AFBS
Special Authorization Drugs and Approval Guidelines

DRUG	DISEASE	APPROVAL GUIDELINES
ABILIFY MAINTENA (Aripiprazole injection)	▪ Schizophrenia ▪ Bipolar Disorder ▪ Major Depressive Disorder	▪ For the treatment of patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in ≥ 1 relapse/hospitalization ▪ For the treatment of manic or mixed episodes in bipolar 1 disorder, as acute monotherapy or in combination with lithium or divalproex sodium ▪ For the treatment of Major Depressive Disorder (MDD) in patients with inadequate response to prior antidepressant treatment
ABRILADA* (Adalimumab)	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic 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 or involvement of the face, palms, soles or genital regions,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

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		physician. ▪ Coordinate with provincial government program <u>PEDIATRIC</u> ▪ 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 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 ▪ <u>Renewal Criteria:</u> 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
ACCRUFER (Ferric Maltol)	Iron Deficiency Anemia (IDA)	For patients diagnosed with iron deficiency anemia (IDA) who have been unresponsive or intolerant to at least two oral iron supplements (e.g. ferrous fumarate, ferrous gluconate, ferrous sulfate)
ACLASTA and generic ZOLEDRONIC ACID	▪ Paget's disease of the bone ▪ Postmenopausal osteoporosis	▪ For the treatment of Paget's disease ▪ For the treatment of osteoporosis in post-menopausal women and men who have a bone mineral density (BMD) T-score of less than or equal to -2.5 AND who have tried and failed, or have an intolerance or contraindicated to oral bisphosphonate therapy
ACTEMRA IV* (Tocilizumab)	▪ Rheumatoid Arthritis ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) ▪ Polyarticular Juvenile Idiopathic Arthritis (pJIA)	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 monthsAND who have tried and failed Cimzia or Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC ▪ For patients aged 2 and older with a confirmed

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		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 aged 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 (sJIA)	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months ▪ For adult patients with a confirmed diagnosis of giant cell arteritis with persistent active disease where the patient has not adequately responded to prednisone at maximum tolerated dose for a period of 3 months ▪ For patients aged 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 patients aged 2 and older 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
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
ADLYXINE (Lixisenatide)	▪ Type II Diabetes	▪ For patients who have tried and failed or did not tolerate maximum doses of metformin (≥2000 mg)

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AFINITOR* and generic EVEROLIMUS*
 	
AFINITOR DISPERZ TAB*
(Everolimus)
	▪ Second-line treatment of metastatic Renal Cell Carcinoma ("RCC")
	▪ Neuroendocrine Tumours of pancreatic origin (PNET)
	▪ Advanced breast cancer
	▪ Renal Angiomyolipoma
	▪ Subependymal giant cell astrocytoma (SEGA)
	▪ Neuroendocrine Tumours of Gastrointestinal (GI) or Lung origin
	▪ Seizures associated with Tuberous Sclerosis Complex (TSC)
		▪ For patients with a confirmed diagnosis of metastatic renal cell carcinoma of clear cell morphology who have tried and failed initial treatment with a tyrosine kinase inhibitor
		▪ For treatment of well- or moderately differentiated PNET in patients with unresectable, locally advanced or metastatic disease that has:
		  ▪ Progressed within the last 12 months, AND
		  ▪ With an ECOG ≤ 2
		▪ For postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer in combination with exemestane after recurrence or progression following treatment with letrozole or anastrozole
		▪ For the treatment of adult patients (≥18 years of age) with renal angiomyolipoma associated with tuberous sclerosis complex (TSC), who do not require immediate surgery
		▪ For the treatment of patients 3 years of age or older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) that have demonstrated serial growth, who are not candidates for surgical resection and for whom immediate surgical intervention is not required
		▪ For the treatment of neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin in adult patients with unresectable, locally advanced or metastatic, well differentiated, and non-functional disease, who are treatment naïve or treatment-experienced who have:
		  ▪ Progressed on or after the last treatment AND
		  ▪ An ECOG ≤ 1
		▪ As add-on therapy for seizures associated with Tuberous Sclerosis Complex (TSC) in patients 2 years and older who have tried and failed at least 2 anti-epileptic drugs: carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
		▪ Coordinate with provincial government program

AIMOVIG
(Erenumab)
	▪ Episodic or chronic migraine	<u>Initial criteria (6 months):</u>
		▪ For the prevention of migraine in adults (18+ years old) with at least 8 migraines per month, who have tried and failed, are intolerant or have a contraindication to at least 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
		
		<u>Renewal criteria (1 year):</u>
		▪ Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline

AJOVY (Fremanezumab)	▪ Episodic or chronic migraine	<u>Initial criteria (6 months):</u> ▪ 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:

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		▪ Number of migraine days per month <u>Renewal criteria (1 year):</u> ▪ Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline
AMGEVITA* (Adalimumab)	<u>ADULT</u> ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis <u>PEDIATRIC</u> ▪ Crohn's Disease ▪ Juvenile Idiopathic Arthritis ▪ Non-infectious anterior uveitis ▪ Ulcerative Colitis	<u>ADULT</u> • 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 or involvement of the face, palms, soles or genital regions,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. ▪ <u>Renewal Criteria:</u> Stability or improvement of vision and control of ocular inflammation confirmed by physician. ▪ Coordinate with provincial government program; <u>PEDIATRIC</u> ▪ 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 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

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		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;
GENERIC AMLODIPINE ORAL SOLUTION (Amlodipine Besylate)	▪ Pediatric Hypertension ▪ Hypertension ▪ Angina	▪ For management of hypertension or angina in patients (>6 years old) who are medically unable to swallow amlodipine tablets
ANDROGEL PUMP (Testosterone 1% pump)	▪ Endogenous testosterone deficiency	▪ For patients who have tried and failed Testosterone packets(i.e. generic Androgel packets)
ANORO ELLIPTA (Umeclidinium/Vilanterol)	▪ Chronic Obstructive Pulmonary Disease (COPD)	▪ For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy
APPRILON and generic DOXYCYCLINE	- Rosacea	▪ For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)
Apretude (Cabotegravir sodium)	▪ Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	▪ For patients who require Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection who have experienced intolerance or have a contraindication to generic Truvada
APTIOM and generic ESLICARBAZEPINE	▪ Partial-onset seizures	▪ For patients with a diagnosis of partial onset seizures who have tried and failed or experienced intolerant side effects to at least 1 standard care drug i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
APTIVUS * (Tipranavir)	▪ HIV Infection	▪ For use in combination with ritonavir for the treatment of HIV in patients 18 years of age and older who have tried and failed or are intolerable to at least one : Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and at least 2 Protease Inhibitors (PI), and in whom no other PI is a treatment option ▪ Coordinate with provincial government program
ARANESP* (Darbepoetin Alfa)	▪ Anemia with chemotherapy ▪ Chronic renal failure	▪ For patient with chronic renal failure ▪ For patient with anemia secondary to chemotherapy ▪ Coordinate with provincial government program

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ATRIPLA* and generic EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	▪ HIV anti-viral	▪ Coordinate with provincial government program
AUBAGIO* and generic TERIFLUNOMIDE* (Teriflunomide)	▪ Relapsing remitting Multiple Sclerosis (RRMS)	▪ Confirmed diagnosis of RRMS ▪ EDSS value required with every application ▪ Coordinate with provincial government program
AVODART and generic DUTASTERIDE	▪ Benign Prostatic Hyperplasia	▪ For male patients in the treatment of benign prostatic hyperplasia
AVONEX* AVONEX PS* REBIF* REBIF MULTIDOSE CARTRIDGE* BETASERON* (Interferon beta-1b)	Relapsing remitting Multiple Sclerosis (RRMS) ▪ Chronic Progressive Multiple Sclerosis ▪ Clinically Isolated Syndrome	▪ For patients with RRMS or progressive MS ▪ For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation ▪ EDSS value required with every application ▪ Coordinate with provincial government program
AVSOLA* (Infliximab)	▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis	ADULT ▪ For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Patients with 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 or involvement of the face, palms, soles or genital regions, 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 6 years of age or older with moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Patients 9 years of age or older with moderately to

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		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)
AWIQLI (insulin icodec)	- Diabetes mellitus	▪ For patients with diabetes mellitus who have had an inadequate response or intolerance to long-acting insulin (e.g. insulin glargine)
BANZEL* and generic RUFINAMIDE*	▪ Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome	▪ For the treatment of Lennox Gastaut Syndrome in children 4 years and older and adults, in combination with other anti-epileptic drugs (e.g. valproic acid, topiramate, lamotrigine)
BASAGLAR (Insulin glargine)	- Diabetes mellitus	▪ For patients who are at high risk for hypoglycemia ▪ For insulin glargine naïve patients, Semglee will be approved
BENLYSTA* (Belimumab)	- Systemic Lupus Erythematosus (SLE)	<u>Initial criteria (1 year):</u> ▪ 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 <u>Renewal criteria (1 year):</u> ▪ 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 or involvement of the face, palms, soles or genital regions, 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

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BIPHENTIN CR and generic METHYLPHENIDATE CR	- Attention deficit hyperactivity disorder	▪ For patients who have tried and failed or had intolerable side effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera
BOSULIF* (Bosutinib)	- Chronic myeloid leukemia (CML)	▪ For the treatment of adults with any phase of Philadelphia chromosome positive chronic myeloid leukemia (chronic, accelerated, or blast phase) who are resistant or tolerant to prior TKI therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate ▪ For adult patients with newly-diagnosed chronic phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) ▪ Coordinate with provincial government program
BOTOX (Onabotulinumtoxin A)	- Blepharospasm - Strabismus - Cervical dystonia (spasmodic torticollis) - Focal spasticity - Cerebral palsy - Hyperhidrosis - Chronic Migraines - Bladder Dysfunction	▪ For the treatment of blepharospasm and strabismus in patients 12 years of age or older ▪ For the treatment of torticollis in adult patients ▪ For the treatment of upper and/or lower limb focal spasticity in patients aged 2 years and older ▪ For axillary hyperhidrosis in patients that have failed or are intolerant to an aluminum chloride preparation ▪ For the prophylaxis of headaches in adults with chronic migraines (≥ 15 per month with headaches lasting 4 hours a day or longer) who have tried and failed 2 prophylactic treatments, e.g. tricyclic antidepressants (amitriptyline, nortriptyline), antiepileptic drugs (topiramate, divalproex), beta blockers (propanolol, metoprolol), calcium channel blockers (verapamil), SNRIs (venlafaxine, duloxetine). ▪ 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

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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 or involvement of the face, palms, soles or genital regions, who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist ▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months ▪ For patients 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD ▪ Coordinate with provincial government program
BRIVLERA and generic BRIVARACETAM	▪ Partial-onset seizures	▪ For use as adjunctive therapy in the treatment of partial onset seizures in **patients 4-5 years of age** who have tried and failed or experienced intolerant side effects to 1 or more standard care drugs ▪ For use as adjunctive therapy in the treatment of partial onset seizures in **patients 6 years and olde**r who have tried and failed or experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
BUTRANS (Buprenorphine transdermal)	▪ Severe pain	▪ For pain management in patients who are unable to tolerate or receive an adequate response to treatment with opioid therapy
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	▪ 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

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	or PM	
BYSTOLIC and generic NEBIVOLOL	▪ Essential hypertension	▪ For the treatment of mild to moderate essential hypertension in patients who have tried and failed or had intolerable side effects to at least two generic drugs in the class of beta1-selective blockers (atenolol, bisoprolol, metoprolol)
CAMBIA (Diclofenac Potassium)	▪ For acute treatment of migraine attacks	▪ For patients 18 years of age and older who have tried and failed or experienced intolerable side effects to at least one drug in each of the following classes: prescription NSAIDs and triptans
CAPRELSA* (Vandetanib)	▪ For the treatment of symptomatic or progressive medullary thyroid cancer (MTC) in adult patients with unresectable or locally advanced or metastatic disease	▪ For patients with unresectable locally advanced or metastatic MTC that have enrolled with the CAPRELSA Restricted Distribution Program ▪ Coordinate with available provincial plans
CAVERJECT (Alprostadil) CIALIS (Tadalafil) LEVITRA (Vardenafil) MUSE (Alprostadil) VIAGRA (Sildenafil) STAXYN (Vardenafil)	• Erectile Dysfunction	• Erectile dysfunction related to one of the following conditions: • Adverse side-effect to prescription drugs (e.g., beta blockers, etc.). Medical documentation must be present to validate the drug as causing the problem (up to one year approval) • Diabetes mellitus and is on medication(s) and/or insulin (Lifetime approval) • Cardiovascular risk factors (e.g., hypertension or obesity) and is on medications or is currently attempting lifestyle measures (up to one year approval) • Aorta-iliac disease with evidence of decreased blood flow (e.g., abnormal Doppler studies or absent pulses) (Lifetime approval) • Post radical prostatectomy and radiation of the prostate (Lifetime approval) • Neurological injury or disease (e.g. multiple Sclerosis, spinal cord injury, stroke) (Lifetime approval) • Endocrine abnormalities (e.g. hypogonadism, hyperprolactinemia, hyper/hypothyroidism, hyper/hypocortisolism) for which they are receiving treatment (Lifetime approval) • Psychiatric disorder for which the patient is receiving medication or treatment from a health care professional with experience treating depression (up to one year approval) • Annual maximum: $1,000 per year

