(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ABRILADA (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa • Ulcerative Colitis	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 moderately to severely 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.

The Special Authorization Drugs and Approval Guidelines document may be updated from time to time by the Company.
Drugs classified as special authorization may vary amongst plan sponsors.
Updated December 2024

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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 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 patients 5 to 17 years of age with moderate to severe 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) • Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ACTEMRA IV (Tocilizumab)	• Rheumatoid Arthritis • Systemic Juvenile Idiopathic Arthritis (sJIA) • Polyarticular Juvenile Idiopathic Arthritis (pJIA)	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease 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 pediatric patients (between ≥ 2 and ≤ 16 years of age) with a confirmed diagnosis of sJIA with fever (>38oC) for at least 2 weeks AND at least ONE of the following symptoms: rash of systemic JIA, serositis, lymphadenopathy, hepatomegaly, splenomegaly AND who have not adequately responded to NSAIDS, corticosteroids and at least a 3 month trial of methotrexate 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 who has tried and failed Cosentyx 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	• 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 • For pediatric patients (between ≥ 2 and ≤ 16 years of age) with a confirmed diagnosis of sJIA with fever (>38oC) for at least 2 weeks AND at least ONE of the following symptoms: rash of systemic JIA, serositis, lymphadenopathy, hepatomegaly, splenomegaly AND who have not adequately responded to NSAIDS, corticosteroids and at least a 3 month trial of methotrexate • 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) • Coordinate with provincial government program • When combination treatment with Opsumit is requested, OPSYNVI will be approved

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ADEMPAS and generic 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
AFINITOR and generic EVEROLIMUS AFINITOR DISPERZ TAB (Everolimus)	• 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)	Initial criteria: • For patients with a confirmed diagnosis of metastatic renal cell carcinoma of clear cell morphology who have tried and failed initial treatment with generic sunitinib Renewal criteria: • Absence of disease progression • 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 within the last 12 months, AND ○ With an ECOG ≤ 2 • 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• Coordinate with provincial government program
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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
AJOVY (Fremanezumab)	• Episodic or chronic migraine	**Initial criteria (6 months):** • For the prevention of migraine in adults (18+ years old) with at least 4 migraines per month, who have tried and failed, are intolerant or have a contraindication to at least 2 migraine prevention therapies (e.g.: tricyclic analgesics, antiepileptic drugs, beta blockers, Botox). • Must indicate: o Number of migraine days per month, AND **Renewal criteria (1 year):** • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
AMGEVITA (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Ulcerative Colitis	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 moderately to severely 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

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DRUG	DISEASE	APPROVAL GUIDELINES
		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 5 to 17 years of age with moderate to severe 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) • Coordinate with provincial government program
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

(Special Authorization drugs may vary depending on plan)

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
AVONEX AVONEX PS REBIF REBIF MULTIDOSE CARTRIDGE BETASERON (Interferon beta-1b)	• Relapsing Remitting Multiple Sclerosis (RRMS) • Chronic Progressive Multiple Sclerosis • Clinically Isolated Syndrome (CIS)	• For patients with RRMS or progressive MS or diagnosed with 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 • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic Arthritis • Ankylosing spondylitis • 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 moderately to severely 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 moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and

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DRUG	DISEASE	APPROVAL GUIDELINES
		a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • Coordinate with provincial government program
BENLYSTA (Belimumab)	• Systemic Lupus Erythematosus (SLE)	**Initial criteria (6 months):** • 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) • Diabetic macular edema (DME)	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) • For the treatment of visual impairment due to diabetic macular edema
BIKTARVY (Bictegravir/Emtricitabine/Tenofovir alafenamide)	• HIV infection in adults	• For treatment of HIV-1 infection in adults • Coordinate with provincial plans
BIMZELX (Bimekizumab)	• 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 oral systemic therapies (e.g. methotrexate, cyclosporine) AND who are being treated by a dermatologist • Coordinate with provincial government program
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

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DRUG	DISEASE	APPROVAL GUIDELINES
BOTOX (OnabotulinumtoxinA)	• 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 (propranolol, 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, generic Vesicare, generic Detrol, generic Detrol LA, generic Toviaz, generic Trosec) ○ Max dose for OAB = 100U every 3 months ○ 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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
BYOOVIZ (Ranibizumab)	• Neovascular (wet) age-related macular degeneration (AMD) • Visual impairment due to diabetic macular edema (DME) • Visual impairment due to macular edema secondary to retinal vein occlusion (RVO) • Visual impairment due to choroidal neovascular (CNV) secondary to pathologic myopia (PM) • Visual impairment due to choroidal neovascularization (CNV) secondary to ocular conditions other than AMD or PM	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD). • For treatment of visual impairment due to diabetic macular edema (DME). • For treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO). • For treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM). • For treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to ocular conditions other than AMD or PM, including but not limited to angioid streaks, post-inflammatory retinochoroidopathy, central serous chorioretinopathy or idiopathic chorioretinopathy • Byooviz will not be authorized concomitantly with verteporfin for treatment of the same eye. • Drug administered by ophthalmologist • Coordinate with provincial government program
CAPRELSA (Vandetanib)	• For the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in adult patients with unresectable or locally advanced or metastatic disease	• For patients with unresectable locally advanced or metastatic MTC that have enrolled with the CAPRELSA Restricted Distribution Program • Coordinate with available provincial plans
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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES

CIBINQO
(Abrocitinib)
	• Atopic Dermatitis	**Initial approval: 6 months duration**
		• For the treatment of patients 12 years and older with confirmed diagnosis of moderate to severe atopic dermatitis:
		  ○ Severity defined as meeting all 3 conditions below:
		  1) BSA ≥ 10% or involvement of the face, palms, soles, or genital regions or EASI ≥16
		  2) IGA ≥ 3
		  3) DLQI ≥ 8
		  ○ Inadequate response, intolerance or contraindication to phototherapy AND one immunosuppressant (e.g. cyclosporine, azathioprine, methotrexate, mycophenolate mofetil)
		
		Renewal criteria : 1 year duration
		• Documented objective evidence of clinical benefit since initiating therapy, defined as:
		  ○ IGA of 0 or 1 or 50% improvement OR
		  ○ Improvement of EASI of at least 75% of initial score

