Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
ABILIFY MAINTENA (Aripiprazole injection)	• Schizophrenia • Bipolar Disorder • Major Depressive Disorder	• For the treatment of patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in ≥ 1 relapse/hospitalization • For the treatment of manic or mixed episodes in bipolar 1 disorder, as acute monotherapy or in combination with lithium or divalproex sodium • For the treatment of Major Depressive Disorder (MDD) in patients with inadequate response to prior antidepressant treatment
ABRILADA (Adalimumab)	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 • Non-infectious anterior uveitis • Hidradenitis Suppurativa	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

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		oral antibiotics (i.e. dicloxacillin, erythromycin, minocycline, tetracycline, doxycycline) AND the Abscess and Nodule count is ≥ 3.
		• 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
		• Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
		
		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 Etanercept or Actemra SC
		• For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant
		  ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician
		• For patients 12 to 17 years of age 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.
		• Coordinate with provincial government program
		• Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies

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ACLASTA and generic ZOLEDRONIC ACID	• Paget's disease of the bone • Postmenopausal osteoporosis	• For the treatment of Paget's disease • For the treatment of osteoporosis in post-menopausal women and men who have a bone mineral density (BMD) T-score of less than or equal to -2.5 AND who have tried and failed, or have an intolerance or contraindicated to oral bisphosphonate therapy
ACTEMRA IV (Tocilizumab)	• Rheumatoid Arthritis • Systemic Juvenile Idiopathic Arthritis (sJIA) • Polyarticular Juvenile Idiopathic Arthritis (pJIA)	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 monthsAND who have tried and failed Cimzia or Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC • For pediatric patients (between ≥ 2 and ≤ 16 years of age) with a confirmed diagnosis of sJIA with fever (>38°C) 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 AND tried and failed Actemra SC • 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 Etanercept or Actemra SC • Coordinate with provincial government program
ACTEMRA SC (Tocilizumab)	• Rheumatoid Arthritis • Giant Cell Arthritis (GCA) • Polyarticular Juvenile Idiopathic Arthritis (pJIA) • Systemic Juvenile Idiopathic Arthritis (sJIA)	• 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 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 • For patients ages 2 and older with a confirmed diagnosis of polyarticular 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

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		• For pediatric patients (between ≥ 2 and ≤ 16 years of age) with a confirmed diagnosis of sJIA with fever (>38°C) 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 • Coordinate with provincial government program
ADCIRCA and generic 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)

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:
		  • Inoperable disease OR
		  • 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

ADLYXINE (Lixisenatide)	• Type II Diabetes	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)

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AFINITOR and generic EVEROLIMUS
 	
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:
		  ○ Progressed within the last 12 months, AND
		  ○ With an ECOG ≤ 2
		• For postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer in combination with exemestane after recurrence or progression following treatment with letrozole or anastrozole
		• For the treatment of adult patients (≥18 years of age) with renal angiomyolipoma associated with tuberous sclerosis complex (TSC), who do not require immediate surgery
		• For the treatment of patients 3 years of age or older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) that have demonstrated serial growth, who are not candidates for surgical resection and for whom immediate surgical intervention is not required
		• 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:
		  ○ Progressed on or after the last treatment AND
		  ○ 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

DRUG	DISEASE	APPROVAL GUIDELINES
AIMOVIG (Erenumab)	• Episodic or chronic migraine	Initial criteria (6 months): • 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 3 migraine prevention therapies (e.g.: tricyclic analgesics, antiepileptic drugs, beta blockers, Botox). • Must indicate: ○ Number of migraine days per month, and ○ If at least 15 headache days per month, must have tried and failed Botox for 6 months unless intolerance or contraindication Renewal criteria (1 year): • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
AJOVY (Fremanezumab)	• Episodic or chronic migraine	Initial criteria (6 months): • 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 3 migraine prevention therapies (e.g.: tricyclic analgesics, antiepileptic drugs, beta blockers, Botox). • Must indicate: ○ Number of migraine days per month, AND ○ If at least 15 headache days per month, must have tried and failed Botox for 6 months unless intolerance or contraindication Renewal Criteria (1 year): • Clinical benefit demonstrated by ≥50% reduction in number of migraine days per month vs. baseline
GENERIC AMLODIPINE ORAL SOLUTION (Amlodipine Besylate)	• Pediatric Hypertension • Hypertension • Angina	• For management of hypertension or angina in patients (>6 years old) who are medically unable to swallow amlodipine tablets
AMGEVITA (Adalimumab)	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	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

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	PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis	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. • 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 • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies 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 Etanercept or Actemra SC • For patients aged 2 or older with a confirmed

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		diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • Coordinate with provincial government program • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
ANDROGEL PUMP (Testosterone 1% pump)	• Endogenous testosterone deficiency	• For patients who have tried and failed Testosterone packets (i.e. generic Androgel packets)
ANORO ELLIPTA (Umeclidinium/Vilanterol)	• Chronic Obstructive Pulmonary Disease (COPD)	• For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy
APPRILON and generic DOXYCYCLINE	• Rosacea	• For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)
APTIOM (Eslicarbazepine Acetate)	• Partial-onset seizures	• For patients with a diagnosis of partial onset seizures who have tried and failed or experienced intolerant side effects to at least 1 standard care drug i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
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 generic EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	• HIV anti-viral	• Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
AUBAGIO and generic TERIFLUNOMIDE	• Relapsing Remitting Multiple Sclerosis (RRMS)	• Confirmed diagnosis of RRMS • EDSS value required with every application • Coordinate with provincial government program
AVODART and generic DUTASTERIDE	• Benign Prostatic Hyperplasia	• For male patients in the treatment of benign prostatic hyperplasia
AVONEX AVONEX PS REBIF REBIF MULTIDOSE CARTRIDGE (	• Relapsing Remitting Multiple Sclerosis (RRMS) • Chronic Progressive Multiple Sclerosis • Clinically Isolated Syndrome (CIS)	• For patients with RRMS OR progressive MS OR clinically isolated syndrome with abnormal brain MRI at presentation • EDSS value required with every application • Coordinate with provincial government program
AVSOLA (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	ADULT • For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND 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 PEDIATRIC

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		• Patients 9 years of age or older with moderately to severely active 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 6 years of age or older 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 provincial government program
BANZEL (Rufinamide)	• Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome	• For the treatment of Lennox Gastaut Syndrome in children 4 years and older and adults, in combination with other anti-epileptic drugs (e.g. valproic acid, topiramate, lamotrigine)
BASAGLAR (Insulin glargine)	• Diabetes mellitus	• For patients who are at high risk for hypoglycemia
BENLYSTA (Belimumab)	• Systemic Lupus Erythematosus (SLE)	Initial Criteria (1 year): • 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 and/or dsDNA positive) AND have a SELENA-SLEDAI score ≥ 6 AND who have tried and failed or are intolerant to corticosteroids AND hydroxychloroquine Renewal Criteria (1 year): • Achieving/maintaining a SELENA-SLEDAI reduction of 4 points or more
BEOVU (Brolucizumab)	• Age related macular degeneration (AMD)	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD)
BETASERON (Interferon beta-1b)	• Clinically Isolated Syndrome (CIS) • Relapsing Remitting Multiple Sclerosis (RRMS) • Chronic Progressive Multiple Sclerosis	• For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation OR for patients with RRMS OR progressive MS • EDSS value required • Coordinate with provincial government program
BIKTARVY (Bictegravir/Emtricitabine/Tenofovir alafenamide)	• HIV infection in adults	• For treatment of HIV-1 infection in adults • Coordinate with provincial plans

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BIPHENTIN CR (Methylphenidate controlled release)	• Attention deficit hyperactivity disorder	• For patients who have tried and failed or had intolerable side effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera
BOSULIF (Bosutinib)	• Chronic myeloid leukemia (CML)	• For the treatment of adults with any phase of Philadelphia chromosome positive chronic myeloid leukemia (chronic, accelerated, or blast phase) 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 (Ph+ CML) • Coordinate with provincial government program

BOTOX
(Onabotulinumtoxin A)
	• Blepharospasm
	• Strabismus
	• Cervical dystonia (spasmodic torticollis)
	• Focal spasticity
	• Axillary Hyperhidrosis
	• Chronic Migraines
	• Bladder Dysfunction
		• For the treatment of blepharospasm and strabismus in patients 12 years of age or older
		  ○ Max dose for blepharospasm = 100U per eye every 2 months
		• For the treatment of torticollis in adult patients
		  ○ Max dose for cervical dystonia (spasmodic torticollis) =400U every 3 months
		• For focal spasticity
		  ○ Max dose for adult upper limb focal spasticity = 400 units every 12 weeks
		  ○ Max dose for adult lower limb focal spasticity = 400 units every 12 weeks
		  ○ Max dose for upper limb spasticity in pediatric patients 2 years of age or older = 200 units every 12 weeks
		  ○ Max dose for lower limb spasticity in pediatric patients 2 years of age or older = 300 units every 12 weeks
		• For axillary hyperhidrosis in patients that have failed or are intolerant to an aluminum chloride preparation
		  ○ 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 2 prophylactic treatments, e.g. tricyclic antidepressants (amitriptyline, nortriptyline), antiepileptic drugs (topiramate, divalproex), beta blockers (propanolol, metoprolol), calcium channel blockers (verapamil), SNRIs (venlafaxine, duloxetine).
		  ○ 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: generic Ditropan, generic Ditropan XL, generic Enablex,

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		generic Vesicare, generic Detrol, generic Detrol LA, Toviaz, generic Trosec ○ Max dose for OAB = 100U every 3 month ○ Max dose for neurogenic bladder = 200U every 3 months
BRENZYS (Etanercept)	• Ankylosing Spondylitis • Rheumatoid Arthritis • Plaque Psoriasis • Psoriatic Arthritis • Juvenile Idiopathic 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 • 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 • 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 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 • Coordinate with provincial government program
BRILINTA and generic TICAGRELOR	• Secondary prevention of atherothrombotic events in Acute Coronary Syndrome	• For use in combination with ASA in patients with Acute Coronary Syndrome (STEMI or NSTEMI) who: ○ have tried and failed or are intolerant to clopidogrel OR ○ require revascularization via PCI • For the secondary prevention of a myocardial infarction (MI) after the initial 12 months of treatment with dual antiplatelet therapy in patients at high risk of a subsequent MI as defined by at least one of the following: age ≥ 65, diabetes treated with a medication, second prior spontaneous MI, angiographic evidence of multivessel coronary artery disease, chronic renal dysfunction (CrCl< 60 mL/min) • Dual antiplatelet therapy will be approved for a maximum of 3 years (initial approval of 1 year

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		with 90 mg strength; subsequent approval of 2 years with 60 mg strength)
BRIVLERA (Brivaracetam)	• Partial-onset seizures	• For use as adjunctive therapy in the treatment of partial onset seizures in patients 4 to 5 years of age who have tried and failed or experienced intolerant side effects to 1 or more standard care drugs • For use as adjunctive therapy in the treatment of partial onset seizures in patients 6 years and older of age who have tried and failed or experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
BUTRANS (Buprenorphine transdermal)	• Severe pain	• For pain management in patients who are unable to tolerate or receive an adequate response to treatment with opioid therapy
BYDUREON (Exenatide extended release) BYETTA (Exenatide)	• Type II Diabetes	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
BYSTOLIC (Nebivolol)	• Essential hypertension	• For the treatment of mild to moderate essential hypertension in patients who have tried and failed or had intolerable side effects to at least two generic drugs in the class of beta1-selective blockers (atenolol, bisoprolol, metoprolol)
CAMBIA (Diclofenac Potassium)	• For acute treatment of migraine attacks	• For patients 18 years of age and older who have tried and failed or experienced intolerable side effects to at least one drug in each of the following classes: prescription NSAIDs and triptans

