AFBS
Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
3TC and generic LAMIVUDINE (Lamivudine)	- HIV anti-viral	- Coordinate with provincial government program
ABILIFY MAINTENA (Aripiprazole injection)	- For the management of the manifestations of: schizophrenia, bipolar disorder and major depression disorder	- For patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations - Manic or mixed episodes in bipolar 1 disorder,, used as acute monograph or cotherapy with lithium or divalproex sodium - Treatment of Major Depressive Disorder (MDD) in patients with inadequate response to prior antidepressant treatment
ABSTRAL (Fentanyl citrate)	- Management of breakthrough pain in cancer patients	- For the treatment of breakthrough pain in patients with cancer, 18 years of age and older, - Who are currently on baseline pain control therapy and who have tried and failed or cannot tolerate other listed short acting / immediate release oral opioids AND Fentora
ACLASTA and generic ZOLEDRONIC ACID (Zoledronic acid)	- Paget's disease of the bone - Postmenopausal osteoporosis	- For the treatment of Paget's disease. - For the treatment of osteoporosis in post-menopausal women and men who have a bone mineral density (BMD) T-score of less than or equal to -2.5 AND - Who have tried and failed, are intolerable or contraindicated to oral bisphosphonate therapy
ACTEMRA IV (Tocilizumab)	- Rheumatoid Arthritis - Systemic Juvenile Idiopathic Arthritis (sJIA) - Polyarticular Juvenile Idiopathic Arthritis (pJIA)	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months, AND who have tried and failed Cimzia or Enbrel or Humira or Simponi or Actemra SC or Remicade or Orencia SC - For pediatric patients (between ≥ 2 and ≤ 16 years of age) with a confirmed diagnosis of sJIA with fever (>38oC) for at least 2 weeks AND at least ONE of the following symptoms: rash of systemic JIA, serositis, lymphadenopathy, hepatomegaly, splenomegaly AND who have not adequately responded to NSAIDS, corticosteroids and at least a 3 month trial of methotrexate - For patients ages 2 and older with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD together with oral corticosteroids, AND who has tried and failed Enbrel - Coordinate with provincial government program
ACTEMRA SC (Tocilizumab)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program

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ACULAR LS (Ketorolac 0.4% ophthalmic solution)	- For the reduction of ocular pain and photophobia following refractive surgery	- For the reduction of ocular pain and photophobia where the patient has tried Ketorolac 0.5% AND had intractable intolerance or adverse effects
ACUVAIL (Ketorolac 0.45% ophthalmic solution)	- For the treatment of pain and inflammation following cataract surgery	- For the reduction of ocular pain and photophobia where the patient has tried regular Acular (0.5%) or its generic equivalents AND had intractable intolerance or adverse effects.
ADCIRCA (Tadalafil)	- Pulmonary Arterial Hypertension	- For patients with a confirmed diagnosis of idiopathic ("primary") pulmonary arterial hypertension (PAH) or PAH associated with connective tissue disease, congenital heart disease or anorexigen WHO functional class II or III who experienced failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin , loop diuretics, digoxin, supplemental oxygen) OR who are not candidates for conventional therapy
ADDERALL XR (Dextroamphetamine and amphetamine extended release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting) or Dextroamphetamine
ADEMPAS (Riociguat)	- Inoperable chronic thromboembolic pulmonary hypertension (CTEPH) - Persistent or recurrent CTEPH after surgical treatment	- Confirmed diagnosis of CTEPH in adult patients with WHO Functional Class II or III pulmonary hypertension with: ▪ Inoperable disease OR ▪ Persistent or recurrent disease post-surgery - Coordinate with provincial government program
AFINITOR AFINITOR DISPERZ TAB (Everolimus)	- Second-line treatment of metastatic Renal Cell Carcinoma (“RCC”) - Neuroendocrine Tumours of pancreatic origin (PNET) - Advanced breast cancer - Renal Angiomyolipoma - Subependymal giant cell astrocytoma (SEGA)	- For patients with a confirmed diagnosis of metastatic renal cell carcinoma of clear cell morphology who have tried and failed initial treatment with a tyrosine kinase inhibitor - For treatment of well- or moderately differentiated PNET in patients with unresectable, locally advanced or metastatic disease that has: ▪ Progressed within the last 12 months, AND ▪ With an ECOG ≤ 2 - For postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer in combination with exemestane after recurrence or progression following treatment with letrozole or anastrozole - For the treatment of adult patients (≥18 years of age) with renal angiomyolipoma associated with tuberous sclerosis complex (TSC), who do not require immediate surgery - For the treatment of patients 3 years of age or older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) that have demonstrated serial growth, who are not candidates for surgical resection and for whom immediate surgical intervention is not required - Coordinate with provincial government program
ANDROGEL (Testosterone 1% pump)	- Endogenous testosterone deficiency	- For patients who have tried Testosterone sachets and have a physical disability that prevents them from physically opening a sachet
ANORO ELLIPTA (Umeclidinium/Vilanterol)	- Chronic Obstructive Pulmonary Disease (COPD)	- For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy

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APTIOM (Eslicarbazepine Acetate)	- Partial-onset seizures in patients with epilepsy who are not satisfactorily controlled with conventional therapy	- For patients with a diagnosis of partial onset seizures AND have tried and failed or have experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin AND one of the following: Vimpat or Fycompa.
APTIVUS (Tipranavir)	- HIV anti-viral	- For patients who have tried and failed or are intolerable to at least one anti-retroviral from each of the following sub-classes: Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
ARANESP (Darbepoetin Alfa)	- Anemia with chemotherapy - Chronic renal failure	- For patient with chronic renal failure - For patient with anemia secondary to chemotherapy - Coordinate with provincial government program
ATRIPLA (Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate)	- HIV anti-viral	- Coordinate with provincial government program
AUBAGIO (Teriflunomide)	- Multiple sclerosis, relapsing remitting	- Confirmed diagnosis of Relapsing Remitting MS - EDSS value required with every application - Coordinate with provincial government program
AVODART and generic DUTASTERIDE (Dutasteride)	- Benign Prostatic Hyperplasia	- For male patients in the treatment of benign prostatic hyperplasia
AVONEX AVONEX PS (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive - Clinically Isolated Syndrome	- For patients with RRMS or progressive MS - For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation - EDSS value required with every application - Coordinate with provincial government program
AXIRON (Testosterone 2% solution)	- Endogenous testosterone deficiency	- For patients with endogenous testosterone deficiency with supporting lab values who have tried Testosterone sachets and have a physical disability that prevents them from physically opening a sachet
BANZEL (Rufinamide)	- Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome	- For the treatment of Lennox Gastaut Syndrome in children 4 years and older and adults, who cannot tolerate or have not achieved adequate control with TWO other anti-epileptic drugs (e.g. valproic acid, topiramate, lamotrigine, carbamazapine)
BARACLUDE and generic ENTECAVIR (Entecavir)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to lamivudine AND who have tried and failed combination therapy with lamivudine/adefovir or lamivudine/tenofovir - For chronic hepatitis B patients who have severe liver disease (e.g. cirrhosis)
BENLYSTA (Belimumab)	- Systemic Lupus Erythematosus (SLE)	- For adult patients (≥ 18 years old) with moderate-severe SLE being treated by a rheumatologist - Patient must be autoantibody positive (within last 3 months) i.e. ANA or dsDNA positive with SELENA-SLEDAI score ≥ 6 who have tried and failed or are intolerant to corticosteroid and hydroxychloroquine - Renewal based on achieving/maintain a SELENA-SLEDAI reduction of 4 points or more

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BETASERON (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive - Clinically Isolated Syndrome	- For patients with RRMS or progressive MS - For patients diagnosed with clinically isolated syndrome and abnormal brain MRI at presentation - EDSS value required - Coordinate with provincial government program
BIPHENTIN CR (Methylphenidate controlled release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting) or Dextroamphetamine
BOSULIF (Bosutinib)	- Chronic myeloid leukemia	- For the treatment of adults with Philadelphia chromosome positive (Ph+) chronic, accelerated, or blast phase chronic myeloid leukemia (CML) who are resistant or tolerant to prior TKI therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate - Coordinate with provincial government program
BRILINTA (Ticagrelor)	- For the secondary prevention of atherothrombotic events in patients with Acute Coronary Syndrome	- For use in combination with ASA, in patients diagnosed with Acute Coronary Syndrome (unstable angina OR ST/non ST elevation Myocardial Infarction) who have tried and failed or are intolerant to optimal clopidogrel + ASA therapy - For patients with STEMI and undergoing revascularization via PCI - Patients with NSTEMI with high risk angiographic features and undergoing revascularization via PCI
BOTOX (Botulinum toxin type A)	- Blepharospasm - Strabismus - Torticollis - Cervical dystonia - Cerebral palsy - Hyperhidrosis - Chronic Migraines - Bladder Dysfunction	- For the treatment of blepharospasm and strabismus in patients 12 years of age or older associated with dystonia - For the treatment of cervical dystonia (spasmodic torticollis) in adults - For the treatment of severe focal spasticity including treatment of upper limb spasticity associated with stroke or spinal cord injury in adults - For the treatment of dynamic equinus foot deformity due to spasticity in pediatric cerebral palsy patients, two years of age or older - For treatment of hyperhidrosis of the axilla (armpit) in patients age of 18 or older who have failed or unable to tolerate aluminum chloride preparations - For prophylaxis of headaches in adults with chronic migraines (≥15 days per month with headache lasting 4 hours a day or longer) who have tried and failed symptomatic (i.e. opioid and non-opioid analgesics, tryptans or ergots) and prophylactic treatment (tricyclic analgesics, antiepileptic drugs or beta blockers) - For the treatment of overactive bladder OR neurogenic bladder associated with multiple sclerosis or subcervical spinal cord injury in adults unresponsive to or are intolerant of at least two of the follow oral anticholinergic medications (Uromax, generic Ditropan, Ditropan XL, Enablex, Vesicare, Detrol, Detrol LA, Toviaz, Trosec) - Coordinate with provincial government program
BYETTA (Exenatide)	- For the treatment of Type II Diabetes	- For use in combination with dual therapy of metformin and a sulfonylurea OR for use in combination with maximum doses of metformin alone (>2000 mg/day) when a sulfonylurea is tried and failed or not tolerated
BYSTOLIC (Nebivolol)	- For the treatment of mild to moderate essential hypertension	- For patients who have tried and failed or had intolerable side effects to at least two generic drugs in the class of beta1-selective blockers (atenolol, bisoprolol, metoprolol)

