Special Authorization Drugs and Approval Guidelines

(Special authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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 who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months or any biologic , 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 - Giant Cell Arthritis (GCA)	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months - For adult patients with a confirmed diagnosis of giant cell arteritis with persistent active disease where the patient has not adequately responded to prednisone at maximum tolerated dose for a period of 3 months - Coordinate with provincial government program
ADCIRCA (Tadalafil)	- Pulmonary Arterial Hypertension	- For patients with pulmonary arterial hypertension (PAH) WHO functional class II or III who do not respond to optimal conventional therapy (i.e. calcium channel blockers, anticoagulation with warfarin, diuretics, digoxin, supplemental oxygen)

DRUG	DISEASE	APPROVAL GUIDELINES
ADEMPAS (Riociguat)	- Inoperable chronic thromboembolic pulmonary hypertension (CTEPH) - Persistent or recurrent CTEPH after surgical treatment - Pulmonary arterial hypertension	- Confirmed diagnosis of CTEPH in adult patients with WHO Functional Class II or III pulmonary hypertension with: o Inoperable disease OR o Persistent or recurrent disease post-surgery - For the treatment of adult patients with WHO FC II-III pulmonary arterial hypertension who have tried and failed or cannot tolerate Revatio or Adcirca (minimum 3 months trial) AND Tracleer (bosentan) - 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) - Neuroendocrine Tumours of Gastrointestinal (GI) or Lung origin - Seizures associated with Tuberous Sclerosis Complex (TSC)	- 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: o Progressed within the last 12 months, AND o 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 - For the treatment of neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin in adult patients with unresectable, locally advanced or metastatic, well differentiated, and non-functional disease, who are treatment naïve or treatment-experienced who have: o Progressed on or after the last treatment AND o An ECOG ≤ 1 - As add-on therapy for seizures associated with Tuberous Sclerosis Complex (TSC) in patients 2 years and older who have tried and failed at least 2 anti-epileptic drugs: carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin - Coordinate with provincial government program
AIMOVIG (Erenumab)	- Episodic or chronic migraine	<u>Initial criteria (6 months):</u> - For the prevention of migraine in adults (18+ years old) with at least 8 migraines per month, who have tried and failed, are intolerant or have a contraindication to at least 2 migraine prevention therapies (ie: tricyclic analgesics, antiepileptic drugs, beta blockers). Must indicate number of migraine days per month <u>Renewal criteria (1 year):</u> - Clinical benefit demonstrated by: o ≥ 30% reduction in number of migraine days per month OR o Reduction in use of acute migraine medications

DRUG	DISEASE	APPROVAL GUIDELINES
APTIVUS (Tipranavir)	- HIV Infection	- For use in combination with ritonavir for the treatment of HIV in patients 18 years of age and older who have tried and failed or are intolerable to at least one : Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and at least 2 Protease Inhibitors (PI), and in whom no other PI is a treatment option - 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 and generics (Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate)	- HIV anti-viral	- Coordinate with provincial government program
AUBAGIO (Teriflunomide)	- Multiple sclerosis, relapsing remitting	- Confirmed diagnosis of Relapsing or Remitting MS - EDSS value required with every application - Coordinate with provincial government program
AVONEX AVONEX PS REBIF REBIF MULTIDOSE CARTRIDGE 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 with abnormal brain MRI at presentation - EDSS value required with every application - Coordinate with provincial government program
BARACLUDE and generic ENTECAVIR (Entecavir)	- Chronic Hepatitis B	- Coordinate with provincial government program
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
BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide)	- HIV infection in adults	- For treatment of HIV-1 infection in adults - Coordinate with provincial plans

DRUG	DISEASE	APPROVAL GUIDELINES
BOSULIF (Bosutinib)	- Chronic myeloid leukemia - Newly diagnosed chronic phase Ph+ chronic myelogenous 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 - For adult patients with newly-diagnosed chronic phase Philadelphia chromosome positive chronic myelogenous leukemia - Coordinate with provincial government program
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 o Max dose for blepharospasm = 100U per eye every 2 months - For the treatment of torticollis in adult patients o Max dose for torticollis =400U every 3 months - For spasticity and other approved clinical conditions o Max dose for spasticity = 400units every 12 weeks - For axillary hyperhidrosis in patients that have failed or are intolerant to an aluminum chloride preparation o Max dose for axillary hyperhidrosis = 50U per axilla every 3 months - For the prophylaxis of headaches in adults with chronic migraines (≥ 15 per month with headaches lasting 4 hours a day or longer) who have tried and failed symptomatic (i.e. opioid and non-opioid analgesics, triptans or ergots) and prophylactic treatment, e.g. tricyclic antidepressants (amitriptyline, nortriptyline), antilepileptic drugs (topiramate, divalproex), beta blockers (propranonol, metoprolol), calcium channel blockers (verapamil), SNRIs (venlafaxine, duloxetine) o Max dose for migraines = 200U every 12 weeks - For the treatment of overactive bladder or neurogenic bladder associated with multiple sclerosis or subcervical spinal cord injury in adults unresponsive to or intolerable to two of the following oral anticholinergics (Uromax, generic Ditropan, Ditropan XL, Enablex, Vesicare, Detrol, Detrol LA, Toviaz, Trosec) o Max dose for OAB = 100U every 3 months o Max dose for neurogenic bladder = 200U every 3 months
BRENZYS (Etanercept)	- Ankylosing Spondylitis - Rheumatoid Arthritis	- For adult patients (18+) with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is ≥ 4 - For adult patients (18+) with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, - Coordinate with provincial government program
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