DRUG	DISEASE	APPROVAL GUIDELINES
CAYSTON* (Aztreonam)	• Treatment of pulmonary infection with Pseudomonas aeruginosa in Cystic Fibrosis Patients	▪ For patients with confirmed Cystic Fibrosis and pulmonary infection with Pseudomonas aeruginosa, who have tried and failed or did not tolerate prior therapy with TOBI ▪ Co-ordinate with provincial programs where possible
CELSENTRI* (Maraviroc)	• HIV anti-viral	▪ For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) ▪ Coordinate with provincial government program
CEQUA (Cyclosporine)	• Moderate to severe dry eye disease	▪ For the treatment of moderate to severe dry eye disease for patients who had an insufficient response to artificial tears
CIBINQO* (Abrocitinib)	▪ Atopic Dermatitis	<u>Initial approval: 6 months duration</u> - 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) <u>Renewal criteria : 1 year duration</u> - 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

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DRUG	DISEASE	APPROVAL GUIDELINES
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 or involvement of the face, palms, soles or genital regions, AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 oral systemic therapies (i.e. methotrexate, cyclosporine) AND who are being treated by a dermatologist ▪ For patients with confirmed diagnosis of severe, active non-radiographic axial spondyloarthritis where symptoms are uncontrolled by NSAIDs ▪ Coordinate with provincial government program
CINQAIR* (Reslizumab)	▪ Severe eosinophilic asthma	▪ For the add on maintenance treatment of severe eosinophilic asthma in patients 18 years or older who meet the following criteria: ▪ Trial and failure of high-dose inhaled corticosteroids and an additional asthma controller (ie. long-acting beta-agonist), AND ▪ Blood eosinophil count of ≥ 400 cells/µL OR induced sputum eosinophil count of 3% or more in the past 12 months, AND≥ 2 clinically significant asthma exacerbation in the past 12 months
COPAXONE* and generic GLATIRAMER ACETATE *	▪ Relapsing Remitting Multiple Sclerosis (RRMS) ▪ Clinically Isolated Syndrome (CIS)	▪ For patients with RRMS AND an EDSS value of less than or equal to 6 ▪ For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation AND an EDSS value of less than or equal to 6 ▪ EDSS value of less than or equal to 6 required with every application ▪ Coordinate with provincial government program where applicable
COMPLERA* (Rilpivirine/emtricitabine/tenofovir disoproxil fumarate)	▪ HIV anti-viral	▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
CONSTELLA (Linaclotide)	▪ Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC)	▪ For patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
CONTRAVE (Naltrexone/Bupropion)	▪ Weight management	<u>Initial Authorization Approval (1 year)</u> ▪ Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with at least one weight-related comorbidity (e.g. controlled hypertension, type 2 diabetes mellitus, or dyslipidemia) ▪ Have tried and will continue prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Contrave ▪ Weight prior to initiation of treatment <u>Subsequent Authorization Approval (1 year):</u> ▪ Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND ▪ Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Contrave ▪ Current weight ▪ Approval dosing limit: maximum of 4 tablets per day ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan
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 or involvement of the face, palms, soles or genital regions, 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

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DRUG	DISEASE	APPROVAL GUIDELINES
COSOPT (Dorzolamide and timolol preservative-free ophthalmic solution)	▪ Elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	▪ For patients who are allergic to or cannot tolerate ophthalmic preservatives
CORZYNA (Ranolazine)	▪ Stable angina	▪ As add-on therapy for patients with stable angina who have insufficient response, intolerance, or contraindication to beta-blockers (e.g. atenolol, bisoprolol) and calcium channel blockers (e.g. amlodipine, diltiazem)
CRESEMBA* (Isavuconazole)	▪ Invasive aspergillosis (IA) ▪ Invasive mucormycosis (IM)	▪ For the treatment of adult patients (18+) with invasive aspergillosis (IA) post-hospital discharge who have failed or cannot tolerate voriconazole and amphotericin B; authorization period: 12 weeks ▪ For the treatment of adult patients (18+) with invasive mucormycosis (IM) post-hospital discharge who have failed or cannot tolerate amphotericin B; authorization period: 6 months ▪ Any doses given in hospital will not be considered
CUVPOSA* (Glycopyrrolate)	▪ Sialorrhea	▪ Confirmed diagnosis of sialorrhea in patients aged 3-18 with cerebral palsy or brain injury ▪ Current patient weight ▪ Maximum dose of 3 mg three times a day
DAKLINZA* (Daclatasvir)	▪ Hepatitis C genotype 3	▪ For adults with chronic hepatitis C genotype 3 in combination with Sovaldi: ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ No diagnosis of cirrhosis ▪ Failure of standard peg-interferon/ribavirin therapy ▪ HCV levels in the past 6 months ▪ Have failed or have a true contraindication to Maviret, Epclusa ▪ Coordinate with provincial government program *Maximum approval 12 weeks* ▪ **Retreatment requests will not be considered**
DAXAS (Roflumilast)	▪ Chronic Obstructive Pulmonary Disease (COPD)	▪ Diagnosis of COPD, including chronic bronchitis and emphysema ▪ Coordinate with provincial coverage if available
DAYVIGO (Lemborexant)	▪ Insomnia	▪ For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
DELSTRIGO* (Doravirine/lamivudine/tenofovir disoproxil fumarate)	▪ HIV Infection	▪ Coordinate with provincial government program
DESCOVY* (Emtricitabine/tenofovir alafenamide)	▪ HIV Infection ▪ Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	▪ For treatment of HIV infection ▪ For patients who require Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection who have tried generic Truvada, unless intolerance or contraindication ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
DEXILANT and generic DEXLANSOPRAZOLE	▪ Erosive esophagitis ▪ Non-erosive gastroesophageal reflux disease (GERD)	▪ For patients who are unresponsive or intolerable to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole
DIACOMIT* (Stiripentol)	▪ Dravet Syndrome or Severe Myoclonic Epilepsy in Infancy (SMEI)	▪ For patients 3 years of age or older with refractory SMEI or Dravet Syndrome: ▪ Must be used in conjunction with clobazam and valproate after failure with clobazam and valproate alone ▪ Coordinate with provincial government program
DOVATO* (Dolutegravir/Lamivudine)	▪ HIV anti-viral	▪ Coordinate with provincial government program
DUAKLIR GENUAIR (Aclidinium bromide and Formoterol Furmarate)	▪ Chronic Obstructive Pulmonary Disease (COPD)	▪ For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on optimal doses of either a LAMA or LABA alone
DUODOPA* (Levodopa/carbidopa intestinal gel)	▪ Parkinson's disease	▪ For individuals with advanced Parkinson's disease and who have tried and failed other oral therapies for control of severe, disabling motor fluctuations ▪ Individuals are being screened and managed by specialists and at appropriate centers where the individuals have responded to the drug during the test phase ▪ Coordinate with provincial government program
DUPIXENT* (Dupilumab)	▪ Severe atopic dermatitis ▪ Severe chronic rhinosinusitis with nasal polyps (CRSwNP) ▪ Severe type 2/eosinophilic asthma ▪ Oral corticosteroid-dependent asthma ▪ Moderate-to-severe prurigo nodularis (PN)	<u>Initial Approval: 6 months duration</u> ▪ For the treatment of patients 6 years and older with confirmed severe atopic dermatitis: ▪ Severity defined as meeting all 3 conditions below: 1) IGA of 3 or more 2) BSA of at least 30% or EASI ≥21 3) DLQI ≥ 10 or severe disruption in sleep (18+ only); ▪ Inadequate response, intolerance or contraindication to phototherapy AND two immunosuppressants (e.g. cyclosporine, azathioprine, methotrexate) <u>Renewal criteria: 1 year duration</u> ▪ IGA of 0 or 1 or 50% improvement, AND ▪ Improvement of EASI of at least 75% of initial score AND ▪ 5 point improvement in DLQI or improvement in sleep (18+ only) <u>Initial Approval: 6 months duration</u> ▪ For the treatment of adult patients (18+) with confirmed severe chronic rhinosinusitis with nasal polyps (CRSwNP) ▪ Severity defined as meeting all 3 conditions below: 1) NPS (nasal polyp score) > 5 (with minimum score of 2 for each nasal cavity) 2) NC (nasal congestion) score of 3 3) Ongoing symptoms for more than 12 weeks (e.g. nasal congestion, blockage, loss of smell, rhinorrhea) ▪ AND tried and failed one product from each

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

DRUG	DISEASE	APPROVAL GUIDELINES
		nodularis: ▪ Nodular lesions ≥20 AND ▪ WI-NRS of 7 or more AND ▪ 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 ▪ **Will not be approved in combination with another biologic (e.g. Nucala, Cinqair, Fasenra, Xolair)**
DYSPORT (Abobotulinumtoxin A)	- Cervical dystonia (spasmodic torticollis) - Focal spasticity	▪ For adult patients with a confirmed diagnosis of cervical dystonia (torticollis) OR focal spasticity affecting the upper limbs ▪ For the treatment of lower limb spasticity in children 2 years of age and older ▪ For the treatment of focal spasticity affecting the lower limbs in adults (18 years of age and older)
EDARBI and generic AZILSARTAN EDARBYCLOR (Azilsartan/Chlorthalidone)	▪ Mild to moderate essential hypertension	▪ For patients who have tried and failed or have had intolerable side effects to at least two generic ACE inhibitor or ACE inhibitor combination product(s) OR generic ARB or generic ARB combination product(s)
ELIDEL (Pimecrolimus 1% cream)	▪ Atopic dermatitis	▪ A confirmed diagnosis of atopic dermatitis (eczema) for individuals who have failed or intolerant to treatments with topical corticosteroid therapy
EMGALITY (galcanezumab)	▪ Episodic or chronic migraine	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

DRUG	DISEASE	APPROVAL GUIDELINES
ENBREL* (Etanercept)	• Rheumatoid Arthritis • Juvenile Rheumatoid Arthritis • Psoriatic arthritis • Ankylosing spondylitis • Chronic plaque psoriasis	erelz ▪ 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 or involvement of the face, palms, soles or genital regions,who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist ▪ Coordinate with provincial government program
ENTRESTO (Sacubitril/Valsartan)	▪ Heart failure with reduced ejection fraction	▪ For adult patients diagnosed with heart failure with reduced ejection fraction AND all of the following: ▪ LVEF ≤ 40% ▪ Patients with NYHA class II or III ▪ Previously treated with an ACEI or ARB ▪ In combination with a beta blocker unless there is a contraindication or an intolerance
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 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) 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, and Ustekinumab ▪ For patients with Crohn's disease or patients with moderate to severe Crohn's disease who have failed to

DRUG	DISEASE	APPROVAL GUIDELINES
		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
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 old and older with severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions,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

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DRUG	DISEASE	APPROVAL GUIDELINES
ERLEADA* (apalutamide)	▪ Non-metastatic castration-resistant prostate cancer (nmCRPC) ▪ Metastatic castration ▪ sensitive prostate cancer	Initial Criteria (6 months): ▪ In combination with Androgen Deprivation Therapy (ADT) for the treatment of patients with non-metastatic castrate resistant prostate cancer (nmCRPC) with prostate-specific antigen (PSA) doubling time of 10 months or less during continuous ADT AND ECOG 0-1 Renewal Criteria (6 months): ▪ Absence of disease progression ▪ Maximum dose: 240 mg once a day Initial Criteria: ▪ For adult patients with a diagnosis of metastatic Castration-Sensitive Prostate Cancer (CSPC) AND one of the following: ▪ has ECOG score of ≤ 1 OR ▪ has received prior docetaxel treatment meeting the following criteria: ▪ received a maximum of 6 cycles of docetaxel therapy for metastatic CSPC AND ▪ received the last dose of docetaxel within 2 months AND ▪ has maintained response to docetaxel therapy Renewal Criteria: ▪ Absence of disease progression ▪ Maximum dose: 240 mg once a day
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
GENERIC ESCITALOPRAM ODT (Escitalopram)	▪ Major Depressive Disorder	▪ For patients who have tried and failed OR had intolerable side effects OR are medically unable to swallow generic escitalopram tablets
EUCRISA (Crisaborole)	▪ Atopic dermatitis	▪ For patients with atopic dermatitis (eczema) who have failed or are intolerant to treatments with topical corticosteroid therapy

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DRUG	DISEASE	APPROVAL GUIDELINES
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 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) ▪ Inadequate response, intolerance or contraindication to bisphosphonates and denosumab ▪ Lifetime approval maximum of 12 months
EXTAVIA* (Interferon beta-1b)	▪ Clinically Isolated Syndrome (CIS) ▪ Relapsing remitting Multiple Sclerosis (RRMS) ▪ Chronic Progressive Multiple Sclerosis	▪ For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation OR for patients with RRMS or progressive MS ▪ EDSS value required ▪ Coordinate with provincial government program
EYLEA* (Aflibercept)	- Wet age-related macular degeneration - Macular edema secondary to Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO) - Diabetic Macular Edema (DME) - Myopic choroidal neovascularization (myopic CNV)	▪ For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) ○ For patients who are previously stabilized on Eylea OR patients who are medically unable to use Eylea HD ○ For aflibercept naïve patients, Eylea HD will be approved ▪ 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 ○ 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) ▪ Wet age-related macular degeneration	▪ For treatment of visual impairment due to diabetic macular edema ▪ For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD)