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CAMBIA (Diclofenac Potassium)	- For acute treatment of migraine attacks	- For patients 18 years of age and older who have tried and failed or experienced intolerable side effects to at least one drug in each of the following classes: prescription NSAIDs and triptans
CAPRELSA (Vandetanib)	- For the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in adult patients with unresectable or locally advanced or metastatic disease	- For patients with unresectable locally advanced or metastatic MTC that have enrolled with the CAPRELSA Restricted Distribution Program - Coordinate with available provincial plans
CAVERJECT (Alprostadil) CIALIS (Tadalafil) LEVITRA (Vardenafil) MUSE (Alprostadil) VIAGRA (Sildenafil) STAXYN (Vardenafil)	- Erectile Dysfunction	Erectile dysfunction related to one of the following conditions: - Adverse side-effect to prescription drugs (e.g., beta blockers, etc.). Medical documentation must be present to validate the drug as causing the problem (up to one year approval) - Diabetes mellitus and is on medication(s) and/or insulin (Lifetime approval) - Aorta-iliac disease with evidence of decreased blood flow (e.g., abnormal Doppler studies or absent pulses) (Lifetime approval) - Post radical prostatectomy and radiation of the prostate (Lifetime approval) - Neurological injury or disease (e.g. Multiple Sclerosis, spinal cord injury) (Lifetime approval) - Endocrine abnormalities (i.e. specifically low testosterone levels not responding to testosterone treatment) (Lifetime approval) - Psychiatric disorder for which the patient is receiving medication or treatment from a psychiatrist (up to one year approval) <u>Annual maximum</u>: $1000 per year
CAYSTON (Aztreonam)	- Treatment of pulmonary infection with *Pseudomonas aeruginosa* in Cystic Fibrosis Patients	- For patients with confirmed Cystic Fibrosis and pulmonary infection with *Pseudomonas aeruginosa*, who have tried and failed or did not tolerate prior therapy with TOBI - Co-ordinate with provincial programs where possible
CELSENTRI (Maraviroc)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
CESAMET (Nabilone)	- For the management of severe nausea and vomiting	- For the management of severe nausea and vomiting associated with cancer chemotherapy in patients that have failed or are contraindicated to conventional antiemetic treatments (metoclopramide, corticosteroids, aprepitant, prochlorperazine, ondansetron)

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CIMZIA (Certolizumab pegol)	- Moderate to Severe Rheumatoid Arthritis - Ankylosing Spondylitis - Psoriatic Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - Coordinate with provincial government program
COMBIVIR (Lamivudine/Zidovudine)	- HIV anti-viral	- Coordinate with provincial government program
COMPLERA and generic COMBINATION (Rilpivirine/emtricitabine/tenofovir disoproxil fumarate)	- HIV anti-viral	- Coordinate with provincial government program
CONCERTA (Methylphenidate controlled release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting) or Dextroamphetamine
CONSTELLA (Linaclotide)	- For treatment of chronic idiopathic constipation and/or irritable bowel syndrome with constipation - Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC)	- For patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
COPAXONE (Glatiramer acetate)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive - Clinically Isolated Syndrome	- For patients with RRMS or progressive MS - For patients diagnosed with Clinically Isolated Syndrome and abnormal brain MRI at presentation - EDSS value required - Coordinate with provincial government program
COSENTYX Secukinumab	- Moderate to severe plaque psoriasis	- For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are treated by a dermatologist - Coordinate with provincial government program
COSOPT (Dorzolamide and timolol preservative-free ophthalmic solution)	- Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	- For patients who are allergic to or cannot tolerate the formulation with the preservative
CRIXIVAN (Indinavir)	- HIV anti-viral	- Coordinate with provincial government program
CYTOVENE (Ganciclovir)	- Cytomegalovirus Retinitis	- For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients - Coordinate with provincial government program

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CUTIVATE (Fluticasone 0.05% cream)	- Atopic dermatitis	- For individuals who have tried and failed to respond to one other corticosteroid other than Hydrocortisone 0.5% or 1%
CYMBALTA (Duloxetine)	- Major Depressive Disorder - Generalized Anxiety Disorder - For treating pain associated with Peripheral Diabetic Neuropathy - For treating pain associated with Fibromyalgia - Chronic Low Back Pain - Osteoarthritis of the Knee	- For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other currently covered SNRIs - Diagnosis of Peripheral Diabetic Neuropathy - For patients with fibromyalgia who have tried and failed (4 week trial minimum) at least one drug from each of the following classes: analgesics/NSAIDs, antidepressants (Amitriptyline, Nortriptyline, Fluoxetine, etc.), and anticonvulsants (gabalin, pregabalin, etc.) - For patients with chronic low back pain who have tried and failed at least one currently covered drug from each of the following classes: analgesics/NSAIDs, muscle relaxants and opiate analgesics - For patients with osteoarthritis of the knee who have tried and failed at least one currently covered drug from each of the following classes: analgesics/NSAIDS and opiate analgesics
DAXAS (roflumilas)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema - Coordinate with provincial coverage if available
DEXILANT (dexlansoparzole)	- Gastroesophageal Reflux Disease (GERD) - Peptic Ulcer Disease (PUD)	- For the treatment of moderate to severe GERD or PUD unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole
DIACOMIT (stiripentol)	- Dravet Syndrome or Severe Myoclonic Epilepsy in Infancy (SMEI)	- For patients 3 years of age or older with refractory SMEI or Dravet Syndrome: ▪ Must be used in conjunction with clobazam and valproate after failure with clobazam and valproate alone - Coordinate with provincial government program
DUAKLIR GENUAIR (Aclidinium bromide and Formoterol Furmarate)	- Chronic Obstructive Pulmonary Disease (COPD)	- - For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on optimal doses of either a LAMA or LABA alone
DUODOPA (Levodopa/carbidopa intestinal gel)	- Parkinson's disease	- For individuals with advanced Parkinson's disease and who have tried and failed other oral therapies for control of severe, disabling motor fluctuations - Individuals are being screened and managed by specialists and at appropriate centers where the individuals have responded to the drug during the test phase - Coordinate with provincial government program
EDARBI (Azilsartan)	- For the treatment of mild to moderate essential hypertension	- For patients who have tried and failed or had intolerable side effects to at least two generic drugs in the class of Angiotensin Receptor Blockers
EDARBYCLOR (Azilsartan/Chlorthalidone)	- For the treatment of mild to moderate essential hypertension	- For patients who have tried and failed or had intolerable side effects to at least two generic drugs in the class of Angiotensin Receptor Blocker-diuretic combinations

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EDURANT (Rilpivirine)	- HIV anti-viral	- Coordinate with provincial government program
EFRACEA (Doxycycline)	- For the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients	- For patients diagnosed with rosacea who have tried and failed one of the following antibiotics (erythromycin, doxycycline, tetracycline and minocycline)
ELIDEL (Pimecrolimus 1% cream)	- Atopic dermatitis	- A confirmed diagnosis of atopic dermatitis (eczema) for individuals who have failed treatments with two or more different topical steroids
ENBREL (Etanercept)	- Moderate to Severe Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients ages 4 to 17 with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist - Coordinate with provincial government program
ENTYVIO vedolizumab	- Moderate to severe ulcerative colitis	- Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND - Who have tried and failed or intolerant effects to Remicade, Humira, or Simponi SC - Coordinate with provincial government program
ERIVEDGE (Vismodegib)	- For the treatment of metastatic or locally advanced basal cell carcinoma	- For patients with histologically confirmed metastatic or locally advanced basal cell carcinoma whose condition is inappropriate for surgery or radiotherapy - Coordinate with available provincial programs