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CAPRELSA (Vandetanib)	• For the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in adult patients with unresectable or locally advanced or metastatic disease	• For patients with unresectable locally advanced or metastatic MTC that have enrolled with the CAPRELSA Restricted Distribution Program • Coordinate with available provincial plans
CAVERJECT (Alprostadil) CIALIS (Tadalafil) LEVITRA (Vardenafil) MUSE (Alprostadil) VIAGRA (Sildenafil) STAXYN (Vardenafil)	• Erectile Dysfunction	• Erectile dysfunction related to one of the following conditions: • Adverse side-effect to prescription drugs (e.g., beta blockers, etc.). Medical documentation must be present to validate the drug as causing the problem (up to one year approval) • Diabetes mellitus and is on medication(s) and/or insulin (Lifetime approval) • Aorta-iliac disease with evidence of decreased blood flow (e.g., abnormal Doppler studies or absent pulses) (Lifetime approval) • Post radical prostatectomy and radiation of the prostate (Lifetime approval) • Neurological injury or disease (e.g. Multiple Sclerosis, spinal cord injury) (Lifetime approval) • Endocrine abnormalities (i.e. specifically low testosterone levels not responding to testosterone treatment) (Lifetime approval) • Psychiatric disorder for which the patient is receiving medication or treatment from a psychiatrist (up to one year approval) • Annual maximum: $1,000 per year
CAYSTON (Aztreonam)	• Treatment of pulmonary infection with Pseudomonas aeruginosa in Cystic Fibrosis Patients	• For patients with confirmed Cystic Fibrosis and pulmonary infection with Pseudomonas aeruginosa, who have tried and failed or did not tolerate prior therapy with TOBI • Co-ordinate with provincial programs where possible
CELSENTRI (Maraviroc)	• HIV anti-viral	• For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) • Coordinate with provincial government program
CEQUA (Cyclosporine)	• Moderate to severe dry eye disease	• For the treatment of moderate to severe dry eye disease for patients who had an insufficient response to artificial tears

DRUG	DISEASE	APPROVAL GUIDELINES
CIMZIA (Certolizumab pegol)	• Moderate to Severe Rheumatoid Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Plaque Psoriasis • Axial Spondyloarthritis	• 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 ≥ 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 oral systemic therapies (i.e. methotrexate, cyclosporine) AND who are being treated by a dermatologist • For patients with confirmed diagnosis of severe, active non-radiographic axial spondyloarthritis where symptoms are uncontrolled by NSAIDs • Coordinate with provincial government program
CINQAIR (Reslizumab)	• Severe eosinophilic asthma	• For the add on maintenance treatment of severe eosinophilic asthma in patients 18 years or older who meet the following criteria: ○ Trial and failure of high-dose inhaled corticosteroids and an additional asthma controller (ie. long-acting beta-agonist), AND ○ Blood eosinophil count of ≥ 400 cells/μL OR induced sputum eosinophil count of 3% or more in the past 12 months, AND≥ 2 clinically significant asthma exacerbation in the past 12 months
COPAXONE (Glatiramer acetate) GLATECT (Glatiramer acetate)	• Relapsing Remitting Multiple Sclerosis (RRMS) • Clinically Isolated Syndrome (CIS)	• For patients with RRMS AND an EDSS value of less than or equal to 6 • For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation AND an EDSS value of less than or equal to 6 • EDSS value of less than or equal to 6 required with every application • Coordinate with provincial government program where applicable

DRUG	DISEASE	APPROVAL GUIDELINES
COMPLERA (Rilpivirine/emtricitabine/tenofovir disoproxil fumarate)	• HIV anti-viral	• Coordinate with provincial government program
CONSTELLA (Linaclotide)	• Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC)	• For patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
CONTRAVE (Naltrexone/Bupropion)	• Anti-Obesity	<u>Initial Authorization Approval (6 months)</u> • Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery AND trial and failure of prescribed lifestyle therapy (diet and exercise) for at least three months prior to starting Contrave AND • trial and failure of therapy with Xenical for at least 6 months prior to Contrave AND continuation of prescribed lifestyle therapy (diet and exercise) while using Contrave • Weight prior to initiation of treatment <u>Subsequent Authorization Approval (6 months):</u> • Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery AND a minimum reduction of 6% of initial body weight and continuation of prescribed lifestyle therapy (diet and exercise) while using Contrave • Current weight • Approval dosing limit: maximum of 4 tablets per day • Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan

Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
COSENTYX (Secukinumab)	• Ankylosing spondylitis • Plaque Psoriasis • Psoriatic Arthritis • Non-radiographic axial spondyloarthritis (nr-axSpA)	• For patients who are 6 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 • For patients with confirmed diagnosis of severe, active non-radiographic axial spondyloarthritis where symptoms are uncontrolled by NSAIDs • Coordinate with provincial government program
COSOPT (Dorzolamide and timolol preservative-free ophthalmic solution)	• Elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	• For patients who are allergic to or cannot tolerate ophthalmic preservatives
CORZYNA (Ranolazine)	• Stable angina	• As add-on therapy for patients with stable angina who have insufficient response, intolerance or contraindication to beta-blockers (e.g. atenolol, bisoprolol) and calcium channel blockers (e.g. amlodipine, diltiazem)
CRESEMBA (Isavuconazole)	• Invasive aspergillosis (IA) • Invasive mucormycosis (IM)	• For the treatment of adult patients (18+) with invasive aspergillosis (IA) post-hospital discharge who have failed or cannot tolerate voriconazole and amphotericin B; authorization period: 12 weeks • For the treatment of adult patients (18+) with invasive mucormycosis (IM) post-hospital discharge who have failed or cannot tolerate amphotericin B; authorization period: 6 months • Any doses given in hospital will not be considered
CUVPOSA (Glycopyrrolate)	• Sialorrhea	• Confirmed diagnosis of sialorrhea in patients aged 3-18 with cerebral palsy or brain injury • Current patient weight • Maximum dose of 3 mg three times a day

Special Authorization Drugs and Approval Guidelines

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**

DAXAS (Roflumilast)	• Chronic Obstructive Pulmonary Disease (COPD)	• Diagnosis of COPD, including chronic bronchitis and emphysema • Coordinate with provincial coverage if available
DAYVIGO (Lemborexant)	• Insomnia	• For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
DELSTRIGO (Doravirine/lamivudine/tenofovir disoproxil fumarate)	• HIV Infection	• Coordinate with provincial government program
DESCOVY (Emtricitabine/tenofovir alafenamide)	• HIV Infection • Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	• For patients who require Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection who have tried generic Truvada, unless intolerance or contraindication • Coordinate with provincial government program
DEXILANT (Dexlansoprazole)	• Erosive esophagitis • Non-erosive gastroesophageal reflux disease (GERD)	• For patients who are unresponsive or intolerable to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole
DIACOMIT (Stiripentol)	• Dravet Syndrome or Severe Myoclonic Epilepsy in Infancy (SMEI)	• For patients 3 years of age or older with refractory SMEI or Dravet Syndrome: ○ Must be used in conjunction with clobazam and valproate after failure with clobazam and valproate alone • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
DOVATO (Dolutegravir/Lamivudine)	• HIV anti-viral	• Coordinate with provincial government program
DUAKLIR GENUAIR (Aclidinium bromide and Formoterol Furmarate)	• Chronic Obstructive Pulmonary Disease (COPD)	• For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on optimal doses of either a LAMA or LABA alone
DUODOPA (Levodopa/carbidopa intestinal gel)	• Parkinson's disease	• For individuals with advanced Parkinson's disease and who have tried and failed other oral therapies for control of severe, disabling motor fluctuations • Individuals are being screened and managed by specialists and at appropriate centers where the individuals have responded to the drug during the test phase • Coordinate with provincial government program
DUPIXENT (Dupilumab)	• Severe atopic dermatitis • Severe chronic rhinosinusitits with nasal polyps (CRSwNP) • Severe type 2/eosinophilic asthma • Oral corticosteroid-dependent asthma	<u>Initial Approval: 6 months duration</u> • For the treatment of patients 6 years and older 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 (18+ only); ○ Inadequate response, intolerance or contraindication to phototherapy AND two immunosuppressants (e.g. cyclosporine, azathioprine, methotrexate) <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 (18+ only) <u>Initial Approval: 6 months duration</u> • For the treatment of adult patients (18+) with confirmed severe chronic rhinosinusitis with nasal polyps (CRSwNP) ○ Severity defined as meeting all 3 conditions below: 1) NPS (nasal polyp score) > 5 (with minimum score of 2 for each nasal cavity) 2) NC (nasal congestion) score of 3 3) Ongoing symptoms for more than 12 weeks (e.g. nasal congestion, blockage,

DRUG	DISEASE	APPROVAL GUIDELINES
		loss of smell, rhinorrhea) ○ Tried and failed each of the below: 1) Intranasal corticosteroid (e.g. generic Mometasone, generic Budesonide, etc.) 2) Oral corticosteroid therapy, unless contraindicated 3) Prior sinonasal surgery for nasal polyps • Will not be approved in combination with another biologic (e.g. Nucala, CInqair, Fasenra, Xolair) Renewal criteria: 1 year duration • Reduction in NPS score of 2 or more, AND • Reduction in NC score of 1 or more Initial Approval: 6 months duration • For add-on maintenance treatment of severe type 2/eosinophilic asthma in patients 6 years or older who meet all of the following criteria: 1) Trial and failure of medium-to-high dose inhaled corticosteroids and an additional asthma controller, e.g. long-acting beta agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), theophylline 2) Documentation of pre-bronchodilator FEV1 ≤ 80% predicted for adults or ≤ 90% for adolescents, i.e. baseline FEV1 3) Two or more clinically significant asthma exacerbations in the last 12 months, e.g. requiring treatment with a systemic corticosteroid or hospitalization/emergency medical care visit for worsening asthma 4) Documentation of blood eosinophils ≥ 150 cells/μL (0.15 GI/L) OR fractional exhaled nitric oxide (FeNO) ≥ 25ppb Renewal criteria: 1 year duration • At least 50% reduction in number of exacerbations while on Dupixent, AND • Improvement in FEV1 from baseline, i.e. current FEV1 Initial Approval: 6 months duration • For add-on maintenance treatment of oral corticosteroid-dependent asthma in patients 6 years or older who meet all of the following criteria: 1) Trial and failure of maintenance systemic corticosteroids for at least 4 weeks i.e. ≥5mg/day of prednisone or equivalent 2) Trial and failure of medium-to-high dose inhaled corticosteroids and an additional asthma controller, e.g. long-acting beta agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), theophylline 3) Documentation of pre-bronchodilator FEV1

DRUG	DISEASE	APPROVAL GUIDELINES
		≤80% predicted for adults or ≤90% for adolescents, i.e. baseline FEV1 4) Two or more clinically significant asthma exacerbations in the last 12 months, e.g. requiring treatment with a systemic corticosteroid or hospitalization/emergency medical care visit for worsening asthma <u>Renewal criteria: 1 year duration</u> • At least 50% reduction in daily oral corticosteroid dose while on Dupixent, AND • Improvement in FEV1 from baseline, i.e. current FEV1 • **Will not be approved in combination with another biologic (e.g. Nucala, Cinqair, Fasenra, Xolair)**
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)
EDARBI (Azilsartan) EDARBYCLOR (Azilsartan/Chlorthalidone)	• Mild to moderate essential hypertension	• For patients who have tried and failed or have had intolerable side effects to at least two generic ACE inhibitor or ACE inhibitor combination product(s) OR generic ARB or generic ARB combination product(s)
ELIDEL (Pimecrolimus 1% cream)	• Atopic dermatitis	• A confirmed diagnosis of atopic dermatitis (eczema) for individuals who have failed or intolerant to treatments with topical corticosteroid therapy