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DRUG	DISEASE	APPROVAL GUIDELINES
FAMPYRA* and generic FAMPRIDINE*	▪ Multiple Sclerosis (MS)	Initial Criteria: ▪ For the symptomatic improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 3.5 – 7) ▪ Coordinate with available provincial plans ▪ An initial 6 months of Fampyra will be approved Renewal Criteria: ▪ Demonstrates a noted improvement in walking speed from baseline based on one of the following clinical tools (e.g. T25FW, Timed Up and Go, MSWS012, Two Minute Walk)
FASENRA* (Benralizumab)	▪ Severe eosinophilic asthma	▪ For the add on maintenance treatment of severe eosinophilic asthma in patients 18 years or older who meet the following criteria: ▪ Trial and failure of high-dose inhaled corticosteroids and an additional asthma controller (ie. long-acting beta-agonist), AND ▪ Blood eosinophil count of ≥ 150 cells/μL (0.15 GI/L) while receiving maintenance treatment with oral corticosteroids OR ≥300 cells/μL in the past 12 months with ≥2 clinically significant asthma exacerbations (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization)
FASLODEX* and generic FULVESTRANT*	▪ Locally advanced or metastatic breast cancer	▪ First-line treatment for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND not previously treated with endocrine therapy AND no active or uncontrolled metastases to the liver or lungs ▪ Second-line treatment for postmenopausal women who have failed or had intractable side effects to tamoxifen and/or other aromatase inhibitors (ex. Letrozole) ▪ In combination with Kisqali, Ibrance OR Verzenio for the treatment of postmenopausal women with HR-positive, HER2- negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment-naïve ▪ Initial Approval for 6 months ▪ Renewal Criteria for 6 months: ▪ Absence of disease progression
FENTANYL	▪ Severe pain	▪ For pain management in patients who are unable to tolerate or receive an adequate response to treatment with long-acting opioids such as sustained release morphine, sustained release hydromorphone, and/or sustained release oxycodone
FENTORA* (Fentanyl citrate)	▪ Breakthrough cancer pain	▪ For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day who are currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) AND have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR

DRUG	DISEASE	APPROVAL GUIDELINES
FETZIMA (Levomilnacipran)	▪ Major Depressive Disorder	▪ For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other extended release SNRIs
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 or involvement of the face, palms, soles or genital regions,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
FOQUEST (Methylphenidate hydrochloride)	▪ Attention deficit hyperactivity disorder	▪ For patients 6 years and older who have tried and failed or had intolerable side effects to generic Ritalin, Concerta, Adderall XR, Dexedrine or Strattera

*Coverage Navigation through provincial government programs and other funding sources may apply, in accordance with your insurance program – ClaimSecure to assist Members with this process

DRUG	DISEASE	APPROVAL GUIDELINES
FORTEO* (Teriparatide)	▪ Osteoporosis ▪ Osteoporosis associated with sustained systemic glucocorticoid therapy	▪ For patients who are previously stabilized on Forteo OR patients who are medically unable to use Osnuvo OR generic Forteo AND one of the following: ▪ For patients with severe osteoporosis and 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 and 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
FREESTYLE LIBRE (Sensors only)	▪ Glucose monitoring for diabetic patients	▪ For blood glucose monitoring in diabetic patients 2 years of age and older treated with insulin ▪ Approval Maximum 26 sensors per calendar year
Fruzaqla* (Fruquintinib)	Metastatic Colorectal Cancer (mCRC)	▪ For the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with or are not considered candidates for all of the following: 1. Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy 2. Anti-VEGF therapy (bevacizumab) 3. Trifluridine-tipiracil or regorafenib 4. Anti-EGFR agent (cetuximab or panitumumab), if RAS wild-type
FUZEON* (Enfuvirtide)	- HIV infection	▪ For treatment experienced patients who have tried at least three anti-retrovirals from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) and where the CD4 count has fallen below 200 cells/uL. Coordinate with provincial government program
FYCOMPA and generic PERAMPANEL	-Partial onset seizures -Primary Generalized Tonic-Clonic Seizures	▪ For patients with a diagnosis of partial onset seizures or primary generalized tonic-clonic seizures (PGTCS) AND who have tried, failed or experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
GELNIQUE (Oxybutynin chloride gel)	-For the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency	▪ For patients who have tried and failed or had intolerable side effects to two of the following oral anticholinergics: generic Uromax, generic Ditropan, generic Ditropan XL, generic Enablex, generic Vesicare, generic Detrol, generic Detrol LA, generic Toviaz, generic Trosec)

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DRUG	DISEASE	APPROVAL GUIDELINES
GENVOYA* (Cobicistat/Emtricitabine/Elvitgravir/Tenofovir Alafenamide)	-HIV Infection	▪ Coordinate with provincial government program
GILENYA* and generic FINGOLIMOD*	-Relapsing remitting Multiple Sclerosis (RRMS)	▪ For the treatment of patients 10 year or older with RRMS in patients who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) ▪ EDSS value required with every application ▪ Coordinate with provincial government program
GIOTRIF* (Afatinib)	-Lung adenocarcinoma	▪ For patients with a confirmed diagnosis of metastatic lung adenocarcinoma (i.e. specific type of non-small cell lung cancer) with activating EGFR mutation(s) who have NOT previously tried and failed EGFR tyrosine kinase inhibitors (e.g. Iressa or Tarceva) ▪ Coordinate with provincial government program
GLATECT* (Glatiramer acetate)	-Relapsing Remitting Multiple Sclerosis (RRMS) -Clinically Isolated Syndrome (CIS)	▪ For patients with RRMS AND an EDSS value of less than or equal to 6 ▪ For patients diagnosed with clinically isolated syndrome with abnormal brain MRI at presentation AND an EDSS value of less than or equal to 6 ▪ EDSS value of less than or equal to 6 required with every application ▪ 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 ▪ 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
GLUMETZA and generic METFORMIN EXTENDED RELEASE	-Diabetes	▪ For patients who have tried and failed or had intolerable side effects to regular release Metformin
GLYXAMBI (Empagliflozin/Linagliptin)	-Diabetes	▪ For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective

DRUG	DISEASE	APPROVAL GUIDELINES
GRASTEK (Standardized allergenic extract, Timothy Grass)	▪ Moderate to severe seasonal grass -pollen allergic rhinitis	▪ For the treatment of allergic rhinitis in patients 5 years of age and older, who are: ▪ Skin test positive to grass pollen and/or positive titre to pollen-specific IgE antibodies ▪ Symptomatic for at least 2 pollen seasons ▪ Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen-specific Immunotherapy injections
HADLIMA* (Adalimumab)	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis PEDIATRIC ▪ Juvenile Idiopathic Arthritis ▪ Non-infevtious 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 or involvement of the face, palms, soles or genital regions,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 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

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ 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 * generic ALITRETINOIN*	▪ Chronic Hand Eczema	▪ Diagnosis of severe CHE characterized by fissures, vesicles, bumps, edema, exudation, scaling or lichenification ▪ Trial of at least 2 of the following high potency topical steroids: amcinonide (Cyclocort), desoximetasone (Topicort), fluocinonide (Lyderm, Tiamol), betamethasone dipropionate (Diprosone), clobetasol propionate (Clobex)
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
HEMANGIOL (Propranolol)	-Proliferating Infantile Hemangioma	▪ For infants 6 months of age or under diagnosed with Infantile Hemangioma ▪ Maximum duration of treatment is 6 months per lifetime
HEPSERA and generic ADEFOVIR	-Chronic hepatitis B	▪ For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) ▪ For hepatitis B patients co-infected with HIV who do not require HAART therapy for HIV
HULIO* (Adalimumab)		ADULT ▪ For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine)

DRUG	DISEASE	APPROVAL GUIDELINES
	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis PEDIATRIC ▪ Crohn's Disease ▪ Juvenile Idiopathic Arthritis ▪ Non-infectious anterior uveitis ▪ 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) ▪ 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 or involvement of the face, palms, soles or genital regions,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 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 5 to 17 years of age with moderate to

DRUG	DISEASE	APPROVAL GUIDELINES
		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
HUMATROPE* (Somatropin)	▪ Growth Hormone Deficiency in children ▪ Small for gestational age ▪ Turner syndrome ▪ Idiopathic Short Stature ▪ Adult Growth Hormone Deficiency	▪ For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate ▪ For the treatment of small for gestational age defined as children born with birth weight below 2.0 standard deviations of normal and who fail to achieve catch-up growth by 2-4 years of age and who have a height velocity <0 standard deviations during the last year ▪ For the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed ▪ For treatment of Idiopathic Short Stature which is defined as: (i) normal birth weight; (ii) diagnostic evaluation that excludes other known causes of short stature; (iii) height at least 2.25 standard deviation scores below the mean for age and sex; (iv) height velocity below the 25th percentile for bone age; and (v) patients whose epiphyses are not closed ▪ For 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
HUMIRA* (Adalimumab)	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic 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 ▪ 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 or involvement of the face, palms,

DRUG	DISEASE	APPROVAL GUIDELINES
		soles or genital regions,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 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who has tried and failed Etanercept or Actemra SC ▪ For patients aged 2 or older with a confirmed diagnosis of non-infectious uveitis where the patient has not adequately responded to corticosteroids and at least one immunosuppressant ▪ Renewal Criteria: Stability or improvement of vision and control of ocular inflammation confirmed by physician ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
HYDROMORPHONE CONTINUOUS RELEASE (e.g. Hydromorph Contin)	▪ Severe pain	▪ For pain management in patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of hydromorphone or the sustained release preparations of morphine
HYRIMOZ* (Adalimumab)	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis PEDIATRIC ▪ Juvenile Idiopathic Arthritis ▪ Crohn's Disease ▪ 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 or involvement of the face, palms, soles or genital regions,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

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

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ 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
IBSRELA (Tenapanor hydrochloride)	▪ Irritable Bowel Syndrome with Constipation (IBS-C)	▪ For patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
ICLUSIG* (Ponatinib hydrochloride)	▪ Chronic myeloid leukemia (CML) ▪ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)	**Chronic Myeloid Leukemia:** Initial Request (3 month approval): ▪ For patients with chronic phase (CP), accelerated phase (AP), or blast phase (BP) chronic myeloid leukemia (CML) who are resistant or intolerant to imatinib AND 2 of the follow nilotinib,dasatinib, or bosutinib, and for whom subsequent treatment with imatinib, nilotinib, dasatinib AND bosutinib is not clinically appropriate ▪ Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase ▪ ECOG≤1 ▪ Proof of enrollment in the Support Program ▪ Coordinate with provincial government program Renewal (3 month approval): ▪ Demonstration of hematological response (i.e. Normalization of WBC) showing absence of disease progression (provide lab values) ▪ Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Proof of continued enrollment in the patient support program ▪ Coordinate with provincial drug programs **<u>Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)</u>** <u>Initial Request (3 month approval):</u> ▪ 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 <u>Renewal (3 month approval):</u> ▪ Demonstration of hematological response (i.e. Normalization of WBC) showing absence of disease progression (provide lab values) ▪ Completion of cardiovascular status demonstrated by: Complete blood count, ALT, AST, bilirubin, alkaline phosphatase ▪ Proof of continued enrollment in the patient support program ▪ Coordinate with provincial drug programs
IDACIO* (Adalimumab)	<u>ADULT</u> ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis <u>PEDIATRIC</u> ▪ Crohn's Disease ▪ Juvenile Idiopathic Arthritis ▪ Non-infectious anterior uveitis	<u>ADULT</u> ▪ 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 or involvement of the face, palms, soles or genital regions,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

DRUG	DISEASE	APPROVAL GUIDELINES
		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 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 ▪ 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 or involvement of the face, palms, soles or genital regions,who have tried phototherapy AND have tried or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
ILUVIEN (Fluocinolone)	▪ Diabetic Macular Edema (DME)	▪ For the treatment of patients with Diabetic Macular Edema who responded successfully to a previous treatment with a course of corticosteroids (i.e. Triamcinolone acetonide, Ozurdex) and did not have a clinically significant rise in intraocular pressure ▪ Validate site of administration ▪ An approval of 1 implant for one affected eye at a time for 36 months
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

DRUG	DISEASE	APPROVAL GUIDELINES
		Renewal Criteria: For the treatment of CLL in symptomatic patients with documentation of no disease progression
REMDANTRY* (Infliximab)	ADULT ▪ Rheumatoid Arthritis ▪ Ankylosing Spondylitis ▪ Psoriatic Arthritis ▪ Plaque Psoriasis ▪ Crohn's Disease ▪ Ulcerative colitis PEDIATRIC ▪ Crohn's Disease ▪ Ulcerative colitis	ADULT ▪ For adult patients (18+) with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months ▪ For adult patients (18+) with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, ▪ For adult patients (18+) with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 ▪ For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions, AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist ▪ For patients 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 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Coordinate with available provincial plans PEDIATRIC ▪ Patients 6 years of age or older with moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ 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)

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

*Coverage Navigation through provincial government programs and other funding sources may apply, in accordance with your insurance program – ClaimSecure to assist Members with this process

DRUG	DISEASE	APPROVAL GUIDELINES
ITULATEK (Standardized Allergen Extract, White Birch)	▪ Moderate to severe seasonal Allergic Rhinitis (AR)	▪ For the treatment of allergic rhinitis in patients 18 years and older who are skin test positive to tree pollen (i.e. pollen from birch, alder and/or hazel), symptomatic for at least 2 pollen seasons and not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen specific immunotherapy injections
IXIFI* (infliximab)	ADULT ▪ Rheumatoid Arthritis ▪ Psoriatic Arthritis ▪ Ankylosing Spondylitis ▪ Plaque Psoriasis ▪ Crohn's Disease ▪ Ulcerative colitis PEDIATRIC ▪ Crohn's Disease ▪ Ulcerative Colitis	ADULTS ▪ For adult patients (18+) with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months ▪ For patients (18+) with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, ▪ For patients (18+) with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 ▪ For patients (18+) with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions, AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist ▪ For patients (18+) with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate or cyclosporine) ▪ For patients (18+) with moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Coordinate with provincial government program PEDIATRIC ▪ Patients 9 years of age or older with moderately to severely active Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate or cyclosporine) ▪ Patients 6 years of age or older with active moderately

DRUG	DISEASE	APPROVAL GUIDELINES
		to severely ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Coordinate with provincial government program
INVEGA SUSTENNA INVEGA TRINZA (Paliperidone injection)	▪ Schizophrenia and related psychotic disorders	▪ For patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations
INVOKANA (Canagliflozin) INVOKAMET (Canagliflozin/metformin)	▪ Diabetes mellitus	▪ For treatment of type-2 diabetic persons where metformin and generic Forxiga are contraindicated, not tolerated or ineffective. ▪ For the treatment of patients with type-2 diabetes who have established cardiovascular disease and where generic Forxiga is contraindicated, not tolerated or ineffective. ▪ For the treatment of patients with type-2 diabetes who have established diabetic nephropathy
IRESSA* and generic GEFITINIB*	▪ First-line treatment of locally advanced (not amenable to curative surgery) or metastatic Non-Small Cell Lung Cancer (“NSCLC”)	▪ For patients with confirmed activating mutations of the EGFR-TK (“mutation-positive”) Coordinate with provincial government program
ISENTRESS* (Raltegravir)	▪ HIV Infection	▪ Coordinate with provincial government program
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.

