APPENDIX A

EXCEPTION DRUG STATUS PROGRAM

NOTES REGARDING THE EXCEPTION DRUG STATUS (EDS) PROGRAM

- Duly licensed practitioners prescribing within their scope of practice (or authorized office staff) 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. In most cases, the Drug Plan requires more information to determine the patient's eligibility for coverage, and will reconsider coverage 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 the date the request is received in our office. Requests for backdating can be made by a health professional or the patient. Patients are expected to meet EDS criteria within the dates requested. However, there is no provision or 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.
- See *NOTES CONCERNING THE FORMULARY*, pages viii-xiii for additional general information regarding Exception Drug Status coverage.
- Coverage may be provided for other products in certain instances.
- 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 review committee 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 length of time to be used

CRITERIA FOR COVERAGE UNDER EXCEPTION DRUG STATUS

Following are the criteria for coverage of certain drugs under Exception Drug Status. Approval of certain medications may be available online EDS adjudication or OEA.

With OEA, the Drug Plan adjudication system will look for certain alternative medications, specific prescibers or age group 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. Professional staff at the Drug Plan 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-VII) tablet; 300mg (Ziagen-VII) (and 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.

abacavir SO_4/ dolutegravir/lamivudine, tablet, 600mg/50mg/300mg (Triumeq – VII) (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-VII) (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 (Trizivir-VII) (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/mlF pre-filled syringe (Orencia-BMY)

(a) For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.
Note: This drug should NOT be used in combination with anti-TNF agents.

abatacept, powder for solution, 250mg/vial (Orencia-BMY)

(b) For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.
Note: This drug should NOT be used in combination with anti-TNF agents.

(c) For treatment of juvenile idiopathic arthritis in children who are intolerant to, or have not had an adequate response from etanercept. Initial treatment should be limited to a maximum of 16 weeks. Retreatment should only be permitted 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-IPS)

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.

acamprosate calcium, delayed release tablet, 333mg (Campral-MYL)

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.

acitretin, capsule, 10mg, (Soriatane-HLR) (and listed generic) ;25mg (Soriatane-HLR) (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-ACL) (possible OEA)

For treatment of:

a) COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, OR

b) Moderate to severe COPD (i.e. Medical Research Council (MRC) dyspnea scale score 3 to 5), in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 < 60 % and low FEV1/FVC < 0.7), without a trial of short-acting agents.

aclidinium bromide/formoterol fumarate dihydrate, powder for inhalation, 400ug/12ug (Duaklir Genuair-AST)

For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had 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-GSK)

For patients unable to swallow the listed tablet formulation

adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)

For treatment of:

(a) active rheumatoid arthritis in patients who have failed methotrexate and leflunomide.

(b) active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide.

(c) psoriatic arthritis in patients who have failed methotrexate and one other DMARD.

(d) psoriatic arthritis in patients who are intolerant to methotrexate and one other DMARD.

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

(e) 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.

(f) Crohn's disease as follows:
Initially for a 6 month period: For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy. Eligible patients should receive an induction dose of 160mg followed by 80mg two weeks later. Clinical response to adalimumab should be assessed after the induction dose.
Ongoing coverage: Adalimumab maintenance therapy should only be provided for responders, as noted above, and for a dose not exceeding 40mg every two weeks. Patients undergoing this treatment should be reviewed every 6 months

(g) For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:
failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; **AND**
failure to respond to, 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. This product should be used in consultation with a specialist in this area.

(h) For treatment of polyarticular juvenile idiopathic arthritis in pediatric patients 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.

(i) 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.

(j) For the treatment of adult 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 abcess 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.

Adcirca - see tadalafil

adefovir dipivoxil, tablet, 10mg (Hepsera-GSI) (and listed generics) (possible OEA)

For treatment of hepatitis B when used in combination with lamivudine, in patients who have developed failure to lamivudine, as defined by an increase in HBV DNA of $\geq$ 1 $\log_{10}$ IU/mL above the nadir, measured on two separate occasions within a interval of at least 1 month, after the first three months of lamivudine therapy, and when failure to lamivudine is not due to poor adherance to therapy.

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-BAY) (possible OEA)

Treatment of wAMD

For the treatment of neovascular (wet) age-related macular degeneration (AMD) if all of the following circumstances apply to the eye to be treated:

(i) The best corrected visual acuity (BCVA) is between 6/12 and 6/96

(ii) The lesion size is less than or equal to 12 disc areas in greatest linear dimension

(iii) There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT) or recent visual acuity changes); and

(iv) Injection will be by a qualified ophthalmologist with experience in intravitreal injections

Coverage will not be provided for patients:

(a) With permanent structural damage to the central fovea or no active disease (as defined in the Royal College of Ophthalmology guidelines); and

(b) Receiving concurrent verteporfin PDT treatment.

The interval between the doses should be no shorter than one month.

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 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 either 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 optimum treatment over three consecutive visits.

Treatment of DME

For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following:

(i.) 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.

(ii.) 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.

(iii.) A haemoglobin A1c of less than 11%.

(iv.) 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.

(v.) The interval between two doses should not be shorter than one month.

(vi.) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness.

(vii.) 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.

Treatment of RVO

For the treatment of visual impairment due to clinically significant macular edema secondary to branch retinal occlusion (BRVO) or central retinal vein occlusion (CRVO) for patients meeting all of the following:

(i.) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less.

(ii.) The interval between two doses should not be shorter than one month.

(iii.) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity.

(iv.) Treatment should be discontinued if there is no improvement after 6 months of initial treatment; and

(v.) 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.

Aggrenox - see dipyridamole/acetylsalicylic acid
Aldara - see imiquimod

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

***alendronate sodium, tablet, 10mg tablet, (listed generics)**

70mg tablet, (Fosamax-MSD) (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, tablet, 40mg (listed generic) (possible OEA)**
For treatment of symptomatic Paget's disease of the bone.

alendronate sodium/vitamin D3 (cholecalciferol), tablet, 70mg/5600IU (Fosavance-MSD) (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; oral drops, 2ug/mL (One-Alpha-LEO) (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-GZY)
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-AVT)

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-GSK) (possible OEA)

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

Amerge - see naratriptan HCl

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

For treatment of:

(a) Active rheumatoid arthritis in patients who have failed methotrexate and leflunomide.

(b) Active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide. (Note - exceptions can be considered in cases where methotrexate or leflunomide are contraindicated). *This product should be used in consultation with a specialist in this area.*

Note: Coverage will not be provided when used in combination with TNF blocking agents (i.e. adalimumab, etanercept and infliximab) due to the significantly higher risk of adverse events. Treatment should be combined with an immunosuppressant.

Anoro Ellipta - see umeclidinium bromide/vilanterol trifenatate

apixaban, tablet, 2.5mg (Eliquis-BMY)

(a) For prophylaxis of venous thromboembolism (VTE) following total knee arthroplasty for up to 14 days following the procedure.

(b) For prophylaxis of venous thromboembolism (VTE) in patients undergoing total hip replacement for up to 35 days following the procedure.

apixaban, tablet, 2.5mg, 5mg (Eliquis-BMY)

For at-risk patients with non-valvular atrial fibrillation, for the prevention of stroke and systemic embolism **AND** in whom:

a) Anticoagulation is inadequate following at least a 2-month trial of warfarin;
OR

b) Anticoagulation using warfarin is contraindicated or not possible due to inability to regularly monitor the patient via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion:

a) Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 25 mL/min) **OR**

b) Patients who are ≥75 years of age and who **do not** have documented stable renal function **OR**

c) Patients who have hemodynamically significant rheumatic valvular heart disease (especially mitral stenosis) **OR**

d) Patients who have prosthetic heart valves.