DRUG	DISEASE	APPROVAL GUIDELINES
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
CIMZIA (Certolizumab pegol)	- Moderate to Severe Rheumatoid Arthritis - Psoriatic Arthritis - Ankylosing Spondylitis - Plaque Psoriasis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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 ≥ 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 other biologic therapies (e.g. Humira, Enbrel, Remicade, Stelara, etc) or specialty drugs (e.g. Otezla) AND who are being treated by a dermatologist - Coordinate with provincial government program
CINQAIR (reslizumab)	- Severe eosinophilic asthma	- For the treatment of asthma in patients 18 years or older who have: o Tried and failed a combination ICS and one other asthma agent, such as long acting beta-agonist or leukotriene receptor antagonists AND o Experienced at least 1 or more exacerbations in the previous 12 months; OR dependency on systemic corticosteroid for at least 6 months; AND o Have a blood eosinophil count ≥ 400 cells/µL OR induced sputum eosinophil count of 3% or more in the past 12 months

DRUG	DISEASE	APPROVAL GUIDELINES
COPAXONE (Glatiramer acetate) GLATECT (Glatiramer acetate)	- Multiple sclerosis - Relapsing remitting Multiple sclerosis (RRMS)	- EDSS value required with every application - Coordinate with provincial government program - For patients who are previously stabilized on Copaxone OR patients who are medically unable to use Glatect - For Glatiramer acetate naïve patients, only Glatect will be approved -
COPAXONE (Glatiramer acetate) GLATECT (Glatiramer acetate)	- Clinical Isolated Syndrome (CIS)	- diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation - EDSS value required with every application - Coordinate with provincial government program - For patients who are previously stabilized on Copaxone OR patients who are medically unable to use Glatect - For Glatiramer acetate naïve patients, only Glatect will be approved
COSENTYX (Secukinumab)	- Ankylosing spondylitis - Plaque Psoriasis - 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 treated by a dermatologist - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is ≥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
COTELLIC (Cobimetinib)	- For the treatment of BRAF V600 mutation-positive unresectable (Stage IIIC or IV) or metastatic melanoma	<u>Initial Criteria (Duration of 6 months):</u> - Confirmed BRAF V600 mutation positive disease - ECOG ≤ 1 - For use in combination with ZELBORAF (Vemurafenib) <u>Renewal Criteria (Duration of 6 months):</u> - Absence of disease progression confirmed by medical imaging or by physical exam

DRUG	DISEASE	APPROVAL GUIDELINES
DAKLINZA (Daclatasvir)	- Hepatitis C genotype 3	- For adults with chronic hepatitis C genotype 3 in combination with Sovaldi: ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ No diagnosis of cirrhosis ▪ Failure of standard peg-interferon/ribavirin therapy ▪ HCV levels in the past 6 months ▪ Have failed or have a true contraindication to Maviret, Epclusa ▪ Coordinate with provincial government program *Maximum approval 12 weeks* - **Retreatment requests will not be considered**
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
DELSTRIGO (Doravirine/lamivudine/tenofovir disoproxil fumarate)	- HIV Infection	- Coordinate with provincial government program
DESCOVY (Emtricitabine/tenofovir alafenamide)	- HIV Infection	- Coordinate with provincial government program
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
DUPIXENT (Dupilumab)	- Severe atopic dermatitis	<u>Initial Approval: 6 months duration</u> - For the treatment of adult patients (18+) with confirmed severe atopic dermatitis: ▪ Severity defined as meeting all 3 conditions below: 1) IGA of 3 or more 2) BSA of at least 30% or EASI ≥21 3) DLQI ≥ 10 or severe disruption in sleep;

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Tried and failed one product from each class below: 1) High potency topical steroids 2) Protopic or Elidel 3) Oral corticosteroid therapy and/or immunosuppressants (cyclosporine, azathioprine, methotrexate, etc) <u>Renewal criteria: 1 year duration</u> - IGA of 0 or 1 or 50% improvement, AND - Improvement of EASI of at least 75% of initial score AND - 5 point improvement in DLQI or improvement in sleep
DYSPORT (Abobotulinumtoxin A)	- Cervical dystonia (spasmodic torticollis) - Focal spasticity	- For adult patients with a confirmed diagnosis of cervical dystonia (torticollis) OR focal spasticity affecting the upper limbs - For the treatment of lower limb spasticity in children 2 years of age and older - For the treatment of focal spasticity affecting the lower limbs in adults (18 years of age and older)
ENBREL (Etanercept)	- Moderate to Severe Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Moderate to severe chronic plaque psoriasis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months - For patients 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease who have 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 who have 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 ≥ 4 - For patients 4 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement 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)	- Ulcerative Colitis - Crohn's Disease	- For patients with active ulcerative colitis who have failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressant (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have tried and failed or experienced intolerant effects to infliximab, Humira, or Simponi SC - For patients with 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) AND who have tried and failed or experienced intolerant effects to another biologic (infliximab, Humira)

DRUG	DISEASE	APPROVAL GUIDELINES
		- Coordinate with provincial government programs
EPCLUSA (Sofosbuvir/Velpatasvir)	- Hepatitis C Infection in genotypes 1-6	- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C genotype 1-6 infections with: ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months ▪ Maviret treatment is not an option due to a true clinical contraindication. - Retreatment requests will not be considered - Coordinate with provincial government programs
EPREX (Erythropoietin)	- Anemia with chemotherapy - Chronic renal failure dialysis - Anemia with AIDS	- For patient with chronic renal failure undergoing dialysis treatment - For patient with anemia secondary to chemotherapy - For patients requiring a transfusion from anemia related to therapy with zidovudine in HIV-infected patients - Coordination with provincial government program if available
ERELZI (etanercept)	- Moderate to Severe Rheumatoid Arthritis - Moderate to Severe Juvenile Idiopathic Arthritis - Ankylosing spondylitis - Psoriatic Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months - For patients 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease who have 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 confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDs and the BASDAI score is ≥ 4 - For patients with a confirmed diagnosis of psoriatic arthritis who have 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