EMGALITY
(galcanezumab)
	• 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 3 migraine prevention therapies (e.g.: tricyclic analgesics, antiepileptic drugs, beta blockers, Botox).
		• Must indicate:
		  ○ Number of migraine days per month, and
		  ○ If at least 15 headache days per month, must have tried and failed Botox for 6 months unless intolerance or contraindication, and
		  ○ Trial and failure of Aimovig or Ajovy for 6 months, unless intolerance or contraindication

DRUG	DISEASE	APPROVAL GUIDELINES
		Renewal criteria (1 year): • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
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
ENTRESTO (Sacubitril/Valsartan)	• Heart failure with reduced ejection fraction	• For adult patients diagnosed with heart failure with reduced ejection fraction AND all of the following: ○ LVEF ≤ 40% ○ Patients with NYHA class II or III ○ Previously treated with an ACEI or ARB ○ In combination with a beta blocker unless there is a contraindication or an intolerance

DRUG	DISEASE	APPROVAL GUIDELINES
ENTYVIO SC (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 at least ONE of the following: Infliximab, Adalimumab, Simponi, or Stelara • 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 at least ONE of the following: Infliximab, Adalimumab, or Stelara • Coordinate with provincial government programs
ENTYVIO IV (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 at least ONE of the following: Infliximab, Adalimumab, Simponi, or Stelara AND are medically unable to use Entyvio 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 at least ONE of the following: Infliximab, Adalimumab, or Stelara AND are medically unable to use Entyvio SC • 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

DRUG	DISEASE	APPROVAL GUIDELINES
		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 • 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 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 • For patients 4 years old and older with 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

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) • Metastatic castration-sensitive prostate cancer	Initial Criteria (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 Criteria (6 months): • Absence of disease progression • Maximum dose: 240 mg once a day Initial Criteria: • For adult patients with a diagnosis of metastatic Castration-Sensitive Prostate Cancer (CSPC) AND one of the following: ○ has ECOG score of ≤ 1 OR ○ has received prior docetaxel treatment meeting the following criteria: ○ received a maximum of 6 cycles of docetaxel therapy for metastatic CSPC AND ○ received the last dose of docetaxel within 2 months AND ○ has maintained response to docetaxel therapy Renewal Criteria: • Absence of disease progression
ESBRIET and generic 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

DRUG	DISEASE	APPROVAL GUIDELINES
GENERIC ESCITALOPRAM ODT (Escitalopram)	• Major Depressive Disorder	• For patients who have tried and failed OR had intolerable side effects OR are medically unable to swallow generic escitalopram tablets
EUCRISA (Crisaborole)	• Atopic dermatitis	• For patients with atopic dermatitis (eczema) who have failed or are intolerant to treatments with topical corticosteroid therapy

EVENITY (Romosozumab)	• Osteoporosis	• For the treatment of osteoporosis in postmenopausal women at high risk of fracture, defined as:
		  ○ Bone mineral density (BMD) with T score ≤ -2.50 AND
		  ○ A history of osteoporotic fractures while on bisphosphonates OR at least two risk factors for fracture (e.g. age ≥ 50, minimum of 3 months of sustained systemic glucocorticoid therapy, confirmed diagnosis of rheumatoid arthritis, non-trauma related fracture after age 40)
		• Lifetime approval maximum of 12 months

EXTAVIA (Interferon beta-1b)	• Clinically Isolated Syndrome (CIS) • Relapsing Remitting Multiple Sclerosis (RRMS) • Chronic Progressive Multiple Sclerosis	• For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation OR for patients with RRMS OR progressive MS • EDSS value required • Coordinate with provincial government program
EYLEA (Aflibercept)	• Wet age-related macular degeneration • Macular edema secondary to Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO) • Diabetic Macular Edema (DME) • Myopic choroidal neovascularization (myopic CNV)	• 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 • For patients with a confirmed diagnosis of myopic choroidal neovascularization (myopic CNV) • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
FAMPYRA and generic 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 months 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)
FASENRA (Benralizumab)	• Severe eosinophilic asthma	• For the add on maintenance treatment of severe eosinophilic asthma in patients 18 years or older who meet the following criteria: ○ Trial and failure of high-dose inhaled corticosteroids and an additional asthma controller (ie. long-acting beta-agonist), AND ○ Blood eosinophil count of ≥ 150 cells/µL (0.15 GI/L) while receiving maintenance treatment with oral corticosteroids OR ≥300 cells/µL in the past 12 months with ≥2 clinically significant asthma exacerbations (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization)
FASLODEX and generic FULVESTRANT	• Locally advanced or metastatic breast cancer	• First-line treatment 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 • Second-line treatment for postmenopausal women who have failed or had intractable side effects to tamoxifen and/or other aromatase inhibitors (ex. Letrozole) • In combination with Kisqali, Ibrance OR Verzenio for the treatment of postmenopausal women with HR-positive, HER2- negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment-naïve ○ Initial Approval for 6 months ○ Renewal Criteria for 6 months: ○ Absence of disease progression
FENTANYL	• Severe pain	• For pain management in patients who are unable to tolerate or receive an adequate response to treatment with long-acting opioids such as sustained release morphine, sustained release hydromorphone, and/or sustained

DRUG	DISEASE	APPROVAL GUIDELINES
		release oxycodone
FENTORA (Fentanyl citrate)	• Breakthrough cancer pain	• For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day who are currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) AND have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR
FETZIMA (Levomilnacipran)	• Major Depressive Disorder	• For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other extended release SNRIs
FIBRISTAL (Ulipristal Acetate)	• For the treatment of moderate to severe signs and symptoms of uterine fibroids	• For women of reproductive age with uterine fibroids • Lifetime approval limit maximum of 360 tablets
FIRDAPSE (Amifampridine phosphate)	• Lambert-Eaton Myasthenic Syndrome (LEMS)	<u>Initial approval (6 months):</u> • For the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome in patients treated by a neurologist • Must include baseline 3TUG value <u>Renewal (1 year):</u> • Demonstrates a noted improvement in symptoms from baseline (i.e. more than 30% reduction in 3TUG value from baseline)
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
FOQUEST (Methylphenidate hydrochloride)	• Attention deficit hyperactivity disorder	• For patients 6 years and older who have tried and failed or had intolerable side effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera

DRUG	DISEASE	APPROVAL GUIDELINES

FORTEO
(Teriparatide)
	• Osteoporosis
	• Osteoporosis associated with sustained systemic glucocorticoid therapy
		• For patients with severe osteoporosis where patient has a bone mineral density (BMD) T score of less than -3.5 SD AND history of non-trauma related fractures while on bisphosphonates
		  ○ For patients who are previously stabilized on Forteo OR patients who are medically unable to use Osnuvo OR generic Teriparatide
		  ○ For Teriparatide naïve patients, only Osnuvo OR generic Teriparatide will be approved
		• For patients with severe osteoporosis where patient has a bone mineral density (BMD) T score of less than -1.5 SD and a minimum of 3 months of sustained systemic glucocorticoid therapy
		  ○ For patients who are previously stabilized on Forteo OR patients who are medically unable to use Osnuvo OR generic Teriparatide
		  ○ For Teriparatide naïve patients, only Osnuvo OR generic Teriparatide will be approved
		• Maximum lifetime treatment: 24 months

FORXIGA
(Dapagliflozin)
	• Heart failure with reduced ejection fraction (HFrEF)
	• Chronic Kidney Disease
		• Adult patients diagnosed with heart failure with reduced ejection fraction (HFrEF) AND all of the following:
		  ○ LVEF < 40%
		  ○ NYHA class II to IV
		  ○ Previously treated with an ACE inhibitor or ARB AND beta-blocker unless there is a contraindication or an intolerance
		• For patients with a confirmed diagnosis of chronic kidney disease who had insufficient response to an ACE inhibitor or ARB

FORXIGA (Dapagliflozin) XIGDUO (dapagliflozin/metformin)	• Diabetes mellitus	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective • For the treatment of patients with type-2 diabetes who have established cardiovascular disease
FREESTYLE LIBRE (Sensors only)	• Glucose monitoring for diabetic patients	• For blood glucose monitoring in diabetic patients 4 years of age and older treated with insulin • Approval Maximum 26 sensors per calendar year

DRUG	DISEASE	APPROVAL GUIDELINES
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
FYCOMPA (Perampanel)	• Partial onset seizures • Primary Generalized Tonic-Clonic Seizures	• For patients with a diagnosis of partial onset seizures or primary generalized tonic-clonic seizures (PGTCS) AND who have tried, failed or experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
GELNIQUE (Oxybutynin chloride gel)	• For the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency	• For patients who have tried and failed or had intolerable side effects to two of the following oral anticholinergics: generic Ditropan, generic Ditropan XL, generic Enablex, generic Vesicare, generic Detrol, generic Detrol LA, Toviaz, or generic Trosec
GENOTROPIN (Somatropin)	• Growth Hormone Deficiency in children • Small for gestational age • Turner Syndrome • Idiopathic Short Stature • Adult Growth Hormone Deficiency	• 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 small for gestational age defined as 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 the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed • For treatment of idiopathic short stature which is defined as: (i) diagnostic evaluation that excludes other causes of short stature; and (ii) height at least 2.25 standard deviation scores below the mean for age and sex; and (iii) patients whose epiphyses are not closed • 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 growth hormone deficiency (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease;

DRUG	DISEASE	APPROVAL GUIDELINES
		surgery (pituitary gland tumour ablation); radiation therapy; or trauma. • Coordinate with provincial government program
GENVOYA (Cobicistat/Emtricitabine/Elvitgravir/Tenofovir Alafenamide)	• HIV Infection	• Coordinate with provincial government program
GILENYA and generic FINGOLIMOD	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For the treatment of patients 10 year or older with RRMS in patients who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) o EDSS value required with every application • Coordinate with provincial government program
GIOTRIF (Afatinib)	• Lung adenocarcinoma	• For patients with a confirmed diagnosis of metastatic lung adenocarcinoma (i.e. specific type of non-small cell lung cancer) with activating EGFR mutation(s) who have NOT previously tried and failed EGFR tyrosine kinase inhibitors (e.g. Iressa or Tarceva) • Coordinate with provincial government program
GLEEVEC and generic IMATINIB	• Chronic myeloid leukemia (CML) • Gastrointestinal Stromal Tumour (GIST) • Acute Lymphoblastic Leukemia (ALL)	• For the treatment of adults with newly diagnosed, Philadelphia-chromosome positive, CML in chronic phase OR for the treatment of adults with any phase Philadelphia chromosome-positive CML (chronic, accelerated, or blast phase) after failure of interferon-alpha therapy • For the treatment of C-Kit positive (CD 117) inoperable recurrent and/or metastatic GIST • For the adjuvant treatment of adult patients who are at intermediate to high risk of relapse following complete resection of Kit (CD117) positive GIST. Maximum total approval up to 3 years. • Coordinate with provincial government program
GLUMETZA and generic METFORMIN ER	• Diabetes	• For patients who have tried and failed or had intolerable side effects to regular release Metformin
GLYXAMBI (Empagliflozin/Linagliptin)	• Diabetes	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective

DRUG	DISEASE	APPROVAL GUIDELINES
GRASTEK (Standardized allergenic extract, Timothy Grass)	• Moderate to severe seasonal grass pollen allergic rhinitis	• For the treatment of allergic rhinitis in patients 5 years of age and older, who are: ○ Skin test positive to grass pollen and/or positive titre to pollen-specific IgE antibodies ○ Symptomatic for at least 2 pollen seasons ○ Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen-specific Immunotherapy injections
HADLIMA (Adalimumab)	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 • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis	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,

DRUG	DISEASE	APPROVAL GUIDELINES

		minocycline, tetracycline, doxycycline) AND the Abscess and Nodule count is ≥ 3.
		• 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
		• Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
		