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ESBRIET (Pirfenidone)	- Idiopathic Pulmonary Fibrosis	- For patients with a confirmed diagnosis of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) as confirmed by clinical chest radiology (HRCT) or a lung biopsy and with a Forced Vital Capacity ≥ 50% predicted AND - For patients who are ineligible for lung transplantation and where pulmonary rehabilitation and supportive care (including oxygen therapy) has not adequately controlled symptoms - Coordinate with available provincial programs
EXTAVIA (Interferon beta-1b)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive - Clinically Isolated Syndrome	- For patients with RRMS or progressive MS - For patients diagnosed with clinically isolated syndrome and abnormal brain MRI at presentation - EDSS value required with every application - Coordinate with provincial government program
EYLEA (aflibercept)	- "Wet" age-related macular degeneration - Macular edema secondary to Central Retinal Vein Occlusion (CRVO) - Diabetic Macular Edema (DME)	- For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) - For treatment of visual impairment due to diabetic macular edema - For treatment of visual impairment due to macular edema secondary to central or branch retinal vein occlusion - Coordinate with provincial government program
FAMPYRA (Fampridine)	- For the symptomatic improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 3.5 – 7)	<u>Initial Criteria:</u> - For patients diagnosed with Multiple Sclerosis with walking disability (EDSS 3.5 – 7) - Coordinate with available provincial plans - An initial 6 weeks of Fampyra will be approved <u>Renewal Criteria:</u> - Demonstrates a noted improvement in walking speed from baseline based on one of the following clinical tools (e.g. T25FW, Timed Up and Go, MSWS012, Two Minute Walk)
FASLODEX (Fulvestrant)	- Hormonal treatment of locally advanced or metastatic breast cancer in postmenopausal women	- Second-line treatment for patients who have failed treatment with or have had intractable side-effects to Tamoxifen and/or Aromatase Inhibitors
FENTORA (Fentanyl citrate)	- Management of breakthrough pain in cancer patients	- For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day - Patient should be currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) AND have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR
FIBRISTAL (Ulipristal Acetate)	- For the treatment of moderate to severe signs and symptoms of uterine fibroids	- For women of reproductive age with uterine fibroids and who are eligible for surgery AND - Limit approval to 3 months per lifetime

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FLUDARA (Fludarabine oral tablet)	- Chronic Lymphocytic Leukemia (CLL)	- For patients who have failed first-line treatment and meet the following criteria: - Provincial cancer drug coverage is not available for Fludarabine oral tablet in the province where the applicant resides AND - Applicant has first tried I.V. / infusion Fludarabine and has developed intolerance or adverse effects to this formulation
FORTEO (Teriparatide)	- Osteoporosis - Osteoporosis associated with sustained systemic glucocorticoid therapy	- Severe osteoporosis where patient has a bone scan of less than -3.5 SD AND a history of non-trauma related fractures while on bisphosphonates - Severe osteoporosis where patient has a bone scan of less than -1.5 SD and a minimum of 3 months of sustained systemic glucocorticoid therapy - Maximum lifetime treatment : 24 months
FORXIGA (Dapagliflozin)	- Type 2 Diabetes	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
FOSAMAX (Alendronate oral solution)	- Bone metabolism regulator	- For patients who have esophageal problems or who have tried and failed or have experienced intolerable side-effects to Alendronate or other oral Bisphosphonates
FUZEON (Enfuvirtide)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
FYCOMPA (Perampanel)	- Adjunctive therapy for partial onset seizures	- For patients with a diagnosis of partial onset seizures AND - Tried, failed or have experienced intolerant side effects to at least 2 standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
GALEXOS (Simeprevir)	- Hepatitis C	<u>Initial Authorization Approval</u> - For adults with chronic hepatitis C genotype 1 infection in combination with peginterferon alpha/ribavirin - Quantitative HCV RNA value from within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - No diagnosis of cirrhosis or cirrhosis with a Child Pugh Score = A (5-6) - An initial 6 weeks of Galexos will be approved <u>Subsequent Authorization Approval</u> - The authorization will be renewed if HCV-RNA is ≤ 100 IU/mL at week 4 of Galexos therapy - The maximum duration of treatment will be 12 weeks of Galexos - Coordinate with provincial government program

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GELNIQUE (Oxybutynin chloride gel)	- For the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency	- For patients who have tried and failed or had intolerable side effects to two of the following oral anticholinergics (Uromax, generic Ditropan, Ditropan XL, Enablex, Vesicare, Detrol, Detrol LA, Trosec)
GILENYA (Fingolimod)	- Multiple sclerosis, relapsing remitting	- Diagnosis of relapsing remitting multiple sclerosis - EDSS value required - Failure or intolerance to one or more therapies for multiple sclerosis treatments i.e. Avonex, Betaseron, Copaxone, Extavia, Rebif, Tysabri - Coordinate with provincial government program
GIOTRIF (afatinib)	- Lung adenocarcinoma	- For patients with a confirmed diagnosis of metastatic lung adenocarcinoma (i.e. specific type of non-small cell lung cancer): ▪ With activating EGFR mutation(s) ▪ Who have NOT previously tried and failed EGFR tyrosine kinase inhibitors (e.g. Iressa or Tarceva) - Coordinate with provincial government program
GLEEVEC and generic IMATINIB (Imatinib)	- Chronic myeloid leukemia - Gastrointestinal Stromal Tumour (GIST)	- For the treatment of newly diagnosed, Philadelphia-chromosome positive, CML in chronic phase OR - For the treatment adult patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase or chronic phase after failure of interferon-alpha therapy - For the treatment of C-Kit positive (CD 117) inoperable recurrent and/or metastatic GIST - Coordinate with provincial government program - program
GLUMETZA (Metformin extended release)	- Diabetes	- For patients who have tried and failed or had intolerable side effects to regular release Metformin
GRASTEK (Standardized allergenic extract, Timothy Grass)	- Treatment of moderate to severe seasonal grass pollen allergic rhinitis	- For the treatment of allergic rhinitis in patients 5 years of age and older, who are ▪ Skin test positive to grass pollen ▪ Symptomatic for at least 2 pollen seasons ▪ Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
HARVONI (Ledipasvir /Sofosbuvir)	- Hepatitis C virus (CHC) genotype 1 infection in adults	- For adults with chronic hepatitis C genotype 1 infection: ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score - Coordinate with available provincial plans
HEPSERA and generic ADEFOVIR (Adefovir)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) - For hepatitis B patients co-infected with HIV who do not require HAART therapy for HIV
HEPTOVIR (Lamivudine)	- Chronic hepatitis B	- For treatment of chronic hepatitis B - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
HOLKIRA PAK (Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir)	- Hepatitis C	- For adults with chronic hepatitis C genotype 1 infection - Fibrosis stage F2 or greater (Metavir scale or equivalent) - No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score - Coordinate with available provincial plans <u>Patients requesting 24 week treatment:</u> - For adults with chronic hepatitis C genotype 1 infection - Fibrosis stage F2 or greater (Metavir scale or equivalent) - Diagnosis of cirrhosis with a Child Pugh Score - Patients who are null responders to standard Peg-Interferon + RBV based therapy
HUMATROPE (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD") - Idiopathic Short Stature ("ISS")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For the treatment of patients with Turner's syndrome under 14 years of age - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - For treatment of ISS which is defined as: (i) normal birth weight; (ii) diagnostic evaluation that excludes other known causes of short stature; (iii) height at least 2.25 standard deviation scores below the mean for age and sex; (iv) height velocity below the 25th percentile for bone age; and (v) patients whose epiphyses are not closed - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
HUMIRA (Adalimumab)	- ADULT - Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy - - PEDIATRIC - Crohn's Disease - Juvenile Idiopathic Arthritis	ADULT - For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist PEDIATRIC - For patients 13 to 17 years of age weighing more than or equal to 40kg with severely active Crohn's who have had inadequate response or intolerable effects to corticosteroids AND an immunosuppressant or aminosalicylate - For therapy in combination with METHOTREXATE, unless intolerable or inappropriate, in patients 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who has tried and failed Enbrel - Coordinate with provincial government program
IBAVYR (Ribavirin)	- Hepatitis C	- For the treatment of CHC in combination with other antiviral agents - If used in combination with Sovaldi with Hepatitis C Genotype 2 or 3, must first try and fail standard Peg-Interferon+ RBV therapy. Ibavyr may also be considered for members contraindicated to Peg-Interferon

DRUG	DISEASE	APPROVAL GUIDELINES
ICLUSIG (ponatinib hydrochloride)	- Chronic phase (CP), accelerated phase (AP), or blast phase (BP) chronic myeloid leukemia (CML) - Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)	**Chronic Myeloid Leukemia:** Initial Request (3 month approval): - For patients who are resistant or intolerant to imatinib AND 2 of the follow nilotinib,dasatinib, or bosutinib, and for whom subsequent treatment with imatinib, nilotinib, dasatinib AND bosutinib is not clinically appropriate - Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase - ECOG≤1 - Proof of enrollment in the Support Program - Coordinate with provincial government program Renewal (3 month approval): - Demonstration of hematological response (i.e. Normalization of WBC) showing absence of disease progression (provide lab values) - Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase - ECOG≤1 - Proof of continued enrollment in the patient support program - Coordinate with provincial drug programs **Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)** Initial Request (3 month approval): - For patients who are resistant or intolerant to imatinib AND dasatinib, and for whom subsequent treatment with imatinib and dasatinib is not clinically appropriate - Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase - ECOG≤1 - Proof of enrollment in the Support Program - Coordinate with provincial government program Renewal (3 month approval): - Demonstration of hematological response (i.e. Normalization of WBC) showing absence of disease progression (provide lab values) - Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase - ECOG≤1 - Proof of continued enrollment in the patient support program - Coordinate with provincial drug programs
IMBRUVICA (Ibrutinib)	- Chronic lymphocytic leukemia (CLL), including 17p deletion	Initial Criteria – 6 months ONLY - For the treatment of CLL in symptomatic patients with evidence of progression: - Who failed or are experiencing recurrent disease despite prior therapy (e.g. Fludarabine, Ofatumumab, Chlorambucil, etc.) OR - For patients with CLL 17p deletion in whom stem cell transplant surgery is inappropriate *** Progression is defined as the presence of ≥ 5x109 B lymphocytes/L in the peripheral blood (i.e. lymphocytosis) for at least 3 months as confirmed by flow cytometry with symptoms. Renewal Criteria: - Documentation of clinical benefits by flow cytometry