CIMZIA (Certolizumab pegol)	• 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	Initial Criteria: • For the add on maintenance treatment of severe eosinophilic asthma in patients 18 years or older who meet the following criteria:

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DRUG	DISEASE	APPROVAL GUIDELINES
		○ 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 (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization) Renewal criteria (1 year approval): • At least 50% reduction in number of exacerbations while on Cinqair AND • If continuous oral corticosteroid use : At least 50% reduction in daily oral glucocorticoid dose
COPAXONE and generic GLATIRAMER ACETATE	• Relapsing Remitting Multiple Sclerosis (RRMS) • Clinical 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
COSENTYX (Secukinumab)	• Plaque Psoriasis • Ankylosing spondylitis • Psoriatic Arthritis • Non-radiographic axial spondyloarthritis (nr-axSpA) • Polyarticular Juvenile Idiopathic Arthritis (juvenile psoriatic arthritis (JPsA) or enthesitis-related arthritis (ERA))	• 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 • For patients ages 6 and older with a confirmed diagnosis of polyarticular juvenile arthritis (juvenile psoriatic arthritis (JPsA) or enthesitis-related arthritis (ERA)) where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND who has tried and failed Actemra SC • Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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
DAKLINZA (Daclatasvir)	• Hepatitis C genotype 3	• For adults with chronic hepatitis C genotype 3 in combination with Sovaldi: ○ Fibrosis stage F2 or greater (Metavir scale or equivalent) ○ No diagnosis of cirrhosis ○ Failure of standard peg-interferon/ribavirin therapy ○ HCV levels in the past 6 months ○ Have failed or have a true contraindication to Maviret, Epclusa ○ Coordinate with provincial government program *Maximum approval 12 weeks* **Retreatment requests will not be considered**
DIACOMIT (Stiripentol)	• Dravet Syndrome or Severe Myoclonic Epilepsy in Infancy (SMEI)	• For patients 3 years of age or older with refractory SMEI or Dravet Syndrome: ○ Must be used in conjunction with clobazam and valproate after failure with clobazam and valproate alone • Coordinate with provincial government program
DELSTRIGO (Doravirine/lamivudine/tenofovir disoproxil fumarate)	• HIV Infection	• Coordinate with provincial government program
DESCOVY (Emtricitabine/tenofovir alafenamide)	• HIV Infection • Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	• For treatment of HIV infection • For patients who require Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection who have experienced intolerance or have a contraindication to generic Truvada • Coordinate with provincial government program
DOVATO (Dolutegravir/Lamivudine)	• HIV anti-viral	• Coordinate with provincial government program

The Special Authorization Drugs and Approval Guidelines document may be updated from time to time by the Company.
Drugs classified as special authorization may vary amongst plan sponsors.
Updated December 2024

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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 rhinosinusitis with nasal polyps (CRSwNP) • Severe type 2/eosinophilic asthma • Oral corticosteroid – dependent asthma • Moderate-to-severe prurigo nodularis (PN)	**Initial Approval: 6 months duration** • For the treatment of patients 6 years and older with confirmed severe atopic dermatitis: o 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); o Inadequate response, intolerance or contraindication to phototherapy AND two immunosuppressants (e.g. cyclosporine, azathioprine, methotrexate) **Renewal criteria: 1 year duration** • 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) **Initial Approval: 6 months duration** • For the treatment of adult patients (18+) with confirmed severe chronic rhinosinusitis with nasal polyps (CRSwNP) o Severity defined as meeting all 3 conditions below: 1) NPS (nasal polyps 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, loss of smell, rhinorrhea); o Tried and failed each of the below: 1) Nasal saline irrigations 2) Intranasal corticosteroid (e.g. generic mometasone, generic budesonide, etc.) 3) Oral corticosteroid therapy and/or immunosuppressants (cyclosporine, azathioprine, methotrexate, etc.) 4) Prior sinonasal surgery for nasal polyps o Will not be approved in combination with another biologic (e.g. Nucala, Cinquair, 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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 ≤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 **Renewal criteria: 1 year duration** • 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)** **Initial Approval: 6 months duration** • For the treatment of adult patients with severe prurigo nodularis: ○ Nodular lesions >20 AND ○ WI-NRS of 7 or more AND ○ IGA of 3 or more • Inadequate response, intolerance, or contraindication to topical corticosteroids or topical calcineurin inhibitors AND phototherapy AND two immunosuppressants (E.g. cyclosporine, azathioprine, methotrexate) **Renewal criteria: 1 year duration** • Reduction in WI-NRS score of 4 points or more • IGA of 0 or 1

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DRUG	DISEASE	APPROVAL GUIDELINES
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)
EMGALITY (galcanezumab)	• 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 antidepressants, antiepileptic drugs, beta blockers, Botox). • Must indicate: o Number of migraine days per month, AND o 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
ENBREL (Etanercept)	• Rheumatoid Arthritis • Juvenile Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Plaque psoriasis	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months • For patients 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ENTYVIO IV (Vedolizumab)	• Ulcerative Colitis • Crohn's Disease	• For patients with moderately to severely 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 TWO of the following: Infliximab, Adalimumab, Simponi SC, Velsipity, Ustekinumab, 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 Ustekinumab AND are medically unable to use Entyvio SC • Coordinate with provincial government programs
ENTYVIO SC (Vedolizumab)	• Ulcerative Colitis • Crohn's Disease	• For patients with moderately to severely 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 TWO of the following: Infliximab, Adalimumab, Simponi SC, Velsipity, Ustekinumab • 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 Ustekinumab • Coordinate with provincial government programs
EPCLUSA (Sofosbuvir/Velpatasvir)	• Hepatitis C Infection in genotypes 1-6	• For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C genotype 1-6 infections with: ○ Fibrosis stage F2 or greater (Metavir scale or equivalent) ○ Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months ○ Maviret treatment is not an option due to a true clinical contraindication. • Retreatment requests will not be considered • Coordinate with provincial government programs

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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)	• Rheumatoid Arthritis • 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 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
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:**