DRUG	DISEASE	APPROVAL GUIDELINES
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 provincial government program
ERLEADA (Apalutamide)	- Non-metastatic castration-resistant prostate cancer (nmCRPC)	- Initial Approval for 6 months: In combination with Androgen Deprivation Therapy (ADT) for the treatment of patients with non-metastatic castrate resistant prostate cancer (nmCRPC) with prostate-specific antigen (PSA) doubling time of 10 months or less during continuous ADT AND ECOG 0-1 - Renewal for 6 months: Absence of disease progression - Maximum dose: 240 mg once a day
ESBRIET (Pirfenidone)	- Idiopathic Pulmonary Fibrosis (IPF)	Initial Criteria: - For patients diagnosed with idiopathic pulmonary fibrosis (IPF) as confirmed by clinical chest radiology (HRCT) or a lung biopsy with a Forced Vital Capacity (FVC) between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted Renewal criteria: - Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months - Coordinate with available provincial programs
EXTAVIA (Interferon beta-1b)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
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)	- Multiple Sclerosis (MS)	Initial Criteria: - For the symptomatic improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 3.5 – 7) - Coordinate with available provincial plans - An initial 6 weeks of Fampyra will be approved Renewal Criteria: - 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)

DRUG	DISEASE	APPROVAL GUIDELINES
FASENRA (Benralizumab)	- Severe eosinophilic asthma	- For the treatment of asthma in patients 18 years or older who have tried and failed a combination of inhaled corticosteroid with one of the following: long acting beta-agonist or leukotriene receptor antagonist, AND meet one of the following: o blood eosinophil count > 300 cells/µL and have experienced 2 or more exacerbations in the previous 12 months OR o blood eosinophil count > 150 cells/µL and have tried and failed or are intolerant to oral corticosteroids
FASLODEX and generic Fulvestrant	- Locally advanced or metastatic breast cancer	- Second-line treatment for postmenopausal women who have failed or had intractable side effects to tamoxifen and/or other aromatase inhibitors (ex. Letrozole) OR - For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND not previously treated with endocrine therapy AND no active or uncontrolled metastases to the liver or lungs
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 Fludara 10mg tablet in the province where the applicant resides AND - Applicant has first tried I.V. / infusion Fludara 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 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
FUZEON (Enfuvirtide)	- HIV infection	- For treatment experienced patients who have tried at least three anti-retrovirals from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) and where the CD4 count has fallen below 200 cells/uL. - Coordinate with provincial government program
GENVOYA (Cobicistat/Emtricitabine/ Elvitgravir/Tenofovir Alafenamide)	- HIV Infection	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
GILENYA (Fingolimod)	- Multiple sclerosis, relapsing remitting	- For the treatment of patients 10 year or older with relapsing remitting multiple sclerosis in patients who have failed or are intolerant to one or more therapies for multiple sclerosis treatments i.e. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Rebif, Plegridy, Tecfidera - EDSS value required - Coordinate with provincial government program
IOTRIF (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
GLATECT (Glatiramer)	- Multiple sclerosis, relapsing remitting (RRMS)	- For patients with RRMS and diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation - EDSS value required with every application - Coordinate with provincial government program
GLEEVEC and generic IMATINIB	- Chronic myeloid leukemia (CML) - Gastrointestinal Stromal Tumour (GIST) - Acute Lymphoblastic Leukemia (ALL)	- 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
GRASTOFIL (Filgrastim)	- Neutropenia associated with chemotherapy, transplant, HIV/AIDS, stem cell mobilization - Severe chronic neutropenia	- Co-ordinate with available provincial plans

DRUG	DISEASE	APPROVAL GUIDELINES
HARVONI (Ledipasvir /Sofosbuvir)	- Hepatitis C virus (CHC) genotype 1 infection	- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C genotype 1 infections with: - Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - Compensated liver disease including compensated cirrhosis - Have failed or have a true contraindication to Maviret - Retreatment requests will NOT be considered - Coordinate with provincial government program
HEPSERA and generic 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

DRUG	DISEASE	APPROVAL GUIDELINES
HUMATROPE (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD") - Idiopathic Short Stature ("ISS")	- For the treatment of patients 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 (Adalimab)	ADULT - Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Moderate to severe chronic plaque psoriasis - Hidradenitis Suppurativa - Non-infectious uveitis 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) - For 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 who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months - For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease who have 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 ≥4 - For patients 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND are being treated by a dermatologist - For patients 18 years and older with a confirmed diagnosis of HS where the HS lesions must be present in at least two distinct areas AND both lesions must be at least Hurley stage II or III AND where the patient has tried and failed therapy for at least two months with oral antibiotics (i.e. dicloxacillin, erythromycin, minocycline, tetracycline, doxycycline) AND the Abscess and Nodule count is ≥ 3. Coordination with provincial government program. Renewal will be granted if: ≥50% reduction from baseline in Abscess and Nodule count AND No increase in abscess or in draining fistula counts - For the treatment of non-infectious uveitis (intermediate, posterior, and pan-uveitis) in patients with inadequate response to corticosteroids OR as a corticosteroid-sparing treatment in corticosteroid-dependent patients. Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician. - Coordinate with provincial government program 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

DRUG	DISEASE	APPROVAL GUIDELINES
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
IBRANCE (Palbociclib)	- Advanced or metastatic breast cancer	Initial Criteria (6 month duration): - For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND - In combination with an aromatase inhibitor (e.g. Anastrozole, Letrozole) given continuously AND - No active or uncontrolled metastases to the brain AND - No resistance to prior (neo-) adjuvant aromatase-inhibitor therapy AND - No previous systemic treatment including chemotherapy for their advanced disease Renewal (6 month duration): Continue until unacceptable toxicity or disease progression
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