Notes:

a) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a $CHADS_2$ score of 1.
b) Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e., adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
c) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months.
d) Dosing: the usual recommended dose is 5 mg twice daily; a reduced dose of apixaban 2.5 mg twice daily is recommended for patients with at least two [2] of the following: age ≥80 years, body weight ≤60 kg, or serum creatinine ≥133 micromole/litre.
e) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see apixaban product monograph).
f) Patients starting apixaban should have ready access to appropriate medical services to manage a bleeding event.
g) There is currently no data to support that apixaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, apixaban is not recommended for these patient populations.

For treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).
Approval Period: Up to six (6) months.

Notes:

- The recommended dose of apixaban for patients initiating acute DVT or PE treatment is 10 mg taken orally twice daily for seven days, followed by 5 mg taken orally twice daily (for treatment up to six months).
- Drug Plan coverage of apixaban for the treatment of DVT or PE is an alternative to heparin/warfarin for up to six months. When used for longer than six months, apixaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy longer than six months should be considered for initiation on heparin/warfarin.
- The recommended dose for the continued prevention of recurrent DVT or PE is 2.5 mg taken orally twice daily (e.g. for treatment beyond six months, this falls outside of criteria for coverage). As previously noted, patients with an intended duration of therapy longer than six months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

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

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

aripiprazole, long acting injection, 300mg, 400mg (Abilify Maintena-OTS)
For treatment of patients exhibiting a compliance problem with an oral antipsychotic and in whom the administration of a conventional injectable extended action antipsychotic is ineffective or poorly tolerated.

Aristospan - see triamcinolone/hexacetonide

asenapine, sublingual tablet, 5mg, 10mg (Saphris-LUD)
(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-BMY) (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.

atomoxetine HCl, capsule, 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg (Strattera-LIL) (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-GSK) (possible OEA)
For treatment of P*neumocystis carinii* pneumonia (PCP) in patients intolerant to trimethoprim/sulfamethoxazole.

Atripla - see efavirenz/emtricitabine/tenofovir disoproxil fumarate
Aubagio - see teriflunomide
Avandia - see rosiglitazone maleate
Avelox - see moxifloxacin HCl
Avonex - see Appendix D
Avonex PS - see Appendix D
Axert - see almotriptan malate

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

aztreonam, inhalation powder for solution, 75mg/vial (Cayston-GSI)
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, 0.5mg/mL, 2mg/mL (Lioresal Intrathecal-NVR) (and 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
+Betaseron - see Appendix D

bezafibrate, tablet, sustained release tablet, 400mg (Bezalip SR-HLR) (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
Biphentin - see methylphenidate HCl

*__bosentan, tablet, 62.5mg, 125mg (Tracleer-ACT) (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
Brilinta - see ticagrelor

budesonide, controlled ileal release capsule, 3mg (Entocort-AST)
(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.

bumetanide, tablet, 1mg, , 5mg (Burinex-LEO) (possible OEA)
For treatment of patients intolerant to furosemide.

buprenorphine/naloxone, sublingual tablet, 2mg/0.5, 8mg/2mg (Suboxone-ICL) (and listed generics)
For treatment of opioid addiction when prescribed by a designated Suboxone (buprenorphine/naloxone) prescriber.

Burinex - see bumetanide

buserelin acetate, intranasal solution, 1.05mg/mL; injection, 1.05mg/mL (Suprefact-HRU)
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-PFI) (and listed generics) (possible OEA)**
For treatment of:
(a) Hyperprolactinemic disorders in patients unresponsive to bromocriptine.
(b) Hyperprolactinemic disorders in patients intolerant to bromocriptine.

calcitonin salmon, injection, 200IU/mL (Calcimar-AVT)
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-HLR) (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-JAN) (possible OEA)

For treatment of patients with Type 2 diabetes who have concurrent prescriptions for metformin and a sulfonylurea.

This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

Please note: This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and/or a sulfonylurea, and for whom insulin is not an option.

Cayston - see aztreonam

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

For treatment of:

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

***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-GSK)
***tablet, 250mg, 500mg (Ceftin-GSK) (and 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-UCB)

Rheumatoid arthritis:

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

Ankylosing spondylitis (A.S.):

For treatment of ankylosing spondylitis (A.S.) 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.

Psoriatic arthritis:

- Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

Treatment should be combined with an immunosuppressant.
Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

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

***ciprofloxacin, ophthalmic solution, 0.3% (Ciloxan-ALC)**
(and listed generics); ophthalmic ointment, 0.3% (Ciloxan-ALC) (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-BAY) (and listed generics); oral suspension100mg/mL (Cipro-BAY)**

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-BAY) (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-BAY)

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

Climara - see estradiol

***clonidine HCl, tablet, 0.025mg (listed generics)**

For treatment of:

(a) Menopausal flushing.
(b) Attention Deficit Hyperactivity Disorder.

***clozapine, tablet, 25mg, 100mg (Clozaril-NVR) (and listed generics)**
tablet, 50mg, 200mg (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-PFR)

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
Copaxone - see Appendix D
Cosentyx – see secukinumab

***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-BAX)

For non-oncology conditions

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

For treatment of:

(a) Nephrotic syndrome.
(b) Severe active rheumatoid arthritis in patients for whom classical slow-acting anti-rheumatic agents are inappropriate or ineffective, and:
(c) For induction and maintenance of remission of severe psoriasis in patients for whom conventional therapy is ineffective or inappropriate.

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

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

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

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.

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

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.

dabigatran, tablet, 110mg, 150mg (Pradaxa-BOE)

Inclusion Criteria:

At-risk patients with non-valvular atrial fibrillation (AF) who require the Drug Product for the prevention of stroke and systemic embolism **AND** in whom:

(a) Anticoagulation is inadequate following a reasonable trial on warfarin; **OR**
(b) Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion Criteria:

Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate
< 30 mL/min) **OR** ≥ 75 years of age and **without** documented stable renal function **OR** hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; **OR** prosthetic heart valves.

Notes:

(a) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least three months (i.e. 30-49 mL/min for 110 mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
(b) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1.
(c) Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
(d) A reasonable trial on warfarin is defined as at least two months of therapy.
(e) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see product monograph).

(f) Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.
(g) There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations.

daclatasvir, tablet, 30mg, 60mg (Daklinza-BMY)
For use as combination therapy with sofosbuvir, alone or with sofosbuvir and ribavirin, 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 3; AND

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

Treatment regimens reimbursed:

Patient Population		**Treatment Regimen and Duration**
Genotype 3	Treatment-naïve or treatment-experienced(1) without cirrhosis	12 weeks in combination with sofosbuvir
	Treatment-naïve or treatment-experienced(1) with compensated cirrhosis(2) or decompensated cirrhosis(2), or post-liver transplant	12 weeks in combination with sofosbuvir and ribavirin

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).

Daklinza - see daclatasvir

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

dapagliflozin, tablet, 5mg, 10mg (Forxiga-AST) (Possible OEA)

For treatment of patients with Type 2 diabetes who have concurrent prescriptions for metformin and a sulfonylurea.

This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

Please note: This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and/or a sulfonylurea, and for whom insulin is not an option.

dapagliflozin/metformin HCl, tablet, 5mg/850mg, 5mg/ 1000mg (Xigduo-AST) (Possible OEA)

For the convenience of patients who have been stabilized on metformin and dapagliflozin.

This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

Please Note: This product should be used in patients with diabetes who are not adequately controlled on, or are intolerant to combination therapy of metformin and a sulfonylurea, and for whom insulin is not an option.

