treatment of iron deficiency anemia in pregnant patients in whom oral iron supplementation is not appropriate.
f) For outpatient treatment of iron deficiency anemia prior to surgery.

iron sucrose, injection, 20mg/mL (Venofer) (possible OEA)

a) For treatment of iron deficiency when patients are intolerant or have inadequate response to oral iron replacement products.
b) For treatment of iron deficiency anemia in patients requiring loading regimens of IV iron therapy.
c) For management of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. 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.
d) For treatment of iron deficiency anemia in patients with inflammatory bowel disease.
e) For treatment of iron deficiency anemia in pregnant patients in whom oral iron supplementation is not appropriate.
f) For outpatient treatment of iron deficiency anemia prior to surgery.

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 (Sporanox)

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) (≤35%) in adult patients with New York Heart Association (NYHA) classes II or III who are in sinus rhythm with a resting heart rate ≥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.

Jadenu – see deferasirox

Janumet - see sitagliptin and metformin hydrochloride
Janumet XR - see sitagliptin and metformin hydrochloride
Januvia - see sitagliptin
Jardiance - see empagliflozin
Jentadueto - see linagliptin/metformin
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
Kivexa - see abacavir SO4/lamivudine
Komboglyze - see saxagliptin HCl/metformin HCl
Kuvan - see sapropterin dihydrochloride
Kynmobi – see apomorphine HCl

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 (Combivir, and 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); 300mg/2mL (pre-filled syringe) (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)
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, 7 day package, 30mg/500mg/500mg (listed generic)
For 14-day eradication of H. pylori-related infections in individuals with peptic ulcer disesase. *Provision will be made for additional coverage in treatment failures.*

lanthanum carbonate hydrate, chewable tablet, 250mg, 500mg, 750mg, 1000mg (Fosrenol) (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.

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

letermovir, tablet, 240mg, 480mg (Prevymis)
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**.**

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.

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.

maraviroc, tablet, 150mg, 300mg (Celsentri) (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
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

	○ 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.

Mictoryl Pediatric - see propiverine HCl

mirabegron, extended release tablet, 25mg, 50mg (Myrbetriq) (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.

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; oral granules, 4mg (Singulair, and listed generics)
(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.

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: 00951169- Sandoz Mycophenolate 00951167- Teva-Mycophenolate 00951163- Apo-Mycophenolate 00951174- Mycophenolate Mofetil (Accord) 00951175- Jamp-Mycophenolate 00951359- Mycophenolate (Sanis) 00950887 Cellcept 200mg/mL powder for oral suspension: 00951560- Mar-Mycophenolate Mofetil 00950937-Cellcept	500mg tablet: 00951172- Mycophenolate Mofetil (Accord) 00951164- Apo-Mycophenolate 00951170- Sandoz Mycophenolate 00951168- Teva-Mycophenolate 00951176- Jamp-Mycophenolate 00951360- Mycophenolate (Sanis) 00950888 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.

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*

naltrexone hydrochloride, tablet, 50mg (Revia, and listed generics)

For alcohol use disorder when used as a component of an alcohol counselling program. Coverage will be reviewed every six 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)

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.

Nipoz i- see filgrastim

nirmatrelvir and ritonavir, 4 x 150mg and 2 x 100mg tablet (daily dose blister card) (Paxlovid)
nirmatrelvir and ritonavir, 2 x 150mg and 2 x 100mg tablet (daily dose blister card) (Paxlovid Renal)
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 immunodeficienciesa

Examples of moderate immunosuppression may include:
• Treatment for cancer including solid tumors
• Treatment with significant immunosuppressing drugsb
• Advanced HIV infection (treated or untreated)
• Moderate primary immunodeficienciesc
• 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 gonoccoccal 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

Norprolac - see quinagolide HCl
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.

Nutropin - see somatropin
Nutropin AQ - see somatropin

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, 20mg/vial, 30mg/vial (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

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.

Olumiant - see baricitinib

omalizumab, sterile powder for reconstitution, 150 mg vial; pre-filled syringe, 150 mg/mL (Xolair)

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:
  - complete symptom control for less than 12 consecutive weeks; or
  - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline 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.

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.

Omnitrope - see somatropin

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, 4mg, 8mg (listed generics); orally disintegrating film, 4mg, 8mg (Ondissolve and listed generics)
For treatment of:
(a) Severe nausea in patients refractory to other anti-emetics. All of the following must be on the profile or have a reason why they are not appropriate for the patient: prochlorperazine, dimenhydrinate, dexamethasone, metoclopramide
(b) Hyperemesis gravidarum

One-Alpha - see alfacalcidol
Onglyza - see saxagliptin
Onpattro - see patisiran
Opsumit - see macitentan
Orencia - see abatacept
Orkambi- see lumacaftor/ivacaftor

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
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 treatment in the hospital.