DRUG	DISEASE	APPROVAL GUIDELINES
		- Proof of enrollment in the Support Program - Coordinate with provincial government program <u>Renewal (3 month approval):</u> - 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	<u>Initial Criteria – 6 months ONLY</u> - 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 - Coordinate with provincial government <u>Renewal Criteria</u>**:** - For the treatment of CLL in symptomatic patients with evidence of progression: - Documentation of clinical benefits by flow cytometry
INCIVEK (Telaprevir)	- Hepatitis C	<u>Initial Criteria:</u> - For adults with chronic hepatitis C genotype 1 infection with compensated liver, including cirrhosis, in combination with peg interferon alpha/ribavirin - An initial 6 weeks of Incivek will be approved <u>Renewal Criteria:</u> - 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
INFERGEN (Interferon alfacon-1)	- Hepatitis C	- For patients who have failed to respond to or relapsed after prior administration of Interferon alpha

DRUG	DISEASE	APPROVAL GUIDELINES
INFLECTRA (Infliximab)	- Rheumatoid Arthritis - Ankylosing Spondylitis - Psoriatic Arthritis - Plaque Psoriasis - Crohn's Disease - Ulcerative colitis	- For adult patients (18+) 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months - For adult patients (18+) 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, - For adult patients (18+) 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 - For adult patients (18+) 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) - For adult patients (18+) with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - 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
INTELENCE (Etravirine)	- HIV infection	- Coordinate with provincial government program
INTRON A (Interferon Alpha-2B)	- Chronic Hepatitis C - Chronic Active Hepatitis B - Chronic Myelogenous Leukemia (CML) - Thrombocytosis Associated with CML - Multiple Myeloma - Non-Hodgkin's lymphoma - Malignant melanoma - AIDS-Related Kaposi Sarcoma - Hairy Cell Leukemia - Basal Cell Carcinoma	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
	- Condylomata Accuminata	
IRESSA and generic 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 Infection	- Coordinate with provincial government program
JADENU (Deferasirox)	- Chronic Iron Overload	- For the management of chronic iron overload in patients with transfusion-dependent anemias aged 6 years or older. - For the management of chronic iron overload in patients with transfusion-dependent anemias aged 2 to 5 who cannot be adequately treated with deferoxamine. - For the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes (NTDT) aged 10 years and older. - For patients who have tried and failed or cannot tolerate or have a contraindication* to deferoxamine. - Coordinate with provincial government program. *Contraindications to deferoxamine may include one or more of the following: known or suspected hypersensitivity to deferoxamine, recurrent injection or infusion-site reactions (e.g., cellulitis), concomitant bleeding disorder, immunocompromised patients with a documented risk of significant infections with parenteral administration (e.g. neutropenia), patients <16 years of age requiring high doses of deferoxamine with concomitant low ferritin levels (risk of growth retardation)
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: ▪ Primary myelofibrosis (also known as chronic idiopathic myelofibrosis) ▪ Post-polycythemia vera myelofibrosis ▪ Post-essential thrombocythemia myelofibrosis - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
JINARC (Tolvaptan)	- Slow progression of kidney enlargement in patients with autosomal dominant polycystic kidney disease (ADPKD)	Initial Criteria: - Confirmed diagnoses of rapidly progressive ADPKD and must have: a) Total kidney volume ≥ 750ml AND b) CrCl ≥ 60ml/min - Proof of enrollment in the Support Program - Coordinate with provincial drug programs Renewal Criteria: - Proof of continued enrollment in the patient support program - Laboratory results demonstrating normal liver (ALT and AST) function - Proof of beneficial effect demonstrated by: a) Urine osmolality of less than 300 mOsm/kg - Coordinate with provincial drug programs
JULUCA (Dolutegravir sodium/Rilpivirine HCl)	- HIV-1 infection in adults	- For treatment of adult HIV-1 patients who are currently on antiretroviral therapy and experiencing side effect(s) or documented drug interaction(s) - Coordinate with provincial plans
KEVZARA (Sarilumab)	- Moderate to Severe Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months or any biologic - Coordinate with provincial government program
KINERET (Anakinra)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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
KISQALI (Ribociclib)	- Advanced or metastatic breast cancer	<u>Initial Criteria (6 month duration):</u> - For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND - In combination with an aromatase inhibitor (e.g. Anastrozole, Letrozole) given continuously AND - No active or uncontrolled metastases to the brain AND - No resistance to prior (neo-) adjuvant aromatase-inhibitor therapy AND - No previous systemic treatment including chemotherapy for their advanced disease <u>Renewal (6 month duration):</u> - Continue until unacceptable toxicity or disease progression