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DRUG	DISEASE	APPROVAL GUIDELINES
		▪ For the treatment of chronic iron overloading patients with non-transfusion-dependent thalassemia syndromes (NTDT) aged 10 years and older AND who have tried and failed or cannot tolerate or have a contraindication* to deferoxamine. ▪ Coordinate with provincial government program. ▪ *Contraindications to deferoxamine may include one or more of the following: known or suspected hypersensitivity to deferoxamine, recurrent injection or infusion-site reactions (e.g., cellulitis), concomitant bleeding disorder, immunocompromised patients with a documented risk of significant infections with parenteral administration (e.g. neutropenia), patients <16 years of age requiring high doses of deferoxamine with concomitant low ferritin levels (risk of growth retardation)
JAKAVI* (Ruxolitinib)	▪ Splenomegaly ▪ Acute Graft-versus-Host Disease (GvHD) ▪ Chronic Graft-versus-Host Disease (GvHD)	▪ 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 **Initial Criteria (6 months):** • For the treatment of acute graft versus host disease in patients: • 12 years and older and • have been diagnosed with acute GvHD following allogenic stem cell transplant • have Grade II to IV acute GvHD as per the National Institutes of Health (NIH) criteria and • are corticosteroid-refractory or corticosteroid-dependent o corticosteroid refractory is defined by one or more of the following criteria: i. progressing based on an organ assessment after at least 3 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/- calcineurin inhibitor for the treatment of grade II to IV acute GvHD ii. failure to achieve at a minimum partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/- calcineurin inhibitor for the treatment of Grade II to IV acute GvHD iii. patients who fail corticosteroid taper defined as fulfilling either one of the following criteria: ▪ requirement for an increase in the corticosteroid dose to methylprednisolone ≥ 2mg/kg/day (or equivalent prednisone dose ≥ 2.5mg/kg/day) ▪ failure to taper the methylprednisolone dose to <0.5mg/kg/day (or equivalent prednisone dose <0.6mg/kg/day) for a minimum 7 days o corticosteroid dependence is defined as the

DRUG	DISEASE	APPROVAL GUIDELINES
		inability to taper prednisone under 2mg/kg per day after an initially successful treatment of at least 7 days or as the recurrence of acute GvHD activity during steroid taper **Renewal Criteria (6 months):** • Achieved an overall response (i.e. complete response, very good partial response, partial response, or stable disease with significant reduction in steroid doses) according to standard NIH criteria AND • Confirmation of absence of disease progression and unacceptable toxicity **Initial Criteria (6 months):** • For the treatment of chronic graft versus host disease in patients: • 12 years and older and • have been diagnosed with chronic GvHD following allogenic stem cell transplant • have moderate to severe chronic GvHD as per the NIH criteria and • have had an inadequate response to corticosteroids or other systemic therapies as defined by meeting at least one of the below: i. A lack of response or disease progression after administration of minimum prednisone 1 mg/kg/day for at least one week (or equivalent); OR ii. Disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least four (4) weeks (or equivalent); OR iii. Increase prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent). **Renewal Criteria (6 months):** • Achieved an overall response (i.e. complete response, very good partial response, partial response, or stable disease with significant reduction in steroid doses) according to standard NIH criteria AND • Confirmation of absence of disease progression and unacceptable toxicity. **Initial Criteria (6 months):** • For the treatment of acute graft versus host disease in patients: • 12 years and older and • have been diagnosed with acute GvHD following allogenic stem cell transplant • have Grade II to IV acute GvHD as per the National Institutes of Health (NIH) criteria and • are corticosteroid-refractory or corticosteroid-dependent • corticosteroid refractory is defined by one or more of the following criteria: - progressing based on an organ assessment after at least 3 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/- calcineurin inhibitor for the treatment of grade II to IV acute GvHD - failure to achieve at a minimum partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/- calcineurin inhibitor for the treatment of Grade II to IV acute GvHD - patients who fail corticosteroid taper defined as

DRUG	DISEASE	APPROVAL GUIDELINES
		fulfilling either one of the following criteria: • requirement for an increase in the corticosteroid dose to methylprednisolone ≥ 2mg/kg/day (or equivalent prednisone dose ≥ 2.5mg/kg/day) • failure to taper the methylprednisolone dose to <0.5mg/kg/day (or equivalent prednisone dose <0.6mg/kg/day) for a minimum 7 days •corticosteroid dependence is defined as the inability to taper prednisone under 2mg/kg per day after an initially successful treatment of at least 7 days or as the recurrence of acute GvHD activity during steroid taper **Renewal Criteria (6 months):** • Achieved an overall response (i.e. complete response, very good partial response, partial response, or stable disease with significant reduction in steroid doses) according to standard NIH criteria AND • Confirmation of absence of disease progression and unacceptable toxicity **Initial Criteria (6 months):** • For the treatment of chronic graft versus host disease in patients: • 12 years and older and • have been diagnosed with chronic GvHD following allogenic stem cell transplant • have moderate to severe chronic GvHD as per the NIH criteria and • have had an inadequate response to corticosteroids or other systemic therapies as defined by meeting at least one of the below: • A lack of response or disease progression after administration of minimum prednisone 1 mg/kg/day for at least one week (or equivalent); OR • Disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least four (4) weeks (or equivalent); OR • Increase prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent). **Renewal Criteria (6 months):** • Achieved an overall response (i.e. complete response, very good partial response, partial response, or stable disease with significant reduction in steroid doses) according to standard NIH criteria AND • Confirmation of absence of disease progression and unacceptable toxicity.
JALYN (Dutasteride and Tamsulosin)	▪ Benign Prostatic Hyperplasia	▪ For male patients in the treatment of benign prostatic hyperplasia
JARDIANCE (Empagliflozin)	▪ Heart Failure ▪ Chronic Kidney Disease	▪ Adult patients diagnosed with heart failure AND all of the following: ▪ NYHA class II to IV

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Previously treated with an ACE inhibitor or ARB, AND beta-blocker unless there is a contraindication or an intolerance ▪ For patients with a confirmed diagnosis of chronic kidney disease who had insufficient response or intolerance to an ACE inhibitor (e.g. ramipril, perindopril etc.) or ARB (e.g. irbesartan, candesartan etc.) and generic Forxiga
JARDIANCE (Empagliflozin) SYNJARDY (empagliflozin/metformin)	▪ Diabetes mellitus	▪ For treatment of type-2 diabetic persons where metformin, another antihyperglycemic agent and generic Forxiga are contraindicated, not tolerated or ineffective. ▪ for the treatment of patients with type-2 diabetes who have established cardiovascular disease and where generic Forxiga is contraindicated, not tolerated or ineffective ▪ For the treatment of patients with type-2 diabetes who have established diabetic nephropathy.
JETREA (Ocriplasmin)	▪ Symptomatic vitreomacular adhesion (VMA)	▪ Confirmed diagnosis of symptomatic vitreomacular adhesion (VMA) ▪ Coordinate with provincial government program ▪ Lifetime maximum: 1 injection per affected eye
JINARC* (Tolvaptan)	▪ Autosomal dominant polycystic kidney disease (ADPKD)	<u>Initial Criteria:</u> ▪ Confirmed diagnoses of rapidly progressive ADPKD, total kidney volume ≥ 750ml AND one of the below: 1. eGFR ≥ 25 to 65 ml/min/1.73m2 (patients 18 – 55 years old) OR 2. 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 <u>Renewal Criteria:</u> ▪ 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
JUBBONTI (Denosumab)	▪ Osteoporosis ▪ Glucocorticoid-induced osteoporosis ▪ Treatment to increase bone mass in men with non-metastatic prostate cancer receiving androgen deprivation therapy ▪ Treatment to increase bone mass in women with non-metastatic breast cancer receiving aromatase inhibitor therapy	▪ For patients who have failed treatment with oral bisphosphonates (alendronate, etidronate, risedronate) or have had intractable intolerance or adverse effects to Bisphosphonate therapy ▪ Approval duration: 2 injections per calendar year

DRUG	DISEASE	APPROVAL GUIDELINES
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)
KALETRA* (Lopinavir/Ritonavir)	-HIV anti-viral	▪ Coordinate with provincial government program
KERENDIA (Finerenone)	--Chronic Kidney Disease	▪ As add-on therapy for patients with Chronic Kidney Disease (CKD) and Type 2 Diabetes Mellitus (T2DM) who have insufficient response to ACE inhibitors or ARBs
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
KEVZARA* (Sarilumab)	-Moderate to Severe Rheumatoid -Arthritis	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months or any biologic ▪ Coordinate with provincial government program
KINERET* (Anakinra)	-Rheumatoid Arthritis	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, AND who have tried and failed Cimzia or Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
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 - Patients must be endocrine therapy naïve or endocrine therapy-free for at least 12 months Renewal Criteria (6 month duration): Continue until unacceptable toxicity or disease progression
KORSUVA (Difelikefalin)	-Moderate to severe pruritus associated with chronic kidney disease (CKD)	▪ Patients with chronic kidney disease (CKD) currently on hemodialysis that are experiencing moderate to severe pruritis AND had an inadequate response to standard of care (e.g. gabapentin, pregabalin)
KUVAN* (Sapropterin)	-Phenylketonuria (PKU)	▪ Diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU) for patients 18 years of age or under ▪ Initial requests must indicated Phe levels prior to starting therapy ▪ Patients must demonstrate responsiveness to 30-day trial and maintain Phe-restrictive diet during treatment ▪ Coordinate with provincial government program Renewal: Evidence of decrease blood phenylalanine concentration relative to levels prior to starting therapy

DRUG	DISEASE	APPROVAL GUIDELINES
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)
LANCORA (Ivabradine)	▪ Heart failure with reduced ejection fraction	▪ For add-on treatment in adult patients with stable chronic heart failure with reduced ejection fraction ▪ (LVEF) ≤ 35%, who are in sinus rhythm with a resting heart rate ≥ 77 beats per minute ▪ Patients with NYHA class II or III ▪ Patient's heart failure is not well-managed OR patient has contraindication or intolerance to at least two of the following therapies: ACE-inhibitors, ARBs, Beta-blockers and/or Diuretics.
LANTUS LANTUS SOLOSTAR (Insulin glargine)	▪ Diabetes mellitus	▪ For patients who are at high risk for Hypoglycemia ▪ For patients who are previously stabilized on Lantus OR patients who are medically unable to use Basaglar and Semglee ▪ For insulin glargine naïve patients, Semglee will be approved
LEMTRADA* (Alemtuzumab)	▪ Relapsing remitting Multiple Sclerosis (RRMS)	▪ For RRMS patients who have had an inadequate response to, or are unable to tolerate, two or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) ▪ 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 ▪ For the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (RCC) in combination with pembrolizumab and with no prior systemic therapy for metastatic RCC.