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• For adult patients with a diagnosis of metastatic Castration-Sensitive Prostate Cancer (CSPC) AND one of the following: a) ECOG score of ≤ 1 OR b) 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
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)	• Relapsing Remitting Multiple Sclerosis (RRMS) • Chronic Progressive Multiple Sclerosis • Clinically Isolated Syndrome (CIS)	• For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation OR 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 patients who are previously stabilized on Eylea OR patients who are medically unable to use Eylea HD

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		○ For aflibercept naïve patients, Eylea HD will be approved • 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
EYLEA HD (Aflibercept)	• Diabetic Macular Edema (DME)	• For treatment of visual impairment due to diabetic macular edema
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	Initial Criteria: • 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) Renewal criteria: • At least 50% reduction in number of exacerbations while on Fasenra AND • If continuous oral corticosteroid use : At least 50% reduction in daily oral glucocorticoid dose
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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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
FINLIUS (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 moderately to severely 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
FIRDAPSE (Amifampridine phosphate)	• Lambert-Eaton Myasthenic Syndrome (LEMS)	**Initial approval (6 months):** • For the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome in patients treated by a neurologist • Must include baseline 3TUG value **Renewal (1 year):** • 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

(Special Authorization drugs may vary depending on plan)

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
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
FUZEON (Enfuvirtide)	• HIV infection	• For treatment experienced patients who have tried at least three anti-retrovirals from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) and where the CD4 count has fallen below 200 cells/uL. • Coordinate with provincial government program
GENVOYA and generic 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 relapsing remitting multiple sclerosis 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 • EDSS value required with every application • Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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
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 • For patients who are previously stabilized on Glatect OR patients who are medically unable to use Copaxone and generics • For glatiramer acetate naïve patients, only Copaxone and generics will be approved • EDSS value of less than or equal to 6 required with every application • Coordinate with provincial government program where applicable
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. • For the treatment of adult patients with Philadelphia chromosome positive (Ph+) Acute Lymphoblastic Leukemia (ALL) • Coordinate with provincial government program
HADLIMA (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Juvenile Idiopathic Arthritis	ADULT • For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • For patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and a 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
	• Non-infectious anterior uveitis	• 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 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
HANZEMA	• Chronic Hand Eczema (CHE)	• Diagnosis of severe CHE characterized by fissures, vesicles,

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DRUG	DISEASE	APPROVAL GUIDELINES
generic ALITRETINOIN		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)
HARVONI (Ledipasvir /Sofosbuvir)	• Hepatitis C virus (CHC) genotype 1 infection	• For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C genotype 1 infections with: • Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months • Fibrosis stage F2 or greater (Metavir scale or equivalent) • Compensated liver disease including compensated cirrhosis • Have failed or have a true contraindication to Maviret • Retreatment requests will NOT be considered • Coordinate with provincial government program
HEPSERA and generic ADEFOVIR	• Chronic hepatitis B	• For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) • For hepatitis B patients co-infected with HIV who do not require HAART therapy for HIV
HULIO (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Ankylosing spondylitis • Psoriatic arthritis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Ulcerative Colitis	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 moderately to severely 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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 5 to 17 years of age with moderate to severe 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) • Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
HUMATROPE (Somatropin)	• Growth Hormone Deficiency in children • Small for gestational age • Turner's syndrome • Idiopathic Short Stature • Adult Growth Hormone Deficiency	• For the treatment of patients under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate • For the treatment of 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 • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Crohn's Disease • Ulcerative Colitis • 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 moderately to severely 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
	• 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 patients 5 to 17 years of age with moderately to severely 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 2 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,

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		minocycline, tetracycline, doxycycline) AND the Abscess and Nodule count is ≥ 3. • Coordinate with provincial government program
HYRIMOZ (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Crohn's Disease • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa • Ulcerative Colitis	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 moderately to severely 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. o Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician. • Coordinate with provincial government program PEDIATRIC

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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. • For patients 5 to 17 years of age with moderate to severe 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) • 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	**Initial Criteria (6 month duration):** • For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND • In combination with an aromatase inhibitor (e.g. Anastrozole, Letrozole) given continuously AND • No active or uncontrolled metastases to the brain AND • No resistance to prior (neo-) adjuvant aromatase-inhibitor therapy AND

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• No previous systemic treatment including chemotherapy for their advanced disease **Renewal (6 month duration):** • Continue until unacceptable **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 **Renewal Criteria (6 month duration)** • Continue until unacceptable toxicity or disease progression
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 support program • Coordinate with provincial drug programs

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
IDACIO (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • 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 moderately to severely 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 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• 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
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

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

INCIVEK (Telaprevir)	• Hepatitis C	**Initial Criteria:** • For adults with chronic hepatitis C genotype 1 infection with compensated liver, including cirrhosis, in combination with peg interferon alpha/ribavirin • An initial 6 weeks of Incivek will be approved **Renewal Criteria:** • The authorization will be renewed if the HCV-RNA is < 1000 IU/ml at week 4 of Incivek therapy • The maximum duration of treatment will be 12 weeks of Incivek therapy • Coordinate with available provincial plans
INFERGEN (Interferon alfacon-1)	• Hepatitis C	• For patients who have failed to respond to or relapsed after prior administration of Interferon alpha

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
INFLECTRA (Infliximab)	ADULT • Rheumatoid Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Plaque Psoriasis • Crohn's Disease • Ulcerative colitis PEDIATRIC • Crohn's Disease • Ulcerative Colitis	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 moderately to severely 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 moderately to severely 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) • 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:

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		○ 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
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
IRESSA and generic GEFITINIB	• First-line treatment of locally Advanced (not amenable to curative surgery) or metastatic • Non-Small Cell Lung Cancer ("NSCLC")	• For patients with confirmed activating mutations of the EGFR-TK ("mutation-positive") • Coordinate with provincial government program
ISENTRESS (Raltegravir)	• HIV Infection	• Coordinate with provincial government program
JADENU 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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
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: ○ eGFR ≥ 25 to 65 ml/min/1.73m2 (patients 18 – 55 years old) OR ○ eGFR ≥ 25 to 45 ml/min/1.73m2 (patients 56 – 65 years old) and historical evidence of a decline in the eGFR of more than 2.0 mL/min/1.73 m2/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
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) ○ EDSS value required with every application • Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• Patients must be endocrine therapy naïve or endocrine therapy-free for at least 12 months **Renewal Criteria (6 month duration):** • Absence of disease progression • Coordinate with provincial government program
KUVAN (Sapropterin)	• Phenylketonuria (PKU)	• Diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU) for patients 18 years of age or under • Initial requests must 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)
LEMTRADA (Alemtuzumab))	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For RRMS patients who have an inadequate response to, or are unable to tolerate two or more therapies for multiple sclerosis e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera ○ 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) • Advanced or metastatic renal cell carcinoma (RCC)	• 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• In combination with pembrolizumab, for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (RCC) with no prior systemic therapy for metastatic RCC
LONSURF (Trifluride/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 secondary to retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Choroidal neovascularisation (CNV) secondary to pathologic myopia (PM) • Choroidal neovascularisation (CNV) secondary to ocular conditions other than AMD or PM	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) • For treatment of visual impairment due to diabetic macular edema (DME) • For treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO) • For treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM) • For the treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to ocular conditions other than AMD or PM, including but not limited to angioid streaks, post-inflammatory retinochoroidopathy, central serous chorioretinopathy or idiopathic chorioretinopathy • Lucentis will not be authorized concomitantly with verteporfin for treatment of the same eye. • Coordinate with provincial government program
LYSODREN (Mitotane)	• Adrenal cortical carcinoma	• For the treatment of unresectable adrenal cortical carcinoma for both functional and non-functional types
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 for multiple sclerosis e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera • EDSS value required with every application • Coordinate with provincial government program • Maximum cumulative dose = 3.5 mg/kg over 2 years, i.e. 1.75 mg/kg/year

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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: ○ Fibrosis stage F2 or greater (Metavir scale or equivalent) OR ○ 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 - 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 (SPMS) 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
MOUNJARO (Tirzepatide)	• Type 2 Diabetes Mellitus	• For adult patients with type 2 diabetes mellitus where metformin plus another antihyperglycemic agent are either contraindicated, not tolerated or ineffective • Coordinate with provincial government program
MOVAPO (Apomorphine hydrochloride)	• Parkinson's disease	• For patients with advanced Parkinson's disease who have tried and failed levodopa/carbidopa and at least one of the following: generic Comtan, generic Mirapex, generic Parlodel, generic Requip, generic Azilect
MOZOBIL generic 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/Ml, AND b) A history of prior failed mobilization (i.e. Neupogen alone or chemo-mobilization)
NEULASTA (Pegfilgrastrim) LAPELGA (Pegfilgrastim)	• Neutropenia associated with anti-neoplastic therapy	• To co-ordinate with available provincial plans

The Special Authorization Drugs and Approval Guidelines document may be updated from time to time by the Company.
Drugs classified as special authorization may vary amongst plan sponsors.
Updated December 2024

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
FULPHILA (Pegfilgrastim) NYVEPRIA (Pegfilgrastim) ZIEXTENZO (Pegfilgrastim)		
NEUPOGEN (Filgrastim) GRASTOFIL (Filgrastim) NIVYESTYM (Filgrastim) NYPOZI (Filgrastim)	• Neutropenia associated with anti-neoplastic therapy, transplant, HIV/AIDS, stem cell mobilization • Severe chronic neutropenia	• To co-ordinate with available provincial plans
NEXAVAR (Sorafenib)	• Metastatic renal cell (clear cell) carcinoma • Unresectable hepatocellular carcinoma • Thyroid Carcinoma	Initial criteria: • For patients with metastatic renal cell carcinoma who are refractory or resistant to treatment with cytokines and generic sunitinib Renewal criteria: • Absence of disease progression • 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
NGENLA (Somatrogon)	• Growth Hormone Deficiency in Children	• For the treatment of children 3 to 11 years of age with endogenous growth hormone deficiency
NORDITROPIN NORDIFLEX (Somatropin)	• Growth Hormone Deficiency in children • Noonan Syndrome • Small for gestational age • Turner's Syndrome	• For the treatment of patients under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate • For the treatment of 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
NUBEQA (Darolutamide)	• Non-metastatic castration resistant prostate cancer • Metastatic castrate-sensitive prostate cancer (mCSPC)	**Initial Criteria:** • For the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC) **Renewal criteria:** • Absence of disease progression Initial Criteria (6 months): • For the treatment of metastatic castrate-sensitive prostate cancer (mCSPC) in combination with docetaxel and androgen deprivation therapy (ADT) in patients who meet the following: ○ Concurrently receiving a gonadotropin-releasing hormone (e.g. Lupron Depot, Firmagon, Zoladex/Zoladex LA) or have undergone a bilateral orchiectomy ○ Did not receive prior treatment with an androgen receptor axis-targeted therapy (e.g. generic Zytiga, Erleada, Xtandi) or chemotherapy for prostate cancer ○ Did not receive ADT in the metastatic setting for more than 6 months or within 1 year of completing adjuvant ADT in the nonmetastatic setting ○ ECOG score of ≤1 • Coordinate with the provincial government program Renewal Criteria (6 months): • Continue until unacceptable toxicity or disease progression
NUCALA (Mepolizumab)	• Severe eosinophilic asthma • Severe chronic rhinosinusitits with nasal polyps (CRSwNP)	Initial Criteria: • 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 (i.e. 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) Renewal criteria: • At least 50% reduction in number of exacerbations while on Nucala AND • If continuous oral corticosteroid use: At least 50% reduction in daily oral glucocorticoid dose Initial Approval (1 year):

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES

		• 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

NUTROPIN (Somatropin)	• Growth Hormone Deficiency in children • Turner's 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 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
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 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 who epiphyses are not closed