		PEDIATRIC
		• 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 Etanercept or Actemra SC
		• For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant
		  ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician
		• Coordinate with provincial government program
		• Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies

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

DRUG	DISEASE	APPROVAL GUIDELINES
HEMANGIOL (Propranolol)	• Proliferating Infantile Hemangioma	• For infants 6 months of age or under diagnosed with Infantile Hemangioma • Maximum duration of treatment is 6 months per lifetime
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
HEPTOVIR (Lamivudine)	• Chronic hepatitis B	• For treatment of chronic hepatitis B • Coordinate with provincial government program
HULIO (Adalimumab)	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 • Non-infectious anterior uveitis	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

DRUG	DISEASE	APPROVAL GUIDELINES
		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. • 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 Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
HUMATROPE (Somatropin)	• Growth Hormone Deficiency in Children • Small for Gestational Age • Turner syndrome • Idiopathic Short Stature • Adult Growth Hormone Deficiency	• 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 small for gestational age defined as 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 the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed • For treatment of idiopathic short stature 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 • For adults who have growth hormone deficiency (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 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 • Coordinate with provincial government program
HUMIRA (Adalimumab)	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	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

DRUG	DISEASE	APPROVAL GUIDELINES
	PEDIATRIC • Crohn's Disease • Moderate to severe active Ulcerative Colitis • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa	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. • 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 • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies 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 patients 5 to 17 years of age 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 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

DRUG	DISEASE	APPROVAL GUIDELINES
		DMARD, AND who has tried and failed Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • For patients 12 to 17 years of age 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. • Coordinate with provincial government program • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
HYDROMORPHONE CONTINUOUS RELEASE (e.g. Hydromorph Contin)	• Severe pain	• For pain management in patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of hydromorphone or the sustained release preparations of morphine
HYRIMOZ (Adalimumab)	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	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

DRUG	DISEASE	APPROVAL GUIDELINES
	PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa	• 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. • 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 Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • For patients 12 to 17 years of age 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

DRUG	DISEASE	APPROVAL GUIDELINES
		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. • Coordinate with provincial government program
IBAVYR (Ribavirin)	• Hepatitis C	• For the treatment of CHC in combination with other antiviral agents • If used in combination with Sovaldi with Hepatitis C Genotype 2 or 3, must first try and fail standard Peg-Interferon+ RBV therapy. Ibavyr may also be considered for members contraindicated to Peg-Interferon
IBRANCE (Palbociclib)	• 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 <u>Initial Criteria (6 month duration)</u> • In combination with generic Faslodex for the treatment of postmenopausal women with HR-positive, HER2- negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment naïve <u>Renewal Criteria (6 month duration)</u> • Continue until unacceptable toxicity or disease progression
IBSRELA (tenapanor hydrochloride)	• Irritable Bowel Syndrome with Constipation (IBS-C)	• For patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna,

DRUG	DISEASE	APPROVAL GUIDELINES
		castor oil).
ICLUSIG (Ponatinib hydrochloride)	• Chronic myeloid leukemia (CML) • Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)	**Chronic Myeloid Leukemia:** Initial Request (3 month approval): • For patients with chronic phase (CP), accelerated phase (AP), or blast phase (BP) chronic myeloid leukemia (CML) 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 • Proof of continued enrollment in the patient support program • Coordinate with provincial drug programs **Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)** Initial Request (3 month approval): • For patients who are resistant or intolerant to imatinib AND dasatinib, and for whom subsequent treatment with imatinib and dasatinib is not clinically appropriate • Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase • ECOG≤1 • Proof of enrollment in the Support Program • Coordinate with provincial government program Renewal (3 month approval): • Demonstration of hematological response (i.e. Normalization of WBC) showing absence of disease progression (provide lab values) • Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase • Proof of continued enrollment in the patient

DRUG	DISEASE	APPROVAL GUIDELINES
		support program • Coordinate with provincial drug programs

DRUG	DISEASE	APPROVAL GUIDELINES
IDACIO (Adalimumab)	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 • Non-infectious anterior uveitis	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. • 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 • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies

DRUG	DISEASE	APPROVAL GUIDELINES
		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 Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • Coordinate with provincial government program • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
ILUMYA (Tildrakizumab)	• Plaque Psoriasis	• For patients 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement who have tried phototherapy AND have tried or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
ILUVIEN (Fluocinolone)	• Diabetic Macular Edema (DME)	• For the treatment of patients with Diabetic Macular Edema who responded successfully to a previous treatment with a course of corticosteroids (i.e. Triamcinolone acetonide, Ozurdex) and did not have a clinically significant rise in intraocular pressure • Validate site of administration • An approval of 1 implant for one affected eye at a time for 36 months

DRUG	DISEASE	APPROVAL GUIDELINES

IMBRUVICA
(Ibrutinib)
	• Chronic lymphocytic leukemia (CLL), including 17p deletion	Initial Criteria – 6 months ONLY
		• For the treatment of CLL in symptomatic patients with evidence of progression:
		  ○ Who failed or are experiencing recurrent disease despite prior therapy (e.g. Fludarabine, Ofatumumab, Chlorambucil, etc.) OR
		  ○ For patients with CLL 17p deletion in whom stem cell transplant surgery is inappropriate
		• ECOG ≤ 1
		• Coordinate with provincial government program
		
		Renewal Criteria:
		• For the treatment of CLL in symptomatic patients with documentation of no disease progression

INFLECTRA (Infliximab)	• Rheumatoid Arthritis • Ankylosing Spondylitis • Psoriatic Arthritis • Plaque Psoriasis • Crohn's Disease • Ulcerative colitis	ADULTS • 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 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 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 (18+) 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 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 patients (18+) with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-

DRUG	DISEASE	APPROVAL GUIDELINES
		mercaptopurine, methotrexate, or cyclosporine) • Coordinate with provincial government program PEDIATRIC • Patients 9 years of age or older with moderately to severely active 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 6 years of age or older 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 provincial government program
INLYTA (Axitinib)	• Metastatic Renal Cell Carcinoma	• For patients who have failed prior systemic therapy with either a cytokine or a tyrosine kinase inhibitor
INQOVI (Decitabine/Cedazuridine)	• Myelodysplastic syndromes (MDS)	Initial Criteria (6 months): • For treatment of adult patients with myelodysplastic syndromes (MDS) AND each of the following: ○ French-American-British subtypes: refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) ○ International Prognostic Scoring System (IPSS) group is intermediate-1 OR intermediate-2 or high-risk patients who are intolerant to Vidaza ○ ECOG between 0 to 2 Renewal Criteria (6 months): • Absence of disease progression
INSPIOLTO RESPIMAT (Tiotropium bromide and olodaterol hydrochloride)	• Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema	• For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on optimal doses of either a LAMA or LABA alone
INTELENCE (Etravirine)	• HIV infection	• Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
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 • Condylomata Accuminata	• Coordinate with provincial government program
INTUNIV XR and generic GUANFACINE XR	• Attention deficit hyperactivity disorder (ADHD)	• For patients 6 to 17 years of age who have tried and failed or had intolerable side-effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera • For patients 6 to 17 years of age requiring adjunctive therapy with psychostimulants
INVEGA SUSTENNA INVEGA TRINZA (Paliperidone injection)	• Schizophrenia and related psychotic disorders	• For patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations
INVOKANA (Canagliflozin) INVOKAMET (Canagliflozin/metformin)	• Diabetes mellitus	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective OR • For the treatment of patients with type-2 diabetes who have established cardiovascular disease • For the treatment of patients with type-2 diabetes who have established diabetic nephropathy
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

DRUG	DISEASE	APPROVAL GUIDELINES
ITULATEK (Standardized Allergen Extract, White Birch)	• Moderate to Severe Seasonal Allergic Rhinitis (AR)	• For the treatment of allergic rhinitis in patients 18 years and older who are skin test positive to tree pollen (i.e. pollen from birch, alder and/or hazel), symptomatic for at least 2 pollen seasons and not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen specific immunotherapy injections
JADENU and generic DEFERASIROX	• Chronic Iron Overload	• For the management of chronic iron overloading patients with transfusion-dependent anemias aged 6 years or older AND who have tried and failed or cannot tolerate or have a contraindication* to deferoxamine. • For the management of chronic iron overloading patients with transfusion-dependent anemias aged 2 to 5 who cannot be adequately treated with deferoxamine. • For the treatment of chronic iron overloading patients with non-transfusion-dependent thalassemia syndromes (NTDT) aged 10 years and older AND 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

JALYN (Dutasteride and Tamsulosin)	• Benign Prostatic Hyperplasia	• For male patients in the treatment of benign prostatic hyperplasia

DRUG	DISEASE	APPROVAL GUIDELINES
JANUVIA (Sitagliptin) JANUMET JANUMET XR (Sitagliptin/metformin)	• Diabetes mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
JARDIANCE (Empagliflozin)	• Chronic Heart failure	• Adult patients diagnosed with chronic heart failure AND all the following: o NYHA class II to IV o Previously treated with an ACE inhibitor or ARB, AND beta-blocker unless there is a contraindication or an intolerance
JARDIANCE (Empagliflozin) SYNJARDY (empagliflozin/metformin)	• Diabetes mellitus	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective • For the treatment of patients with type-2 diabetes who have established cardiovascular disease
JETREA (Ocriplasmin)	• Symptomatic vitreomacular adhesion (VMA)	• Confirmed diagnosis of symptomatic vitreomacular adhesion (VMA) • Coordinate with provincial government program Lifetime maximum: 1 injection per affected eye
JINARC (Tolvaptan)	• Autosomal dominant polycystic kidney disease (ADPKD)	Initial Criteria: • Confirmed diagnosis of rapidly progressive ADPKD, total kidney volume ≥ 750ml AND one of the below: o eGFR ≥ 25 to 65 ml/min/1.73m^2 (patients 18 – 55 years old) OR o eGFR ≥ 25 to 45 ml/min/1.73m^2 (patients 56 – 65 years old) and historical evidence of a decline in the eGFR of more than 2.0 mL/min/1.73 m^2/year • 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 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

DRUG	DISEASE	APPROVAL GUIDELINES
KALETRA (Lopinavir/Ritonavir)	• HIV anti-viral	• Coordinate with provincial government program
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 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 Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC • Coordinate with provincial government program
KESIMPTA (Ofatumumab)	• Relapsing Remitting Multiple Sclerosis	• For RRMS patients who have had an inadequate response to, or are unable to tolerate, one or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) o EDSS value required with every application • 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 Criteria (6 month duration):</u> • Continue until unacceptable toxicity or disease progression

DRUG	DISEASE	APPROVAL GUIDELINES
		Initial Criteria (6 month duration): • In combination with generic Faslodex for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment naïve (i.e. Kisqali, Verzenio, Ibrance) Renewal Criteria (6 month duration): • Absence of disease progression Initial Criteria (6 month duration): • For the treatment of pre- and peri-menopausal women with hormone receptor- positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in combination with an aromatase inhibitor (AI) and a luteinizing hormone releasing hormone (LHRH) agonist • Patients must be endocrine therapy naïve or endocrine therapy-free for at least 12 months Renewal Criteria (6 month duration): • Continue until unacceptable toxicity or disease progression
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 indicate 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
KYNMOBI (Apomorphine hydrochloride)	• Parkinson's Disease	• For adult patients (18+) with a confirmed diagnosis of Parkinson's disease who have: ○ Tried and failed Levodopa/Carbidopa AND at least one of the following: generic Comtan, generic Mirapex, generic Parlodel, generic Requip, or generic Azilect, AND ○ Tried and failed Movapo or are medically unable to use Movapo (must specify clinical rationale)