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DRUG	DISEASE	APPROVAL GUIDELINES
LEQVIO (Inclisiran)	▪ Heterozygous familial hypercholesterolemia (HeFH) ▪ Atherosclerotic Cardiovascular Disease (ASCVD)	<u>Initial Authorization (12 months):</u> ▪ Familial Hypercholesterolemia (FH) with or without ASCVD. Diagnosed with Heterozygous Familial Hypercholesterolemia as confirmed by genotyping or clinical criteria (Simon Broome criteria, World Health Organization/Dutch Lipid Network criteria or Canadian FH definition) ▪ Must be greater than 18 years of age for Heterozygous 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 month ▪ Current LDL-C value required *Please provide clinical rationale should step therapy regimens not been tried <u>Renewal Criteria (1 year approval):</u> ▪ Document evidence of LDL-C level reduction of at least 25% from initial baseline <u>Initial Authorization (12 months):</u> ▪ ASCVD – In patients with clinical Atherosclerotic Cardiovascular Disease (ASCVD) without Familial Hypercholesterolemia. Diagnosed with clinical atherosclerotic cardiovascular disease (i.e. all clinical conditions of atherosclerotic origin, including acute coronary syndrome (ACS), myocardial infarction (MI), stable or unstable angina, coronary artery disease documented using angiography, coronary or other arterial revascularization (coronary artery bypass graft surgery, femoral popliteal bypass graft surgery, etc.), stroke, transient ischemic attack, documented carotid disease, peripheral artery disease, and abdominal aortic aneurysm): ▪ Must be greater than 18 years of age ▪ Statin use: 1. As adjunct to diet and statin therapy in patients who are unable to reach LDL-C target despite adherence to high-dose statin (e.g. atorvastatin 80 mg or rosuvastatin 40 mg) for at least 3 months OR 2. Statin intolerant: Tried and failed compliant therapy with at least 2 statins at maximum tolerated dose, used concomitantly with one other cholesterol lowering medication (i.e. Ezetrol or Fenofibrates)* plus lifestyle modifications for at least three months *Please provide clinical rationale should step therapy regimens not been tried <u>Renewal Criteria (1 year approval) :</u> Achieving LDL-C target goal - less than 2 mmol/L or documented evidence of LDL-C level reduction of at least 25% from initial baseline

DRUG	DISEASE	APPROVAL GUIDELINES
LEVEMIR LEVEMIR FLEXPEN LEVEMIR FLEXTOUCH (Insulin detemir)	▪ Diabetes mellitus	▪ For patients who are at high risk for hypoglycemia
LEVULAN KERASTICK (Aminolevulinic acid hydrochloride)	▪ Actinic keratosis	▪ For the treatment of actinic keratoses of the face and scalp
LODALIS and generic COLESEVELAM LODALIS SACHET (Colesevelam)	▪ Hypercholesterolemia	▪ For patients who had an inadequate response to or are unable to tolerate statins ▪ Lodalis sachet will only be considered if patient is medically unable to swallow Lodalis tablets.
LONSURF* (Trifluridine/Tipiracil)	▪ Metastatic colorectal cancer ▪ Metastatic Gastric Cancer or Adenocarcinoma of the gastroesophageal junction	▪ For patients with a diagnosis of metastatic colorectal cancer AND treated previously with, or not a candidate for all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin, irinotecan, an anti-VEGF therapy (bevacizumab), AND if KRAS wild type, an anti-EGFR therapy (cetuximab, panitumumab) ▪ For patients with a diagnosis of metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction AND treated previously with, or not a candidate for ALL of the following: fluoropyrimidine-based chemotherapy , platinum-based therapy, irinotecan, taxane-based therapy, anti-VEGF therapy (ramicirumab) AND if HER2+, a HER2+ targeted therapy (i.e. trastuzumab)
LUCENTIS* (Ranibizumab)	▪ End-stage or “wet” age-related macular degeneration (“AMD”) ▪ Macular edema 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
LUNESTA and generic ESZOPICLONE	▪ Insomnia	For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)

DRUG	DISEASE	APPROVAL GUIDELINES
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 ore 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 ▪ Maximum cumulative dose = 3.5 mg/kg over 2 years, i.e. 1.75 mg/kg/year
MAVIRET* (Glecaprevir/Pibrentasvir)	▪ Hepatitis C	▪ For patients 12 years or older with chronic hepatitis C genotype 1-6 infections with a Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months AND one of the following: ▪ 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, or coexisting chronic liver disease (e.g. autoimmune hepatitis) ▪ Coordinate with provincial government program
MAYZENT* (Siponimod)	▪ Secondary progressive multiple sclerosis	▪ Treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease as confirmed by evidnce 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
METHOFILL (methotrexate)	▪ Psoriasis ▪ Psoriatic arthritis ▪ Rheumatoid Arthritis (RA)	▪ For patients who have tried and failed oral tablets of methotrexate
METOJECT (Methotrexate)	▪ Neoplastic diseases ▪ Severe, disabling psoriasis, rheumatoid arthritis, psoriatic arthritis or other seronegative arthritides	▪ For the treatment of maintenance of neoplastic diseases in patients who have a physical disability which prevents them from drawing-up a syringe

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DRUG	DISEASE	APPROVAL GUIDELINES
METOJECT SC and generic METHOTREXATE	- Psoriasis - Psoriatic arthritis Rheumatoid Arthritis (RA)	▪ For patients who have tried and failed oral tablets of methotrexate
METVIX-PDT (Methyl Aminolevulinate)	▪ Primary superficial basal cell carcinoma (BCC) outside the H-zone of the face ▪Actinic keratosis	▪ For the treatment of BCC or actinic keratosis in individuals with multiple lesions, large lesions, bleeding disorders, poor vascularization, delayed healing, body not amenable to surgery, unsuitable for invasive therapy, concerns regarding disfigurement or inadequate response to previous therapies, etc; and ▪ Maximum annual reimbursement of $1800 per patient per year
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
MOVANTIK (Naloxegol oxalate)	▪ Opioid-induced constipation (OIC)	▪ For treatment of opioid-induced constipation (OIC) in adults (>18 years old) with non-cancer pain, who have tried and failed: ▪ Dietary and lifestyle measures (i.e. high fiber diet, increased water intake, physical exercise) AND ▪ One medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil)
MOZOBIL and 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/μL, AND ▪ A history of prior failed mobilization (i.e. Neupogen alone or chemo-mobilization)
MYFEMBREE (Relugolix, estradiol, and norethindrone acetate)	▪ Heavy menstrual bleeding associated with uterine fibroids ▪ Moderate to severe pain associated with endometriosis	▪ For premenopausal women for the management of heavy menstrual bleeding associated with uterine fibroids who are ineligible for surgery, or where the surgical wait time is beyond 3 months ▪ For the management of moderate to severe pain associated with endometriosis where the patient has tried and failed or had intolerable side effects to standard therapy (E.g. oral contraceptives) ▪ Lifetime approval to a maximum duration of 2 years

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MYRBETRIQ (Mirabegron)	▪ Overactive bladder (OAB)	For patients with OAB with urgency, urgency incontinence and urinary frequency who have tried and failed or had intolerable side effects to one of the following oral anticholinergics: generic Ditropan,generic Ditropan XL, generic Enablex, generic Vesicare, generic Detrol, generic Detrol LA, generic Toviaz, generic Trosec)
NEULASTA (Pegfilgrastrim)* LAPELGA (Pegfilgrastim)* FULPHILA (Pegfilgrastim)* NYVEPRIA (Pegfilgrastim)* ZIEXTENZO (Pegfilgrastim)*	▪ Neutropenia associated with anti-neoplastic therapy	▪ To co-ordinate with available provincial plans
NEUPOGEN* (Filgrastim) GRASTOFIL* (Filgrastim) NIVESTYM* (Filgrastim) NYPOZI* (Filgrastim)	▪ Neutropenia associated with anti-neoplastic therapy, transplant, HIV/AIDS, stem cell mobilization ▪ Severe chronic neutropenia	▪ To co-ordinate with available provincial plans
NEUPRO (Rotigotine)	▪ For the treatment of signs and symptoms of idiopathic Parkinson's disease – adjunct or monotherapy	▪ For patients who have tried and failed or had intolerable side effects to at least one oral dopamine agonist (i.e. generic Mirapex, generic Parlodel, generic Requip)
NEXAVAR* (Sorafenib)	▪ Metastatic renal cell (clear cell) carcinoma ▪ Unresectable hepatocellular carcinoma ▪ Thyroid Carcinoma	▪ For patients with metastatic renal cell carcinoma who are refractory or resistant to treatment with cytokines ▪ For patients with unresectable hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG between 0 and 2. ▪ If ECOG between 0 to 1, must indicate intolerance (such as uncontrolled hypertension) or contraindication to Lenvima ▪ Locally advanced or metastatic, progressive differentiated thyroid carcinoma secondary to radioactive iodine ▪ Coordinate with provincial government program

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DRUG	DISEASE	APPROVAL GUIDELINES
NEXIUM and generic ESOMEPRAZOLE NEXIUM GRANULES (Esomeprazole)	▪ Gastroesophageal Reflux Disease ▪ Duodenal and Gastric Ulcers ▪ Zollinger-Ellison Syndrome	▪ For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole ▪ For the treatment of H. Pylori positive (verified by serology or endoscopy or breath-test) Peptic ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole ▪ For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantoprazole
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 children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate ▪ For the treatment of children with short stature associated with Noonan syndrome ▪ For the treatment of small for gestational age defined as children born with birth weight below 2.0 standard deviations of normal and who fail to achieve catch-up growth by 2-4 years of age and who have a height velocity <0 standard deviations during the last year ▪ For the treatment of children with short stature associated with Turner Syndrome ▪ Coordinate with provincial government program
NUBEQA* (Darolutamide)	▪ Non-metastatic castration resistant prostate cancer ▪ Metastatic castrate-sensitive prostate cancer (mCSPC)	<u>Initial Criteria (6 months):</u> ▪ For the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC) <u>Renewal Criteria (6 months):</u> ▪ Absence of disease progression <u>Initial Criteria (6 months):</u> ▪ 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: o Concurrently receiving a gonadotropin-releasing hormone (e.g. Lupron Depot, Firmagon, Zoladex/Zoladex LA) or have undergone a bilateral orchiectomy o Did not receive prior treatment with an androgen receptor axis-targeted therapy (e.g. generic Zytiga, Erleada, Xtandi) or chemotherapy for prostate cancer o Did not receive ADT in the metastatic setting for

DRUG	DISEASE	APPROVAL GUIDELINES
		more than 6 months or within 1 year of completing adjuvant ADT in the nonmetastatic setting ○ ECOG score of ≤1 ▪ Coordinate with 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)	▪ For the add on maintenance treatment of severe eosinophilic asthma in patients 6 years or older who meet the following criteria: ▪ Trial and failure of high-dose inhaled corticosteroids (18 years or older) or medium-to-high dose corticosteroids (6 to 17 years old) and an additional asthma controller (ie. long-acting beta-agonist), AND ▪ Blood eosinophil count of ≥ 150 cells/μL (0.15 GI/L) while receiving maintenance treatment with oral corticosteroids OR ≥300 cells/μL in the past 12 months with ≥2 clinically significant asthma exacerbations (use of systemic corticosteroids for at least 3 days, emergency room visit, or hospitalization) Initial Approval (1 year): ▪ For the treatment of adult patients (18+) with confirmed severe chronic rhinosinusitis with nasal polyps (CRSwNP) ▪ Severity defined as meeting all 3 conditions below: 1. NPS (nasal polyp score) > 5 (with minimum score of 2 for each nasal cavity) 2. 22-Item Sinonasal Outcome Test (SNOT-22) score > 50 3. Ongoing symptoms for more than 12 weeks (e.g. nasal congestion, blockage, loss of smell, rhinorrhea) ▪ Tried and failed each of the below: 1. Intranasal corticosteroid (e.g. generic Mometasone, generic Budesonide, etc.) 2. Oral corticosteroid therapy, unless contraindicated 3. Prior sinonasal surgery for nasal polyps ▪ Will not be approved in combination with another biologic (e.g. Xolair, Cinqair, Fasenra, Dupixent) Renewal (1 year): Reduction in NPS score of 1 or more AND Reduction in SNOT-22 score of 9 or more

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NUCYNTA IR (Tapentadol)	▪ Moderate to severe acute pain	▪ Pain management in a specified acute pain diagnosis ▪ For patient who are unable to tolerate or receive an adequate response to the immediate release preparations of either hydromorphone, oxycodone or morphine
NUCYNTA CR / ER (Tapentadol)	▪ Moderate to severe chronic pain	▪ Pain management in a specified chronic pain diagnosis ▪ For patient who are unable to tolerate or receive an adequate response to the sustained release preparations of either hydromorphone, oxycodone or morphine
GENOTROPIN* (Somatropin)	▪ Growth Hormone Deficiency in children ▪ Small for gestational age ▪ Turner's syndrome ▪ Idiopathic Short Stature ▪ Adult Growth Hormone Deficiency	▪ For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate ▪ For the treatment of small for gestational age defined as children born with birth weight below 2.0 standard deviations of normal and who fail to achieve catch-up growth by 2-4 years of age and who have a height velocity <0 standard deviations during the last year ▪ For the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed ▪ For treatment of Idiopathic Short Stature which is defined as: (i) normal birth weight; (ii) diagnostic evaluation that excludes other known causes of short stature; (iii) height at least 2.25 standard deviation scores below the mean for age and sex; (iv) height velocity below the 25th percentile for bone age; and (v) patients whose epiphyses are not closed ▪ For 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

DRUG	DISEASE	APPROVAL GUIDELINES
NUTROPIN* (Somatropin)	- Growth Hormone Deficiency in children - Turner Syndrome - Adult Growth Hormone Deficiency	▪ For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate ▪ For the treatment of patients with Turner's syndrome in patients whose epiphyses are not closed ▪ For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented ▪ For adults who have Growth Hormone Deficiency (GH ≤ 5 mcg/L) due to multiple hormone deficiencies as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. ▪ Coordinate with provincial government program
OCALIVA* (Obeticholic acid)	- Primary biliary cholangitis (PBC)	▪ For the treatment of primary biliary cholangitis in adults: ▪ In combination with URSO/URSO DS in patients who have had an inadequate response to an appropriate dose of URSO/URSO DS for at least 1 year OR ▪ As monotherapy in patients who are intolerant to URSO/URSO DS
OCREVUS* (Ocrelizumab)	- Relapsing remitting Multiple Sclerosis (RRMS) - Primary Progressive Multiple Sclerosis (PPMS)	<u>RRMS:</u> - For patients with RRMS who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) - EDSS value required with every application - Coordinate with provincial government program <u>PPMS:</u> ▪ Confirmed diagnosis of primary progressive multiple sclerosis ▪ EDSS score between 3.0 and 6.5 ▪ EDSS value required with every application
ODEFSEY* (Emtricitabine/Rilpivirine/Tenofovir Alafendamide)	- HIV-1 infection	▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
OFEV* (Nintedanib)	- Idiopathic Pulmonary Fibrosis - Systemic Sclerosis Interstitial Lung Disease (SSc-ILD) - Chronic Progressive Fibrosing Interstitial Lung Disease (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 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