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		• For the 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
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)	**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, Glattiramer, Extavia, Plegridy, Rebif, generic Tecfidera ○ EDSS value required with every application • Coordinate with provincial government program **PPMS:** • Confirmed diagnosis of primary progressive multiple sclerosis ○ EDSS value required with every application • EDSS score between 3.0 and 6.5
ODEFSEY (Emtricitabine/Rilpivirine/Tenofovir Alafendamide)	• HIV-1 infection	• Coordinate with provincial government program
OFEV (Nintedanib)	• Idiopathic Pulmonary Fibrosis • Systemic Sclerosis Interstitial Lung Disease (SSc-ILD) • Chronic Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)	**Initial Criteria:** • For patients diagnosed with idiopathic pulmonary fibrosis (IPF) as confirmed by clinical chest radiology (HRCT) or a lung biopsy with a Forced Vital Capacity (FVC) between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted **Renewal criteria:** • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months Coordinate with provincial government program

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		Initial Criteria • 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 **Renewal Criteria:** • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months Coordinate with provincial government program **Initial Criteria** • For patients diagnosed with PF-ILD with features of diffuse lung disease ≥ 10% fibrosis on a HRCT scan AND a Forced Vital Capacity (FVC) ≥ 45% of predicted AND a Percent Carbon Monoxide Diffusing Capacity (DLCO%) between 30% to 79% of predicted **Renewal Criteria:** • Stable disease, defined as FVC not decreased by ≥ 10% during the previous 12 months Coordinate with provincial government program
OLUMIANT (Baricitinib)	• Rheumatoid Arthritis	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 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
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 adults who have Growth Hormone Deficiency (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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
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 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
ORENCIA IV (Abatacept)	• Rheumatoid Arthritis • 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

(Special Authorization drugs may vary depending on plan)

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
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
OTEZLA and generic 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
PDP-LEVETIRACETAM SOLUTION (Levetiracetam 100mg/ml)	• Epilepsy	• Patient is medically unable to swallow Levetiracetam tablets AND one of the following: ○ For adjunctive management of adult patients with epilepsy who have tried and failed, or are intolerant to a standard therapy ○ For adjunctive treatment of partial onset seizures in patients 1 month of age to less than 18 years of age with epilepsy ○ For adjunctive treatment of myoclonic seizures in adolescents from 12 years of age with Juvenile Myoclonic Epilepsy ○ 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
PHEBURANE (Sodium phenybutyrate)	• Urea cycle disorder	• Diagnosis of urea cycle disorders; AND • For patients who weighs ≥ 20 kg WITH a BSA ≤ 1.5 m2 and prescribed with a usual recommended dose of 9.9-13.0 g/m2/day; AND • Patient is currently on dietary protein restrictions; AND • Initial request must indicate ammonia levels prior to starting therapy
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 and generic 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
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 DELAYED RELEASE 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
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)	• Primary Hyperlipidemia (Heterozygous familial or non-familial hypercholesterolemia) • Atherosclerotic Cardiovascular Disease (ASCVD)	**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* 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% **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 clinical atherosclerotic cardiovascular disease (ASCVD) i.e. MI, PCI, CABG, stroke, who require additional lowering of LDL-C despite trial and failure of maximum

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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. **Renewal Criteria – 1 year approval:** • Patient must provide LDL levels showing a decrease of 25%
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 • For the prevention of CMV disease in adult kidney transplant recipients who are at high risk (defined as donor CMV-seropositive [D+]/recipient CMV-seronegative [R-]) with intolerance, contraindication, or documented resistance to generic Valcyte.
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)
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
QULIPTA (Atogepant)	• Episodic or Chronic Migraine	Initial Criteria (6 months): • For the prevention of episodic migraine in adults (18+ years old) with at least 4 migraines per month, who have tried and failed, are intolerant or have a contraindication to at least 2 migraine prevention therapies (e.g.: tricyclic analgesics, antiepileptic drugs, beta blockers) • Must indicate: Number of migraine days per month

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		Renewal Criteria (1 year): • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
RANOPTO (Ranibizumab)	• End-stage or "wet" age-related macular degeneration ("AMD") • Diabetic macular edema • Macular edema secondary to retinal vein occlusion (RVO) • Choroidal neovascularization (CNV) secondary to pathologic myopia (PM). • choroidal neovascularization (CNV) secondary to ocular conditions other than AMD or PM, including but not limited to angioid streaks, post-inflammatory retinochoroidopathy, central serous chorioretinopathy or idiopathic chorioretinopathy	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD). • For treatment of visual impairment due to diabetic macular edema (DME). • For treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO). • For treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM). • For treatment of visual impairment due to choroidal neovascularization (CNV) secondary to ocular conditions other than AMD or PM, including but not limited to angioid streaks, post-inflammatory retinochoroidopathy, central serous chorioretinopathy or idiopathic chorioretinopathy • Ranopto will not be authorized concomitantly with verteporfin for treatment of the same eye. • Drug administered by ophthalmologist • Coordinate with provincial government program
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 • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • 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 moderately to severely 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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 moderately to severely 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) • Coordinate with provincial government program
REMSIMA SC (Infliximab)	• 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
RENFLEXIS (Infliximab)	• Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • 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 moderately to severely 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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 moderately to severely 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) • Coordinate with provincial government program
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

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DRUG	DISEASE	APPROVAL GUIDELINES

		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:
		  ○ 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
		  ○ 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
		
		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

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, Thalidomide) and whose ECOG is of 2 or less. • Coordinate with provincial government program
REVOLADE and generic ELTROMBOPAG OLAMINE	• Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	• For adult patients who are splenectomised and have tried and failed corticosteroids and immunoglobulins • For adult patients who are non-splenectomised (where surgery is contraindicated) and have tried and failed corticosteroids and immunoglobulins • For pediatric patients 1 year of age or older who have tried and failed corticosteroids and immunoglobulins • Platelet counts less than 30 x 109/L