DRUG	DISEASE	APPROVAL GUIDELINES
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 - Renewal: Evidence of decrease blood phenylalanine concentration relative to levels prior to starting therapy
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, , Plegridy, Rebif, , Tecfidera - Coordinate with provincial government program - Initial Treatment Course: 12 mg/day for 5 consecutive days (60 mg total dose) - Second Treatment Course: 12 mg/day for 3 consecutive days (36 mg total dose) administered 12 months after the initial treatment course
LENVIMA (Lenvatinib)	- Radioactive iodine-refractory differentiated thyroid cancer	- For the treatment of patients with locally advanced or metastatic, progressive, radioactive iodine refractory differentiated thyroid cancer
LUCENTIS (Ranibizumab)	- End-stage or “wet” age-related macular degeneration (“AMD”) - Macular edema following Central or Branch Retinal Vein Occlusion - Diabetic macular edema - Pathological Myopia	- Drug administered by ophthamologist - Lucentis will not be authorized concomitantly with verteporfin for treatment of the same eye. - Validate site of administration - Authorization period of 1 year - Coordinate with provincial government program
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
MAVENCLAD (cladribine)	- 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, Plegridy, Rebif, Tecfidera - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
MAVIRET (glecaprevir/pibrentasvir)	- Hepatitis C	- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C genotype 1-6 infections with: o Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months o Fibrosis stage F2 or greater (Metavir scale or equivalent) - Coordinate with provincial government program
MEKINIST (Trametinib)	- 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 provincial government program
MOVAPO (apomorphine hydrochloride)	- Parkinson's disease	- For patients with advanced Parkinson's disease who have tried and failed levodopa/carbidopa and at least one of the following: Comtan, Mirapex, Parlodel, Requip, Azilect
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)
NEULASTA (Pegfilgrastim)	- Neutropenia associated with chemotherapy, transplant, AIDS	- To co-ordinate with available provincial plans
NEUPOGEN (Filgrastim)	- Neutropenia associated with chemotherapy, transplant, HIV/AIDS, stem cell mobilization - Severe chronic neutropenia	- To co-ordinate with available provincial plans
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

DRUG	DISEASE	APPROVAL GUIDELINES
NORDITROPIN NORDIFLEX (somatropin)	- Growth Hormone Deficiency ("GHD") in children - Idiopathic Short Stature ("ISS")	**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 **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
NUCALA (Mepolizumab)	- Asthma	- For the treatment of asthma in patients 18 years or older who have tried and failed a combination of three of the four following drugs used concomitantly: ICS, LABA, LRA, and long- acting theophylline AND who have experienced at least 2 exacerbations in the previous 12 months OR have a dependency on systemic corticosteroids for at least 6 months; AND a blood eosinophil count ≥ 150 cells/µL (0.15 GI/L) or ≥300 cells/µL in the past 12 months - Coordinate with provincial government program
NUTROPIN GENOTROPIN (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
OCALIVA (obeticholic acid)	- Primary biliary cholangitis (PBC)	- For the treatment of primary biliary cholangitis in adults: ▪ In combination with URSO/URSO DS in patients who have had an inadequate response to an appropriate dose of URSO/URSO DS for at least 1 year OR ▪ As monotherapy in patients who are intolerant to URSO/URSO DS

DRUG	DISEASE	APPROVAL GUIDELINES
OCREVUS (ocrelizumab)	- Multiple sclerosis, relapsing remitting (RRMS) - Primary Progressive Multiple Sclerosis (PPMS)	RRMS - For patients with RRMS who have failed or are intolerant to one or more therapies for multiple sclerosis treatments i.e. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Plegridy, Rebif, Tecfidera - EDSS value required - Coordinate with provincial government program PPMS: - Confirmed diagnosis of primary progressive multiple sclerosis - EDSS score between 3.0 and 6.5
ODEFSEY (emtricitabine/rilpivirine/tenofovir alafendamide)	- HIV-1 infection	- Coordinate with provincial government program
OFEV (nintedanib)	- Idiopathic Pulmonary Fibrosis	Initial Criteria - For patients diagnosed with idiopathic pulmonary fibrosis (IPF) as confirmed by clinical chest radiology (HRCT) or a lung biopsy with a Forced Vital Capacity (FVC) between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted Renewal criteria: - Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months - Coordinate with provincial government program
OLUMIANT (Baricitinib)	- 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 15 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program
OMNITROPE (Somatropin)	- Growth Hormone Deficiency (“GHD”) in children - Small for gestational age (SGA) - Adult Growth Hormone Deficiency (“Adult GHD”) - Turner Syndrome - 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 growth failure in children born with birth weight below 2.0 standard deviations of normal and who fail to achieve catch-up growth by 2-4 years of age and who have a height velocity <0 standard deviations during the last year - 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 the treatment of patients with Turner’s syndrome in patients whose epiphyses are not closed - For treatment of ISS which is defined as: (i) diagnostic evaluation that excludes other causes of short stature; and (ii) height at least 2.25 standard deviation scores

DRUG	DISEASE	APPROVAL GUIDELINES
		below the mean for age and sex; and (iii) patients whose epiphyses are not closed - Coordinate with provincial government program
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 or cannot tolerate Revatio or Adcirca (minimum 3 months trial) - For WHO FC III, patients must also have tried and failed or cannot tolerate Tracleer (bosentan) - Coordinate with provincial government program**May be used in conjunction with phosphodiesterase-5 inhibitors (i.e. Revatio or Adcirca)
ORENCIA IV (Abatacept)	- Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis - 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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 - 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

DRUG	DISEASE	APPROVAL GUIDELINES
ORENCIA SC (Abatacept)	- Rheumatoid Arthritis - 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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 - Coordinate with provincial government program
OTEZLA (Apremilast)	- Plaque psoriasis - 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 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
PEGASYS, (Peg interferon alfa-2b)	- 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
PHEBURANE (Sodium phenybutyrate)	- Urea cycle disorder	- Diagnosis of urea cycle disorders; AND - For patients who weighs ≥ 20 kg WITH a BSA ≤ 1.5 m2 and prescribed with a usual recommended dose of 9.9-13.0 g/m2/day; AND - Patient is currently on dietary protein restrictions; AND - Initial request must indicate ammonia levels prior to starting therapy