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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) 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 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 ≤

DRUG	DISEASE	APPROVAL GUIDELINES
		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
OMLYCLO* (Omalizumab)	▪ Severe allergic asthma ▪ Chronic idiopathic urticaria	Initial Criteria: ▪ 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. ▪ 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
ONRELTEA (Brimonidine 0.33% topical gel)	▪ Facial erythema (redness) of rosacea	▪ For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)
OPSUMIT* (Macitentan)	▪ Pulmonary Hypertension	▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II AND who have had an inadequate response or intolerance to a Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) ▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class III AND who have had an inadequate response or

DRUG	DISEASE	APPROVAL GUIDELINES
		intolerance to both of the following: 1. Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) 2. Generic Tracleer with or without generic Adcirca ▪ Coordinate with provincial government program ▪ May be used in conjunction with phosphodiesterase-5 inhibitor (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 AND who have had an inadequate response or intolerance to a Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) ▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class III AND who have had an inadequate response or intolerance to both of the following: 1. Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) 2. Generic Tracleer with or without generic Adcirca
ORALAIR (Grass Pollen Allergen Extract)	▪ Treatment of moderate to severe seasonal grass pollen allergic rhinitis	▪ For the treatment of allergic rhinitis in patients 5 to 50 years old, who are skin test positive to grass pollen and who are not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
ORENCIA IV* (Abatacept)	▪ Rheumatoid Arthritis ▪ Moderate to Severe Juvenile Rheumatoid Arthritis ▪ Psoriatic Arthritis	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, AND who have tried and failed Cimzia or Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC ▪ For patients ages 6 and older with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who have tried and failed Etanercept or Actemra SC ▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
ORENCIA SC* (Abatacept)	▪ Rheumatoid Arthritis ▪ Psoriatic Arthritis	▪ For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months ▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months ▪ Coordinate with provincial government program
ORGOVYX (Relugolix)	▪ Prostate Cancer	▪ For adults patients who have advanced prostate cancer
ORILISSA (Elagolix)	▪ Pelvic pain associated with endometriosis	▪ For the management of pelvic pain associated with endometriosis where the patient has tried and failed or had intolerable side effects to standard therapy (e.g. oral contraceptives)
OSNUVO* and generic TERIPARATIDE*	▪ Osteoporosis ▪ Osteoporosis associated with sustained systemic glucocorticoid therapy	▪ For patients with severe osteoporosis and 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 and 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

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DRUG	DISEASE	APPROVAL GUIDELINES
OTEZLA* and generic APREMILAST	▪ Plaque psoriasis ▪ Psoriatic Arthritis ▪ Behcet's disease	▪ For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions, AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are treated by a dermatologist ▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months ▪ For adults with a confirmed diagnosis of Behçet's disease who have experienced oral ulcers at least 3 times within the past 12 months and have tried and failed or did not tolerate at least one topical therapy (e.g. hydrocortisone, triamcinolone, betamethasone, fluocinonide, clobetasol, etc.) and at least one systemic therapy (e.g. corticosteroids, colchicine, azathioprine, cyclosporine, cyclophosphamide, thalidomide, etc.) ▪ Coordinate with provincial government program
OXYCODONE IMMEDIATE RELEASE (i.e. Oxycodone IR, Supeudol)	▪ Severe pain	▪ For pain management in patients who are unable to tolerate or receive an adequate response to other prescription pain medications
OXYCODONE CONTINUOUS RELEASE (i.e. Oxyneo, Oxycodone CR)	▪ Severe pain	▪ For pain management in patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the sustained release preparations of morphine
OXYTROL (Oxybutynin transdermal system)	▪ Urinary incontinence	▪ For individuals who have tried and failed oral anticholinergics (ex. Oxybutynin)
OZEMPIC (Semaglutide)	▪ Type 2 Diabetes Mellitus	▪ For adult patients with type 2 diabetes mellitus where metformin and another antihyperglycemic agent are contraindicated, not tolerated or ineffective ▪ Ozempic dose greater than 1mg : For patients requiring a dose greater than 1mg : o The prescriber must provide documented clinical justification (e.g. inadequate glycemic control) for the dose increase AND o The patient must have tried Mounjaro unless contraindicated, not tolerated or ineffective. ▪ Coordinate with provincial government program

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DRUG	DISEASE	APPROVAL GUIDELINES
OZURDEX (Dexamethasone)	▪ Macular edema following Central Retinal Vein Occlusion ▪ Non-infectious Uveitis ▪ Diabetic Macular Edema (DME) who are pseudophakic	<u>Initial Authorization Approval for Macular Edema following Central Retinal Vein Occlusion (6 month approval):</u> ▪ Patient must meet the following criteria to receive 1 implant per affected eye(s) for six months: ▪ For treatment of macular edema following Central Retinal Vein Occlusion o Validate site of administration ▪ Coordinate with provincial government plan <u>Subsequent Authorization Approval for Macular Edema following Central Retinal Vein Occlusion (6 month approval):</u> ▪ Patient must have received a beneficial effect from the initial injection with a subsequent loss in visual acuity to receive an additional 1 implant per affected eye(s) for six months ▪ Renewal will not be granted in the following circumstances: o Patient experienced vision deterioration without any beneficial effect from initial injection o Patient continues to benefit from initial injection and has not experienced a subsequent loss in visual acuity ▪ Coordinate with provincial government plan Maximum lifetime approval of 2 implants per affected eye <u>Initial Authorization Approval for Non-infectious Uveitis (6 month approval):</u> ▪ Patient must meet the following criteria to receive 1 implant per affected eye for 6 months: ▪ For the treatment of non-infectious uveitis (posterior) in patients with inadequate response to corticosteroids OR as a corticosteroid-sparing treatment in corticosteroid-dependent patients. <u>Subsequent Authorization Approval for Non-Infectious Uveitis (6 month approval):</u> ▪ Stability or improvement of vision and control of ocular inflammation confirmed by physician. Maximum lifetime approval of 2 implants per affected eye(s) <u>Initial Criteria for Diabetic Macular Edema:</u> ▪ For the treatment of Diabetic Macular Edema who are pseudophakic ▪ Validate site of administration ▪ Coordinate with available provincial programs ▪ Maximum approval of 2 implants per affected eye(s) <u>Subsequent Authorization Approval for Diabetic Macular Edema:</u> ▪ Must demonstrate presence of macular edema after initial positive response with Ozurdex ▪ Coordinate with available provincial programs ▪ Maximum approval of 2 injections per affected eye for 1 year Maximum lifetime approval of 6 implants per affected eye in 3 years

DRUG	DISEASE	APPROVAL GUIDELINES
PAXIL CR (Paroxetine controlled release)	▪ Depression	▪ Patient must have tried and failed and/or had adverse side-effects to regular release SSRIs or extended release SNRIs or atypical antidepressants
PDP-LEVETIRACETAM SOLUTION* (Levetiracetam 100 mg/ml)	▪ Epilepsy	Patient is medically unable to swallow Levetiracetam tablets AND one of the following: ▪ 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
PENNSAID and generic DICLOFENAC 1.5% SOLUTION	▪ Medical conditions requiring chronic NSAIDs	▪ For the treatment of patients requiring chronic NSAIDs who have failed to respond or had intolerable side-effects to at least two Non-Steroidal Anti-Inflammatory Drugs (NSAID) OR for patients with a documented history of a clinically significant ulcer or GI bleed
PERSERIS	▪ Schizophrenia	▪ For patients who are non-compliant or non-adherent with conventional oral therapy (e.g. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations

DRUG	DISEASE	APPROVAL GUIDELINES
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
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 been previously treated with or are not considered candidates for fluconazole (e.g. prophylaxis of invasive mold infections in patients undergoing allogeneic hematopoietic stem cell transplant) ▪ 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 been previously treated with or are not considered candidates for fluconazole (e.g. prophylaxis of invasive mold infections in patients undergoing allogeneic hematopoietic stem cell transplant) ▪ 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)

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

DRUG	DISEASE	APPROVAL GUIDELINES
PREVYMIS* (Letermovir)	▪ Cytomegalovirus (CMV) infection	▪ For the prevention of cytomegalovirus (CMV) infection in adult patients who underwent allogeneic hematopoietic stem cell transplant (HSCT) AND have documentation of being CMV-seropositive ▪ 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)
PRISTIQ and generic DESVENLAFAXINE	▪ Major Depressive Disorder	▪ For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other extended release SNRIs
PROLIA (Denosumab)	▪ Osteoporosis ▪ Glucocorticoid-induced osteoporosis ▪ Treatment to increase bone mass in men with non-metastatic prostate cancer receiving androgen deprivation therapy ▪ Treatment to increase bone mass in women with non-metastatic breast cancer receiving aromatase inhibitor therapy	▪ For patients who have failed treatment with oral bisphosphonates (alendronate, etidronate, risedronate) or have had intractable intolerance or adverse effects to Bisphosphonate therapy ▪ For patients who are previously stabilized on Prolia OR patients who are medically unable to use Jubbonti ▪ For denosumab naïve patients, Jubbonti will be approved ▪ Approval duration: 2 injections per calendar year
PROSCAR and generic FINASTERIDE	▪ Benign Prostatic Hyperplasia	▪ For the treatment of benign prostatic hyperplasia
PULMOZYME* (Dornase alfa)	▪ Cystic fibrosis	▪ For treatment in patients, aged 5 years or older, diagnosed with cystic fibrosis and who have a forced vital lung capacity more than 40%

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DRUG	DISEASE	APPROVAL GUIDELINES
QUILLIVANT ER (methylphenidate hydrochloride)	▪ Attention deficit hyperactivity disorder	▪ For patients aged 6-12 years diagnosed with ADHD who have tried and failed or had intolerable side effects to two standard therapies (e.g. generic Ritalin, Concerta, Adderall XR, Dexedrine, Strattera, generic Vyvanse)
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	<u>Initial Criteria (6 Months)</u> ▪ For the prevention of migraines 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 headache days per month <u>Renewal criteria: 1 year</u> ▪ Clinical benefit demonstrated by ≥ 50% reduction in number of headache days per month vs. baseline
QUVIVIQ (Daridorexant)	▪ Insomnia	▪ For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
RAGWITEK (Standardized allergen extract, Short Ragweed)	▪ Moderate to severe seasonal short ragweed allergic rhinitis	▪ For the treatment of allergic rhinitis in patients 5 years of age and older, who are ▪ Skin test positive to short ragweed pollen ▪ Symptomatic for at least 1 pollen season for age 5 to 6 OR for 2 pollen seasons for age 7 or older ▪ Not adequately controlled by at least one drug in three of the four following classes: intranasal corticosteroids, oral antihistamines, leukotriene receptor antagonists, and allergen Specific ImmunoTherapy injections
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	▪ 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

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DRUG	DISEASE	APPROVAL GUIDELINES
	chorioretinopathy or idiopathic chorioretinopathy	
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 ▪ Chronic Plaque Psoriasis	ADULT ▪ For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ Patients with 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 or involvement of the face, palms, soles or genital regions,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 6 years of age or older with moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine)

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ 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)
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 ▪ Chronic plaque psoriasis	<u>ADULT</u> ▪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 or involvement of the face, palms, soles or genital regions,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 <u>PEDIATRIC</u> ▪Patients 6 years of age or older with moderately to severely active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy and 5-ASA product OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - 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)

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

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DRUG	DISEASE	APPROVAL GUIDELINES
RESOTRAN and generic PRUCALOPRIDE	▪ Chronic idiopathic constipation	▪ For adult female patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil)

DRUG	DISEASE	APPROVAL GUIDELINES
RESTASIS and generic CYCLOSPORINE	▪ Moderate to moderately severe dry eyes	▪ For the treatment of moderate to moderately severe dry eye disease and for patients who had insufficient response to artificial tears
RETISERT (Fluocinolone acetonide)	▪ For treatment of chronic Non-Infectious Posterior Uveitis	▪ For the treatment of chronic Non-Infectious Posterior Uveitis in patients who have tried and failed oral prednisone or an equivalent corticosteroid alone and/or an immunosuppressive agent (cyclosporine, azathioprine, methotrexate etc.)
REVATIO* and generic SILDENAFIL (low dose)*	▪ Pulmonary Hypertension	▪ For patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III who do not respond to optimal conventional therapy (i.e. calcium channel blockers, anticoagulation with warfarin, diuretics, digoxin, supplemental oxygen) ▪ Coordinate with provincial government program
REVLIMID* and generic LENALIDOMIDE*	▪ Multiple Myeloma	▪ For the treatment of refractory or recurrent multiple myeloma, in combination with dexamethasone, in patients who have tried and failed at least two therapies (e.g. Bortezomib, Melphalan + Prednisone, Thalomide) and whose ECOG is of 2 or less. ▪ Coordinate with provincial government program
REVOLADE* and generic ELTROMBOPAG OLAMINE (Eltrombopag Olamine)	▪ Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	▪ For adult patients who are splenectomised and have tried and failed corticosteroids and immunoglobulins ▪ For adult patients who are non-splenectomised (where surgery is contraindicated) and have tried and failed corticosteroids and immunoglobulins ▪ For pediatric patients 1 year of age or older who have tried and failed corticosteroids and immunoglobulins ▪ Platelet counts less than 30 x 109/L ▪ Adults: Maximum approval is 1 year of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 109/L ▪ Pediatrics: Maximum approval is 9 months of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 109/L

DRUG	DISEASE	APPROVAL GUIDELINES
RILUTEK and generic RILUZOLE	▪ Amyotrophic lateral sclerosis (ALS)	▪ For the treatment of ALS in patients with symptoms of less than 5 years and who still have a vital lung capacity of 60% or more in the absence of tracheotomy
RINVOQ* (Upadacitinib)	▪ Rheumatoid Arthritis ▪ Psoriatic Arthritis ▪ 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: o Symptoms are uncontrolled by NSAIDS o BASDAI score is ≥ 4 o 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: o Treatment is prescribed and supervised by a specialist physician experienced in the diagnosis and treatment of atopic dermatitis o 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; o 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.