DRUG	DISEASE	APPROVAL GUIDELINES
INCIVEK (Telaprevir)	- Hepatitis C	Initial Criteria: - For adults with chronic hepatitis C genotype 1 infection with compensated liver, including cirrhosis, in combination with peginterferon alpha/ribavirin - An initial 6 weeks of Incivek will be approved Renewal Criteria: - The authorization will be renewed if the HCV-RNA is < 1000 IU/ml at week 4 of Incivek therapy - The maximum duration of treatment will be 12 weeks of Incivek therapy - Coordinate with available provincial plans
INCRUSE ELLIPTA	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema
INFERGEN (Interferon alfacon-1)	- Hepatitis C	- For patients who have failed to respond to or relapsed after prior administration of Interferon alpha
INFLECTRA (Infliximab)	- Rheumatoid Arthritis - Ankylosing Spondylitis - Psoriatic Arthritis - Plaque Psoriasis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist - Coordinate with available provincial plans
INLYTA (Axitinib)	- Metastatic Renal Cell Carcinoma	- For patients who have failed prior systemic therapy with either a cytokine or a tyrosine kinase inhibitor
INSPIOLTO RESPIMAT (Tiotropium Bromide and Olodaterol Hydrochloride)	- Chronic Obstructive Pulmonary Disease (COPD)	- For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on optimal doses of either a LAMA or LABA alone
INTELENCE (Etravirine)	- HIV infection	- For combination antiretroviral therapy in patients who have evidence of resistance to at least one antiretroviral therapy from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse - Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
INTUNIV XR (Guanfacine Hydrochloride)	- Attention deficit hyperactivity disorder	- For individuals who have tried and failed or had intolerable side-effects to Methylphenidate, generic Concerta, or Dextroamphetamine OR - For individuals using concomitantly with psychostimulants
INVEGA SUSTENNA (Paliperidone injection)	- For the management of the manifestations of schizophrenia and related psychotic disorders	- For patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations
INVIRASE (Saquinavir)	- HIV anti-viral	- Coordinate with provincial government program
INVOKANA (Canagliflozin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
IRESSA (Gefitinib)	- First-line treatment of locally advanced (not amenable to curative surgery) or metastatic Non-Small Cell Lung Cancer (“NSCLC”)	- For patients with confirmed activating mutations of the EGFR-TK (“mutation-positive”) - Coordinate with provincial government program
ISENTRESS (Raltegravir)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
JAKAVI (Ruxolitinib)	- Splenomegaly	- For the treatment of splenomegaly and/or its associated symptoms (weight loss, fever, night sweats, fatigue, bone pain, pruritus, peripheral edema) in adult patients diagnosed with: 1. Primary myelofibrosis (also known as chronic idiopathic myelofibrosis) 2. Post-polycythemia vera myelofibrosis 3. Post-essential thrombocythemia myelofibrosis - AND where allogenic stem cell transplantation is deemed inappropriate - Coordinate with provincial government program
JALYN (Dutasteride and Tamsulosin)	- Benign Prostatic Hyperplasia	- For male patients in the treatment of benign prostatic hyperplasia
JANUVIA (Sitagliptin) JANUMET JANUMET XR (Sitagliptin/metformin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
JARDIANCE (Empagliflozin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)

DRUG	DISEASE	APPROVAL GUIDELINES
JETREA (Ocriplasmin)	- Symptomatic vitreomacular adhesion (VMA)	- Confirmed diagnosis of symptomatic vitreomacular adhesion (VMA) - Coordinate with provincial government program - Lifetime maximum: 1 injection per affected eye
JINARC (Tolvaptan)	- Autosomal Dominant Polycystic Kidney Disease (ADPKD)	<u>Special Authorization Criteria:</u> - Confirmed diagnoses of rapidly progressive ADPKD and must have: a) CKD Stage 2-3 AND b) Total kidney volume ≥ 750ml AND c) CrCl ≥ 60ml/min AND - Proof of enrolment in the support programs - Coordinate with provincial drug program <u>Renewal Criteria:</u> - Proof of continued enrollment in the patient support program - Laboratory results demonstrating normal liver (ALT and AST) function - Coordinate with provincial drug programs - Proof of beneficial effect demonstrated by: a) Urine osmolality of less than 300 mOsm/kg
KALETRA (Lopinavir/Ritonavir)	- HIV anti-viral	- Coordinate with provincial government program
KAZANO (Alogliptin/Metformin)	- Type 2 Diabetes	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg/day)
KINERET (Anakinra)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months, AND who have tried and failed Cimzia or Enbrel or Humira or Simponi or Actemra SC or Remicade or Orencia SC - Coordinate with provincial government program
KIVEXA (Abacavir/Lamivudine)	- HIV anti-viral	- Coordinate with provincial government program
KUVAN (Sapropterin)	- Phenylketonuria (PKU)	- Diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU) for patients 18 years of age or under - Initial requests must indicated Phe levels prior to starting therapy - Patients must demonstrate responsiveness to 30-day trial and maintain Phe-restrictive diet during treatment - Coordinate with provincial government program - <u>Renewal:</u> Evidence of decrease blood phenylalanine concentration
LANTUS LANTUS SoloSTAR (Insulin glargine)	- Diabetes mellitus	- For patients who have tried and failed on existing longer acting insulins AND/OR patients currently using or are candidates for insulin infusion pump therapy

DRUG	DISEASE	APPROVAL GUIDELINES
LEMTRADA (Alemtuzumab)	- Multiple sclerosis, relapsing remitting	- Diagnosis of relapsing remitting multiple sclerosis - EDSS value required - Failure or intolerance to one or more therapies for multiple sclerosis i.e. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tysabri, Tecfidera - Coordinate with provincial government program
LEVEMIR LEVEMIR FLEXPEN LEVEMIR FLEXTOUCH (Insulin detemir)	- Diabetes mellitus	- For patients who have tried and failed on existing longer acting insulins AND/OR patients currently using or are candidates for insulin infusion pump therapy
LIPIDIL EZ (Fenofibrate nanocrystal formulation)	- Hypercholesterolemia	- For patients who have failed to respond or have had intolerable side-effects to microcoated and/or micronized Fenofibrate
LODALIS and LODALIS SACHET (Colesevelam)	- Hypercholesterolemia	- For patients who cannot tolerate HMG-Co-A-Reductase Inhibitors or where these drugs are contraindicated AND who have failed to respond or have had intolerable side effects to resins (Colestid, Questran or Olestyr) - As adjunctive therapy with HMG-Co-A-Reductase Inhibitors where such drugs have not provided sufficient lipid control AND who failed to respond or have had intolerable side-effects to resins (Colestid, Questran or Olestyr)
LUCENTIS (Ranibizumab)	- End-stage or “wet” age-related macular degeneration (“AMD”) - Treatment of macular edema following Central or Branch Retinal Vein Occlusion - Diabetic macular edema - Pathological Myopia	- For treatment of choroidal neovascularization associated with wet AMD - For treatment of visual impairment due to diabetic macular edema - For treatment of visual impairment due to macular edema secondary to central or branch retinal vein occlusion - For treatment of myopic choroidal neovascularization secondary to pathological myopia - Must be administered by an ophthalmologist - Coordinate with provincial government program
MARINOL (dronabinol)	- For the treatment of anorexia - For the management of severe nausea and vomiting	- For the treatment of anorexia associated with weight loss in patients with AIDS - For the management of severe nausea and vomiting associated with cancer chemotherapy in patients that have failed or are contraindicated to conventional antiemetic treatments (metoclopramide, corticosteroids, aprepitant, prochlorperazine, ondansetron)
MACUGEN (Pegaptanib)	- End-stage or “wet” age-related macular degeneration (“AMD”)	- For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate. - Validate site of administration - Coordinate with provincial government program
MEKINIST (Trametinib)	- For the treatment of BRAF V600 mutation-positive unresectable (Stage IIIC or IV) or metastatic melanoma	- Confirmed BRAF V600 mutation positive disease – unresectable or metastatic melanoma - ECOG ≤ 1 - Coordinate with available provincial plans