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-NVR) (possible OEA)

For treatment of patients intolerant to oxybutynin chloride.

darunavir, tablet, 75mg, 150mg, 600mg, 800mg (Prezista-JAN) (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-JAN) (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
DDAVP Melt - see desmopressin

deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR) (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-APP) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

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

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

Note: Should not be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR) or deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox-APP).

deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox-APP)

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

Note: Should not be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

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

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

delavirdine mesylate, tablet, 100mg (Rescriptor-VII) (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.*

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

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:
   - o 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.
   - o 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; (DDAVP-FEI) (and listed generics); orally disintegrating tablet, 60ug, 120ug, 240ug (DDAVP Melt-FEI)**

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 (DDAVP-FEI) (and listed generics)**

For treatment of diabetes insipidus.

desmopressin, injection, 4ug/mL (DDAVP-FEI); intranasal solution, 150ug/dose (Octostim-FEI)

For prophylaxis of mild hemophilia A and mild von Willebrand's disease.

Detrol LA - see tolterodine L-tartrate
DexIron - see iron dextran
Diacomit - see stiripental

didanosine, capsule (enteric coated beadlet), 125mg, 200mg, 250mg, 400mg (Videx EC-BMY) (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.*

dienogest, tablet, 2mg (Visanne-BAY) (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-BGN)
See Appendix D

dipyridamole/acetylsalicylic acid, capsule, 200mg/25mg (Aggrenox-BOE) (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

dolutegravir, tablet, 50mg (Tivicay-VII) (possible OEA)
For management of HIV disease in patients 12 years of age and older.
This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Note: Tivicay is not recommended for patients weighing less than 40 kgs.

When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment, for post-exposure prophylaxis (PEP).

donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI) (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.*

dornase alfa, inhalation solution, 1mg/mL (Pulmozyme-HLR)

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 6 months of therapy before additional coverage is granted.

Renewal of coverage will be provided for a 6 month period if any of the following criteria are met:

(a) FEV_1 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
Duragesic - see fentanyl
Duragesic Mat - see fentanyl
Dysport Therapeutic - see abobotulinumtixinA
Edecrin - see ethacrynic acid
Edurant – see rilpivirine

efavirenz, capsule, 50mg, 200mg(Sustiva-BMY); tablet, 600mg (Sustiva-BMY) (and 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 (Atripla-BMY) (and 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.

Effient - see prasugrel

elbasvir/grazoprevir, tablet, 50mg/100mg (Zepatier-MRK)

For use as monotherapy or combination therapy with ribavirin 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 or 4; AND

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

Treatment regimens reimbursed*:

Patient Population		Treatment Regimen and Duration
Genotype 1	Treatment-naïve without cirrhosis, or with compensated cirrhosis(2)	12 weeks**
	Treatment-experienced(1) relapsers without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) genotype 1b with null response, partial response, or virologic breakthrough or rebound, or intolerance to prior treatment	12 weeks
	Treatment-experienced(1) genotype 1a with null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment	16 weeks in combination with ribavirin
Genotype 4	Treatment-naïve without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) relapsers without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) with null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment	16 weeks in combination with ribavirin

**Combination therapy with sofosbuvir (Sovaldi) will not be considered for funding.*
*** As approved by Health Canada, 8 weeks may be considered in treatment-naïve genotype 1b patients without significant fibrosis or cirrhosis.*

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).

Eldepryl - see selegiline HCl
Elidel - see pimecrolimus
Eliquis - see apixaban
Elmiron - see pentosan polysulfate sodium

eltrombopag olamine, tablet, 25mg, 50mg (Revolade-GSK)

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 Revolade 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-GSI) (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-GSI) (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.

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

For treatment of patients with Type 2 diabetes who have concurrent prescriptions for metformin and a sulfonylurea.

This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

Please note: This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and/or a sulfonylurea, and for whom insulin is not an option.

emtrictabine/rilpivirine/tenofovir disoproxil fumarate, tablet, 200mg/25mg/300mg (Complera-GSI) (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-GSI) (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
Enbrel - see etanercept

enfuvirtide, powder for solution, 108mg/vial (vial) (Fuzeon-HLR)

For management of HIV disease on a case-by-case basis, following committee review of each case. (It was noted that enfuvirtide is not first-line therapy. The most appropriate use of this product is for "salvage therapy"). *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*

enoxaparin, syringe, 30mg/mL, 40mg/mL, 60mg/mL, 80mg/mL, 100mg/mL, 120mg/mL (Lovenox-AVT); injection solution, 100mg/mL (3mL); 150mg/mL (Lovenox HP-AVT)

(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.

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

For treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2000IU/mL.

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

Entocort - see budesonide
Entresto - see sacubitril/valsartan
Entyvio - see vedolizumab
Epclusa –see sofosbuvir/velpatasvir

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

For treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as an adjunct to standard therapy

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

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-JAN)

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.

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

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

Eprex - see epoetin alfa
Erelzi - see etanercept
Esbriet - see pirfenidone

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

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-AST) (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
Estraderm - see estradiol

estradiol, transdermal gel (metered dose pump), 0.06% (Estrogel-MRK); transdermal gel, 0.1% (Divigel-TVM); +transdermal therapeutic system, 25ug, 50ug, 75ug, 100ug (Climara-BEX), 25ug, 50ug (Oesclim-PAL) *transdermal therapeutic system, 25ug, 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR)
(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-NVR) (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, powder for injection (vial), 25mg/vial; pre-filled syringe /autoinjector, 50mg/mL (Enbrel-AMG)

For treatment of:

(a) For patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide and have had initial approval of Enbrel before October 1, 2017.

Effective October 1, 2017, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept for the treatment of rheumatoid arthritis.

(b) Active juvenile rheumatoid arthritis in pediatric patients who have failed one DMARD.

Effective April 1, 2018, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept for the treatment of juvenile rheumatoid arthritis.

(c) Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.

(d) **For patients with ankylosing spondylitis who have had initial approval of Enbrel before October 1, 2017, according to the following criteria.**

Effective October 1, 2017, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept for the treatment of ankylosing spondylitis.

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.

(e) For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

i) Failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine **AND**

ii) Failure to respond to, 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. This product should be used in consultation with a specialist in this area.

For all of the above indications this product should be used in consultation with a specialist in this area.

etanercept, subcutaneous injection, pre-filled syringe/pre-filled pen, 50mg/mL (Brenzys-MRK)
For treatment of:

(a) Active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.
Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.

(b) 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.

For all of the above indications this product should be used in consultation with a specialist in this area.

etanercept, solution for injection, 25mg/0.5mL pre-filled syringe, 50mg/mL pre-filled syringe, 50mg/mL pre-filled autoinjector (Erelzi-SDZ)
For treatment of:

a) Active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

b) Active juvenile rheumatoid arthritis in pediatric patients who have failed one DMARD.

Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.

c) 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 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, the 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. 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.

For all of the above indications this product should be used in consultation with a specialist in this area.

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

Etibi – see ethambutol

ethambutol, tablet, 100mg, 400mg (Etibi-VAE)
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.

etodolac, capsule, 200mg, 300mg (listed generic) (possible OEA)
For treatment of patients intolerant to other NSAIDs listed in the Formulary.

etravirine, tablet, 100mg, 200mg (Intelence-JAN) (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.*

Evista - see raloxifene HCl

evolocumab, solution for injection, 120mg/mL, 140mg/mL (Repatha-AMG)

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.

Exelon - see rivastigmine
Exjade - see deferasirox
Extavia - see Appendix D
Eylea - see aflibercept

ezetimibe, tablet, 10mg (Ezetrol-MRK) (and listed generics)

For the treatment of hypercholesterolemia, as adjunctive therapy with HMG-CoA reductase inhibitor ('statin'), in patients who have not reached treatment goals on maximum tolerated statin therapy alone

OR

For treatment of hypercholesterolemia, as monotherapy, in patients who are intolerant to statins, OR when appropriate, fibrates.

Note:

Statin intolerance will be determined by evidence of a trial of 2 different statins.

Ezetrol - see ezetimibe

febuxostat, tablet, 80mg (Uloric-TAK)

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 (listed generics) 25ug/hr, 37ug/hr, 50ug/hr, 75ug/hr, 100ug/hr (Duragesic Mat-JAN) (and 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-PFI) (possible OEA)

For treatment of patients intolerant to oxybutynin chloride.