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
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.

*__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.

Please 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; 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

prasugrel, tablet, 10mg (listed generics)

In combination with ASA for patients with:

a) ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab. Treatment must be initiated in hospital.

OR

b) Acute coronary syndrome who failed on optimal therapy with ASA and either clopidogrel or ticagrelor, as defined by definite stent thrombosis, or recurrent STEMI, or non-ST elevation myocardial infarction (NSTEMI) or unstable angina (UA) after prior revascularization via PCI.

Approval: Up to 12 months

Notes:

a) Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. Definite stent thrombosis must be confirmed by angiography or by pathologic evidence of acute thrombosis.
b) As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as peptic ulcer or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).
c) As per the product monograph, prasugrel is not recommended in patients > than 75 years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight < 60 kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

Prevacid - see lansoprazole
Prevacid FasTab - see lansoprazole
Prevymis - see letermovir
Precobix - see darunivir/cobicistat
Prezista - see darunavir
Probuphine - see buprenorphine hydrochloride
Procysbi - see cysteamine bitartrate
Procytox - see cyclophosphamide

progesterone (micronized), capsule, 100mg (Prometrium, and listed generics) (possible OEA)

For treatment of patients:

(a) Intolerant to medroxyprogesterone acetate (Provera).
(b) Having low high-density lipoproteins.
(c) For women with a singleton gestation, who are greater than 20 weeks gestation, and identified as being high-risk for pre-term birth (cervix less than 15 mm, or past history of pre-term birth).

Prograf - see tacrolimus
Prolia - see denosumab
Prometrium - see progesterone (micronized)

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

quinagolide HCl, tablet, 0.075mg, 0.150mg (Norprolac) (possible OEA)

For the treatment of hyperprolactineamia in patients who have failed or are intolerant to bromocriptine.

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; chewable tablet, 25mg, 100mg (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, solution for intravenous infusion, 10mg/mL (30mL vial) (mg), 100mg/mL (3mL vial) (mg), 100mg/mL (11mL vial) (mg) (Ultomiris)

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.

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.

Rebif - see Appendix D
Rebif Initiation Pack - see Appendix D
Reblozyl – see luspatercept
Redesca - see enoxaparin
Remodulin - see Treprostinil
Renagel - see sevelamer HCl
Renflexis - see infliximab
Renvela - see sevelamer carbonate
Retrovir - see zidovudine
Revatio - see sildenafil citrate
Revestive - see teduglutide
Revia – see naltrexone hydrochloride
Revolade - see eltrombopag olamine
Rexulti - see brexpiprazole
Reyataz - see atazanavir SO4

ribavirin, tablet, 200mg (Ibavyr)

For use within a listed combination therapy regimen for the treatment of chronic hepatitis C. Patients must meet the EDS criteria, and be approved for, the listed adjunctive hepatitis C therapy to be used in combination with ribavirin.

Treatment must be prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan.

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 pruritis (itching) in patients with cholestatic liver disease who are unresponsive or intolerant to cholestyramine.

(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, 360mg/2.4mL (mg) (Skyrizi)

Indication	Criteria
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. 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.

risankizumab, 75mg/0.83mL pre-filled syringe; risankizumab, 150mg/mL pre-filled syringe; risankizumab, 150mg/mL pre-filled pen (Skyrizi)

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 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 (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)
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.

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 refractory chronic immune thrombocytopenia (ITP) with bleeding complications in patients who: a) Have undergone a splenectomy[1]; and b) Have tried and are unresponsive to other treatment modalities[2]. 1) Where surgery is contraindicated, the requesting physician must provide a rationale for why a splenectomy cannot be considered, and where possible, include both a preoperative/surgical evaluation of the patient's risks and a consideration of risks of laparoscopic and open surgical interventions if these are available. 2) Patients must be refractory to corticosteroids. In addition, patients must be refractory to *one* of the following second-line treatment modalities: • Azathioprine • Cyclophosphamide • Mycophenolate mofetil • Danazol • Dapsone

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). ○ 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.

As announced on October 20, 2022, new and existing patients using rituximab will be subject to the Saskatchewan Biosimilars Initiative coverage policy. Please refer to Formulary Bulletin #221 accessible at https://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin-0221-Oct-2022.pdf for policy details.

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)

(a) A diagnosis of probable Alzheimer's disease as per DSM-V criteria.
(b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60-days prior to application for coverage by a clinician.
(c) A Functional Activities Questionnaire (FAQ) must be completed.