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DRUG	DISEASE	APPROVAL GUIDELINES
		• 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
RINVOQ (Upadacitinib)	• Rheumatoid Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Atopic Dermatitis • Crohn's Disease • 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 a confirmed diagnosis of active ankylosing spondylitis AND all of the following: ○ Symptoms are uncontrolled by NSAIDS ○ BASDAI score is ≥ 4 ○ Inadequate response to at least ONE biologic DMARD (i.e. Adalimumab, Etanercept, Infliximab, Cimzia, Cosentyx, Simponi IV, Simponi SC, Taltz), unless use of those therapies are inappropriate **Initial Approval (20 weeks duration):** • For the treatment of patients 12 years of age and older with confirmed diagnosis of refractory moderate to severe atopic dermatitis: ○ Treatment is prescribed and supervised by a specialist physician experienced in the diagnosis and treatment of atopic dermatitis ○ Severity defined as meeting all 3 conditions below: 1) PGA/IGA of 3 or more 2) BSA of ≥10% or involvement of the face, palms, soles or genital regions or EASI ≥16 3) DLQI ≥ 8; ○ Inadequate response, intolerance or contraindication to 1 of 4 systemic immunomodulators (e.g. cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) AND maximally tolerated medical topical therapies combined with phototherapy • Upadacitinib should not be used in combination with phototherapy, any immunomodulatory drugs (including biologics) or other JAK inhibitor treatment for moderate to severe AD • Rinvoq 15mg and Rinvoq 30mg may be approved at therapy initiation. **Renewal Criteria (12 months duration):**

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DRUG	DISEASE	APPROVAL GUIDELINES
		• Documented objective evidence of clinical benefit since initiating therapy, defined as: o 75% or greater improvement from baseline in EASI score 20 weeks after treatment initiation, and maintenance of 75% response thereafter OR o PGA/IGA of 0 or 1 or 50% improvement **Dose increase to Rinvoq 30mg will not be authorized for patients with moderate disease. Maintenance Rinvoq 30mg will only be approved for patients with severe disease with the following baseline values:** 1) IGA of 3 or more, AND 2) BSA of at least 30% or involvement of the face, palms, soles or genital regions or EASI ≥21, AND 3) DLQI ≥ 10 or severe disruption in sleep **Initial Approval (12 weeks duration):** • For adult patients with confirmed diagnosis of moderate to severe active Crohn's Disease who have failed to response to corticosteroids AND an immunosuppressant agent (eg. azathioprine, 6-mercaptopurine, methotrexate) • Rinvoq 45 mg may be approved at therapy initiation **Renewal Criteria (12 months duration):** • Rinvoq 15 mg and Rinvoq 30mg may be approved for maintenance • Documentation of clinical rationale for 30mg daily maintenance dose required **Initial Approval (8 weeks duration):** • For adult patients with confirmed diagnosis of moderate to severe active Ulcerative Colitis who have failed to respond to corticosteroids AND a 5-ASA product or an immunosuppressant agent (eg. azathioprine, 6-mercaptoputine) • Rinvoq 45 mg may be approved at therapy initiation **Renewal Criteria (12 months duration):** • Rinvoq 15 mg and Rinvoq 30mg may be approved for maintenance • Documentation of clinical rationale for 30mg daily maintenance dose required **Coordinate with available provincial plans for coverage.**
RITUXAN (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 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) o For patients who are medically unable to use a Rituximab biosimilar o For Rituxumab naïve patients, only a Rituximab biosimilar will be approved **Retreatment criteria: 1 year** ▪ Evidence of beneficial clinical effect ▪ Renewal no less than 6 months after the last dose of Rituxan.

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DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Dose: Two doses of 1000 mg IV infusions 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
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 i.e. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab. **Retreatment criteria: 1 year** ▪ Evidence of beneficial clinical effect ▪ Renewal no less than 6 months after the last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusions 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/ m2 body surface area, administered as an IV infusion once weekly for 4 weeks
RUKOBIA (Fostemsavir)	• HIV-1 infection in heavily treatment-experienced (HTE) adults with multidrug-resistant HIV-1 infection	• For use in combination with other antiretroviral agents for treatment-experienced HIV-1 patients 18 years of age and older who have: ○ Inadequate response, have documented resistance or are intolerable to an anti-retroviral from at least four of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI) (e.g., generic Viread, generic Retrovir), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) (e.g. generic Sustiva, generic Viramune), Protease Inhibitors (PI) (e.g. Norvir, generic Prezista), Integrase Strand Transfer Inhibitors (ISTIs) (e.g. Isentress, Tivicay), CCR5 antagonists (e.g. Celsentri), and/or Fusion Inhibitors (e.g. Fuzeon)

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		○ Documented remaining sensitivity to at least 1, but not more than 2, fully-active anti-retroviral agents ○ Medically unable to use other remaining active anti-retroviral agents (must specify clinical rationale)
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 i.e. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab. **Retreatment criteria: 1 year** ▪ Evidence of beneficial clinical effect ▪ Renewal no less than 6 months after the last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusions 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). ○ Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks
RYDAPT (midostaurin)	• Newly diagnosed FLT3-mutated acute myeloid leukemia (AML)	• For adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3-mutation positive AND one of the following: a) In combination with cytarabine and daunorubicin induction chemotherapy (one-time induction approval: 112 capsules) • b) In combination with cytarabine consolidation (post-induction) chemotherapy (one-time consolidation approval: 224 capsules)
RYMTI (Etanercept)	• Rheumatoid Arthritis • Ankylosing Spondylitis • Plaque Psoriasis • Psoriatic Arthritis • Moderate to Severe Juvenile Idiopathic Arthritis	• For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months. • For patients 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

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DRUG	DISEASE	APPROVAL GUIDELINES
		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.
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
SAIZEN (Somatropin)	• Growth Hormone Deficiency in children • Small for gestational age • Turner's 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

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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 analgesics, opioids, antidepressants or anticonvulsants, with little or no effect
SAPHNELO (Anifrolumab)	• Systemic Lupus Erythematosus (SLE)	Initial Criteria (1 year duration): • 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 SLEDAI-2K score ≥ 6 AND who have tried and failed or are intolerant to an oral corticosteroid dose of at least 10mg/day of prednisone or its equivalent AND at least one other standard therapy (e.g. azathioprine, methotrexate, mycophenolate mofetil, hydroxychloroquine) Renewal Criteria (1 year duration): • Reduction in oral corticosteroid dose to ≤ 7.5 mg/day of prednisone or its equivalent • Reduction in disease activity measured by: o Reduction of SLEDAI-2K score to 5 or less
SCEMBLIX (Asciminib)	• Chronic myeloid leukemia (CML)	• For adult patients with chronic phase (CP) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) who are resistant or intolerant to at least two prior TKI therapies (e.g. imatinib, bosutinib, dasatinib, nilotinib) • 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
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