Fibristal - see ulipristal acetate

fidaxomicin, film-coated tablet, 200mg (Dificid-OPT)

- **fidaxomicin, film-coated tablet, 200mg (Dificid-OPT)**

  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, 300mcg/mL (Neupogen-AMG)

For treatment of the following conditions on a case by case basis where there is a suitable documented reason that filgrastim, sterile solution for injection, 480mcg/0.8mL (Grastofil-APX) is not appropriate:

(a) Congenital, cyclic, or idiopathic neutropenia in patients with absolute neutrophil count of less than or equal to 500.
(b) Non-cancer patients who have undergone bone marrow transplantation.
(c) AIDS patients with absolute neutrophil counts of less than 500.

Effective July 1, 2017, all EDS requests for filgrastim will be assessed for coverage with Grastofil and the Drug Plan will only cover Grastofil brand for patients seeking EDS approval for filgrastim for the indications above. The Saskatchewan Drug Plan will cover Grastofil and Neupogen for patients who were granted EDS approval for Neupogen before July 1, 2017 until that EDS coverage expires.

filgrastim, injection solution, 300mcg/mL (Grastofil-APX); 480mcg/0.8mL (Grastofil-APX)

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.

Effective July 1, 2017, all EDS requests for filgrastim will be assessed for coverage with Grastofil and the Drug Plan will only cover Grastofil brand for patients seeking EDS approval for filgrastim for the indications above. The Saskatchewan Drug Plan will cover Grastofil and Neupogen for patients who were granted EDS approval for Neupogen before July 1, 2017 until that EDS coverage expires.

fingolimod hydrochloride, capsule, 0.5mg (Gilenya-NVR)

See Appendix D

Firazyr – see icatibant acetate
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.

Foradil - see formoterol fumarate

+formoterol fumarate, powder for inhalation (capsule), 12ug (Foradil-NVR); powder for inhalation (package), 6ug/dose, 12ug/dose (Oxeze Turbuhaler-AST) (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) COPD unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators.

formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ug/200ug (Symbicort Turbuhaler-AST)
(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)**.**

Forxiga - see dapagliflozin
Fosamax - see alendronate sodium

fosamprenavir calcium, tablet, 700mg; oral suspension, 50mg/mL
(Telzir-VII) (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)
Fosrenol - see lanthanum carbonate hydrate
Fragmin - see dalteparin sodium
Fraxiparine - see nadroparin calcium
Fraxiparine Forte - see nadroparin calcium
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.*

gatifloxacin, ophthalmic solution, 0.3% (Zymar-ALL) (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
Glatect - see glatiramer acetate

glatiramer acetate, injection, 20mg (pre-filled syringe) (Copaxone-TVM) (Glatect-PED)

See Appendix D

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

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-NVR) (possible OEA)

For treatment of:

a) COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, **OR**
b) Moderate to severe COPD (i.e. Medical Research Council (MRC) dyspnea scale score 3 to 5), in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 < 60 % and low FEV1/FVC < 0.7), without a trial of short-acting agents.

GlucoNorm - see repaglinide

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

(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-JAN)
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.-JAN)
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-TST)
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
Harvoni - see ledipasvir/sofosbuvir
Hepsera - see adefovir dipivoxil
Heptovir - see lamivudine

Holkira Pak - see ombitasvir/paritaprevir/ritonavir and dasabuvir
Hp-PAC - see lansoprazole/clarithromycin/amoxicillin
Humatrope - see somatropin
Humira - see adalimumab
Humira Pen - see adalimumab
Hydrea - see hydroxyurea

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

Ibavyr - see ribavirin

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

imiquimod, topical cream, 5% (Aldara-VAE)
For treatment of:
(a) Genital warts in patients unresponsive to podofilox.
(b) Genital warts in patients with a large wart area.
(c) 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.

Imitrex - see sumatriptan
Incruse Ellipta - see umeclidinium bromide

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

indacaterol maleate, inhalation powder capsule, 75mcg
(Onbrez Breezhaler-NVR) (possible OEA)
For treatment of:
COPD unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators

indacaterol/glycopyrronium, inhalation powder capsule, 110UG/50UG
(Ultibro Breezhaler- NVR)
For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

infliximab, injection (mg),100mg/vial (Remicade-JAN)
Rheumatoid arthritis:

- Active rheumatoid arthritis in patients who have failed treatment with methotrexate and leflunomide;
  OR
- Active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide.

Treatment should be combined with an immunosuppressant. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

Plaque psoriasis:

- For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

i) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; **AND**
ii) failure to respond to, 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.

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

Psoriatic arthritis:

- Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

Treatment should be combined with an immunosuppressant. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

Ankylosing spondylitis (A.S.):

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.

Crohn's Disease:

(a) *Moderate to severe Crohn's Disease*:

• For treatment of patients who demonstrate continuing symptoms despite the use of optimal conventional therapies, such as glucocorticoids and immunosuppressive therapy.

• For treatment of patients who are intolerant to conventional therapy, including glucocorticoids and immunosuppressive therapy.

(b) Fistulizing Crohn's Disease:

For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae (i.e. any type of fistulizing Crohn's Disease).

Clinical response should be assessed after the induction dose. Ongoing coverage will only be provided for those who respond to treatment.
Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

<u>Ulcerative colitis:</u>

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

Clinical response should be assessed after the three-dose induction phase before proceeding to maintenance 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.

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infliximab, powder for solution, 100mg/vial (Inflectra-HOS)

Rheumatoid arthritis:

- For treatment of active rheumatoid arthritis in patients who have failed treatment with methotrexate and leflunomide;
  OR
- For treatment of active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide.

Treatment should be combined with an immunosuppressant. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

Plaque psoriasis:

- For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

1) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; **AND**
2) failure to respond to, 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.

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

Psoriatic arthritis:

- Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

Treatment should be combined with an immunosuppressant. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

Ankylosing spondylitis (A.S.):

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.

Crohn's Disease:

(a) *Moderate to severe Crohn's Disease*:

• For treatment of patients who demonstrate continuing symptoms despite the use of optimal conventional therapies, such as glucocorticoids and immunosuppressive therapy.

• For treatment of patients who are intolerant to conventional therapy, including glucocorticoids and immunosuppressive therapy.

(b) Fistulizing Crohn's Disease:

• For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae (i.e. any type of fistulizing Crohn's Disease).
Clinical response should be assessed after the induction dose. Ongoing coverage will only be provided for those who respond to treatment.
Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

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

Clinical response should be assessed after the three-dose induction phase before proceeding to maintenance 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.

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

insulin aspart, injection solution, 100U/mL (5x3mL) (10mL) (NovoRapid-NOO)
(a) For treatment of Type 1 diabetes.
(b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.

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 alfa-2b, powder for injection, 10 million IU; injection solution albumin (human) free, 6 million IU/mL (0.5mL), 10 million IU/mL (0.5mL, 1mL); multi-dose pen (kit) albumin (human) free, 18 million IU/pen, 30 million IU/pen, 60 million IU/pen (Intron-A-MRK)
For treatment of:
(a) Chronic active hepatitis B for a period of up to 6 months.
(b) Chronic active hepatitis C. Coverage will be provided for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks therapy.
Note: Interferons are not interchangeable. Pharmacists should dispense the product specified by the physician.
Note: This product should be used in consultation with a specialist in this area.

Intron A - see interferon alfa-2b

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

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

+interferon beta-1b, powder for injection, 0.3mg (vial) (Betaseron-BAY) + (Extavia-NVR)

See Appendix D

Intron A - see interferon alfa-2b
Invega Sustenna - see paliperidone palmitate
Invirase - see saquinavir
Invokana – see canagliflozin

***iron dextran, injection, 50mg/mL (DexIron-MYL)**

For treatment of iron deficiency when patients are intolerant to oral iron replacement products. *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. patient*s.