DRUG	DISEASE	APPROVAL GUIDELINES
LANCORA (Ivabradine)	• Heart failure with reduced ejection fraction	• For add-on treatment in adult patients with stable chronic heart failure with reduced ejection fraction • (LVEF) ≤ 35%, who are in sinus rhythm with a resting heart rate ≥ 77 beats per minute • Patients with NYHA class II or III • Patient's heart failure is not well-managed OR patient has contraindication or intolerance to at least two of the following therapies: ACE-inhibitors, ARBs, Beta-blockers and/or Diuretics.
LANTUS LANTUS SOLOSTAR (Insulin glargine)	• Diabetes mellitus	• For patients who are at high risk for Hypoglycemia • For patients who are previously stabilized on Lantus OR patients who are medically unable to use Basaglar • For insulin glargine naïve patients, Lantus will be approved under Basaglar
LEMTRADA (Alemtuzumab)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For RRMS patients who have had an inadequate response to, or are unable to tolerate, two or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) o EDSS value required with every application • 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 • Unresectable hepatocellular carcinoma (HCC)	• For the treatment of patients with locally advanced or metastatic, progressive, radioactive iodine refractory differentiated thyroid cancer • For patients with unresectable hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG between 0 and 1
LEVEMIR LEVEMIR FLEXPEN LEVEMIR FLEXTOUCH (Insulin detemir)	• Diabetes mellitus	• For patients who are at high risk for hypoglycemia
LEVULAN KERASTICK (Aminolevulinic acid hydrochloride)	• Actinic keratosis	• For the treatment of actinic keratoses of the face and scalp

DRUG	DISEASE	APPROVAL GUIDELINES
LODALIS and generic COLESEVELAM LODALIS SACHET (Colesevelam)	• Hypercholesterolemia	• For patients who had an inadequate response to or are unable to tolerate statins • Lodalis sachet will only be considered if patient is medically unable to swallow Lodalis tablets.
LONSURF (Trifluridine/Tipiracil)	• Metastatic colorectal cancer • Metastatic Gastric Cancer or Adenocarcinoma of the gastroesophageal junction	• For patients with a diagnosis of metastatic colorectal cancer AND treated previously with, or not a candidate for 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 patients with a diagnosis of metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction AND treated previously with, or not a candidate for ALL of the following: fluoropyrimidine-based chemotherapy , platinum-based therapy, irinotecan, taxane-based therapy, anti-VEGF therapy (ramicirumab) AND if HER2+, a HER2+ targeted therapy (i.e. trastuzumab)
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
LUNESTA (Eszopiclone)	• Insomnia	• For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
LYSODREN (Mitotane)	• Adrenal cortical carcinoma	• For the treatment of unresectable adrenal cortical carcinoma for both functional and non-functional types

DRUG	DISEASE	APPROVAL GUIDELINES
MAVENCLAD (Cladribine)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For RRMS patients who have had an inadequate response to, or are unable to tolerate, two or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) o EDSS value required • Coordinate with provincial government program • Maximum cumulative dose = 3.5 mg/kg over 2 years, i.e. 1.75 mg/kg/year
MAVIRET (Glecaprevir/Pibrentasvir)	• Hepatitis C	• For patients 12 years or older with chronic hepatitis C genotype 1-6 infections with a Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months AND one of the following: o Fibrosis stage F2 or greater (Metavir scale or equivalent) OR o Fibrosis stage F0 or F1 with one of the following conditions: - HCV genotype 3, - diabetes, - organ transplant (pre- AND post-transplant), - chronic renal disease, - immunocompromised patients, - women of child-bearing age that wish to become pregnant, - co-infection with HIV or HBV, - cryoglobulinemia, or - coexisting chronic liver disease (e.g. autoimmune hepatitis) • Coordinate with provincial government program
MAYZENT (Siponimod)	• Secondary progressive multiple sclerosis	• Treatment of patients with secondary progressive multiple sclerosis with active disease as confirmed by evidence of relapses or imaging features (e.g. lesions of MRI scan, history of relapse in the last two years) • Trial and failure, intolerance or contraindication to one other agent (e.g. Avonex, Rebif, Extavia, Betaseron) • EDSS score less than 7 required with every application • To be used as monotherapy
METOJECT (Methotrexate)	• Neoplastic diseases • Severe, disabling psoriasis, rheumatoid arthritis, psoriatic arthritis or other seronegative arthritides	• For the treatment of maintenance of neoplastic diseases in patients who have a physical disability which prevents them from drawing-up a syringe

DRUG	DISEASE	APPROVAL GUIDELINES
METOJECT SC and generic METHOTREXATE	• Psoriasis • Psoriatic arthritis • Rheumatoid Arthritis (RA)	• For patients who have tried and failed oral tablets of methotrexate
METVIX-PDT (Methyl Aminolevulinate)	• Primary superficial basal cell carcinoma (BCC) outside the H-zone of the face • Actinic keratosis	• For the treatment of BCC or actinic keratosis in individuals with multiple lesions, large lesions, bleeding disorders, poor vascularization, delayed healing, body not amenable to surgery, unsuitable for invasive therapy, concerns regarding disfigurement or inadequate response to previous therapies, etc; and • Maximum annual reimbursement of $1800 per patient per year
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: generic Comtan, generic Mirapex, generic Parlodel, generic Requip, generic Azilect
MOVANTIK (Naloxegol oxalate)	• Opioid-induced constipation (OIC)	• For treatment of opioid-induced constipation (OIC) in adults (>18 years old) with non-cancer pain, who have tried and failed: ○ Dietary and lifestyle measures (i.e. high fiber diet, increased water intake, physical exercise) AND ○ One medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil)
MOZOBIL (Plerixafor)	• Stem cell mobilization for autologous transplantation for patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM)	• In combination with G-CSF for NHL and MM patients that are eligible for autologous stem cell transplantation WHERE patients are predicted to mobilize poorly for the following reasons: a) A peak CD34+ circulating cell count of < 15 cells/μL, AND b) A history of prior failed mobilization (i.e. Neupogen alone or chemo-mobilization)
MYRBETRIQ (Mirabegron)	• Overactive bladder (OAB)	• For patients with OAB with urgency, urgency incontinence and urinary frequency who have tried and failed or had intolerable side effects to one of the following oral anticholinergics: generic Ditropan, generic Ditropan XL, generic

DRUG	DISEASE	APPROVAL GUIDELINES
		Enablex, generic Vesicare, generic Detrol, generic Detrol LA, Toviaz, or generic Trosec
NESINA (Alogliptin) KAZANO (Alogliptin/metformin)	• Type 2 Diabetes	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
NEULASTA (Pegfilgrastrim) LAPELGA (Pegfilgrastim) FULPHILA (Pegfilgrastim) NYVEPRIA (Pegfilgrastim) ZIEXTENZO (Pegfilgrastim)	• Neutropenia associated with anti-neoplastic therapy	• To co-ordinate with available provincial plans
NEUPOGEN (Filgrastim) GRASTOFIL (Filgrastim) NIVESTYM (Filgrastim)	• Neutropenia associated with anti-neoplastic therapy, transplant, HIV/AIDS, stem cell mobilization • Severe chronic neutropenia	• To co-ordinate with available provincial plans
NEUPRO (Rotigotine)	• For the treatment of signs and symptoms of idiopathic Parkinson's disease – adjunct or monotherapy	• For patients who have tried and failed or had intolerable side effects to at least one oral dopamine agonist (i.e. generic Mirapex, generic Parlodel, generic Requip)
NEXAVAR (Sorafenib)	• Metastatic renal cell (clear cell) carcinoma • Unresectable hepatocellular carcinoma • Thyroid Carcinoma	• For patients with metastatic renal cell carcinoma who are refractory or resistant to treatment with cytokines • For patients with unresectable hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG between 0 and 2. ○ If ECOG between 0 to 1, must indicate intolerance (such as uncontrolled hypertension) or contraindication to Lenvima • Locally advanced or metastatic, progressive differentiated thyroid carcinoma secondary to radioactive iodine • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
NEXIUM and generic ESOMEPRAZOLE NEXIUM GRANULES (Esomeprazole)	• Gastroesophageal Reflux Disease • Duodenal and Gastric Ulcers • Zollinger-Ellison Syndrome	• For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole • For the treatment of H. Pylori positive (verified by serology or endoscopy or breath-test) Peptic ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole • For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole
NORDITROPIN NORDIFLEX (Somatropin)	• Growth Hormone Deficiency in children • Noonan Syndrome • Small for gestational age • Turner's Syndrome	• 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 children with short stature associated with Noonan syndrome • For the treatment of small for gestational age defined as 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 the treatment of children with short stature associated with Turner Syndrome • Coordinate with provincial government program
NUBEQA (Darolutamide)	• Non-metastatic castration resistant prostate cancer	<u>Initial Criteria (6 months):</u> • For the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC) <u>Renewal Criteria (6 months):</u> • Absence of disease progression
NUCALA (Mepolizumab)	• Severe eosinophilic asthma • Severe chronic rhinosinusitits with nasal polyps (CRSwNP)	• For the add on maintenance treatment of severe eosinophilic asthma in patients 6 years or older who meet the following criteria: ○ Trial and failure of high-dose inhaled corticosteroids (18 years or older) or medium-to-high dose corticosteroids (6 to 17 years old) and an additional asthma controller (ie. long-acting beta-agonist), AND ○ Blood eosinophil count of ≥ 150 cells/μL (0.15 GI/L) while receiving maintenance treatment with oral corticosteroids OR ≥300 cells/μL in the past 12 months with

DRUG	DISEASE	APPROVAL GUIDELINES
		≥2 clinically significant asthma exacerbations (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization) Initial Approval (1 year): • For the treatment of adult patients (18+) with confirmed severe chronic rhinosinusitis with nasal polyps (CRSwNP) ○ Severity defined as meeting all 3 conditions below: 1) NPS (nasal polyp score) > 5 (with minimum score of 2 for each nasal cavity) 2) 22-Item Sinonasal Outcome Test (SNOT-22) score > 50 3) Ongoing symptoms for more than 12 weeks (e.g. nasal congestion, blockage, loss of smell, rhinorrhea) ○ Tried and failed each of the below: 1) Intranasal corticosteroid (e.g. generic Mometasone, generic Budesonide, etc.) 2) Oral corticosteroid therapy, unless contraindicated 3) Prior sinonasal surgery for nasal polyps ○ Will not be approved in combination with another biologic (e.g. Xolair, Cinqair, Fasenra, Dupixent) Renewal (1 year): • Reduction in NPS score of 1 or more AND • Reduction in SNOT-22 score of 9 or more
NUCYNTA IR (Tapentadol)	• Moderate to moderately severe pain	• Pain management in a specified acute pain diagnosis • For patient who are unable to tolerate or receive an adequate response to the immediate release preparations of either hydromorphone, oxycodone or morphine
NUCYNTA CR / ER (Tapentadol)	• Moderate to severe acute pain	• Pain management in a specified chronic pain diagnosis • For patient who are unable to tolerate or receive an adequate response to the sustained release preparations of either hydromorphone, oxycodone or morphine
NUTROPIN (Somatropin)	• Growth Hormone Deficiency in Children • Turner Syndrome • Adult Growth Hormone Deficiency	• 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 in patients whose epiphyses are not closed • For adolescents/adults who were growth hormone-deficient during childhood and who

DRUG	DISEASE	APPROVAL GUIDELINES
		have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented • For adults who have growth hormone deficiency (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
OCREVUS (Ocrelizumab)	• Relapsing Remitting Multiple Sclerosis (RRMS) • Primary Progressive Multiple Sclerosis (PPMS)	<u>RRMS:</u> • For patients with RRMS who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) o EDSS value required with every application • Coordinate with provincial government program <u>PPMS:</u> • Confirmed diagnosis of primary progressive multiple sclerosis • EDSS score between 3.0 and 6.5 • EDSS value required with every application
ODEFSEY (Emtricitabine/Rilpivirine/Tenofovir Alafendamide)	• HIV-1 infection	• Coordinate with provincial government program
OFEV (Nintedanib)	• Idiopathic Pulmonary Fibrosis • Systemic Sclerosis Interstitial Lung Disease (SSc-ILD) • Progressive Fibrosing Insterstitial Lung Disease (PF-ILD)	<u>Initial Criteria:</u> • 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 • Coordinate with provincial government program <u>Renewal criteria:</u> • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months <u>Initial Criteria:</u>