DRUG	DISEASE	APPROVAL GUIDELINES
METOJECT (Methotrexate)	- Treatment or maintenance of neoplastic diseases - Severe, disabling psoriasis, rheumatoid arthritis, psoriatic arthritis or other seronegative arthritides where standard therapeutic interventions have failed	- For patients who have a physical disability which prevents them from drawing-up a syringe
METVIX-PDT (Methyl Aminolevulinate)	- Primary superficial basal cell carcinoma (BCC) outside the H-zone of the face - Actinic keratosis	- For the treatment of BCC - Rationale for use is identified i.e. for individuals with multiple lesions, large lesions, bleeding disorders, poor vascularization, delayed healing, body not amenable to surgery, unsuitable for invasive therapy, concerns regarding disfigurement or inadequate response to previous therapies, etc; and - Maximum annual reimbursement of $1800 per patient per year
MOVANTIK (Naloxegol Oxalate)	- Opioid-induced constipation	- For treatment of opioid-induced constipation (OIC) in adults (>18 years old) with non-cancer pain adult, who have tried and failed 1. Dietary and lifestyle measures (i.e. high fiber diet, increased water intake, physical exercise) AND 2. One medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil)
MOZOBIL (Plerixafor)	- Stem cell mobilization for autologous transplantation for patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM)	- In combination with G-CSF for NHL and MM patients that are eligible for autologous stem cell transplantation WHERE patients are predicted to mobilize poorly for the following reasons: 1. A peak CD34+ circulating cell count of < 15 cells/μL, AND 2. A history of prior failed mobilization (i.e. Neupogen alone or chemo-mobilization)
MYRBETRIQ (Mirabegron)	- For the treatment of overactive bladder (OAB) with urgency, urgency incontinence and urinary frequency	- For patients who have tried and failed or had intolerable side effects to two of the following oral anticholinergics (Uromax, generic Ditropan, Ditropan XL, Enablex, Vesicare, Detrol, Detrol LA, Trosec)
NESINA (Alogliptin**)**	- Type 2 Diabetes	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
NEULASTA (Pegfilgrastim)	- Neutropenia associated with chemotherapy, transplant	- For patients who require GCSF (Neupogen 300mcg) treatment for more than or equal to 12 consecutive days OR who require GCSF (Neupogen 480mcg) treatment for more than or equal to 8 consecutive days OR have tried and failed and/or had intolerable adverse effects to Neupogen - Co-ordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
NEUPRO (Rotigotine)	- For the treatment of signs and symptoms of idiopathic Parkinson's disease – adjunct or monotherapy	- For patients who have tried and failed or had intolerable side effects to at least one oral dopamine agonist (i.e. generic Mirapex, generic Parlodel, generic Requip)
NEXAVAR (Sorafenib)	- Metastatic renal cell (clear cell) carcinoma - Advanced hepatocellular carcinoma - Thyroid Carcinoma	- For patients who are refractory or resistant to treatment with cytokines - For patients with advanced hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG between 0 and 2. - Locally advanced or metastatic, progressive differentiated thyroid carcinoma secondary to radioactive iodine - Coordinate with provincial government program
NORDITROPIN NORDIFLEX (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD")	**Treatment for children with growth failure:** - For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency. Other causes of short stature should be excluded. - The treatment of growth disturbance (current height Standard Deviation Score (SDS) < -2) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 standard deviations (SD), who failed to show catch-up growth (Height Velocity SDS < 0 during the last year) by 2 years of age or later - Patients who have tried and failed therapy with Omnitrope or where it is deemed unsuitable for the patient's condition - Coordinate with provincial government program **Patients born small for gestational age** - For treatment of ISS which is defined as: (i) normal birth weight; (ii) diagnostic evaluation that excludes other known causes of short stature; (iii) height at least 2.25 standard deviation scores below the mean for age and sex; (iv) height velocity below the 25th percentile for bone age; and (v) patients whose epiphyses are not closed - Coordinate with provincial government program
NORVIR (Ritonavir)	- HIV anti-viral	- Coordinate with provincial government program
NUCYNTA IR (Tapentadol)	- For the management of moderate to severe acute pain	- Pain management in a specified acute pain diagnosis - For patient who are unable to tolerate or receive an adequate response to the immediate release preparations of either hydromorphone, oxycodone or morphine
NUCYNTA CR / ER (Tapentadol)	- For the management of moderate to moderately severe pain	- Pain management in a specified chronic pain diagnosis - For patient who are unable to tolerate or receive an adequate response to the sustained release preparations of either hydromorphone, oxycodone or morphine

DRUG	DISEASE	APPROVAL GUIDELINES
NUTROPIN SAIZEN (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For the treatment of patients with Turner's syndrome under 14 years of age - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - Coordinate with provincial government program
NUVARING (etonogestrel/ethinyl estradiol)	- Conception Control	- For patients who do not tolerate oral contraceptives
OFEV (Nintedanib)	- Idiopathic Pulmonary Fibrosis (IPF)	- For patient with a confirmed diagnosis of idiopathic pulmonary fibrosis (IPF) as confirmed by clinical chest radiology (HRCT) or a lung biopsy who are ineligible for lung transplantation AND where pulmonary rehabilitation and supportive care (including oxygen therapy) has not adequately controlled symptoms - Coordinate with provincial government program
OMNITROPE (Somatropin)	- Growth Hormone Deficiency ("GHD") in children - Adult Growth Hormone Deficiency ("Adult GHD")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - Coordinate with provincial government program
ONGLYZA (Saxagliptin) KOMBOGLYZE (Saxagliptin/Metformin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
ONBREZ BREEZHALER (Indacaterol)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema
ONRELTEA (Brimonidine 0.33% topical gel)	- Facial erythema (redness) of rosacea	- For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroCream, MetroGel, MetroLotion, Finacea) AND one oral therapy (i.e. generic doxycycline, tetracycline, minocycline)

DRUG	DISEASE	APPROVAL GUIDELINES
ONSOLIS (Fentanyl citrate)	- Management of breakthrough pain in cancer patients	- For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day - Patient should be currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) AND have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR
OPSUMIT (macitentan)	- Pulmonary Hypertension	- For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND who have tried and failed: ▪ Conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) AND ▪ Revatio or Adcirca - Coordinate with provincial government program **May be used in conjunction with phosphodiesterase-5 inhibitors (i.e. Revatio or Adcirca)
ORALAIR (Grass Pollen Allergen Extract)	- Treatment of moderate to severe seasonal grass pollen allergic rhinitis	- For the treatment of allergic rhinitis in patients 5 to 50 years old, who are skin test positive to grass pollen and who are not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
ORENCIA IV (Abatacept)	- Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months, AND who have tried and failed Cimzia or Enbrel or Humira or Simponi or Actemra SC or Remicade or Orencia SC - For patients ages 6 and older with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who have tried and failed Enbrel - Coordinate with provincial government program
ORENCIA SC (Abatacept)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
OTEZLA (Apremilast)	- Moderate to severe plaque psoriasis	- For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are treated by a dermatologist - Coordinate with provincial government program
OXYTROL (Oxybutynin transdermal system)	- Urinary incontinence	- For individuals who have tried and failed oral anticholingerics (ex. Oxybutynin)
OZURDEX (Dexamethasone)	- Treatment of macular edema following Central Retinal Vein Occlusion - Diabetic Macular Edema (DME) who are pseudophakic	<u>Initial Authorization Approval:</u> - Patient must meet the following criteria to receive 1 implant per affected eye(s) for six months: - For treatment of macular edema following Central Retinal Vein Occlusion - Validate site of administration <u>Subsequent Authorization Approval:</u> - Patient must have received a beneficial effect from the initial injection with a subsequent loss in visual acuity to receive an additional 1 impant per affected eye(s) for six months - Renewal will not be granted in the following circumstances: ▪ Patient experienced vision deterioration without any beneficial effect from initial injection ▪ Patient continues to benefit from initial injection and has not experienced a subsequent loss in visual acuity - <u>Maximum lifetime approval:</u> 6 injections in 3 years per affected eye(s) - Coordinate with provincial government plan <u>DME who are pseudophakic</u> <u>Initial Criteria:</u> - For the treatment of Diabetic Macular Edema who are pseudophakic - Validate site of administration - Coordinate with available provincial program **An approval of 2 implants/affected eye for 1 year** <u>Renewal Criteria</u> - Must demonstrate presence of macular edema after initial positive response with Ozurdex
PAXIL CR (Paroxetine controlled release)	- Depression	- Patient must have tried and failed and/or had adverse side-effects to regular release SSRIs or extended release SNRIs or atypical antidepressants
PEGASYS, PEGASYS RBV PEGETRON PEGETRON REDIPEN (Peginterferon alfa-2b and ribavirin)	- Hepatitis C - Hepatitis B	- For all Hepatitis C patients, an initial 16 weeks will be approved. For genotypes 2 and 3, an additional 8 weeks and for all other genotypes, an additional 32 weeks will be approved if they are responsive to the initial therapy as measured by Early Viral Response (EVR) protocol - For chronic Hepatitis B patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease). An initial 16 weeks will be approved; an additional 32 weeks will be approved if there is response to the initial therapy as measured by HbeAg seroconversion or EVR protocol