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

For treatment of:
(a) Iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoetin.
(b) Iron deficiency anemia in patients intolerant to oral iron replacement products.

*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. patient*s.

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

(a) For treatment of iron deficiency when patients are intolerant to oral iron replacement products and intravenous iron dextran.
(b) For treatment of patients who are intolerant to oral iron replacement products who require loading regimens of intravenous iron therapy.

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

For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

- failure to respond to, contraindication to, or intolerant of methotrexate and cyclosporine; AND
- failure to respond to, 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.

Isentress - see raltegravir

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

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-JAN)

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-SEV) (possible OEA)

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

- Patients with NYHA class II to III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) in combination with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA).
- Patients with at least one hospitalization due to heart failure in the last year.
- Resting heart rate must be documented as ≥ 77 bpm on average using either an ECG on at least three separate visits or by continuous monitoring.

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

ivacaftor, tablet, 150mg (Kalydeco-VER)

For treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene.

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.
The patients 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 pre-treatment 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 for 6 months. Patients will be limited to receiving a one-month supply per prescription.

Jadenu – see deferasirox
Janumet - see sitagliptin and metformin hydrochloride
Januvia - see sitagliptin phosphate
Jardiance - see empagliflozin
Jentadueto - see linagliptin/metformin
Jetrea - see ocriplasmin
Kaletra - see lopinavir/ritonavir
Kalydeco - see ivacaftor

***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-TEV)**

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

Kineret - see anakinra
Kivexa - see abacavir SO4/lamivudine

Komboglyze - see saxagliptin HCl/metformin HCl
Kuvan - see sapropterin dihydrochloride

lacosamide, tablet, 50mg, 100mg, 150mg, 200mg (Vimpat-UCB)

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 (Heptovir-GSK) (and listed generics); oral solution, 5mg/mL (Heptovir-GSK) (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-VII) (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-VII) (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.

Lancora - see ivabradine HCl

lanreotide acetate, injection, 60mg, 90mg, 120mg (Somatuline Autogel-TCI)

For treatment of acromegaly.

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

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 (Hp-PAC-ABB)

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-SCI) (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-GSI)

For use as monotherapy or as combination with ribavirin 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 six 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)	12 weeks in combination with ribavirin
	Treatment-naïve or treatment-experienced(1) liver transplant recipients without cirrhosis, or with compensated cirrhosis(2)	12 weeks in combination with ribavirin
	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.

(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-AVT) (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
Leucovorin - see leucovorin calcium

leucovorin calcium, tablet, 5mg (Leucovorin-PFI) (possible OEA)
For treatment of folic acid deficiency in patients who have been on long-term therapy with trimethoprim/sulfamethoxazole.

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

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**.**

***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 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.

***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 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.

linagliptin, tablet, 5mg (Trajenta-BOE) (possible OEA)
For treatment of patients with Type 2 diabetes who have had previous prescriptions for metformin and a sulfonylurea.

Please Note: *This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and a sulfonylurea, **and for whom insulin is not an option.***

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

For the convenience of patients who have been stabilized on metformin and linagliptin.

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, **and for whom insulin is not an option.***

linezolid, tablet, 600mg (Zyvoxam-PFI) (and listed generics); oral suspension, 100mg/5ml (Zyvoxam-PFI)

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.

Lioresal Intrathecal - see baclofen

lisdexamfetamine dimesylate, capsule, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg (Vyvanse-SCI)

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.

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

Losec - see omeprazole
Lovenox - see enoxaparin
Lovenox HP - see enoxaparin
Lucentis - see ranibizumab
Lupron Depot - see leuprolide acetate

lurasidone HCl, tablet 20mg, 40mg, 60mg, 80mg, 120mg (Latuda-SNV)

For manifestations of schizophrenia.

maraviroc, tablet, 150mg, 300mg (Celsentri-VII) (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.

Maxalt - see rizatriptan benzoate
Maxalt RPD - see rizatriptan benzoate

***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 (Mobicox-BOE) (and listed generics) (possible OEA)**

For treatment of patients intolerant to other NSAIDs listed in the formulary.

mepolizumab, powder for inection, 100mg/mL (Nucala-GSK)

For add-on maintenance treatment of adult patients with severe eosinophilic asthma who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one

or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]), and have a blood eosinophil count of ≥ 150 cells/mcL at initiation of treatment with mepolizumab or ≥ 300 cells/mcL in the past 12 months,
And one of the following:

- Patients who have experienced two or more clinically significant asthma exacerbations in the past 12 months and who show reversibility (at least 12% and 200 mL) on pulmonary function tests (i.e., spirometry)

- Are treated with daily oral corticosteroids (OCS).
  Note: Patients should be managed by a specialist in the treatment of asthma.

Discontinuation Criteria

1. Failure to achieve a decrease in any clinically significant exacerbations[1] at 12 months
OR
2. Failure to achieve a decrease in the maintenance OCS[2] dose at 12 months

[1]Significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.
[2]A decrease in the maintenance OCS is defined as a decrease in OCS use of at least 25%.

Mepron - see atovaquone

mercaptopurine, tablet, 50mg (Purinethol-NOP) (Mercaptopurine Tablets-STE)
For treatment of:
(a) Crohn's disease.
(b) Rheumatoid arthritis

Metadol - see methadone

methadone HCl, tablet, 1mg, 5mg, 10mg, 25mg; oral suspension, 1mg/mL, 10mg/mL (Metadol (PC)-PAL)
Coverage restricted to Drug Plan registered palliative care patients only. An Exception Drug Status request is not required for these patients.

methylphenidate HCl, extended release capsule, 10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg, 80mg (Biphentin-PFR)
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-APC)
(possible OEA)
For treatment of overactive bladder (OAB) for patients intolerant to, or with an inadequate response to oxybutynin.

Note: Should not be used in combination with other pharmacologic treatments for OAB.

Mobicox - see meloxicam

***modafinil, tablet, 100mg (Alertec-TVM) (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/ formoteral fumarate dihydrate, inhalation aerosol, 100mcg/5mcg, 200mcg/5mcg (Zenhale-MRK)

For treatment of asthma in patients uncontrolled on inhaled steroid therapy.

***montelukast sodium, chewable tablet, 4mg, 5mg; tablet, 10mg; oral granules, 4mg (Singulair-MSD)**
(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).

moxifloxacin HCl, tablet, 400mg (Avelox-BAY) (and 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 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.

moxifloxacin HCl, ophthalmic solution, 0.5% (Vigamox-ALC) (and listed generics) (possible OEA)

For treatment of ophthalmic infections unresponsive to alternative agents.

Mycobutin - see rifabutin

***mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept-HLR)**
(and listed generics); powder for oral suspension, 200mg/mL (CellCept-HLR)

(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-NVR) (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-VAE) (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-AVT); syringe, 19,000IU/mL (0.6mL, 0.8mL, 1mL)
(Fraxiparine Forte-AVT)

(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 contracindication 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.

nafarelin acetate, intranasal solution, 2mg/mL (Synarel-HLR)
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-TEV) (and listed generic)
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 (Amerge-GSK) (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.*

natalizumab, solution for IV infusion, 20mg/mL (Tysabri-BGN)
See Appendix D

nelfinavir mesylate, tablet, 250mg, 625mg (Viracept-PFI) (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.

Neoral - see cyclosporine
Neupogen - see filgrastim
Neupro - see rotigotine

***nevirapine, tablet, 200mg (Viramune-BOE) (and listed generics); extended release tablet, 400mg (Viramune XR-BOE) (and 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.