DRUG	DISEASE	APPROVAL GUIDELINES
		• For patients diagnosed with Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) as confirmed by central assessment of chest HRCT scan with at least 10% fibrosis, a Forced Vital Capacity (FVC) of at least 40% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30 to 89% predicted • Coordinate with provincial government program Renewal Criteria: • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months Initial Criteria: • For patients diagnosed with PF-ILD with features of diffuse lung disease ≥ 10% on a HRCT scan and a Forced Vital Capacity (FVC) must be ≥ 45% of predicted and a Percent Carbon Monoxide Diffusing Capacity (DLCO%) ≥ 30% to < 80% of predicted • Coordinate with provincial government program Renewal Criteria: • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months
OLUMIANT (Baricitinib)	• 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 • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
OMNITROPE (Somatropin)	• Growth Hormone Deficiency in children • Small for gestational age • Turner Syndrome • Idiopathic Short Stature • Adult Growth Hormone Deficiency	• 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 small for gestational age defined as 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 the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed • For treatment of idiopathic short stature which is defined as: (i) diagnostic evaluation that excludes other causes of short stature; and (ii) height at least 2.25 standard deviation scores below the mean for age and sex; and (iii) patients whose epiphyses are not closed • 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 growth hormone deficiency (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. • Coordinate with provincial government program
ONGLYZA and generic SAXAGLIPTIN KOMBOGLYZE (saxagliptin/metformin)	• Diabetes mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
ONRELTEA (Brimonidine 0.33% topical gel)	• Facial erythema (redness) of rosacea	• For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)
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 generic Tracleer • Coordinate with provincial government program • May be used in conjunction with phosphodiesterase-5 inhibitors (i.e. Revatio) • When combination treatment with Adcirca is

DRUG	DISEASE	APPROVAL GUIDELINES
		requested, OPSYNVI will be approved
OPSYNVI (macitentan/tadalafil)	• Pulmonary Arterial Hypertension	• For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND had insufficient response to generic Revatio or Adcirca (minimum 3 months trial) ○ For WHO FC III, patients must also have tried and failed or cannot tolerate generic Tracleer
ORALAIR (Grass Pollen Allergen Extract)	• Treatment of moderate to severe seasonal grass pollen allergic rhinitis	• For the treatment of allergic rhinitis in patients 5 to 50 years old, who are skin test positive to grass pollen and who are not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
ORENCIA IV (Abatacept)	• Rheumatoid Arthritis • Moderate to Severe Juvenile Rheumatoid Arthritis • 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 Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab 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 Etanercept or Actemra SC • 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
ORILISSA (Elagolix)	• Pelvic pain associated with endometriosis	• For the management of pelvic pain associated with endometriosis where the patient has tried and failed or had intolerable side effects to oral contraceptives
OSNUVO Generic TERIPARATIDE	• Osteoporosis • Osteoporosis associated with sustained systemic glucocorticoid therapy	• For patients with severe osteoporosis where patient has a bone mineral density (BMD) T score of less than -3.5 SD AND history of non-trauma related fractures while on bisphosphonates • For patients with severe osteoporosis where patient has a bone mineral density (BMD) T score of less than -1.5 SD and a minimum of 3 months of sustained systemic glucocorticoid therapy • Maximum lifetime treatment: 24 months

DRUG	DISEASE	APPROVAL GUIDELINES
OTEZLA (Apremilast)	• Plaque psoriasis • Psoriatic Arthritis • Behçet'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 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 adults with a confirmed diagnosis of Behçet's disease who have experienced oral ulcers at least 3 times within the past 12 months and have tried and failed or did not tolerate at least one topical therapy (e.g. hydrocortisone, triamcinolone, betamethasone, fluocinonide, clobetasol, etc.) and at least one systemic therapy (e.g. corticosteroids, colchicine, azathioprine, cyclosporine, cyclophosphamide, thalidomide, etc.). • Coordinate with provincial government program
OXYCODONE IMMEDIATE RELEASE (i.e. Oxycodone IR, Supeudol)	• Severe pain	• For pain management in patients who are unable to tolerate or receive an adequate response to other prescription pain medications
OXYCODONE CONTINUOUS RELEASE (i.e. Oxyneo, Oxycodone CR)	• Severe pain	• For pain management in patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the sustained release preparations of morphine
OXYTROL (Oxybutynin transdermal system)	• Urinary incontinence	• For individuals who have tried and failed oral anticholinergics (ex. Oxybutynin)
OZEMPIC (Semaglutide)	• Diabetes Mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
OZURDEX (Dexamethasone)	• Macular edema following Central Retinal Vein Occlusion • Non-infectious Uveitis • Diabetic Macular Edema (DME) who are pseudophakic	Initial Authorization Approval for Macular Edema following Central Retinal Vein Occlusion (6 month approval): • Patient must meet the following criteria to receive 1 implant per affected eye(s) for six months: ○ For treatment of macular edema following Central Retinal Vein Occlusion

DRUG	DISEASE	APPROVAL GUIDELINES
		○ Validate site of administration • Coordinate with provincial government plan <u>Subsequent Authorization Approval for Macular Edema following Central Retinal Vein Occlusion (6 month approval):</u> • Patient must have received a beneficial effect from the initial injection with a subsequent loss in visual acuity to receive an additional 1 implant per affected eye(s) for six months • Renewal will not be granted in the following circumstances: ○ Patient experienced vision deterioration without any beneficial effect from initial injection ○ Patient continues to benefit from initial injection and has not experienced a subsequent loss in visual acuity • Coordinate with provincial government plan Maximum lifetime approval of 2 implants per affected eye <u>Initial Authorization Approval for Non-infectious Uveitis (6 month approval):</u> • Patient must meet the following criteria to receive 1 implant per affected eye for 6 months: ○ For the treatment of non-infectious uveitis (posterior) in patients with inadequate response to corticosteroids OR as a corticosteroid-sparing treatment in corticosteroid-dependent patients. <u>Subsequent Authorization Approval for Non-Infectious Uveitis (6 month approval):</u> • Stability or improvement of vision and control of ocular inflammation confirmed by physician. Maximum lifetime approval of 2 implants per affected eye(s) <u>Initial Criteria for Diabetic Macular Edema:</u> • For the treatment of Diabetic Macular Edema who are pseudophakic • Validate site of administration • Coordinate with available provincial programs • Maximum approval of 2 implants per affected eye(s) <u>Subsequent Authorization Approval for Diabetic Macular Edema:</u> • Must demonstrate presence of macular edema after initial positive response with Ozurdex • Coordinate with available provincial programs • Maximum approval of 2 injections per affected eye for 1 year Maximum lifetime approval of 6 implants per affected

DRUG	DISEASE	APPROVAL GUIDELINES
		eye in 3 years
PAXIL CR (Paroxetine controlled release)	• Depression	• Patient must have tried and failed and/or had adverse side-effects to regular release SSRIs or extended release SNRIs or atypical antidepressants
PDP-LEVETIRACETAM SOLUTION (Levetiracetam 100 mg/ml)	• Epilepsy	• Patient is medically unable to swallow Levetiracetam tablets AND one of the following: o For adjunctive management of adult patients with epilepsy who have tried and failed, or are intolerant to a standard therapy o For adjunctive treatment of partial onset seizures in patients 1 month of age to less than 18 years of age with epilepsy o For adjunctive treatment of myoclonic seizures in adolescents from 12 years of age with Juvenile Myoclonic Epilepsy o For adjunctive treatment of primary generalized tonic-clonic seizures in adolescents from 12 years of age with idiopathic generalized epilepsy
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
PENNSAID and generic DICLOFENAC 1.5% SOLUTION	• Medical conditions requiring chronic NSAIDs	• For the treatment of patients requiring chronic NSAIDs who have failed to respond or had intolerable side-effects to at least two Non-Steroidal Anti-Inflammatory Drugs (NSAID) OR for patients with a documented history of a clinically significant ulcer or GI bleed

DRUG	DISEASE	APPROVAL GUIDELINES
PERSERIS (Risperidone Injection)	• Schizophrenia	• For patients who are non-compliant or non-adherent with conventional oral therapy (e.g. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations
PHEBURANE (Sodium phenybutyrate)	• Urea cycle disorder	• Diagnosis of urea cycle disorders; AND • For patients who weighs ≥ 20 kg WITH a BSA ≤ 1.5 m^2 and prescribed with a usual recommended dose of 9.9-13.0 g/m^2/day; AND • Patient is currently on dietary protein restrictions; AND • Initial request must indicate ammonia levels prior to starting therapy
PIFELTRO (Doravirine)	• HIV anti-viral	• Coordinate with provincial government program
PLEGRIDY (Peg interferon beta-1a)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• Diagnosis of RRMS • EDSS value with every application • 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
PONVORY (Ponesimod)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For patients with RRMS who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) • EDSS value required with every application • Coordinate with provincial government program
POSANOL DR TABLET and generic 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

DRUG	DISEASE	APPROVAL GUIDELINES
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	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%
PREVACID FASTAB (Lansoprazole)	• Gastroesophageal Reflux Disease • Duodenal and Gastric Ulcers • Zollinger-Ellison Syndrome	• For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole • For the treatment of H. Pylori positive (verified by serology or endoscopy or breath-test) Peptic ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole • For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole

DRUG	DISEASE	APPROVAL GUIDELINES
PREVYMIS (Letermovir)	• Cytomegalovirus (CMV) infection	• For the prevention of cytomegalovirus (CMV) infection in adult patients who underwent allogeneic hematopoietic stem cell transplant (HSCT) AND 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 and generic 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)
PRISTIQ and generic DESVENLAFAXINE	• Major Depressive Disorder	• For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other extended release SNRIs
PROBUPHINE (Buprenorphine hydrochloride)	• Opioid Dependence	• For management of opioid dependence in patients currently stable on Suboxone
PROLIA (Denosumab)	• Osteoporosis • Glucocorticoid-induced osteoporosis • Treatment to increase bone mass in men with non-metastatic prostate cancer receiving androgen deprivation therapy • Treatment to increase bone mass in women with non-metastatic breast cancer receiving aromatase inhibitor therapy	• For patients who have failed treatment with oral bisphosphonates (alendronate, etidronate, risedronate) or have had intractable intolerance or adverse effects to Bisphosphonate therapy • Approval duration: 2 injections per calendar year

DRUG	DISEASE	APPROVAL GUIDELINES
PROSCAR and generic FINASTERIDE	• Benign Prostatic Hyperplasia	• For the treatment of benign prostatic hyperplasia
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
RAGWITEK (Standardized allergen extract, Short Ragweed)	• Moderate to severe seasonal short ragweed allergic rhinitis	• For the treatment of allergic rhinitis in patients 5 years of age and older, who are o Skin test positive to short ragweed pollen o Symptomatic for at least 1 pollen season for age 5 to 6 OR 2 pollen seasons for age 7 or older • Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
RAPAFLO and generic SILODOSIN	• Benign prostatic hyperplasia	• For the treatment of benign prostatic hyperplasia in patients who have tried and failed or are intolerant to at least two of the following medications: Flomax CR, Hytrin, Cardura, Xatral
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	ADULT • For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active

DRUG	DISEASE	APPROVAL GUIDELINES
		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 PEDIATRIC • Patients 9 years of age or older with moderately to severely active 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 6 years of age or older 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 provincial government program
REMSIMA SC (Infliximab)	• Moderate to severe Rheumatoid Arthritis	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide, and/or sulfasalazine) for a period of 3 months