The Special Authorization Drugs and Approval Guidelines document may be updated from time to time by the Company.
Drugs classified as special authorization may vary amongst plan sponsors.
Updated December 2024

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DRUG	DISEASE	APPROVAL GUIDELINES
		• Coordinate with provincial government program
SILIQ (Brodalumab)	• Plaque psoriasis	• For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
SIMLANDI (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • 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 moderately to severely 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

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DRUG	DISEASE	APPROVAL GUIDELINES
		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 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
SIMPONI IV (Golimumab)	• 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

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DRUG	DISEASE	APPROVAL GUIDELINES
		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
SIMPONI SC (Golimumab)	• Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • 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 moderately to severely 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 • Psoriatic Arthritis • Crohn's Disease	• 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 • For adult 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 20mg/week AND leflunomide or sulfasalazine for a period of 3 months • For patient with moderate to severe Crohn's Disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) • Coordinate with provincial government program

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DRUG	DISEASE	APPROVAL GUIDELINES
SOMATULINE AUTOGEL (Lanreotide)	• Acromegaly	• Coordinate with provincial government program
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
SOTYKTU (Deucravacitinib)	• Plaque psoriasis	• For patients who are 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 treated by a dermatologist
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) • Moderate to severe episode of major depressive disorder requiring urgent psychiatric care	Initial Criteria (6 month approvals): • 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

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DRUG	DISEASE	APPROVAL GUIDELINES
		• 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 Renewal Criteria (6 month approvals): • 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) • For patients experiencing a moderate to severe episode of major depressive disorder, which according to clinical judgement requires urgent psychiatric care ○ Prescriber must specify severity of symptoms, e.g. current Montgomery-Asberg Depression Rating Scale (MADRS) score, PHQ-9 score, Hamilton Depression Rating Scale (HDRS), Clinical Global Impression-Severity of Suicidality-Revised (CGI-SS-r) ○ Must be used in combination with at least one oral antidepressant therapy: SSRI, SNRI and/or other antidepressant drug class (e.g. bupropion, mirtazapine, etc.) ○ Must be enrolled in Janssen Journey Program ○ Maximum duration of approval: 4 weeks
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 Lymphoblastic Leukemia (ALL) resistant or intolerant to prior therapy • Coordinate with provincial government program
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 moderately to severely active Ulcerative Colitis who failed or are

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DRUG	DISEASE	APPROVAL GUIDELINES
		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
STIVARGA (Regorafenib)	• Metastatic Colorectal Cancer • Metastatic and/or unresectable gastrointestinal stromal tumors (GIST)	• For patients with a diagnosis of metastatic colorectal cancer (CRC) AND ○ Treated previously with all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin, irinotecan, an anti-VEGF therapy (bevacizumab), AND ○ If KRAS wild type, an anti-EGFR therapy (cetuximab, panitumumab) • For metastatic and/or unresectable GIST patients who have tried and failed or is intolerable to imatinib and sunitinib therapy • ECOG ≤ 1 • Coordinate with provincial government program
STRIBILD (Cobicistat/Tenofovir/Emtricitabine/ Elvitegravir)	• HIV anti-viral	• Coordinate with available provincial government programs
SUTENT and generic SUNITINIB	• Gastrointestinal Stromal Tumour (GIST) • Treatment of metastatic Renal Cell Carcinoma (“RCC”) of clear cell histology	• For GIST patients who have tried and failed or had no response to Gleevec (imatinib) <u>Initial criteria:</u> • As a first line agent for patients with a diagnosis of metastatic RCC of clear cell histology • As a second-line agent for patients with a diagnosis of metastatic RCC who have progressed on cytokine-based therapy or immunotherapy • ECOG of two or less must be documented. • Coordinate with provincial government program <u>Renewal criteria:</u> • Absence of disease progression • 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

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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 Leflunomide 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 where symptoms 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 Scelrosis (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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES

TEZSPIRE
(Tezepelumab)
	• Severe asthma	Initial Criteria (1 year duration):
		• For add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who meet the following criteria:
		  ○ 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
		  ○ 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
		• Baseline assessment of asthma using an asthma control questionnaire e.g ACQ, ACT
		• Will not be approved in combination with another biologic (e.g. Dupixent, Nucala, Cinqair, Fasenra, Xolair)
		
		Renewal Criteria (1 year duration):
		• At least 50% reduction in number of exacerbations while on Tezspire
		• Demonstrates improvement in symptoms based on an asthma control questionnaire (e.g ACQ, ACT)

THALOMID (Thalidomide)	• Multiple myeloma	• For patients ≥ 65 years of age who are not eligible for autologous stem cell transplantation • For use in combination with dexamethasone OR melphalan and prednisone • ECOG ≤ 2 • Coordinate with provincial government program
THYROGEN (Thyrotropin alpha Injection)	• 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

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DRUG	DISEASE	APPROVAL GUIDELINES
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
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 have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months • Coordinate with provincial government program
TRIUMEQ (Dolutegravir/Abacavir/ Lamivudine)	• HIV infection in adults	• Coordinate with provincial government program
TRUVADA and generic EMTRICITABINE/TENOFOVIR	• HIV infection in adults	• Coordinate with provincial government program
TRUXIMA (Rituximab)	• Rheumatoid Arthritis • Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)	**Initial criteria: 1 year** • For the treatment of patients with RA who have tried and failed or could not tolerate at least one or more anti-TNF treatment (i.e. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) **Retreatment criteria: 1 year** • Evidence of beneficial clinical effect • Renewal no less than 6 months after the last dose of rituximab • Dose: Two doses of 1000 mg IV infusions 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
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

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DRUG	DISEASE	APPROVAL GUIDELINES
TYSABRI (Natalizumab)	• Relapsing Remitting Multiple Sclerosis (RRMS)	• For RRMS patients who 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 ○ 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 ○ EDSS value required with every application • Coordinate with provincial government program
UPTRAVI (Selexipag)	• Pulmonary Arterial Hypertension (PAH) WHO functional class (FC) II–III (idiopathic, heritable, or associated with connective tissue disease or congenital heart disorders)	• For patients who have tried and failed or cannot tolerate at least one ERA (i.e. Tracleer, Volibris, Opsumit) or PDE-5 inhibitor (i.e. Revatio, Adcirca) • May be used as monotherapy OR an add-on to existing ERA/PDE-5 inhibitor OR triple combination therapy
VABYSMO (Faricimab)	• Wet age-related macular degeneration • Diabetic Macular Edema (DME)	• For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) • For treatment of visual impairment due to diabetic macular edema • Coordinate with provincial government program
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
VELSIPITY (Etrasimod)	• Ulcerative Colitis	• For patients with moderately to severely 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)