DRUG	DISEASE	APPROVAL GUIDELINES
PENNSAID and generic DICLOFENAC (Diclofenac 15% topical solution)	- Osteoarthritis	- A confirmed diagnosis of osteoarthritis, where the patient failed to respond OR had intolerable side-effects to Meloxicam AND at least one Non-Steroidal Anti-Inflammatory Drug (NSAID) - A confirmed diagnosis of osteoarthritis, where the patient also has documented history of clinically significant ulcer OR GI bleed AND/OR intractable intolerance to oral Non-Steroidal Anti-inflammatory Drugs (NSAIDs) AND Meloxicam
PERIOSTAT (Doxycycline low dose)	- Periodontitis	- For patients who have tried and failed or cannot tolerate Chlorhexidine gluconate mouth rinse and/or a combination of Amoxicillin and Metronidazole therapy
PLEGRIDY (Peginterferon beta-1a)	- Multiple sclerosis, relapsing remitting	- Diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS) - EDSS value - Trial and failusre or intolerance to Copaxone and/or Extavia - Coordinate with provincial government program
POMALYST (Pomalidomide)	- Multiple Myeloma	- For the treatment of refractory or recurrent multiple myeloma, in combination with dexamethasone, in patients who have tried and failed at least two therapies including lenalidomide (Revlimid) AND bortezomib (Velcade) AND whose ECOG is 3 or less - Coordinate with provincial government program
POSANOL DELAYED RELEASE TABLET (Posaconazole)	- Invasive Aspergillosis / Candida	- For the prophylaxis of aspergillosis and/or candidiasis in high risk patients with prolonged neutropenia or hematopoietic stem cell transplant patients who have failed or cannot tolerate fluconazole OR - For patients with invasive aspergillosis who have failed or cannot tolerate amphotericin B or itraconazole
POSANOL SUSPENSION (Posaconazole)	- Invasive Aspergillosis / Candida - Oropharyngeal Candidiasis (OPC)	- For the prophylaxis of aspergillosis and/or candidiasis in high risk patients with prolonged neutropenia or hematopoietic stem cell transplant patients who have failed or cannot tolerate fluconazole OR - For patients with invasive aspergillosis who have failed or cannot tolerate amphotericin B or itraconazole - For the treatment of Oropharyngeal Candidiasis in patients who have failed treatment with two other antifungals (systemic or oral or combination)

DRUG	DISEASE	APPROVAL GUIDELINES
PREVACID FASTAB (Lansoprazole)	- Gastroesophageal Reflux Disease - Duodenal and Gastric Ulcers - Zollinger-Ellison Syndrome	- For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole - For the treatment of H. Pylori positive (verified by serology or endoscopy or breath-test) Peptic ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole - For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole
PREZCOBIX (Darunavir/Cobicistat)	- Combination with other antiretroviral agents for the treatment of HIV infection in treatment-naïve and in treatment-experienced patients without DRV RAMS	- For the treatment of treatment-naïve HIV patients OR - For the treatment of treatment-experienced HIV patients who have NOT tried and failed Prezista (i.e. without Darunavir Resistance-Associated Mutations) - Coordinate with provincial government program
PREZISTA (Darunavir)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program ** Prezista 400mg and 800mg also indicated for treatment-naïve patients (once-daily dosing)
PRISTIQ (Desvenlafaxine)	- Major Depressive Disorder	- For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other SNRIs
PROLIA (Denosumab)	- Postmenopausal osteoporosis	- For patients who have failed treatment with oral bisphosphonates (alendronate, etidronate, risedronate) or have had intractable intolerance or adverse effects to Bisphosphonate therapy
RAGWITEK (Standardized allergen extract, Short Ragweed)	- Treatment of moderate to severe seasonal short ragweed allergic rhinitis	- For the treatment of allergic rhinitis in patients 18 years of age and older, who are ▪ Skin test positive to short ragweed pollen ▪ Symptomatic for at least 2 pollen seasons ▪ Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
RAPAFLO (Silodosin)	- For the treatment of the signs and symptoms of benign prostatic hyperplasia	- For patients who have tried and failed or are intolerant to at least two of the following medications: Flomax CR, Hytrin, Cardura, Xatral

DRUG	DISEASE	APPROVAL GUIDELINES
REBIF REBIF MULTIDOSE CARTRIDGE (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
RELISTOR (methylnaltrexone bromide)	- Opiod-Induced Constipation (OIC)	- For patients with Opiod-Induced Constipation (OIC) receiving palliative care, who have tried and failed traditional laxatives and/or enemas
REMICADE (Infliximab)	- Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist - Coordinate with provincial government program
RESCRIPTOR (Delavirdine)	- HIV anti-viral	- Coordinate with provincial government program
RESOTRAN (prucalopride)	- For treatment of chronic idiopathic constipation in adult female patients	- For adult female patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
RESTASIS (Cyclosporine 0.05%)	- For treatment of moderate to moderately severe dry eyes	- For patients characterized with moderate to moderately severe ocular staining, reduction in tear production and fluctuating visual symptoms, such as blurred vision AND who have tried and failed artificial tears

DRUG	DISEASE	APPROVAL GUIDELINES
RETISERT (Fluocinolone acetonide)	- For treatment of chronic Non-Infectious Posterior Uveitis	- For the treatment of chronic Non-Infectious Posterior Uveitis in patients who have tried and failed oral prednisone or an equivalent corticosteroid alone and/or an immunosuppressive agent (cyclosporine, azathioprine, methotrexate etc.)
RETROVIR (Zidovudine)	- HIV anti-viral	- Coordinate with provincial government program
REVATIO and generic SILDENAFIL (Sildenafil low dose)	- Pulmonary Hypertension	- For patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
REVOLADE (Eltrombopag Olamine)	- Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	- For patients who are splenectomized and have tried and failed corticosteroids and immunoglobulins - For patients who are non-splenectomized (where surgery is contraindicated) and have tried and failed corticosteroids and immunoglobulins - Platelet counts less than 30 x 10^9/L - Maximum approval is 1 year of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 10^9/L
REYATAZ (Atazanavir)	- HIV anti-viral	- Coordinate with provincial government program
RISPERIDAL CONSTA (Risperidone injection)	- For the management of the manifestations of schizophrenia and related psychotic disorders	- Reserved for patients who are non-compliant or non-adherent with conventional oral therapy, resulting in multiple relapses/hospitalizations
RITUXAN (Rituximab)	- Rheumatoid Arthritis	- For patients who have tried and failed or could not tolerate at least one or more anti-TNF treatment i.e. Cimzia or Enbrel or Humira or Simponi or Actemra SC or Remicade or Orencia SC - Coordinate with provincial government program
ROSIVER (Ivermectin)	- Rosacea	- For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroCream, MetroGel, MetroLotion, Finacea) AND one oral therapy (i.e. generic doxycycline, tetrocycline, minocycline)
SATIVEX (Tetrahydro-cannabinol and cannabidiol buccal spray)	- For symptomatic relief of neuropathic pain in adults with multiple sclerosis	- Adult MS patients with neuropathic pain who have tried other medications such analgesics, opioids, antidepressants or anti-convulsants, with little or no effect

DRUG	DISEASE	APPROVAL GUIDELINES
SAXENDA (Liraglutide)	- Obesity	Initial Authorization Approval: - Patient must meet each of the following criteria to receive coverage for Saxenda for up to six months: - Patient has been prescribed lifestyle therapy (diet and exercise) for six months or more prior to using Saxenda - Patient must try and fail therapy with Saxenda for at least 6 months prior to Saxenda - Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Saxenda - Patient with a Body Mass Index (BMI) greater than or equal to 30 OR - Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ▪ Hypertension and is on medication ▪ Diabetes mellitus and is on medication ▪ Hyperlipidemia and is on medication ▪ Coronary artery disease and is on medication Subsequent Authorization Approval: - Patient must meet each of the following criteria to receive additional coverage for Saxenda for up to six months: - Patient must achieve and continuously maintain a minimum reduction of 6% of initial body weight. Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Saxenda - Patient with a Body Mass Index (BMI) greater than or equal to 30 OR - Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ▪ Hypertension and is on medication ▪ Diabetes mellitus and is on medication ▪ Hyperlipidemia and is on medication ▪ Coronary artery disease and is on medication Maximum Lifetime Coverage: $1500/individual
SEBIVO (Telbivudine)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) - Coordinate with provincial government program
SENSIPAR (Cinacalcet)	- Hyperparathyroidism secondary to Chronic Kidney Disease (“CKD”)	- For patients with hyperparathyroidism secondary to CKD with parathyroid hormone levels greater than 33pmol/L or 300pg/mL
SILENOR (Doxepin)	- Insomnia	- For patients who have failed to respond or have had intolerable side effects to: - at least two identified benzodiazepines (temazepam, oxazepam, lorazepam, and triazolam), AND - one other specified hypnotic agent (i.e. Tryptan or Imovane)