DRUG	DISEASE	APPROVAL GUIDELINES

		Renewal Criteria (12 months duration):
		• Documented objective evidence of clinical benefit since initiating therapy, defined as:
		  ○ 75% or greater improvement from baseline in EASI score 20 weeks after treatment initiation, and maintenance of 75% response thereafter OR
		  ○ 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 (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 (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.

RISPERDAL CONSTA (Risperidone injection)	▪ For the management of the manifestations of schizophrenia and related psychotic disorders	Reserved for patients who are non-compliant or non-adherent with conventional oral therapy, resulting in multiple relapses/hospitalizations
RITUXAN* (Rituximab)	▪ Rheumatoid Arthritis ▪ Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) ▪ Microscopic Polyangiitis (MPA)	Initial criteria (1 year): For the treatment of patients with rheumatoid arthritis who have tried and failed or could not tolerate at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) ▪ For patients who are medically unable to use a Rituximab biosimilar ▪ For Rituxumab naïve patients, only a Rituximab biosimilar will be approved

DRUG	DISEASE	APPROVAL GUIDELINES
		Retreatment Criteria (1 year): ▪ Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months For the treatment of adult patients with severe GPA or MPA: ▪ For patients who are medically unable to use a Rituximab biosimilar ▪ For Rituxumab naïve patients, only a Rituximab biosimilar will be approved ▪ In combination with glucorticoids ▪ Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). ▪ Approval for 1 year Dose: 375 mg/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 e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab. Retreatment Criteria (1 year): ▪ Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months For the treatment of adult patients with severe GPA or MPA: ▪ In combination with glucorticoids ▪ 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
ROSIVER (Ivermectin)	▪ Rosacea	▪ For the treatment of rosacea in patients who have tried and failed at least one topical treatment (i.e. Noritate, MetroGel, Finacea)

DRUG	DISEASE	APPROVAL GUIDELINES
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) ▪ Documented 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)	<u>Initial Criteria (1 year):</u> ▪ 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. <u>Retreatment Criteria (1 year):</u> ▪ Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months For the treatment of adult patients with severe GPA or MPA: ▪ In combination with glucorticoids ▪ Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). ▪ Approval for 1 year Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks
RYBELSUS (Semaglutide)	▪ Diabetes Mellitus	▪ For adult patients with type 2 diabetes mellitus where metformin and another antihyperglycemic agent are contraindicated, not tolerated or ineffective
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) In combination with cytarabine consolidation (post-induction) chemotherapy (one-time consolidation approval: 224 capsules)

DRUG	DISEASE	APPROVAL GUIDELINES
RYMTI* (Etanercept)	▪ Rheumatoid Arthritis ▪ Ankylosing Spondylitis ▪ Chronic 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 or involvement of the face, palms, soles or genital regions, who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist. ▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months. ▪ For patients 4 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease who have not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD.
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) ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
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
SAPHNELO* (Anifrolumab)	▪ Systemic Lupus Erythematosus (SLE)	<u>Initial Criteria (1 year duration):</u> ▪ 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) <u>Renewal Criteria (1 year duration):</u> ▪ Reduction in oral corticosteroid dose to ≤ 7.5 mg/day of prednisone or its equivalent ▪ Reduction in disease activity measured by: ▪ Reduction of SLEDAI-2K score to 5 or less
SATIVEX* (Tetrahydro-cannabinol and cannabidiol buccal spray)	▪ For symptomatic relief of spasticity in adults with multiple sclerosis	For adult MS patients with spasticity who have tried other medications such as analgesics, opioids, antidepressants or anticonvulsants, with little or no effect
SAXENDA (Liraglutide)	▪ Weight management	<u>Initial Authorization Approval (1 year):</u> ▪ Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with at least one weight-related comorbidity (e.g. hypertension, type 2 diabetes, or dyslipidemia) ▪ Have tried and will continue prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Saxenda ▪ Weight prior to initiation of treatment ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable <u>Subsequent Authorization Approval (1 year):</u> ▪ Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Saxenda ▪ Current weight ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable PEDIATRIC <u>Initial Authorization Approval for Pediatric (1 year):</u> ▪ Patients 12 to less than 18 years of age with an initial BMI corresponding to ≥30 kg/m^2 for adults by international cut-offs AND ▪ A body weight above 60kg AND ▪ Inadequate response to reduced calorie diet and increased physical activity ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable <u>Subsequent Authorization Approval for Pediatric (1 year):</u> ▪ Patients 12 to less than 18 years of age with an initial BMI corresponding to ≥30 kg/m2 for adults by international cut-offs AND ▪ Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND ▪ Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Saxenda ▪ Current Weight ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable
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
SEBIVO (Telbivudine)	▪ Chronic hepatitis B	▪ For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) ▪ Coordinate with provincial government program
SENSIPAR* and generic CINACALCET*	▪ Hyperparathyroidism secondary to Chronic Kidney Disease (“CKD”)	▪ For patients with hyperparathyroidism secondary to CKD with parathyroid hormone levels greater than 33pmol/L or 300pg/mL
SEMGLEE (Insulin glargine)	▪ Diabetes mellitus	▪ For patients who are at high risk for hypoglycemia
SILENOR (Doxepin Hydrochloride)	▪ Insomnia	▪ For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)

DRUG	DISEASE	APPROVAL GUIDELINES
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 or involvement of the face, palms, soles or genital regions,AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist

SIGNIFOR/ SIGNIFOR LAR
(Pasireotide) *
	▪ Cushing's Disease	Initial Criteria
		▪ For the treatment of Cushing's Disease in adult patients:
		  ▪ Who have tried and failed or are experiencing recurrent disease despite prior surgical intervention OR
		  ▪ Whose condition or who have comorbidities that render surgery inappropriate
		▪ Baseline urinary free cortisol levels
		▪ 6 months approval
		
		Renewal Criteria
		▪ Documentation of clinical benefits with Signifor
		  ▪ Normalization of urinary free cortisol OR
		  ▪ More than 50% decrease in urinary free cortisol
		
		▪ Coordinate with provincial government program

SIMLANDI* (Adalimumab)	ADULT ▪ Crohn's Disease ▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis PEDIATRIC ▪ Juvenile Idiopathic Arthritis ▪ Non-infectious anterior uveitis ▪ Hidradenitis Suppurativa	ADULT ▪ For patients with fistulizing Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) ▪ For patients with 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 or involvement of the face, palms, soles or genital regions,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

DRUG	DISEASE	APPROVAL GUIDELINES
		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 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, 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 uncontrolled by NSAIDs and the BASDAI score is greater than or equal to 4 For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months

DRUG	DISEASE	APPROVAL GUIDELINES
SIMPONI SC* (Golimumab)	▪ 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 ▪ Ulcerative Colitis	▪ For patients 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions, 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) ▪ 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 (ex: azathioprine, 6-mercaptopurine) ▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
Sogroya (Somapacitan)	▪ Adult Growth Hormone Deficiency ▪ GrowthHormone Deficiency in Children	▪ For the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (Growth Hormone Deficiency (GHD)). ▪ For the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD).
SOLIQUA (Insulin glargine/lixisenatide)	▪ Diabetes mellitus	▪ For adults with type 2 diabetes mellitus who are inadequately controlled on basal insulin or a GLP-1 agonist (e.g. Ozempic, Rybelsus, Trulicity)
SOMATULINE * (Lanreotide)	▪ Acromegaly ▪ Enteropancreatic neuroendocrine tumors	▪ For the treatment of acromegaly in patients who have tried and failed or are ineligible for surgery and/or radiation therapy and other medical therapies ▪ For the treatment enteropancreatic neuroendocrine tumors characterized as Grade 1 or Grade 2 (equivalent to Ki67 < 10%) that are unresectable, locally advanced or metastatic
SOMAVERT* (Pegvisomant)	▪ Treatment of Acromegaly	▪ For patients who have tried and failed surgery and/or radiation therapy and other medical therapies OR are ineligible for surgery and/or radiation therapy and other medical therapies
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, or involvement of the face, palms, soles or genital regions,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-

DRUG	DISEASE	APPROVAL GUIDELINES
		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 requires urgent psychiatric care	<u>Initial Criteria (6 month approvals):</u> ▪ For patients with major depressive disorder who have tried and failed three courses of antidepressants from each of the following drug classes for at least 4 weeks: SSRI, SNRI and/or one other antidepressant drug class (e.g. bupropion, mirtazapine, etc.) o One course must be combination therapy using two antidepressants for at least 4 weeks ▪ Prescriber must specify severity of symptoms, e.g. current Montgomery-Asberg Depression Rating Scale (MADRS) score, PHQ-9 score, Hamilton Depression Rating Scale (HDRS) ▪ Must be enrolled in Janssen Journey Program <u>Renewal Criteria (6 month approvals):</u> ▪ Clinical benefit as demonstrated by remission or response, e.g. current Montgomery-Asberg Depression Rating Scale (MADRS) score, PHQ-9 score, Hamilton Depression Rating Scale (HDRS) ▪ 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

DRUG	DISEASE	APPROVAL GUIDELINES
STEGLATRO (Ertugliflozin) SEGLUROMET (ertugliflozin/metformin)	▪ Diabetes mellitus	▪ For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective
STEGLUJAN (Ertugliflozin/Sitagliptin)	▪ Diabetes mellitus	▪ For treatment of type-2 diabetic persons where metformin and a sulfonylurea are contraindicated, not tolerated or ineffective
STELARA* (Ustekinumab)	▪ Plaque psoriasis ▪ Psoriatic Arthritis ▪ Crohn's Disease ▪ Ulcerative Colitis	▪ For patients who are 6 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions,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
STEQEYMA* (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 or involvement of the face, palms, soles or genital regions, 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 Celltrion CONNECT ▪ 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

DRUG	DISEASE	APPROVAL GUIDELINES
		their IV induction dose and are registered with Celltrion CONNECT ▪ 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 or are not considered candidates for all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin, irinotecan, an anti-VEGF therapy (bevacizumab), trifluridine-tipiracil AND ▪ If KRAS wild type, an anti-EGFR therapy (cetuximab, panitumumab) ▪ For metastatic and/or unresectable GIST patients who have tried and failed or is intolerable to imatinib and sunitinib therapy ▪ ECOG ≤ 1 ▪ Coordinate with provincial government program
STRIBILD* (Cobicistat/Tenofovir/Emtricitabine/ Elvitegravir)	▪ HIV anti-viral	▪ Coordinate with available provincial government programs
SUBLINOX and generic ZOLPIDEM	▪ Insomnia	▪ For patients 18 years and older who have failed to respond or have had intolerable side effects to at least one of the following: benzodiazepines, sedating antidepressants (e.g. trazodone) and hypnotic agents (e.g. Imovane)
SUBLOCADE (Buprenorphine)	▪ Opiod Dependence	▪ For management of opioid dependence in patients clinically stable on generic Suboxone at a daily dose greater than 8 mg (buprenorphine)
SUNOSI (Solriamfetol)	▪ Excessive daytime sleepiness (EDS) in narcoleptic patients ▪ Excessive daytime sleepiness (EDS) in patients with obstructive sleep apnea (OSA)	▪ For the treatment of excessive daytime sleepiness (EDS) in adult patients associated with narcolepsy or obstructive sleep apnea (OSA) who have tried standard therapy (e.g. generic Alertec)

*Coverage Navigation through provincial government programs and other funding sources may apply, in accordance with your insurance program – ClaimSecure to assist Members with this process

DRUG	DISEASE	APPROVAL GUIDELINES
SUTENT and generic SUNITINIB*	▪ Gastrointestinal Stromal Tumour (GIST) ▪ First-line treatment of metastatic Renal Cell Carcinoma ("RCC")	For GIST patients who have tried and failed or had no response to Gleevec (imatinib) Diagnosis of metastatic RCC. ECOG of two or less must be documented ▪ Coordinate with provincial government program
SYMTUZA* (Darunavir/Cobicistat/Emtricitabine/Tenofovir alafenamide)	▪ HIV anti-viral	▪ Coordinate with available provincial government programs
TALTZ* (Ixekizumab)	▪ Plaque Psoriasis ▪ Psoriatic Arthritis ▪ Ankylosing Spondylitis ▪ Non-radiographic axial spondyloarthritis (nr-axSpA)	▪ For patients who are 6 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement or involvement of the face, palms, soles or genital regions,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 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 tried and failed 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