DRUG	DISEASE	APPROVAL GUIDELINES
PIFELTRO (Doravirine)	- HIV anti-viral	- Coordinate with provincial government program
PLEGRIDY (Peg interferon beta-1a)	- Multiple sclerosis, relapsing remitting	- Diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS) - EDSS value - 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)
PRALUENT (Alirocumab)	- Heterozygous Familial Hypercholesterolemia - Primary Hyperlipidemia	<u>Initial Request – 6 months approval:</u> - For use as adjunctive therapy to diet and maximally tolerated statin therapy for the treatment of adults (18 years and older) with a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia* or clinical atherosclerotic cardiovascular disease (i.e. MI, PCI, CABG, stroke) who require additional lowering of LDL-C despite trial and failure of maximum tolerated statin therapy with at least 2 statins AND one other cholesterol lowering medication (i.e. Ezetrol or Fenofibrates) concomitantly for at least six months. Current LDL-C value required. *Diagnosis must be confirmed either by genotyping or clinical criteria (Simon Broome criteria or World Health

DRUG	DISEASE	APPROVAL GUIDELINES
		Organization/Dutch Lipid Network criteria with a score of >8 points) <u>Renewal Criteria – 1 year approval:</u> - Patient must provide LDL levels showing a decrease of 25%
PREVYMIS (Letermovvir)	- Cytomegalovirus (CMV) infection	- For the prevention of cytomegalovirus (CMV) infection in adult patients who underwent allogeneic hematopoietic stem cell transplant (HSCT) <u>AND</u> have documentation of being CMV-seropositive
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 infection	- For patients who have tried and failed traditional PIs while receiving HAART - Coordinate with provincial government program - ** Prezista 400mg and 800mg also indicated for treatment-naïve patients (once-daily dosing)
PULMOZYME (Dornase alfa)	- Cystic fibrosis	- For treatment in patients, aged 5 years or older, diagnosed with cystic fibrosis and who have a forced vital lung capacity more than 40%
QUINSAIR (Levofloxacin)	- Cystic Fibrosis	- For patients aged 18 or over with confirmed Cystic Fibrosis and pulmonary infection with Pseudomonas aeruginosa, who have tried and failed or did not tolerate prior therapy with TOBI inhaled solution or TOBI Podhaler - Coordinate with provincial programs
RELISTOR (methylnaltrexone bromide)	- Opioid-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 - Moderate to severe chronic plaque psoriasis	- 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

DRUG	DISEASE	APPROVAL GUIDELINES
		arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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
RENFLEXIS (infliximab)	- Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Moderate to severe chronic plaque psoriasis	- 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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

DRUG	DISEASE	APPROVAL GUIDELINES
REPATHA (Evolocumab)	- Homozygous Familial Hypercholesterolemia - Primary Hyperlipidemia	**Homozygous Familial Hypercholesterolemia:** Initial Request – 6 months approval: - Diagnosed with Homozygous Familial Hypercholesterolemia, confirmed by an untreated LDL-C level of > 13.0mmol/L - Must be greater than 12 years of age - Tried and failed compliant therapy with at least 2 statins at maximum tolerated dose, used concomitantly with one other cholesterol lowering medication (i.e. Ezetrol or Fenofibrates) plus lifestyle modifications for six months - Current, on therapy, LDL-C levels - Must continue with diet and exercise & other lifestyle modifications while on Repatha Renewal Criteria – 1 year approval: - Must provide LDL-C levels showing a decrease of at least 25% from initial baseline **Primary Hyperlipidemia:** Initial Request – 6 months approval: - For use as adjunctive therapy to diet and maximally tolerated statin therapy for the treatment of adults (18 years and older) with a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia* or clinical atherosclerotic cardiovascular disease (i.e. Mi, PCI, CABG, stroke) who require additional lowering of LDL-C despite trial and failure of maximum tolerated statin therapy with at least 2 statins AND one other cholesterol lowering medication (i.e. Ezetrol or Fenofibrates) concomitantly for at least six months. Current LDL-C value required. *Diagnosis must be confirmed either by genotyping or clinical criteria (Simon Broome criteria or World Health Organization/Dutch Lipid Network criteria with a score of >8 points) Renewal Criteria – 1 year approval: - Patient must provide LDL levels showing a decrease of 25%
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.)
REVATIO and generic SILDENAFIL (low dose)	- Pulmonary Hypertension	- For patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III who do not respond to optimal conventional therapy (i.e. calcium channel blockers, anticoagulation with warfarin, diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
REVLIMID (Lenalidomide)	- 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 (e.g. Bortezomib, Melphalan + Prednisone, Thalomide) and whose ECOG is of 2 or less. - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
REVOLADE (Eltrombopag Olamine)	- Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	- For adult patients who are splenectomised and have tried and failed corticosteroids and immunoglobulins - For adult patients who are non-splenectomised (where surgery is contraindicated) and have tried and failed corticosteroids and immunoglobulins - For pediatric patients 1 year of age or older who have tried and failed corticosteroids and immunoglobulins - Platelet counts less than 30 x 109/L - Adults: Maximum approval is 1 year of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 109/L Pediatrics: Maximum approval is 9 months of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 109/L
RILUTEK and generic RILUZOLE (Riluzole)	- Amyotrophic lateral sclerosis (ALS)	- For the treatment of ALS in patients with symptoms of less than 5 years and who still have a vital lung capacity of 60% or more in the absence of tracheotomy
RITUXAN (Rituximab)	- Rheumatoid Arthritis - Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) - Microscopic Polyangiitis (MPA)	- For the treatment of patients with RA 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 SCFor the treatment of adult patients with severe GPA or MPA: • In combination with glucorticoids • Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). • Approval for 1 year • Dose: 375 MG/M2 body surface area, administered as an IV infusion once weekly for 4 weeks - Renewal criteria: 2 year • evidence of beneficial clinical effect • Renewal no less than 6 months after the last dose of Rituxan. • Dose: 2 doses of 500 mg IV infusions separated by 2 weeks, followed by a 500 mg IV infusion every 6 months - - Coordinate with provincial government program
RYDAPT (Midostaurin)	- Newly diagnosed FLT3-mutated acute myeloid leukemia (AML)	- For adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3-mutation positive AND one of the following: a) In combination with cytarabine and daunorubicin induction chemotherapy (one-time induction approval: 112 capsules) b) In combination with cytarabine consolidation (post-induction) chemotherapy (one-time consolidation approval: 224 capsules)
SANDOSTATIN SANDOSTATIN LAR OCPHYL (Octreotide)	- Metastatic Carcinoid Syndrome - Vasoactive Intestinal Peptide-Secreting Tumour (VIPoma) - Acromegaly - Emergency management for the bleeding of Gastro-oesophageal varices - Prevention of complications following pancreatic surgery	- For treatment of severe diarrhea and flushing in patients with carcinoid or VIP secreting tumours who are adequately controlled with subcutaneously administered Sandostatin - For acromegalic patients are adequately controlled with subcutaneously administered Sandostatin OR those in whom surgery, radiotherapy or dopamine agonist treatment is inappropriate or ineffective, or in the interim period until radiotherapy becomes fully effective - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
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
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 anticonvulsants, with little or no effect -
SENSIPAR AND GENERIC 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
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
SILIQ (Brodalumab)	- 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 being treated by a dermatologist
SIMPONI IV (Golimumab)	- 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 at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months Coordinate with provincial government program - 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