DRUG	DISEASE	APPROVAL GUIDELINES
SIGNIFOR/ SIGNIFOR LAR (Pasireotide)	- Cushing's Disease	Initial Criteria - For the treatment of Cushing's Disease in adult patients: ▪ Who have tried and failed or are experiencing recurrent disease despite prior surgical intervention OR ▪ Whose condition or who have comorbidities that render surgery inappropriate - Baseline urinary free cortisol levels - 6 months approval Renewal Criteria - Documentation of clinical benefits with Signifor ▪ Normalization of urinary free cortisol OR ▪ More than 50% decrease in urinary free cortisol Coordinate with provincial government program
SIMPONI IV (Golimumab)	- Moderate to Severe Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program
SIMPONI SC (Golimumab)	- Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Moderate to severe active Ulcerative Colitis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy AND 5-ASA products AND/OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - Coordinate with provincial government program
SOMAVERT (Pegvisomant)	- Treatment of Acromegaly	- For patients who have tried and failed surgery and/or radiation therapy and other medical therapies OR are ineligible for surgery and/or radiation therapy and other medical therapies

DRUG	DISEASE	APPROVAL GUIDELINES
SOVALDI (sofosbuvir)	- Hepatitis C	- For adults with chronic hepatitis C with: ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6) - For genotype 1, must use in combination with peg-interferon/ribavirin - For genotype 2 & 3, must use in combination with ribavirin only after failure to standard peg-interferon/ribavirin therapy - For genotype 4, must use in combination with peg-interferon/ribavirin after failure to standard peg-interferon/ribavirin therapy - Coordinate with provincial government program
SPIRIVA / SPIRIVA RESPIMAT (Tiotropium Bromide)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema
SPIRIVA RESPIMAT	- Asthma	- For patients who have tried and failed therapy with a combination of inhaled corticosteroid (equivalent to, but not limited to ≥500 mcg fluticasone/day or ≥800 mcg budesonide/day) and a long acting β2 agonist and who experienced one or more severe exacerbations in the previous year.
SPRYCEL (Dasatinib)	- Chronic myeloid leukemia	- For the treatment of Chronic Myeloid Leukemia (CML) for patients who have tried and failed Gleevec - Coordinate with provincial government program
STELARA (Ustekinumab)	- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy - Psoriatic Arthritis	- For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months - Coordinate with provincial government program
STIVARGA (Regorafenib)	- Metastatic Colorectal Cancer - Metastatic and/or unresectable gastrointestinal stromal tumors (GIST)	- For patients with a diagnosis of metastatic colorectal cancer (CRC) AND ▪ Treated previously with all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin, irinotecan, an anti-VEGF therapy (bevacizumab), AND ▪ If KRAS wild type, an anti-EGFR therapy (cetuximab, panitumumab) - For metastatic and/or unresectable GIST patients who have tried and failed or is intolerable to imatinib and sunitinib therapy - ECOG ≤ 1 - Coordinate with provincial government program
STRATTERA and generic ATOMOXETINE (Atomoxetine)	- Attention deficit hyperactivity disorder	- individuals who have tried and failed or had intolerable side-effects to Methylphenidate, generic Concerta, or Dextroamphetamine OR - those individuals who have had history or a propensity to abuse other stimulants such as Methylphenidate, generic Concerta or Dextroamphetamine

DRUG	DISEASE	APPROVAL GUIDELINES
SUBLINOX and generic ZOLPIDEM (Zolpidem)	- Insomnia	- For patients who have failed to respond or have had intolerable side effects to: 1. at least two identified benzodiazepines (temazepam, oxazepam, lorazepam, and triazolam), AND 2. one other specified hypnotic agent (i.e. Tryptan or Imovane)
SUSTIVA and generic EFAVIRENZ (Efavirenz)	- HIV anti-viral	- Coordinate with provincial government program
SUTENT (Sunitinib)	- Gastrointestinal Stromal Tumour (GIST) - First-line treatment of metastatic Renal Cell Carcinoma ("RCC")	- For GIST patients who have tried and failed or had no response to Gleevec (imatinib) - Diagnosis of metastatic RCC. ECOG of two or less must be documented - Coordinate with provincial government program
TAFINLAR (Dabrafenib mesylate)	- For the treatment of BRAF V600 mutation-positive unresectable (Stage IIIC or IV) or metastatic melanoma	- Confirmed BRAF V600 mutation positive disease – unresectable or metastatic melanoma - ECOG ≤ 1 - Coordinate with available provincial plans
TARCEVA and generic ERLOTINIB (Erlotinib)	- Second or Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC") - Maintenance treatment of locally advanced or metastatic NSCLC	- For patients who have tried and failed first-line and second-line chemotherapy or are ineligible for second-line therapy. Treatment with cisplatin or carboplatin must be documented. ECOG performance status must be three or less - Maintenance treatment in patients with stable disease after 4 cycles of standard platinum based first line chemotherapy. ECOG performance status must be one or less - Coordinate with provincial government program
TASIGNA (Nilotinib)	- For treatment of newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase - Second-line treatment of accelerated phase of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML)	- For adult patients with accelerated phase Ph+CML resistant to OR intolerant of at least one prior therapy including imatinib - Coordinate with provincial government program
TECFIDERA (Dimethyl Fumarate)	- Multiple sclerosis, relapsing remitting	- Coordinate with provincial government program - EDSS value required
TELZIR (Fosamprenavir)	- HIV anti-viral	- Coordinate with provincial government program
THALOMID (Thalomide)	- Multiple myeloma	- For patients ≥ 65 years of age who are not eligible for autologous stem cell transplantation - For use in combination with dexamethasone OR melphalan and prednisone - ECOG ≤ 2 - Coordinate with provincial government program
THYROGEN (Thyrotropin alpha injection)	- Adjunctive therapy to radioiodine imaging of thyroid cancer	- Patient(s) must have well-differentiated thyroid cancer AND cannot tolerate Thyroid Hormone Suppression Therapy (THST) withdrawal - Validate site of administration

DRUG	DISEASE	APPROVAL GUIDELINES
TIVICAY (Dolutegravir)	- HIV anti-viral	- For patients who have tried and failed at least one anti-retroviral drug from each of the following sub-classes: Non-Nucleoside Reverse Transcriptase Inhibitors (nNRTIs) and Protease Inhibitors (PIs) - Coordinate with provincial government program
TOBI PODHALER (Tobramycin)	- Cystic fibrosis	- For management of cystic fibrosis patients, aged 6 years or older, with chronic pulmonary Pseudomonas aeruginosa infections - Coordinate with provincial government
TOCTINO (Alitretinoin)	- Chronic Hand Eczema (CHE)	- Diagnosis of severe CHE characterized by fissures, vesicles, bumps, edema, exudation, scaling or lichenification - Trial of at least 2 of the following high potency topical steroids: amcinonide (Cyclocort), desoximetasone (Topicort), fluocinonide (Lyderm, Tiamol), betamethasone dipropionate (Diprosone), clobetasol propionate (Clobex)
TOUJEO (Insulin Glargine)	- Diabetes mellitus	- For patients who have tried and failed on existing longer acting insulins AND/OR patients currently using or are candidates for insulin infusion pump therapy
TRACLEER and generic BOSENTAN (Bosentan)	- Pulmonary Hypertension	- For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class III AND who have tried and failed Revatio or Adcirca - For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
TRAJENTA (Linagliptin) JENTADUETO (Linagliptin/Metformin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
TRINTELLIX (Vortioxetine Hydrobromide)	- Major depressive disorder (MDD)	- For individuals diagnosed with major depressive disorder and who have previously tried and failed therapy with any other antidepressant
TRIUMEQ (Dolutegravir/Abacavir/ Lamivudine)	- HIV infection in adults	- Coordinate with provincial government program
TRIZIVIR (Abacavir/Lamivudine/Zidovudine)	- HIV anti-viral	- Coordinate with provincial government program
TRUSOPT (Dorzolamide (preservative-free ophthalmic solution)	- Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	- For patients who are allergic to or cannot tolerate the formulation with the preservative

DRUG	DISEASE	APPROVAL GUIDELINES
TRUVADA (Emtricitabine/Tenofovir)	- HIV anti-viral	- Coordinate with provincial government program
TUDORZA GENUAIR (Aclidinium bromide)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema
TYKERB (Lapatinib)	- Advanced or metastatic breast cancer	- In combination with Xeloda, for patients with tumours over-expressing ErbB2 (HER2) who have tried and failed taxanes, anthracyclines and trastuzumab - Coordinate with provincial government program
TYSABRI (Natalizumab)	- Treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) in patients who have had an inadequate response to, or are unable to tolerate, other MS therapies	- For RRMS - patients have had an inadequate response to, or are unable to tolerate, other therapies. Patients should have evidence of lesions on their MRI scan, an EDSS value less than 6 and have had at least one relapse in previous year - For patients with rapidly evolving severe MS, they must have had two or more disabling relapses in one year and at least nine T2-hyperintense lesions in their cranial MRI or at least one gadolinium-enhancing (Gd-enhancing) lesion - Coordinate with provincial government program
ULORIC (Febuxostat)	- To lower serum uric acid levels in patients with gout	- For patients who have tried and failed or had intolerable side effects to allopurinol
ULTIBRO BREEZHALER (Indacaterol maleate / Glycopyrronium bromide)	- Chronic Obstructive Pulmonary Disease (COPD)	- For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy
UROCIT-K (Potassium citrate)	- Kidney Stones	- For patients with renal tubular acidosis (RTA) with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stone
VALCYTE and generic VALGANCICLOVIR VALCYTE POS (Valganciclovir)	- Cytomegalovirus Retinitis	- For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients - For the prevention of CMV disease in solid organ transplant patients at risk (i.e. risk is defined as donor +ve/recipient -ve for CMV, or recipient +ve post-active treatment of CMV disease with IV ganciclovir, or recipient +ve in patients receiving antilymphocyte antibody [ALA]). - Coordinate with provincial government program
VFEND and generic VORICONAZOLE (Voriconazole)	- Treatment of invasive aspergillosis - Treatment of Candidemia in non-neutropenic patients and *Candida* infections	- For the treatment of invasive aspergillosis for post-hospital discharge only - For patients with candidemia who cannot tolerate Amphotericin B and Fluconazole or who have infections with Fluconazole-resistant *Candida* species - Coordinate with provincial government program
VICTOZA (Liraglutide)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)