DRUG	DISEASE	APPROVAL GUIDELINES
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	ADULTS • 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 PEDIATRIC • Patients 9 years of age or older with moderately to severely active 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 6 years of age or older 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 provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
REPATHA (Evolocumab)	• Familial Hypercholesteremia • Atherosclerotic Cardiovascular Disease (ASCVD)	Initial Authorization (6 months): • Familial Hypercholesterolemia with or without ASCVD. Diagnosed with Homozygous Familial Hypercholesterolemia or Heterozygous Familial Hypercholesterolemia as confirmed by genotyping or clinical criteria (Simon Broome criteria or World Health Organization/Dutch Lipid Network criteria) • Must be greater than 18 years of age for Heterozygous Familial Hypercholesterolemia (greater than 12 years of age for Homozygous Familial Hypercholesterolemia) • Statin use: • 1. Patient unable to reach LDL-C target despite adherence to high-dose statin (e.g. atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least three months OR • 2. Statin intolerant: 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 at least three months • Current LDL-C value required Renewal Criteria (1 year approval) • Document evidence of LDL-C level reduction of at least 25% from initial baseline Maximum approval dosage is 140mg every two weeks or 420 mg once monthly Initial Authorization (6 months): • ASCVD - In patients with clinical Atherosclerotic Cardiovascular Disease (ASCVD) without Familial Hypercholesterolemia. Diagnosed with clinical atherosclerotic cardiovascular disease (i.e. prior MI, prior stroke or transient ischemic attack (TIA), symptomatic peripheral arterial disease, acute coronary syndrome or unstable angina, chronic coronary artery disease, coronary or other arterial revascularization): • Must be greater than 18 years of age ○ Statin use: ○ 1. As adjunct to diet and statin therapy in patients who are unable to reach LDL-C target despite adherence to high-dose statin (e.g. atorvastatin 80 mg or rosuvastatin 40 mg) for at least 3 months OR ○ 2. Statin intolerant: 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 at least three months

DRUG	DISEASE	APPROVAL GUIDELINES
		Renewal Criteria (1 year approval) • Achieving LDL-C target goal - less than 2 mmol/L or evidence of LDL-C level reduction of at least 25% from initial baseline Maximum approval dosage is 140mg every two weeks or 420 mg once monthly
RESOTRAN and generic PRUCALOPRIDE	• Chronic idiopathic constipation	• For adult female patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil)
RESTASIS and generic CYCLOSPORINE	• Moderate to moderately severe dry eyes	• For the treatment of moderate to moderately severe dry eye disease and for patients who had insufficient response to artificial tears
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 (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 and generic 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
REVOLADE (Eltrombopag Olamine)	• Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	• For adult patients who are splenectomised and have tried and failed corticosteroids and immunoglobulins

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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
RIABNI (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) • Microscopic Polyangiitis (MPA)	Initial criteria (1 year): • For the treatment of patients with rheumatoid arthritis who have tried and failed or could not tolerate at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) Retreatment Criteria (1 year): • Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab • Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months • For the treatment of adult patients with severe GPA or MPA: ○ In combination with glucocorticoids ○ Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). ○ Approval for 1 year ○ Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks
RILUTEK and generic 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
RINVOQ (Upadacitinib)	• 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

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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
RISPERDAL CONSTA (Risperidone injection)	• For the management of the manifestations of schizophrenia and related psychotic disorders	• Reserved for patients who are non-compliant or non-adherent with conventional oral therapy, resulting in multiple relapses/hospitalizations
RITUXAN (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) • Microscopic Polyangiitis (MPA)	<u>Initial criteria (1 year):</u> • For the treatment of patients with rheumatoid arthritis who have tried and failed or could not tolerate at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) ○ For patients who are medically unable to use a Rituximab biosimilar ○ For Rituxumab naïve patients, only a Rituximab biosimilar will be approved <u>Retreatment Criteria (1 year):</u> • Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab • Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months • For the treatment of adult patients with severe GPA or MPA: ○ For patients who are medically unable to use a Rituximab biosimilar ○ For Rituximab naïve patients, only a Rituximab biosimilar will be approved ○ In combination with glucocorticoids ○ Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). ○ Approval for 1 year ○ Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks

DRUG	DISEASE	APPROVAL GUIDELINES
RIXIMYO (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) • Microscopic Polyangiitis (MPA)	Initial Criteria (1 year): • For the treatment of patients with RA • Trial and failure or intolerance to at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) Retreatment Criteria (1 year): • Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab • Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months • For the treatment of adult patients with severe GPA or MPA: o In combination with glucocorticoids o Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). o Approval for 1 year o Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks
ROSIVER (Ivermectin)	• Rosacea	• For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)
RUXIENCE (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) • Microscopic Polyangiitis (MPA)	Initial Criteria (1 year): • For the treatment of patients with RA • Trial and failure or intolerance to at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab.) Retreatment Criteria (1 year): • Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab • Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months • For the treatment of adult patients with severe GPA or MPA: o In combination with glucocorticoids o Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). o Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks

Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
RYBELSUS (Semaglutide)	• Diabetes Mellitus	• For patients who tried and failed, or did not tolerate maximum doses of metformin (≥ 2000 mg daily)
RYDAPT Mmidostaurin)	• 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)
SAIZEN (Somatropin)	• Growth Hormone Deficiency in children • Small for gestational age • Turner syndrome • Adult Growth Hormone Deficiency	• 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 small for gestational age defined as 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 the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed • 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 growth hormone deficiency (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
SANDOSTATIN and generic OCTREOTIDE SANDOSTATIN LAR and generic OCTREOTIDE	• Metastatic Carcinoid Syndrome • Vasoactive Intestinal Peptide-Secreting Tumour (VIPoma) • Acromegaly • Emergency management for the bleeding of Gastro-esophageal 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
SATIVEX (Tetrahydro-cannabinol and cannabidiol buccal spray)	• For symptomatic relief of spasticity in adults with multiple sclerosis	• For adult MS patients with spasticity who have tried other medications such as analgesics, opioids, antidepressants or anticonvulsants, with little or no effect
SAXENDA (Liraglutide)	• Anti-Obesity	<u>Initial Authorization Approval (6 months):</u> • Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery disease AND trial and failure of prescribed lifestyle therapy (diet and exercise) for at least three months prior to starting Saxenda AND • trial and failure of therapy with Xenical for at least 6 months prior to Saxenda AND continuation of prescribed lifestyle therapy (diet and exercise) while using Saxenda • Weight prior to initiation of treatment • Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan <u>Subsequent Authorization Approval (6 months):</u> • Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery AND a minimum reduction of 6% of initial body weight and continuation of prescribed lifestyle therapy (diet and exercise) while using Saxenda • Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan

DRUG	DISEASE	APPROVAL GUIDELINES
SEBIVO (Telbivudine)	• Chronic hepatitis B	• For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) • Coordinate with provincial government program
SENSIPAR 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
SILENOR (Doxepin Hydrochloride)	• Insomnia	• For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
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
SIGNIFOR/ SIGNIFOR LAR (Pasireotide)	• Cushing's Disease	Initial Criteria • For the treatment of Cushing's Disease in adult patients: o Who have tried and failed or are experiencing recurrent disease despite prior surgical intervention OR o 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 o Normalization of urinary free cortisol OR o More than 50% decrease in urinary free cortisol • Coordinate with provincial government program
		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)

DRUG	DISEASE	APPROVAL GUIDELINES
SIMLANDI (Adalimumab)	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 • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa	• 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. • 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 • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies PEDIATRIC • 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

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 15 mg/week AND at least one other DMARD, AND who has tried and failed Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • For patients 12 to 17 years of age 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. • Coordinate with provincial government program • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies
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 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

DRUG	DISEASE	APPROVAL GUIDELINES
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 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 • 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 systemic therapies AND who are being treated by a dermatologist • Coordinate with provincial government program
SOLIQUA (Insulin glargine/lixisenatide)	• Diabetes mellitus	• For adults with type 2 diabetes mellitus who are inadequately controlled on basal insulin or a GLP-1 agonist (e.g. Ozempic, Rybelsus, Trulicity)
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

DRUG	DISEASE	APPROVAL GUIDELINES
SOMAVERT (Pegvisomant)	• Treatment of Acromegaly	• For patients who have tried and failed surgery and/or radiation therapy and other medical therapies OR are ineligible for surgery and/or radiation therapy and other medical therapies

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

SPRAVATO (Esketamine)	• Major Depressive Disorder (MDD)	<u>Initial Criteria (6 month approvals):</u> • For patients with major depressive disorder who have tried and failed three courses of antidepressants from each of the following drug classes for at least 4 weeks: SSRI, SNRI and/or one other antidepressant drug class (e.g. bupropion, mirtazapine, etc.) ○ One course must be combination therapy using two antidepressants for at least 4 weeks • Prescriber must specify severity of symptoms, e.g. current Montgomery-Asberg Depression Rating Scale (MADRS) score, PHQ-9 score, Hamilton Depression Rating Scale (HDRS) • Must be enrolled in Janssen Journey Program <u>Renewal Criteria (6 month approvals):</u> • Clinical benefit as demonstrated by remission or response, e.g. current Montgomery-Asberg Depression Rating Scale (MADRS) score, PHQ-9 score, Hamilton Depression Rating Scale (HDRS)
SPRYCEL and generic DASATINIB	• Chronic myeloid leukemia (CML) • Acute Lymphoblastic Leukemia	• For the treatment of adults with any phase of Philadelphia chromosome-positive chronic myeloid leukemia (chronic, accelerated, or blast phase) for patients who have tried and failed imatinib • For the treatment of adults with Philadelphia chromosome positive (Ph+) Acute Lymphoblatic Leukemia (ALL) resistant or intolerant to prior therapy • Coordinate with provincial government

DRUG	DISEASE	APPROVAL GUIDELINES
		program
STEGLATRO (Ertugliflozin) SEGLUROMET (ertugliflozin/metformin)	• Diabetes mellitus	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective
STEGLUJAN (Ertugliflozin/Sitagliptin)	• Diabetes mellitus	• For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective
STELARA (Ustekinumab)	• Plaque psoriasis • Psoriatic Arthritis • Crohn's Disease • Ulcerative Colitis	• For patients who are 6 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 • For patients with active Ulcerative Colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA OR immunosuppressants (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
SUBLINOX and generic ZOLPIDEM	• Insomnia	• For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
SUBLOCADE (Buprenorphine)	• Opiod Dependence	• For management of opioid dependence in patients clinically stable on generic Suboxone at a daily dose greater than 8 mg (buprenorphine) or who have had inadequate response to Probuphine
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
TALTZ (Ixekizumab)	• Plaque Psoriasis • Psoriatic Arthritis • Ankylosing Spondylitis • Non-radiographic axial spondyloarthritis (nr-axSpA)	• For patients who are 6 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

DRUG	DISEASE	APPROVAL GUIDELINES
		or Sulfasalazine for a period of 3 months • For patients with a confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDs and the BASDAI score is ≥ 4 • For patients with confirmed diagnosis of severe, active non-radiographic axial spondyloarthritis are uncontrolled by NSAIDs AND who have had inadequate response or experienced intolerant effects to Cosentyx • Coordinate with provincial government program
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)	• Chronic myeloid leukemia (CML)	• For adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) • For adult patients with accelerated phase Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) resistant to OR intolerant of at least one prior therapy including imatinib • Coordinate with provincial government program
TECFIDERA and generic DIMETHYL FUMARATE	• Relapsing Remitting Multiple Sclerosis (RRMS)	• Diagnosis of RRMS • Coordinate with provincial government program • EDSS value required with every application
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