DRUG	DISEASE	APPROVAL GUIDELINES
		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
SIMPONI SC (Golimumab)	- Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Moderate to severe active Ulcerative Colitis - Severe active non-radiographic axial spondyloarthritis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) 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) For patients with a confirmed diagnosis of severe active non-radiographic axial spondyloarthritis where symptoms are uncontrolled by NSAIDs - Coordinate with provincial government program
SKYRIZI (Risankizumab)	- Plaque psoriasis	- For patients 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 other biologic therapies (eg. Humira, Etanercept, Infliximab, Stelara, etc.) AND who are being treated by a dermatologist
SOMATULINE AUTOGEL (Lanreotide)	- Acromegaly	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
SOMATULINE (Lanreotide)	- Acromegaly - Enteropancreatic neuroendocrine tumors	- For the treatment of acromegaly in patients who have tried and failed or are ineligible for surgery and/or radiation therapy and other medical therapies - For the treatment enteropancreatic neuroendocrine tumors characterized as Grade 1 or Grade 2 (equivalent to Ki67 < 10%) that are unresectable, locally advanced or metastatic
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 - Have failed or have a true contraindication to Maviret Coordinate with provincial government program
SPRYCEL (Dasatinib)	- Chronic myeloid leukemia - Acute Lymphoblastic Leukemia	- For the treatment of adults with Philadelphia chromosome positive (Ph+) chronic, accelerated, or blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate - For the treatment of adults with Philadelphia chromosome positive (Ph+) Acute Lymphoblatic Leukemia (ALL),resistant or intolerant to prior therapy - Coordinate with provincial government program
STELARA (Ustekinumab)	- Plaque psoriasis - Psoriatic Arthritis - Crohn's Disease	- 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 - For maintenance treatment for patients with confirmed diagnosis of Crohn's Disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have received their IV induction dose and are registered with Bioadvance - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
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
STRIBILD (Cobicistat/Tenofovir/ Emtricitabine/ Elvitegravir/)	- HIV anti-viral	- Coordinate with available provincial government programs
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
SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)	- HIV anti-viral	- Coordinate with available provincial government programs
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
TALTZ (Ixekizumab)	- Plaque Psoriasis - 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 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

DRUG	DISEASE	APPROVAL GUIDELINES
TARCEVA and generic 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
TEMODAL and generic TEMOZOLOMIDE	- Tumours, Brain, Primary Treatment (Astrocytoma)	- For the second-line treatment of glioblastoma multiforme or astrocytoma - For the treatment of newly diagnosed glioblastoma multiforme concurrently with radiation and post radiation. - 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 and coordinate with provincial program/cancer agency - Approval duration: 2 treatments per calendar year
TIVICAY (Dolutegravir)	- HIV anti-viral	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
TOBI PODHALER and generic TOBRAMYCIN (Tobramycin for inhalation)	- 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)
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 or cannot tolerate Revatio or Adcirca (minimum 3 months trial) - For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV - Coordinate with provincial government program
TREMFYA (Guselkumab)	- Moderate to severe chronic plaque psoriasis	- For patients 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND are being treated by a dermatologist
TRIUMEQ (Dolutegravir/Abacavir/ Lamivudine)	- HIV infection in adults	- Coordinate with provincial government program
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, i.e. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Plegridy, Rebif, Tecfidera - . 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
UPTRAVI (Selexipag)	- Pulmonary Arterial Hypertension (PAH) WHO functional class (FC) II–III (idiopathic, heritable, or associated with connective tissue disease or congenital heart disorders)	- For patients who have tried and failed or cannot tolerate at least one ERA (i.e. Tracleer, Volibris, Opsumit) or PDE-5 inhibitor (i.e. Revatio, Adcirca) - May be used as monotherapy OR an add-on to existing ERA/PDE-5 inhibitor OR triple combination therapy
VALCYTE and generic 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]).