Nexium - see esomeprazole magnesium trihydrate

nintedanib, capsule, 100mg, 150mg (OFEV-BOE)

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 6 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 Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

Notes:

Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

Nizoral - see ketoconazole
Norditropin Nordiflex – see somatropin

*** norfloxacin, tablet, 400mg (Apo-Norflox-APX) (Novo-Norfloxacin-NOP) (pms-Norfloxacin-PMS)**

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) (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
Norvir - see ritonavir
NovoRapid - see insulin aspart
Nplate - see romiplostim
Nucala - see mepolizumab
Nutropin - see somatropin
Nutropin AQ - see somatropin

obeticholic acid, tablets, 5mg, 10mg (Ocaliva-INP)

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

ocriplasmin, solution for intrvitreal injection, 2.5mg/ml (Jetrea-ALC) (possible OEA)

For the treatment of **symptomatic** vitreomacular adhesion (VMA) if the following clinical criteria and conditions are met:

Clinical Criteria:

- Diagnosis of VMA should be confirmed through optical coherence tomography
- Patient does not have any of the following: large diameter macular holes (> 400 micrometre), high myopia (> 8 dioptre spherical correction or axial length > 28 millimetre), aphakia, history of retinal detachment, lens zonule instability, recent ocular surgery or intraocular injection (including laser therapy), proliferative diabetic retinopathy, ischemic retinopathies, retinal vein occlusions, exudative age-related macular degeneration, or vitreous hemorrhage.

Conditions:

- Ocriplasmin should be administered by a retinal specialist or by a qualified ophthalmologist experienced in intravitreal injections.
- Treatment with ocriplasmin should be limited to a single injection per eye (i.e. retreatments are not covered).

Octostim - see desmopressin

***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-NVR)**

(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
Oesclim - see estradiol
OFEV – see nintedanib

***ofloxacin, ophthalmic solution, 0.3% (Ocuflox-ALL) (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.

omalizumab, sterile powder for reconstitution, 150 mg vial (Xolair – NVR)

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-AST) (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, 100IU/vial (Botox-ALL)

For treatment of:
(a) Eye dystonias, that is, blepharospasm and strabismus.
(b) Cervical dystonia, that is, torticollis.
(c) Other forms of severe spasticity.
(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.

Onbrez Breezhaler - see indacaterol maleate

ondansetron, orally disintegrating tablet, 4mg, 8mg (Zofran ODT-GSK); orally disintegrating film, 4mg, 8mg (Ondissolve-TAK)

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
Orencia - see abatacept

***oxcarbazepine, tablet, 150mg, 300mg, 600mg (Trileptal-NVR) (and listed generics); oral suspension, 60mg/mL (Trileptal-NVR) (Possible OEA)**

For treatment of partial seizures in patients intolerant to carbamazepine.

Oxeze Turbuhaler - see formoterol fumarate
Oxsoralen - see methoxsalen

oxycodone HCl, controlled release tablet, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg (Oxyneo-PFR)

For the treatment of pain in palliative and cancer patients.

Oxyneo - see oxycodone HCl

paliperidone palmitate, pre-filled syringe, 50mg, 75mg, 100mg, 150mg

(Invega Sustenna-JAN); prolonged release pre-filled syringe, 175mg/0.875mL, 263mg/1.315mL, 350mg/1.75mL, 525mg/2.625mL (Invega Trinza-JAN)

For the treatment of patients exhibiting a compliance problem with an oral antipsychotic and in whom the administration of a conventional injectable extended action antipsychotic is ineffective or poorly tolerated.

***pamidronate disodium, injection, 30mg, (listed generics); *injection, 60mg (listed generics); *injection, 90mg (listed generics) (possible OEA)**

For treatment of osteoporosis in patients intolerant to oral bisphosphonates.

PDP-Isoniazid – see isoniazid
Pegasys - peginterferon alfa-2a

peginterferon alfa-2a, injection (pre-filled syringe), 180ug/0.5mL (Pegasys Proclick-HLR)

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-BGN)

See Appendix D

pentosan polysulfate sodium, capsule, 100mg (Elmiron-JAN)

For treatment of interstitial cystitis where other treatments have failed.

perampanel, tablet, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg (Fycompa-EIS)

For the adjunctive treatment of refractory partial-onset 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

pilocarpine HCl, tablet, 5mg (Salagen-PFI)

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-NVR) (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-TAK) (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-HLR)
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
Pradaxa - see dabigatran
Praluent –see alirocumab

prasugrel, tablet, 10mg (Effient-LIL)

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

a) Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis[a], 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
Precobix - see darunivir/cobicistat
Prezista - see darunavir
Procysbi - see cysteamine bitartrate
Procytox - see cyclophosphamide

progesterone (micronized), capsule, 100mg (Promem-MRK) (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)

propiverine HCl, tablet, 5mg (Mictoryl Pediatric-DUI)
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-FEI) (possible OEA)
For the treatment of hyperprolactineamia in patients who have failed or are intolerant to bromocriptine.

***raloxifene HCl, tablet, 60mg (Evista-LIL) (and listed generics) (possible OEA)**
For treatment of:
a) Osteoporosis in patients unresponsive to etidronate disodium/calcium after receiving it for 1 year.
b) Osteoporosis in patients intolerant to etidronate disodium/calcium.

raltegravir, tablet, 400mg (Isentress-MSD) (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-NVR) (possible OEA)
(a) For the treatment of neovascular (wet) age-related macular degeneration (AMD)
if all of the following circumstances apply to the eye to be treated:
(i) The best corrected visual acuity (BCVA) is between 6/12 and 6/96
(ii) The lesion size is less than or equal to 12 disc areas in greatest linear dimension
(iii) There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT) or recent visual acuity changes)
(iv) Injection will be by a qualified ophthalmologist with experience in intravitreal injections

Must be administered by a qualified ophthalmologist with experience in intravitreal injections.

Coverage will not be provided for patients:
(a) With permanent structural damage to the central fovea or no active disease
(as defined in the Royal College of Ophthalmology guidelines).
(b) Receiving concurrent verteporfin PDT treatment.

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 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 either baseline and/or
best recorded level since 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 optimum
treatment over 3 consecutive visits.

(b) 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.

(c) 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.

(d) 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
Rebif - see Appendix D
Rebif Initiation Pack - see Appendix D
Remicade - see infliximab
Remodulin - see treprostinil
Renagel - see sevelamer HCl

***repaglinide, tablet, 0.5mg, 1mg, 2mg (GlucoNorm-NOO)**
(and listed generics) (possible OEA)
For treatment of:
(a) Diabetes in patients uncontrolled on sulfonylureas.
(b) Diabetes in patients intolerant to sulfonylureas.

Rescriptor - see delavirdine mesylate
Retrovir - see zidovudine
Revatio - see sildenafil citrate
Revia – see naltrexone hydrochloride
Revolade - see eltrombopag olamine
Reyataz - see atazanavir SO4

ribavirin, tablet, 200mg, 400mg, 600mg (Ibavyr-PED)
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-PFI)

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.

Rifadin – see rifampin

rifampin, capsule, 150mg, 300mg (Rifadin-AVT) (Rofact-VAE)
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.

rifaxmin, tablet, 550mg (Zaxine-SAL)
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-JAN) (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-AVT) (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.

riociguat, tablet, 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg (Adempas-BAY)
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.

***risedronate sodium, tablet, 5mg (Actonel-WCI) (and listed generics); 35mg (listed generics); 150mg (Actonel-WCI) (and listed generics); delayed release tablet, 35mg (Actonel DR-WCI) (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-JAN)

For treatment of patients exhibiting a compliance problem with an oral antipsychotic and in whom the administration of a conventional injectable extended action antipsychotic is ineffective or poorly tolerated.

ritonavir, oral solution, 80mg/mL (Norvir-ABV); tablet, 100mg (Norvir-ABV) (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.