(d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with rivastigmine therapy. List all current medications patient was taking at the time of assessment.
(e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

- **Eligible patients currently taking rivastigmine** would require assessment at 6 month intervals. To continue receiving rivastigmine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

- **Eligible new patients** will enter a 3 month treatment period with rivastigmine. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with rivastigmine. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving rivastigmine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

The MMSE score must remain at 10 or greater at all times to be eligible for coverage.

- Patients who do not meet criteria to continue rivastigmine can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.

- Rivastigmine does not need to be discontinued prior to MMSE or FAQ testing.

- A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such.

- Coverage will not be considered for patients who have failed on other drugs in this class.

Initial EDS application for rivastigmine (Exelon) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available online at **http://formulary.drugplan.health.gov.sk.ca** *or by calling the Drug Plan. EDS renewals can be submitted either by telephone, mail or fax.*

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 refractory chronic idiopathic thrombocytopenic purpura ("ITP") with bleeding complications in patients who meet the following conditions:
a) have undergone a splenectomy[1]; and
b) have tried and are unresponsive to other treatment modalities[2].

Dosage: To a maximum of 10 mcg/kg once weekly.

Renewal of requests for romiplostim will be assessed on a case-by-case basis.

Note: After one year of continuous treatment, therapeutic options should be reassessed.

1. Where surgery is contraindicated, the requesting physician must provide a rationale for why a splenectomy cannot be considered, and where possible, include both a preoperative/surgical evaluation of the patient's risks and a consideration of risks of laparoscopic and open surgical interventions if these are available. The requesting physician's rationale must be evaluated by an independent physician.

2. Patients must be refractory to two of the following first line treatment modalities:
- Corticosteroids
- IV anti-D

- Intravenous immune globulin (IVIG)

In addition, patients must be refractory to two of the following second-line treatment modalities:
- Azathioprine
- Cyclosporine
- Cyclophosphamide
- Mycophenolate
- Rituximab
- Danazol
- Dapsone

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).

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
Ruzurgi - see amifampridine
Rymti – see etanercept

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 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) COPD in patients where there has been concurrent or past use of *a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta-2 agonist (LABA)*.

Sandostatin LAR - see octreotide
Saphnelo - see anifrolumab
Saphris - see asenapine

sapropterin dihydrochloride, tablet, 100mg; sachet 100mg, 500mg (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.

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 6 months after the initial approval period.

Renewal duration: 6 months

saxagliptin, tablet, 2.5mg, 5mg (Onglyza) (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 sulfonylurea.

secukinumab, subcutaneous solution, 75mg/0.5mL, 150mg/1.0mL (Cosentyx)

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. 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.
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	For the treatment of ankylosing spondylitis (AS) according to the following criteria: **Initial Application (for a 16-week medication trial):** o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; AND o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment. **Second Application (following the initial 16-week approval, requests will be considered for a one-year approval timeframe):** o Adequate response to treatment assessed at 16 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS. **Subsequent Annual Renewal Applications (beyond the first 16 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):** o 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. **Notes:** o Requests for coverage for this indication must be made by a rheumatologist. o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.

Seebri Breezhaler - see glycopyrronium bromide

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.

semaglutide, solution, 1.34mg/mL (2mg/pen, 4mg/pen) (Ozempic) (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.

Serevent - see salmeterol xinafoate
Serevent Diskus - see salmeterol xinafoate

sevelamer carbonate, tablet, 800mg (Renvela) (Accel-Sevelamer); powder for oral suspension, 0.8g/sachet, 2.4g/sachet (Renvela) (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.

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).

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, cartridge, 5mg/2mL (Nutropin AQ NuSpin 5); 10 mg/2mL (Nutropin AQ NuSpin 10) 20mg/2mL (Nutropin AQ NuSpin 20)**
- **somatropin, injection, vial, 5mg; cartridGEge, 6mg, 12mg, 20 mg (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
Sovaldi - see sofosbuvir
Spinraza - see nusinersen
Sporanox - see itraconazole

stavudine, capsule, 40mg (Zerit) (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.

Stelara - see ustekinumab

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.

Strattera - see atomoxetine HCl
Stribild - see elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

sumatriptan, tablet, 25mg (listed generics); 50mg, 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.*

Suprax - see cefixime
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.

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.*

Tegsedi - see inotersen
Telzir - see fosamprenavir calcium

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 (Aubagio, and 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) (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.

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 pre-filled syringe, 100mg/mL (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)

For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

tipranavir, capsule, 250mg (Aptivus) (possible OEA)

For the management of HIV disease in patients who have been shown to be non-responsive or resistant to all currently listed protease inhibitors (except Prezista).

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

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, solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial) (Actemra)

For the treatment of:

a) 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.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

b) 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.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

a) 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.