DRUG	DISEASE	APPROVAL GUIDELINES
THYROGEN (Thyrotropin alpha Injection)	• Thyroid cancer	• Adjunctive therapy to radioiodine ablation of thyroid cancer • Adjunctive diagnostic tool in the follow-up of patients with thyroid cancer • Validate site of administration and coordinate with provincial program/cancer agency
TIVICAY (Dolutegravir)	• HIV anti-viral	• Coordinate with provincial government program
TOBI and generic TOBRAMYCIN TOBI PODHALER (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 and generic ALITRETINOIN	• Chronic Hand Eczema (CHE)	• Diagnosis of severe CHE characterized by fissures, vesicles, bumps, edema, exudation, scaling or lichenification • Trial of at least 2 of the following high potency topical steroids: amcinonide (Cyclocort), desoximetasone (Topicort), fluocinonide (Lyderm, Tiamol), betamethasone dipropionate (Diprosone), clobetasol propionate (Clobex)
TOUJEO (Insulin glargine)	• Diabetes mellitus	• For patients who are at high risk for hypoglycemia
TRACLEER and generic 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 (miminum 3 months trial) • For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV • Coordinate with provincial government program
TRAJENTA (Linagliptin) JENTADUETO (Linagliptin/Metformin)	• Diabetes mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
TREMFYA (Guselkumab)	• Plaque Psoriasis • Psoriatic Arthritis	• 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 adult patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease who

DRUG	DISEASE	APPROVAL GUIDELINES
		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
TRESIBA (Insulin degludec)	• Diabetes mellitus	• For patients who are at high risk for hypoglycemia
TRINTELLIX (Vortioxetine Hydrobromide)	• Major depressive disorder	• For individuals diagnosed with major depressive disorder and who have previously tried and failed therapy with any other antidepressant
TRIUMEQ (Dolutegravir/Abacavir/ Lamivudine)	• HIV infection in adults	• Coordinate with provincial government program
TRULANCE (Plecanatide)	• Irritable bowel syndrome with constipation (IBS-C)	• For adult patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
TRULICITY (Dulaglutide)	• Diabetes mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
TRUSOPT (Dorzolamide preservative-free ophthalmic solution)	• Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	• For patients who are allergic to or cannot tolerate the formulation with the preservative
TRUVADA and generic EMTRICITABINE/TENOFOVIR	• HIV anti-viral • Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
TRUXIMA (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) • Microscopic Polyangiitis (MPA)	Initial Criteria (1 year): • For the treatment of patients with rheumatoid arthrits who have tried and failed or could not tolerate at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) Retreatment Criteria (1 year): • Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab • Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months • For the treatment of adult patients with severe GPA or MPA: o In combination with glucocorticoids o Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). o Approval for 1 year o Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks
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)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For RRMS patients have had an inadequate response to, or are unable to tolerate, two or more therapies, (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) AND have evidence of lesions on their MRI scan, an EDSS value less than 6 AND have had at least one relapse in previous year o EDSS value required with every application • 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 o EDSS value required with every application • Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
ULORIC and generic FEBUXOSTAT	• To lower serum uric acid levels in patients with gout	• For patients who have tried and failed or had intolerable side effects to allopurinol
ULTIBRO BREEZHALER (Indacaterol/Glycopyrronium)	• Chronic Obstructive Pulmonary Disease (COPD)	• For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy
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
UROCIT-K (Potassium citrate)	• Kidney Stones	• For patients with kidney stones or renal tubular acidosis (RTA)
VALCYTE and generic VALGANCICLOVIR	• Cytomegalovirus Retinitis • Prevent CMV in solid organ transplant patients	• For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients • For the prevention of CMV disease in solid organ transplant patients at risk (i.e. risk is defined as donor +ve/recipient -ve for CMV, or recipient +ve post-active treatment of CMV disease with IV ganciclovir, or recipient +ve in patients receiving antilymphocyte antibody [ALA]). • Coordinate with provincial government program
VASCEPA (Icosapent ethyl)	• Hypertriglyceridemia	• For patients with established Cardiovascular Disease OR Diabetes Mellitus with at least one other cardiovascular risk factor (e.g. hypertension, renal dysfunction, retinopathy), who are stable on a cholesterol lowering agent (e.g. statin, fenofibrate, ezetimibe) and have a triglyceride level of ≥1.53 mmol/L
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

DRUG	DISEASE	APPROVAL GUIDELINES
VERKAZIA (Cyclosporine)	• Severe vernal keratoconjunctivitis (VKC)	• For the treatment of severe VKC in children from 4 years of age through adolescence (12-18 years) with trial and failure of, intolerance, or contraindication to two of the following: topical antihistamines (e.g. pheniramine), topical mast cell stabilizers (e.g. sodium cromoglycate), topical dual-action drugs (e.g. olopatidine), topical vasoconstrictors (e.g. naphazoline), topical corticosteroids (e.g. prednisolone)
VERZENIO (Abemaciclib)	• 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 • Endocrine-naïve/sensitive 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 AND • In combination with an aromatase inhibitor (e.g. Anastrozole, Letrozole) <u>Renewal (6 month duration):</u> • Continue until unacceptable toxicity or disease progression <u>Initial Criteria (6 month duration)</u> • In combination with generic Faslodex for the treatment of postmenopausal women with HR-positive, HER2- negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment naïve <u>Renewal Criteria (6 month duration)</u> • Continue until unacceptable toxicity or disease progression
VFEND and generic 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
VIBERZI (Eluxadoline)	• Irritable bowel syndrome with diarrhea (IBS-D)	• 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)

Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
VICTOZA (Liraglutide)	• Diabetes mellitus	• For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)
VIIBRYD (Vilazodone)	• Major depressive disorder	• For individuals diagnosed with major depressive disorder and who have previously tried and failed therapy with any other antidepressant
VIMOVO XR and generic NAPROXEN/ESOMEPRAZOLE	• Chronic medical conditions requiring NSAIDs (i.e. Osteoarthritis, Rheumatoid arthritis, Ankylosing Spondylitis)	• For patients who have failed to respond or had intolerable side-effects with the concomitant use of an NSAID with at least two of the following proton pump inhibitors: Rabeprazole, Lansoprazole, Omeprazole, and/or Pantoprazole
VIMPAT and generic LACOSAMIDE	• Monotherapy or Adjunctive therapy for partial onset seizures	• For patients with a diagnosis of partial onset seizures who have tried, failed or have experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
VISANNE and generic DIENOGEST	• Pelvic pain associated with endometriosis	• For patients who have failed to respond or have had intolerable side-effects to oral contraceptives
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
VOCABRIA (Cabotegravir) CABENUVA (Cabotegravir/Rilpivirine)	• HIV-1 infection	• For treatment of adult HIV-1 patients who have tried oral antiretroviral therapy or experienced side effect(s) or documented drug interaction(s) • Coordinate with provincial plans

DRUG	DISEASE	APPROVAL GUIDELINES
VOLIBRIS and generic AMBRISENTAN	• Pulmonary Hypertension	• For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND who have tried and failed 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

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
VYVANSE (Lisdexamfetamine)	• Attention deficit hyperactivity disorder • Binge Eating Disorder (BED)	• For patients who have tried and failed or had intolerable side effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera • For patients with a confirmed diagnosis of Binge Eating Disorder (BED)
WELLBUTRIN SR/XL and generic BUPROPION	• Depression	• For patients with a confirmed diagnosis of depression

DRUG	DISEASE	APPROVAL GUIDELINES
XELJANZ (Tofacitinib)	• Rheumatoid Arthritis • Psoriatic Arthritis • Ulcerative Colitis	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND 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 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, Adalimumab, Simponi SC, Entyvio and Stelara • Coordinate with provincial government program
XELODA and generic 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 • 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
XENICAL (Orlistat)	• Obesity	<u>Initial Authorization Approval (6 months):</u> • Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery • trial and failure of prescribed lifestyle therapy (diet and exercise) for at least three months prior to starting Xenical AND ccontinuation of prescribed lifestyle therapy (diet and exercise) while using Xenical • Weight prior to initiation of treatment • Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan <u>Subsequent Authorization Approval (6 months):</u> • Body Mass Index (BMI) greater than or equal to

DRUG	DISEASE	APPROVAL GUIDELINES
		30 OR a BMI of 27-29 with one of the following disease conditions that is also being treated with medication: hhypertension, diabetes mellitus, hyperlipidemia, and/or coronary artery AND a minimum reduction of 6% of initial body weight and continuation of prescribed lifestyle therapy (diet and exercise) while using Xenical • Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan
XEOMIN (Incobotulinumtoxin A)	• Blepharospasm • Cervical dystonia (spasmodic torticollis) • Spasticity of the upper limbs • Chronic sialorrhea	• 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 spasticity of the upper limbs in adult patients • For adult patients with chronic sialorrhea associated with neurological disorders (e.g. Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy, stroke, brain injury)
XGEVA (denosumab)	• Bone metastases	• For patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumors AND have tried and failed or experienced intolerable side effects with bisphosphates (Clasteon or Zometa)

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
		  ○ Maximum lifetime approval: 3 injections/vials 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/vials

XIIDRA (Lifitegrast)	• Moderate to severe dry eyes	• For the treatment of moderate to severe dry eye disease and for patients who had insufficient response to artificial tears

DRUG	DISEASE	APPROVAL GUIDELINES

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)
		  ○ Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen
		  ○ 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

XTANDI (Enzalutamide)	• Metastatic castration-resistant prostate cancer (mCRPC) • Non-metastatic castration-resistant prostate cancer (nmCRPC) • Metastatic castration-sensitive prostate cancer (mCSPC)	<u>Initial Criteria (6 months):</u> • For patients with a diagnosis of metastatic CRPC who received prior chemotherapy containing docetaxel Coordinate with provincial government program <u>Renewal Criteria (6 months):</u> • Absence of disease progression <u>Initial Criteria (6 months):</u> • In combination with Androgen depriviation Therapy (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 • Coordinate with provincial government program <u>Renewal Criteria (6 months):</u> • Absence of disease progression <u>Initial Criteria (6 months):</u>

DRUG	DISEASE	APPROVAL GUIDELINES
		• For adult patients with a diagnosis of metastatic Castration-Sensitive Prostate Cancer (mCSPC) AND meet the following: o ECOG score of ≤ 2 o Must maintain androgen-deprivation therapy (ADT) with Lupron Depot, Firmagon or Zoladex • Coordinate with provincial government program Renewal Criteria (6 months): • Absence of disease progression
XULTOPHY (Insulin degludec/Liraglutide)	• Diabetes mellitus	• Trial and failure with a basal insulin (i.e. Levemir, Basaglar, Lantus, Toujeo, Tresiba) OR • Trial and failure with a GLP-1 agonist (i.e. Ozempic, Victoza, Byetta, Trulicity)
XYREM (Sodium oxybate)	• Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients	• Diagnosis of narcolepsy with chronic symptoms of cataplexy
YUFLYMA (Adalimumab)	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 • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa	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

DRUG	DISEASE	APPROVAL GUIDELINES
		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. • 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 • Hulio OR Hyrimoz will be the preferred adalimumab where biosimilar switch policy applies PEDIATRIC • 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 Etanercept or Actemra SC • For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ○ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician • For patients 12 to 17 years of age 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. • Coordinate with provincial government program • Hulio OR Hyrimoz will be the preferred

DRUG	DISEASE	APPROVAL GUIDELINES
		adalimumab where biosimilar switch policy applies
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) • Lifetime approval maximum of 126 tablets • For adult patients susceptible to overt hepatic encephalopathy AND have tried lactulose (unless severe intolerance or contraindication) • Coordinate with provincial government program
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.
ZUACTA (Zucapsaicin cream)	• Osteoarthritis	• A confirmed diagnosis of osteoarthritis, where the patient failed to respond OR had intolerable side-effects to Meloxicam AND at least one Non-Steroidal Anti-Inflammatory Drug (NSAID)
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 and generic ABIRATERONE	• 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