DRUG	DISEASE	APPROVAL GUIDELINES
		- Coordinate with provincial government program
VEMLIDY (tenofovir alafenamide)	- Chronic Hepatitis B	- For adult patients with a confirmed diagnosis of chronic Hepatitis B infection with compensated liver disease - 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
VISUDYNE (Verteprofine)	- Age related macular degeneration - Pathological myopia	- For the treatment of age-related macular degeneration in patients with neovascularization of 50% or more on the macular surface AND no provincial coverage is available.
VIZIMPRO (Dacomitinib)	- Locally advanced or metastatic non-small cell lung cancer (NSCLC)	- For patients with a confirmed diagnosis of unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations who have tried and failed at least one EGFR tyrosine kinase inhibitor (e.g. Iressa, Tarceva, or Giotrif) - Coordinate with provincial government program
VOLIBRIS and genericAmbrisentan	- 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 or cannot tolerate Revatio or Adcirca (minimum 3 months trial) o For WHO FC III, patients must also have tried and failed or cannot tolerate Tracleer (bosentan) - Coordinate with provincial government program
VOSEVI (Sofosbuvir/Velpatasvir/Voxilaprevir)	- Hepatitis C	- For adult patients with chronic hepatitis C infection, without cirrhosis or with compensated cirrhosis, who have: - Genotypes 1 – 6 and previously treated with an NS5A inhibitor OR - Genotypes 1 – 4 and previously treated with sofosbuvir but not an NS5A inhibitor OR - Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - Retreatment due to re-infection will not be considered - 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
XELODA and generic CAPECITABINE (Capecitabine)	- Adjuvant treatment of stage III (Dukes' stage C) colon cancer - Metastatic colorectal cancer - Metastatic breast cancer	- For the first-line treatment of metastatic colorectal cancer - For the treatment of metastatic colorectal cancer in combination with oxaliplatin after failure of irinotecan-containing combination chemotherapy

DRUG	DISEASE	APPROVAL GUIDELINES
		- For treatment of advanced or metastatic breast cancer after failure of standard therapy including a taxane unless contraindicated OR in combination with docetaxel after failure of prior anthracycline containing chemotherapy - Coordinate with provincial government program
XELJANZ (Tofacitinib)	- Rheumatoid Arthritis - Psoriatic Arthritis - Ulcerative colitis	- For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months or any biologic - 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 active ulcerative colitis who have failed or are intolerant to oral corticosteroid therapy AND a 5-ASA product or immunosuppressant (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have failed or have patient-specific contraindication(s) to at least 2 of the following: infliximab, Humira, Simponi SC, and Entyvio - Coordinate with provincial government program
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
XIAFLEX (Collagenase Clostridium Histolyticum)	- Dupuytren's Contracture with a Palpable Cord - Peyronie's disease	- For patients with a confirmed diagnosis of Dupuytren's Contracture with a palpable cord ▪ Coordinate with provincial government program ▪ Approval maximum: 3 injections per finger - For the treatment of patients with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees • Maximum lifetime approval of 8 injections
XOLAIR Pre-Filled Syringes (PFS) (Omalizumab)	- Severe allergic asthma - Chronic idiopathic urticaria	- For allergic asthma, Xolair vials will only be considered if patient has a latex allergy or contraindication to Xolair PFS - For the treatment of patients 12 years or older who have moderate to severe asthma and 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 high-dose or maximum tolerated doses of ICS with two or more of the following drug classes: LABA, LTRA, and theophylline - For pediatric patients age 6-11 with moderate-severe persistent allergic asthma, with uncontrolled symptoms despite high doses of an inhaled corticosteroid (ICS) and/or a leukotriene receptor antagonist (LTRA) o Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen o Documentation of weight and pretreatment serum IgE - For the treatment of chronic idiopathic urticaria in patients 12 years and older who remain symptomatic despite an adequate trial of a maximum-tolerated dose of H-1 antihistamine for at least 3 months. Prescriber must clearly specify the severity of symptoms (i.e. impact on quality of life, and the extent of the lesions etc.) - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
XTANDI (Enzalutamide)	- Metastatic castration-resistant prostate cancer (mCRPC) - Non-metastatic castration-resistant prostate cancer (nmCRPC)	- For patients with a diagnosis of CRPC AND - Received prior chemotherapy containing docetaxel - In combination with ADT for the treatment of men with non-metastatic castrate resistant prostate cancer (nmCRPC) in patients who are at high risk of developing metastases (i.e. prostate-specific antigen (PSA) doubling time of 10 months or less during continuous ADT) AND ECOG 0-1 - Renewal criteria: Absence of disease progression - Initial and renewal duration: 6 months - 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
ZAXINE (Rifaximin)	- Irritable bowel syndrome with diarrhea (IBS-D) - For reduction in risk of overt hepatic encephalopathy	- For treatment of irritable bowel syndrome with diarrhea (IBS-D) in adult patients who have tried and failed dietary and lifestyle measures and standard therapy (i.e. Imodium) o Lifetime approval maximum of 126 tablets - 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
ZEPATIER (elbasvir/grazoprevir)	- Hepatitis C Infection	- For treatment-naïve or treatment-experienced* adult patients with or without cirrhosis diagnosed with chronic hepatitis C genotype 1 and genotype 4 with: - Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months - Fibrosis stage F2 or greater (Metavir scale or equivalent) - Have failed or have a true contraindication to Maviret - Retreatment requests will not be considered - Coordinate with provincial government program - Maximum approval 12 weeks - *Treatment relapse or failure to standard peg-interferon/ribavirin OR peg-interferon/ribavirin/boceprevir, simeprevir, or telaprevir.
ZYDELIG Idelalisib	- Treatment of patients 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

DRUG	DISEASE	APPROVAL GUIDELINES
ZYTIGA (Abiraterone acetate)	- Metastatic prostate cancer (castration resistant prostate cancer – CRPC) - Hormone-sensitive high-risk metastatic prostate cancer	- For treatment of CRPC in combination with prednisone in patients who have received prior chemotherapy containing docetaxel - For treatment of CRPC in combination with prednisone in patients who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy - For the treatment of newly diagnosed patients with hormone-sensitive metastatic (or castration resistant) prostate cancer in combination with prednisone - Coordinate with provincial government program