DRUG	DISEASE	APPROVAL GUIDELINES
VICTRELIS (Boceprevir)	- Hepatitis C	Initial Authorization Approval: - For adults with chronic hepatitis C genotype 1 infection in combination with peginterferon alpha/ribavirin (Pegetron) - Quantitative HCV RNA value from within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6) - An initial 12 weeks of Victrelis will be approved Subsequent Authorization Approval: - The authorization will be renewed if the HCV-RNA is ≤ 100 IU/ml at week 8 of Victrelis therapy (week 12 of total treatment) - The maximum duration of treatment will be 44 weeks of Victrelis therapy - Coordinate with available provincial plans -
VICTRELIS TRIPLE (Boceprevir/Ribavirin/ Peginterferon alfa-2b)	- Hepatitis C	Initial Authorization Approval: - For adults with chronic hepatitis C genotype 1 infection - Quantitative HCV RNA value from within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6) - An initial 12 weeks of Victrelis Triple will be approved Subsequent Authorization Approval: - The authorization will be renewed if the HCV-RNA is ≤ 100 IU/ml at week 8 of Victrelis Triple therapy (week 12 of total treatment) - The maximum duration of treatment will be 44 weeks of Victrelis Triple therapy - Coordinate with available provincial plans
VIDEX (Didanosine)	- HIV anti-viral	- Coordinate with provincial government program
VIMOVO (Naproxen/Esomperazole)	- Osteoarthritis - Rheumatoid Arthritis - Ankylosing Spondylitis	- For patients who are unresponsive to one of the following: Rabeprazole, Lansoprazole, Omeprazole, Esomeprazole and/or Pantaprazole
VIMPAT (lacosamide)	- Adjunctive therapy for partial onset seizures	- For patients with a diagnosis of partial onset seizures AND - Tried, failed or have experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
VIRACEPT (Nelfinavir)	- HIV anti-viral	- Coordinate with provincial government program
VIRAMUNE (Nevirapine)	- HIV anti-viral	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
VIREAD (Tenofovir)	- HIV anti-viral - Hepatitis B	- Coordinate with provincial government program - Hepatitis B for paitents 18 years of age and older WITH I. Compensated liver disease, with evidence of active viral replication II. Elevated serum alanine aminotransferase (ALT), or evidence of fibrosis III. Evidence of lamivudine-resistant hepatitis B virus or decompensated liver disease
VISANNE (Dienogest)	- For the management of pelvic pain associated with endometriosis	- For patients who have failed to respond or have had intolerable side-effects to oral contraceptives
VOLIBRIS (Ambrisentan)	- Pulmonary Hypertension	- For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND who have tried and failed Revatio or Adcirca - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
VOTRIENT (Pazopanib Hydrochloride)	- Metastatic renal cell (clear cell) carcinoma (mRCC)	- For patients who have received no prior systemic therapies OR who have documented failure to first line cytokine based therapy - Coordinate with provincial government program
VYVANSE (Lisdexamfetamine)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting) or Dextroamphetamine
XELJANZ (Tofacitinib)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
XENICAL (Orlistat) Dr. BERNSTEIN DIET INJECTION (Vitmain B6 & Vitamin B12 compound)	- Obesity	Initial Authorization Approval: - Patient must meet each of the following criteria to receive coverage for Xenical for up to six months: - Patient has been prescribed lifestyle therapy (diet and exercise) for six months or more prior to using Xenical - Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Xenical - Patient with a Body Mass Index (BMI) greater than or equal to 30 OR - Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ▪ Hypertension and is on medication ▪ Diabetes mellitus and is on medication ▪ Hyperlipidemia and is on medication ▪ Coronary artery disease and is on medication Subsequent Authorization Approval: - Patient must meet each of the following criteria to receive additional coverage for Xenical for up to six months: - Patient must achieve and continuously maintain a minimum reduction of 6% of initial body weight. Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Xenical - Patient with a Body Mass Index (BMI) greater than or equal to 30 OR - Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ▪ Hypertension and is on medication ▪ Diabetes mellitus and is on medication ▪ Hyperlipidemia and is on medication ▪ Coronary artery disease and is on medication Maximum Lifetime Coverage: $1500/individual
XEOMIN (Botulinum toxin type A)	- Blepharospasm - Cervical dystonia (spasmodic torticollis) - Post-stroke spasticity of the upper limbs	- For the treatment of blepharospasm in patients 18 years of age or older - For the treatment of torticollis in adult patients - For the treatment of post-stroke spasticity of the upper limbs in adult patients
XGEVA (Denosumab)	- Bone metastases	- For patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumors - For patients who have tried and failed or experienced intolerable side effects with bisphosphates (Clasteon, Bonefos, Zometa or Aredia)
XIAFLEX (Collagenase Clostridium Histolyticum)	- Dupuytren's Contracture with a Palpable Cord	- For patients with a confirmed diagnosis of Dupuytren's Contracture with a palpable cord AND - Who are ineligible or inappropriate for surgical intervention - Coordinate with provincial government program - Approval maximum: 3 injections per finger

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XOLAIR (Omalizumab)	- For adults and adolescents (12 years and older) with moderate to severe persistent asthma who have a positive skin test - Chronic idiopathic urticaria	- Moderate to severe asthmatics who are skin test positive or have in-vitro reactivity to a perennial aeroallergen with a baseline IgE level within 30-700IU/ml and who are not adequately controlled by a concomitant therapy of Inhaled Corticosteroids ("ICS") and Long-Acting Beta-Agonists ("LABA") and Leukotriene-Recepetor Agonists ("LRA") OR - If any of the previously mentioned drugs cannot be used concomitantly, a combination of three of the four following drugs: ICS, LABA, LRA, and/or long-acting Theophylline - Treatment of chronic idiopathic urticaria despite treatment with a first generation antihistamine (chlorpheniramine, diphenhydramine) AND a second generation antihistamine (cetirizine, fexofenadine, loratadine, or desloratadine) for at least 3 months
XTANDI (Enzalutamide)	- Metastatic prostate cancer (castration resistant prostate cancer – CRPC)	- For patients with a diagnosis of CRPC AND - Received prior chemotherapy containing docetaxel - Coordinate with provincial government program
XYREM (Sodium oxybate)	- Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients	- Diagnosis of narcolepsy with chronic symptoms of cataplexy
ZADITOR (Ketotifen preservative-free ophthalmic solution)	- Temporary relief of itching from allergic conjunctivis	- For patients who are allergic to or cannot tolerate the formulation with the preservative
ZAXINE (Rifaximin)	- For reduction in risk of overt hepatic encephalopathy	- For adult patients susceptible to overt hepatic encephalopathy WITH - MELD score of ≤ 25 or Child-Pugh score of A or B - Coordinate with provincial government program
ZELBORAF (Vemurafenib)	- For the treatment of BRAF V600 mutation-positive unresectable (Stage IIIC or IV) or metastatic melanoma	<u>Initial Criteria:</u> - Confirmed BRAF V600 mutation positive disease - ECOG ≤ 1 - Coordinate with available provincial plans - An initial approval for 4 months <u>Renewal Criteria:</u> - For patients who experience a beneficial clinical effect AND who do not have evidence of disease progression
ZERIT (Stavudine)	- HIV anti-viral	- Coordinate with provincial government program
ZIAGEN (Abacavir)	- HIV anti-viral	- Coordinate with provincial government program
ZUACTA (Zucapsaicin cream)	- Osteoarthritis	- A confirmed diagnosis of osteoarthritis, where the patient failed to respond OR had intolerable side-effects to Meloxicam AND at least one Non-Steroidal Anti-Inflammatory Drug (NSAID)

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ZYDELIG Idelalisib	- Treatment of patietns with relapsed Chronic Lymphocytic Leukemia (CLL)	- For the treatment of patients with who have relapsed CLL - Who failed or are experiencing recurrent disease despite 1 prior therapy (e.g. bendamustine + rituximab, fludarabine + cyclophosphamide + rituximab, single-agent rituximab, fludarabine + rituximab, chlorambucil, fludarabine, ofatumumab, chlorambucil, etc.) - Must be taken in combination with rituximab - Coordinate with provincial government program
ZYTIGA (Abiraterone acetate)	- For treatment of metastatic prostate cancer (castration resistant prostate cancer – CRPC)	- For treatment of CRPC in combination with prednisone in patients who have received prior chemotherapy containing docetaxel OR - For treatment of CRPC in combination with prednisone in patients who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy - Coordinate with provincial government program