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DRUG	DISEASE	APPROVAL GUIDELINES
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

VERZENIO
(Abemaciclib)
	• Advanced or metastatic breast cancer
	• Adjuvant – Early Breast Cancer
		Initial Criteria (6 month duration):
		• For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND
		• 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)
		
		Renewal (6 month duration):
		• Continue until unacceptable toxicity or disease progression
		
		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
		
		Renewal Criteria (6 month duration)
		• Continue until unacceptable toxicity or disease progression
		
		Initial Criteria (6 months duration):
		• For the adjuvant treatment of women with hormone receptor-positive, human epidermal growth factor 2-negative (HR+/HER2-), node-positive, early breast cancer without metastases AND
		• In combination with endocrine therapy (e.g. anastrozole, letrozole, tamoxifen) AND
		• Ki-67 index score ≥ 20% AND
		• Last tumour resection within the last 16 months AND
		• One of the following:
		  ○ At least 4 positive lymph nodes OR
		  ○ 1 to 3 positive lymph nodes AND grade 3 tumour or primary tumour size ≥ 5 cm
		• Must be CDK 4/6 inhibitor treatment naïve
		
		Renewal Criteria (6 months duration):
		• Continue until unacceptable toxicity or disease progression
		• Maximum treatment duration of 2 years

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DRUG	DISEASE	APPROVAL GUIDELINES
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
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	• 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
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

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DRUG	DISEASE	APPROVAL GUIDELINES
		• Coordinate with provincial government program
VOTRIENT and generic 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
VYALEV (Foslevodopa/Foscarbidopa	• 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. • Coordinate with provincial government program.
VYEPTI (Eptinezumab)	• Migraines	Initial criteria (6 months): • For the prevention of migraine in adults (18+ years old) with at least 4 migraines per month, who have tried and failed, are intolerant or have a contraindication to at least 2 migraine prevention therapies (i.e.: tricyclic analgesics, antiepileptic drugs or beta blockers). • Must indicate: Baseline number of migraine days per month Renewal criteria after initial trial (will be approved for 1-year duration): • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
WAKIX (Pitolisant)	• Excessive daytime sleepiness (EDS) in narcoleptic patients • Cataplexy in narcoleptic patients	• For the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy who have tried and failed or are intolerant to at least three of the following therapies: generic Alertec, generic Ritalin, generic Dexedrine, and Sunosi. • For the treatment of cataplexy in adult patients with narcolepsy who have tried and failed or are intolerant to at least one prior therapy (e.g. SSRI, SNRI)
		• 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

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DRUG	DISEASE	APPROVAL GUIDELINES
WEZLANA (Ustekinumab)	• Plaque psoriasis • Psoriatic Arthritis • Crohn's Disease • Ulcerative Colitis	• 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 Amgen Entrust • For patients with moderately to severely 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 Amgen Entrust • 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
XELJANZ and generic 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 moderately to severely 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 ONE of the following: infliximab, Adalimumab, Simponi SC, Velsipity, and Ustekinumab • Coordinate with provincial government program

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DRUG	DISEASE	APPROVAL GUIDELINES
XELJANZ XR	• 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
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)
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
XOLAIR Pre-Filled Syringes (PFS) (Omalizumab)	• Severe allergic asthma • Chronic idiopathic urticaria	Initial Criteria: • 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 aged 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 • In all cases, must provide number of clinically significant asthma exacerbations (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization) over the last 12 months Renewal Criteria: • At least 50% reduction in number of exacerbations while on Xolair AND • If continuous oral corticosteroid use: At least 50% reduction in daily oral glucocorticoid dose

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DRUG	DISEASE	APPROVAL GUIDELINES
		• 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)	**Initial Criteria (6 month duration):** • For patients with a diagnosis of metastatic CRPC who received prior chemotherapy containing docetaxel **Renewal Criteria (6 month duration):** • Absence of disease progression **Initial Criteria (6 month duration):** • 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 **Renewal Criteria (6 month duration):** • Absence of disease progression **Initial Criteria (6 month duration):** • For adult patients with a diagnosis of metastatic Castration-Sensitive Prostate Cancer (mCSPC) AND meet the following: ○ ECOG score of ≤ 2 ○ Must maintain androgen-deprivation therapy (ADT) with Lupron Depot, Firmagon or Zoladex **Renewal Criteria (6 month duration):** • Absence of disease progression • Coordinate with provincial government program
XYREM (Sodium Oxybate)	• Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients	• Diagnosis of narcolepsy with chronic symptoms of cataplexy who have tried and failure or are intolerant to at least two prior therapies one of which is Wakix
XYWAV (Calcium, Magnesium, Potassium, and Sodium Oxybates)	• Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients	• For the treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients with chronic symptoms of cataplexy who have tried and failed or are intolerant to at least two prior therapies, one of which is Wakix.
YUFLYMA (Adalimumab)	ADULT • Crohn's Disease • Ulcerative Colitis • Rheumatoid Arthritis • Psoriatic arthritis	ADULT • For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine)

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
	• Ankylosing spondylitis • Plaque psoriasis • Hidradenitis Suppurativa • Non-infectious Uveitis PEDIATRIC • Juvenile Idiopathic Arthritis • Non-infectious anterior uveitis • Hidradenitis Suppurativa	• For patients with moderately to severely 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 <u>PEDIATRIC</u> • 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

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		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
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.
ZEPOSIA (Ozanimod)	• Ulcerative Colitis	• 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)
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,

(Special Authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
		chlorambucil, fludarabine, ofatumumab, chlorambucil, etc.) • Must be taken in combination with rituximab • Coordinate with provincial government program
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