Rituxan - see rituximab

rituximab, injection solution, 10mg/mL (Rituxan-HLR)

(a) 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. Rituxan should not be used concomitantly with anti-TNF agents.

b) For induction of remission in patients with severely active granulomatosis with polyangiitis (GPA), also known as Wegener's Granulomatosis or microscopic polyangiitis (MPA) who have a severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

c) For treatment of antibody-mediated rejection in kidney, lung, heart or liver transplant patients.

d) 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

Please contact the Drug Plan for billing information.

rivaroxaban, tablet, 10mg (Xarelto-BAY)

(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.

rivaroxaban, tablet, 15mg, 20mg (Xarelto-BAY)

a) At-risk patients with non-valvular atrial fibrillation who require rivaroxaban for the prevention of stroke and systemic embolism **AND** in whom:
    - Anticoagulation is inadequate following a reasonable trial on warfarin;

    OR

    - Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion Criteria:

Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) **OR** ≥ 75 years of age and **without** documented stable renal function **OR** hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; **OR** prosthetic heart valves.

Notes:

(i) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate of 30-49 mL/min for 15 mg once daily dosing or ≥ 50 mL/min for 20 mg once daily dosing that is maintained for at least 3 months.

(ii) At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

(iii) Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period(i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).

(iv) A reasonable trial on warfarin is defined as at least 2 months of therapy.

(v) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see rivaroxaban product monograph).

(vi) Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

(vii) There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so rivaroxaban is not recommended in these populations.

(b) Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

Approval Period: Up to six (6) months

Notes:

(i) The recommended dose of rivaroxaban for patients initiating DVT or PE treatment *is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.*

(ii) Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

(iii) Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

***rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon-NVR) (and listed generics); oral solution, 2mg/mL ((Exelon-NVR)**

(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.*

***rizatriptan benzoate, tablet, 5mg (listed generics); tablet, 10mg (Maxalt-MRK) (and listed generics); *orally disintegrating tablet, 5mg, 10mg (Maxalt RPD-MSD) (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-AMG)
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

rosiglitazone maleate, tablet, 2mg, 4mg, 8mg (Avandia-GSK)

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-UCB)

For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

rufinamide, tablet, 100mg, 200mg, 400mg (Banzel-EIS)

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).

sacubitril/valsartan, tablet, 24.3mg/25.7mg, 48.6mg/51.4mg, 97.2mg/102.8mg (Entresto-NVR) (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-GSK) (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) COPD unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators.

salmeterol xinafoate/fluticasone propionate, metered dose inhaler (package), 25ug/125ug, 25ug/250ug (Advair-GSK); powder for inhalation (package), 50ug/100ug, 50ug/250ug, 50ug/500ug (Advair Diskus-GSK) (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
Saphris - see asenapine

sapropterin dihydrochloride, tablet, 100mg (Kuvan-BPC)
See Inherited Metabolic Disease Benefit List

saquinavir, capsule, 200mg, 500mg (Invirase-HLR) (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.

saxagliptin, tablet, 2.5mg, 5mg (Onglyza-AST) (possible OEA)
For treatment of patients with Type 2 diabetes who have had previous prescriptions
for metformin and a sulfonylurea.

Please Note: *This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and a sulfonylurea, and for whom insulin is not an option.*

saxagliptin/metformin HCl, tablet, 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (Komboglyze-AST) (possible OEA)
For the convenience of patients who have been stabilized on metformin and saxagliptin.

Please Note: *This product should be used in patients with diabetes who are not adequately controlled on, or are intolerant to combination therapy of metformin and a sulfonylurea, and for whom insulin is not an option.*

secukinumab, subcutaneous solution, 150mg/1.0mL (Cosentyx-NVR)

a) For treatment of adult patients with **severe debilitating** plaque psoriasis who meet all of the following criteria:

   i) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; AND

   ii) failure to respond to, 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.
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.

b) For the treatment of psoriatic arthritis in patients who have had an inadequate response to, or are intolerant to, methotrexate and one other DMARD.

Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

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

Initial Application (for a 16-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 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):

- 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 16 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 at a time regardless of the condition for which it is being prescribed.

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-ACT)

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.

Serevent - see salmeterol xinafoate
Serevent Diskus - see salmeterol xinafoate

sevelamer HCl, tablet, 800mg (Renagel-GZY) (and listed generic) (possible OEA)

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

sildenafil citrate, tablet, 20mg (Revatio-PFI) (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.

Simponi - see golimumab
Singulair - see montelukast sodium

sirolimus, tablet, 1mg; oral solution, 1mg/mL (Rapamune-WYA)

For prophylaxis of graft rejection in transplant patients.

sitagliptin and metformin hydrochloride, tablet, 50mg/500mg, 50mg/850mg, 50mg/1000mg (Janumet-MRK); modified release tablet, 50mg/1000mg (Janumet XR-MRK) (possible OEA)

For the convenience of patients who have been stabilized on metformin and sitagliptin.

Please Note: This product should be used in patients with diabetes who are not adequately controlled on, or are intolerant to combination therapy of metformin and a sulfonylurea, and for whom insulin is not an option.

sitagliptin phosphate, tablet, 25mg, 50mg (Januvia-MRK)

For the treatment of patients with Type 2 diabetes with reduced renal function who are not adequately controlled on or intolerant to metformin **AND** a sulfonylurea, **and in whom insulin is not an option.**

sitagliptin phosphate, tablet, 100mg (Januvia-MRK) (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,* ***and for whom insulin is not an option.***

sodium phenylbutyrate, oral granules, 483mg/g (Pheburane-MEC)

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-GSI)

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 six 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-GSI)

For use as monotherapy or as combination therapy with ribavirin 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 six 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
	Treatment-naïve or treatment-experienced(1) with decompensated cirrhosis(2)	12 weeks in combination with ribavirin

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/voxilaprevir, tablet, 400mg/100mg/100mg (Vosevi-GSI)
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 six 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.

(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).

solifenacin succinate, tablet, 5mg, 10mg (Vesicare-APC) (possible OEA)
For treatment of patients intolerant to oxybutynin chloride.

+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 (Genotropin-PFI); 5mg (Humatrope-LIL); 5mg/1.5mL prefilled pen (Norditropin Nordiflex-NOO); 5.3mg/pen (Genotropin-PFI); cartridge, 6mg, 12mg (Humatrope Cartridge-LIL); 10mg/1.5mL pre-filled pen (Norditropin Nordiflex-NOO) 12mg/pen (Genotropin-PFI); 15mg/1.5mL pre-filled pen (Norditropin Nordiflex-NOO); 24mg (Humatrope Cartridge-LIL)
For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone. (Note: These products are not interchangeable)

+somatropin, injection, vial, 3.33mg, 5mg (Saizen-SRO); vial, 5mg, 10mg (Omnitrope-SDZ); cartridge, 6mg, 12mg (Saizen-SRO); cartridge, 10 mg (Nutropin AQ Nuspin-HLR), 5mg/2ml (Nutropin AQ NuSpin 5); cartridge, 20mg (Saizen-SRO); cartridge, 20mg/2ml (Nutropin AQ NuSpin 20)
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

Spiriva - see tiotropium bromide monohydrate
Spiriva Respimat - see tiotropium bromide monohydrate
Sporanox - see itraconazole

stavudine, capsule, 15mg, 20mg, 30mg, 40mg (Zerit-BMY) (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, 500mg (Diacomit-BCX)
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

Suboxone - see buprenorphine/naloxone

***sumatriptan, tablet, 25mg (listed generics); 50mg, 100mg; injection solution, 6mg/0.5ml (Imitrex-GSK) (and listed generics); nasal spray, 5mg, 20mg (Imitrex-GSK)**
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
Sustiva - see efavirenz
Symbicort Turbuhaler - see formoterol fumarate dihydrate/budesonide
Synarel - see nafarelin acetate
3TC - see lamivudine

tacrolimus, capsule, 0.5mg, 1mg, 5mg (Prograf-APC); extended-release capsule, 0.5mg, 1mg, 3mg, 5mg; (Advagraf-APC); ampoule, 5mg/mL (Prograf-APC)
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-LEO) (possible OEA)
For treatment:
(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.

tadalafil, tablet, 20mg (Adcirca-LIL) (and listed generic) (possible OEA)
For the treatment of pulmonary arterial hypertension on the recommendation of a specialist. Note: The maximum dose that will be provided as a benefit is 40mg once daily.