This medication should be prescribed by a rheumatologist**.**

tocilizumab, subcutaneous solution, 162mg/0.9mL pre-filled syringe, autoinjector (Actemra)

For the treatment of:

a) Moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic 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.

- Actemra should not be used concomitantly with TNF alpha inhibitors.
- This product should be used in consultation with a specialist in this area.

b) 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.

c) 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.

- Actemra should not be used concomitantly with TNF alpha inhibitors.
- This product should be used in consultation with a specialist in this area.

d) 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.
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.

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)
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.

Triamcinolone Hexacetonide - see triamcinolone hexacetonide

triamcinolone hexacetonide, injection suspension, 20mg/mL (Triamcinolone Hexacetonide Injectable Suspension)
For the management of pediatric chronic inflammatory arthropathies.

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
Tudorza Genuair- see aclidinium bromide
Tysabri - see natalizumab
Ultibro Breezhaler - see indacaterol/glycopyrronium
Ultomiris – see ravulizumab

umeclidinium bromide, powder for inhalation, 62.5ug (Incruse Ellipta) (possible OEA)

For treatment of COPD.

umeclidinium bromide/vilanterol trifenatate, powder for inhalation, 62.5ug/25ug (Anoro Ellipta)

For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

upadacitinib, extended release tablets, 15mg, 30mg, 45mg (Rinvoq)

Indication	Criteria
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.*

Uptravi - see selexipag

ustekinumab, solution for injection, 45mg/0.5mL, 90mg/1.0ml, 5mg/mL (130mg/26mL) (Stelara)

Indication	Criteria
Plaque Psoriasis (solution for injection, 45mg/0.5mL, 90mg/1.0ml 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.

Psoriatic arthritis (solution for injection, 45mg/0.5mL, 90mg/1.0ml 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 (solution for infusion, 5mg/mL (130mg/26mL), solution for injection, 90mg/1.0ml only)	For treatment of adult patients with moderate to severely active Crohn's disease (CD) who have had an inadequate response to, loss of response to, or were intolerant to either immunomodulators or one or more tumor necrosis factor-alpha antagonists, or have had an inadequate response to, intolerance to or demonstrated dependence on corticosteroids. Clinical response should be assessed in the eight weeks following the single intravenous (IV) induction dose. Ongoing coverage of the maintenance subcutaneous injections will only be provided for those who respond to treatment. **Note:** This product should be used in consultation with a specialist in this area.

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)
Treatment of *Clostridium difficile* infection (CDI) for:
- completion of treatment initiated in hospital, or
- patients experiencing severe infection, or
- patients who have not responded to, or are intolerant to, metronidazole within 5 days of treatment onset, or
- patients experiencing recurrent CDI in which a taper and pulse regimen is recommended

Notes:
- Severity is defined as:
  Mild – Moderate: WBC < 15 x 109/L and SCr ≤133 µmol/L
  Severe: WBC > 15 x 109/L and/or SCr > 133 µmol/L
- Recurrence defined as an episode of CDI that occurs in a patient within eight weeks following the diagnostic test date of the primary episode of CDI, providing the patient was treated successfully for the primary episode and symptoms of CDI resolved completely.
- Tapered and pulse regimen: reduction of vancomycin dose at weekly intervals over four to eight weeks in which the dosing interval of the last week(s) is every three days.

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.

Velphoro - see iron (sucroferric oxyhydroxide)
Venofer - see iron sucrose
Verkazia – see cyclosporine (ophthalmic emulsion)
Vfend - see voriconazole
Videx EC - see didanosine
Vigamox - see moxifloxacin HCl

vilanterol/fluticasone furoate, powder for inhalation, 25mcg/100mcg (Breo Ellipta)

(a) For treatment of COPD in patients where there has been concurrent or past use of a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta-2 agonist (LABA).

(b) 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.

vilanterol/fluticasone furoate, powder for inhalation, 25mcg/200mcg, (Breo Ellipta)

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
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
Vyalev – see foslevodopa/foscarbidopa
Vyepti - see eptinezumab
Vyndamax- see tafamidis
Vyndaqel - see tafamidis meglumine
Vyvanse - see lisdexamfetamine dimesylate
Waymade-Trientine- see trientine
Xarelto - see rivaroxaban
Xeljanz - see tofacitinib
Xeomin - see incobotulinumtoxin A
Xolair - see omalizumab
Yuflyma - see adalimumab
Zaditen - see ketotifen fumarate
Zaxine - see rifaxmin
Zenhale - see mometasone furoate/ formoteral fumarate dehydrate
Zerit - see stavudine
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.

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
Zovirax - see acyclovir
Zymar - see gatifloxacin
Zyvoxam - see linezolid