Taltz - see ixekizumab
Tecfidera - see Appendix D
Telzir - see fosamprenavir calcium

tenofovir disoproxil fumarate, tablet, 300mg (Viread-GSI) (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) Chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2000IU/mL.

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

teriflunomide, tablet, 14mg (Aubagio-GZY)
See Appendix D

ticagrelor, tablet, 90mg (Brilinta-AST) (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).

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-LEO)

(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.

tiotropium bromide monohydrate, inhalation solution, 2.5ug (Spiriva Respimat-BOE) powder capsule, 18ug/dose (Spiriva-BOE) (possible OEA)

(a) For treatment of COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, or
(b) For treatment of moderate to severe COPD (i.e. Medical Research Council (MRC) dyspnea scale score 3 to 5), in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 <60% and low FEV1/FVC <0.7), without a trial of short-acting agents.

tiotropium bromide monohydrate/olodaterol HCl, inhalation solution, 2.5ug/2.5ug (Inspiolto Respimat-BOE)

For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

tipranavir, capsule, 250mg (Aptivus-BOE) (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.

Tivicay - see dolutegravir

***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-NVR)

For the treatment of cystic fibrosis patients intolerant to injectable tobramycin when used for inhalation.

tobramycin, inhalation solution, 60mg/mL (TOBI-CCL) (and listed generic)

For treatment of cystic fibrosis patients intolerant to injectable tobramycin when used for inhalation.

tocilizumab, solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial); subcutaneous solution, 162mg/0.9mL (Actemra-HLR)

a) For treatment of moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs), in patients who have failed to respond to an adequate trial of DMARDs.

Patients should be assessed after 16 weeks of treatment and therapy continued only if there is a clinical response to treatment.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

b) For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

c) For treatment of polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs.

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

tofacitinib, tablet, 5mg (Xeljanz-PFI)

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

Maximum daily dose is 10 mg per day.

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

tolterodine l-tartrate, extended-release capsule, 2mg, 4mg (Detrol LA-PFI) (and listed generics) (possible OEA)

For treatment of patients intolerant to oxybutynin chloride.

Toviaz - see fesoterodine fumerate
Tracleer - see bosentan
Trajenta - see linagliptin

treprostinil, injection solution, 1mg, 2.5mg, 5mg, 10mg (Remodulin-NTI)

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, injection suspension, 20mg/mL (Aristospan-STI)

For intra-articular injection in the management of pediatric chronic inflammatory arthropathies.

Trileptal - see oxcarbazepine
Triumeq - see abacavir/dolutegravir/lamivudine
Trizivir - see abacavir SO_4/lamivudine/zidovudine

Trosec - see trospium chloride

trospium chloride, tablet, 20mg (Trosec-SNV) (possible OEA)
For treatment of patients intolerant to oxybutynin chloride.

Tidorza Genuair - see aclidinium bromide
Tysabri - see natalizumab

ulipristal acetate, tablet, 5mg (Fibristal-ASP)
For the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age who are eligible for surgery. Approval duration will not exceed three months (i.e. 13 weeks), per patient, per lifetime.
Patients should be under the care of an obstetrician/gynecologist or a physician experienced in the management of gynecological conditions such as uterine fibroids.

Uloric - see febuxostat
Ultibro Breezhaler - see indacaterol/glycopyrronium

umeclidinium bromide, powder for inhalation, 62.5UG (Incruse Ellipta-GSK) (possible OEA)
(a) For treatment of COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, or
(b) For treatment of moderate to severe COPD (i.e. Medical Research Council (MRC) dyspnea scale score 3 to 5), in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 <60% and low FEV1/FVC <0.7), without a trial of short-acting agents.

umeclidinium bromide/vilanterol trifenatate, powder for inhalation, 62.5/25UG (Anoro Ellipta- GSK)
For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

Uptravi - see selexipag

ustekinumab, solution for injection, 45mg/0.5mL, 90mg/1.0ml (Stelara-JAN)
For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:
i) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine and
ii) failure to respond to, 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. This product should be used in consultation with a specialist in this area.

For treatment of psoriatic arthritis in patients who have had an inadequate response to, or are intolerant to methotrexate and one other DMARD.
Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.
This product should be used in consultation with a specialist in this area.

ustekinumab, solution for infusion, 5mg/mL (130mg/26mL), solution for injection, 90mg/1.0ml (Stelara-JAN)

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.

Notes:

- Clinical response should be assessed in the eight weeks following the single IV induction dose. Ongoing coverage of the maintenance SC injections will only be provided for those who respond to treatment.
- This product should be used in consultation with a specialist in this area.

Valcyte - see valganciclovir HCl

valganciclovir HCl, tablet, 450mg (Valcyte-HLR) (and listed generics); powder for oral solution, 50mg/mL (Valcyte-HLR)

(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.

Vancocin - see vancomycin HCl

vancomycin HCl, capsule, 125mg, 250mg (Vancocin-LIL) (and listed generics);
***injection, 500mg, 1g (listed generics)**

For treatment of Clostridium difficile infections for up to two consecutive two week periods after no response, allergies or intolerance to a course of metronidazole. *Repeat approvals will only be granted with laboratory evidence of C. difficile toxin.*

Note: For treatment of second or later recurrence for Clostridium difficile infections, further coverage may be considered for up to 8 weeks.

vedolizumab, solution for infusion, 300mg/vial (Entyvio-TAK)

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

Note: Clinical response should be assessed after the three dose induction phase. 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.

(b)For the treatment of moderate to severely active Crohn's Disease (CD) patients who demonstrate continuing symptoms despite the use of optimal conventional

therapies, such as glucocorticoids and immunosuppressive therapy, or are intolerant to glucocorticoids and immunosuppressive therapy.

Note: Clinical response should be assessed after the three dose induction phase. 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.

Venofer - see iron sucrose
Vesicare - see solifenacin succinate
Vfend - see voriconazole
Videx EC - see didanosine
Vigamox - see moxifloxacin HCl

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

(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-GSK)

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
Viracept - see nelfinavir
Viramune - see nevirapine
Viread - see tenofovir disoproxil fumarate
Visanne - see dienogest
Vitamin A Acid - see tretinoin
Volibris - see ambrisentan

voriconazole, tablet, 50mg, 200mg; (Vfend-PFI) (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
Vyvanse - see lisdexamfetamine dimesylate
Xarelto - see rivaroxaban
Xeljanz - see tofacitinib
Xeomin - see incobotulinumtoxin A
Xigduo – see dapagliflozin/metformin HCl
Xolair - see omalizumab
Zaditen - see ketotifen fumarate
Zaxine - see rifaxmin
Zenhale - see mometasone furoate/ formoteral fumarate dehydrate
Zepatier - see elbasvir/grazoprevir
Zerit - see stavudine
Ziagen - see abacavir SO_4

zidovudine, syrup, 10mg/mL; injection, 10mg/mL (Retrovir-GSK)
***capsule, 100mg (Retrovir-GSK) (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.

Zithromax - see azithromycin
Zoladex - see goserelin acetate

zoledronic acid, solution, 5mg/100mL (Aclasta-NVR)
(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-AST) (and listed generics); *orally dispersible tablet, 2.5mg (Zomig Rapimelt-AST) (and listed generics); nasal spray, 5mg (Zomig Nasal Spray-AST)
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

LEGEND:

***These brands of products have been approved as interchangeable.**
+These brands of products have NOT been approved as interchangeable.