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DRUG	DISEASE	APPROVAL GUIDELINES
TECFIDERA* and generic DIMETHYL FUMARATE*	▪ Relapsing remitting Multiple Sclerosis (RRMS)	▪ Diagnosis of RRMS ▪ EDSS value required with every application ▪ Coordinate with provincial government program
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
TEZSPIRE* (Tezepelumab)	▪ Severe asthma	▪ <u>Initial Criteria (1 year):</u> ▪ 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) ▪ <u>Renewal Criteria (1 year):</u> ▪ 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* (Thalomide)	▪ Multiple myeloma	▪ For patients ≥ 65 years of age who are not eligible for autologous stem cell transplantation ▪ For use in combination with dexamethasone OR melphalan and prednisone ▪ ECOG ≤ 2 ▪ Coordinate with provincial government program
THYROGEN (Thyrotropin alpha Injection)	▪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

DRUG	DISEASE	APPROVAL GUIDELINES
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
TOUJEO (Insulin glargine)	▪ Diabetes mellitus	▪ For patients who are at high risk for hypoglycemia
TRACLEER* and generic BOSENTAN*	▪ Pulmonary Hypertension	▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class III AND who have tried and failed or cannot tolerate Revatio or Adcirca (miminum 3 months trial) ▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV ▪ Coordinate with provincial government program
TRAJENTA (Linagliptin) JENTADUETO (Linagliptin/Metformin)	▪ Diabetes mellitus	▪ For patients who had an inadequate response to, or are unable to tolerate maximum doses of metformin (≥2000 mg) AND generic DPP-4 inhibitor (e.g generic Januvia, generic Onglyza) unless use of those therapies are inappropriate.
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 or involvement of the face, palms, soles or genital regions, 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
TRESIBA (Insulin degludec)	▪ Diabetes mellitus	▪ For patients who are at high risk for hypoglycemia
TRINTELLIX and generic VORTIOXETINE	▪ Major depressive disorder	▪ For individuals diagnosed with major depressive disorder and who have previously tried and failed therapy with any other antidepressant
TRIUMEQ* (Dolutegravir/Abacavir/ Lamivudine)	▪ HIV infection in adults	▪ Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
TRULANCE (Plecanatide)	▪ Irritable bowel syndrome with constipation (IBS-C)	▪ For adult patients who have tried and failed dietary and lifestyle measures (i.e. high fibre diet, increased water intake, physical exercise) and at least one medication in at least two of the following classes: stool softeners (docusate), osmotic agents (magnesium citrate, magnesium hydroxide, magnesium sulfate, polyethylene glycol 3350, sodium enema), hyperosmotic agents (glycerin suppositories, lactulose) and stimulants (bisacodyl, senna, castor oil).
TRULICITY (Dulaglutide)	▪ Diabetes mellitus	▪ For adult patients with type 2 diabetes mellitus where metformin and another antihyperglycemic agent are contraindicated, not tolerated or ineffective
TRUSOPT (Dorzolamide preservative-free ophthalmic solution)	▪ Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	▪ For patients who are allergic to or cannot tolerate the formulation with the preservative
TRUVADA* and generic EMTRICITABINE/TENOFOVIR	▪ HIV anti-viral ▪ Pre-Exposure Prophylaxis (PrEP) of HIV-1 infection	▪ Coordinate with provincial government program
TRUXIMA* (Rituximab)	▪ Rheumatoid Arthritis ▪ Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) ▪ Microscopic Polyangiitis (MPA)	<u>Initial Criteria (1 year):</u> ▪ For the treatment of patients with RA ▪ Trial and failure or intolerance to at least one or more anti-TNF treatment e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab. <u>Retreatment Criteria (1 year):</u> ▪ Evidence of clinical benefit and it has not been less than 6 months since their last dose of rituximab ▪ Dose: Two doses of 1000 mg IV infusion separated by 2 weeks, followed by retreatment every 6 months For the treatment of adult patients with severe GPA or MPA: ▪ In combination with glucorticoids ▪ Trial and failure, intolerance or contraindicated to use cyclophosphamide (Ex: Cytoxan or Procytox or generic cyclophosphamide). ▪ Approval for 1 year Dose: 375 mg/m^2 body surface area, administered as an IV infusion once weekly for 4 weeks

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DRUG	DISEASE	APPROVAL GUIDELINES
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 o Coordinate with provincial government program
TYSABRI* (Natalizumab)	▪ Relapsing remitting Multiple Sclerosis (RRMS)	▪ For RRMS patients have had an inadequate response to, or are unable to tolerate, two ore more therapies, (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) AND have evidence of lesions on their MRI scan, an EDSS value less than 6 and have had at least one relapse in previous year o EDSS value required with every application ▪ For patients with rapidly evolving severe MS, they must have had two or more disabling relapses in one year and at least nine T2-hyperintense lesions in their cranial MRI or at least one gadolinium-enhancing (Gd-enhancing) lesion o EDSS value required with every application ▪ Coordinate with provincial government program
GENERIC FEBUXOSTAT	▪ To lower serum uric acid levels in patients with gout	▪ For patients who have tried and failed or had intolerable side effects to allopurinol
ULTIBRO BREEZHALER (Indacaterol/Glycopyrronium)	▪ Chronic Obstructive Pulmonary Disease (COPD)	▪ For patients diagnosed with COPD, including chronic bronchitis and emphysema who have tried and failed on long-acting bronchodilator monotherapy
UPTRAVI* (Selexipag)	▪ Pulmonary Arterial Hypertension (PAH) WHO functional class (FC) II–III (idiopathic, heritable, or associated with connective tissue disease or congenital	▪ 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

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DRUG	DISEASE	APPROVAL GUIDELINES
	heart disorders)	
UROCIT-K (Potassium citrate)	▪ Kidney Stones	▪ For patients with renal tubular acidosis (RTA) with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stone
VABYSMO* (Faricimab)	▪ Wet age-related macular degeneration ▪ Diabetic Macular Edema (DME) ▪ Macular edema secondary to retinal vein occlusion (RVO)	▪ For patients diagnosed with neovascular (wet) age-related macular degeneration (AMD) ▪ For treatment of visual impairment due to diabetic macular edema ▪ For the treatment of macular edema secondary to retinal vein occlusion (RVO) where another anti-VEGF agent (e.g. Ranibizumab or Aflibercept) is contraindicated, not tolerated or ineffective ▪ Approval duration: 6 months ▪ 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
VASCEPA (Icosapent ethyl)	▪ Hypertriglyceridemia	▪ For patients with established Cardiovascular Disease OR Diabetes Mellitus with at least one other cardiovascular risk factor (e.g. hypertension, renal dysfunction, retinopathy), who are stable on a cholesterol lowering agent (e.g. statin, fenofibrate, ezetimibe) and have a triglyceride level of ≥1.53 mmol/L
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)

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
Veozah (Fezolinetant)	▪ Vasomotor Symptoms (VMS) associated with menopause	▪ For treatment of vasomotor symptoms in menopausal women where prior therapy is contraindicated, not tolerated or ineffective (e.g. hormone therapy, SSRI, SNRIs).
VERKAZIA (Cyclosporine)	▪ Severe vernal keratoconjunctivitis (VKC)	▪ For the treatment of severe VKC in children from 4 years of age through adolescence (12-18 years) with trial and failure of, intolerance, or contraindication to two of the following: topical antihistamines (e.g. pheniramine), topical mast cell stabilizers (e.g. sodium cromoglycate), topical dual-action drugs (e.g. olopatidine), topical vasoconstrictors (e.g. naphazoline), topical corticosteroids (e.g. prednisolone)
VERZENIO* (Abemaciclib)	▪ Advanced or metastatic breast cancer ▪ Adjuvant – Early Breast Cancer	<u>Initial Criteria (6 month duration):</u> ▪ For postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer AND ▪ Endocrine-naïve/sensitive AND ▪ No active or uncontrolled metastases to the brain AND ▪ No resistance to prior (neo-) adjuvant aromatase-inhibitor therapy AND ▪ No previous systemic treatment including chemotherapy for their advanced disease AND ▪ In combination with an aromatase inhibitor (e.g. Anastrozole, Letrozole) <u>Renewal (6 month duration):</u> ▪ Continue until unacceptable toxicity or disease progression <u>Initial Criteria (6 month duration)</u> ▪ In combination with generic Faslodex for the treatment of postmenopausal women with HR-positive, HER2- negative advanced or metastatic breast cancer following disease progression on endocrine therapy AND must be CDK 4/6 inhibitor treatment naïve <u>Renewal Criteria (6 month duration)</u> ▪ Continue until unacceptable toxicity or disease progression <u>Initial Criteria (6 month duration)</u> ▪ 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

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Last tumour resection within the last 16 months AND ▪ One of the following: o At least 4 positive lymph nodes OR o 1 to 3 positive lymph nodes AND - grade 3 tumour OR - primary tumour size ≥ 5 cm OR - Ki-67 index score ≥ 20% ▪ Must be CDK 4/6 inhibitor treatment naïve <u>Renewal Criteria (6 month duration)</u> ▪ Continue until unacceptable toxicity or disease progression ▪ Maximum treatment duration of 2 years
VERQUVO (Vericiguat)	▪ Symptomatic chronic heart failure with reduced ejection fraction	▪ For the treatment of symptomatic chronic heart failure with reduced ejection fraction in adults meeting <u>ALL</u> of the following criteria: ▪ LVEF < 45% ▪ NYHA class II-IV ▪ Recent heart failure decompensation event requiring hospitalization and/or IV diuretic therapy ▪ To be used in combination with an ACEi/ARB, a beta-blocker, and/or an aldosterone antagonist.
VFEND* and generic VORICONAZOLE*	▪ Treatment of invasive aspergillosis ▪ Treatment of Candidemia in non-neutropenic patients and *Candida* infections	▪ For the treatment of invasive aspergillosis for post-hospital discharge only ▪ For patients with candidemia who cannot tolerate Amphotericin B and Fluconazole or who have infections with Fluconazole-resistant Candida species ▪ Coordinate with provincial government program
VIBERZI (Eluxadoline)	▪ Irritable bowel syndrome with diarrhea (IBS-D)	▪ For treatment of irritable bowel syndrome with diarrhea (IBS-D) in adult patients who have tried and failed dietary and lifestyle measures and standard therapy (i.e. Imodium)
VICTOZA (Liraglutide)	▪ Diabetes mellitus	▪ For adult patients with type 2 diabetes mellitus where metformin and another antihyperglycemic agent are contraindicated, not tolerated or ineffective
VIIBRYD and generic VILAZODONE	▪ Major depressive disorder	▪ For individuals diagnosed with major depressive disorder and who have previously tried and failed therapy with any other antidepressant
VIMOVO XR and generic NAPROXEN/ESOMEPRAZOLE	▪ Chronic medical conditions requiring NSAIDs (i.e. Osteoarthritis, Rheumatoid arthritis, Ankylosing Spondylitis)	▪ For patients who have failed to respond or had intolerable side-effects with the concomitant use of an NSAID with at least two of the following proton pump inhibitors: Rabeprazole, Lansoprazole, Omeprazole, and/or Pantoprazole
VIMPAT and generic LACOSAMIDE	▪ Monotherapy or Adjunctive therapy for partial onset seizures	▪ For patients with a diagnosis of partial onset seizures who have tried, failed or have experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin

DRUG	DISEASE	APPROVAL GUIDELINES
VISANNE and generic DIENOGEST	▪ Pelvic pain associated with endometriosis	▪ For patients who have failed to respond or have had intolerable side-effects to oral contraceptives
VISUDYNE* (Verteprofine)	▪ Age related macular degeneration ▪ Pathological myopia	▪ For the treatment of age-related macular degeneration in patients with neovascularization of 50% or more on the macular surface AND no provincial coverage is available
VIZIMPRO* (Dacomitinib)	▪ Locally advanced or metastatic non-small cell lung cancer (NSCLC)	▪ For patients with a confirmed diagnosis of unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations who have tried and failed at least one EGFR tyrosine kinase inhibitor (e.g. Iressa, Tarceva, or Giotrif) ▪ Coordinate with provincial government program
VOCABRIA* (Cabotegravir) CABENUVA* (Cabotegravir/Rilpivirine)	▪ HIV	▪ 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 AND who have had an inadequate response or intolerance to a Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) ▪ For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class III AND who have had an inadequate response or intolerance to both of the following: 1) Phosphodiesterase-5 inhibitor (i.e. generic Revatio, generic Adcirca) 2) Generic Tracleer with or without generic Adcirca ▪ Coordinate with provincial government program

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DRUG	DISEASE	APPROVAL GUIDELINES
VOSEVI* (Sofosbuvir/Velpatasvir/Voxilaprevir)	▪ Hepatitis C	▪ For adult patients with chronic hepatitis C infection, without cirrhosis or with compensated cirrhosis, who have: ▪ Genotypes 1 – 6 and previously treated with an NS5A inhibitor OR ▪ Genotypes 1 – 4 and previously treated with sofosbuvir but not an NS5A inhibitor OR ▪ Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ Retreatment due to re-infection will not be considered ▪ Coordinate with provincial government program
VOTRIENT* 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
VRAYLAR (Cariprazine)	▪ Bipolar I Disorder ▪ Schizoprenia	▪ For the treatment of adult patients with Bipolar I Disorder who has had an inadequate response or intolerance to at least 1 conventional oral therapy (e.g. aripiprazole, asenapine, paliperidone, quetiapine, risperidone, divalproex, lithium, valproic acid, lurasidone, lamotrigine) ▪ For the treatment of adult patients with Schizophrenia who has had an inadequate response or intolerance to at least 1 antipsychotic agent (e.g. aripiprazole, asenapine, brexipiprazole, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone) ▪
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	<u>Initial criteria (6 months):</u> • 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 <u>Renewal criteria after initial trial (will be approved for 1-year duration):</u> • Clinical benefit demonstrated by ≥ 50% reduction in number of migraine days per month vs. baseline

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DRUG	DISEASE	APPROVAL GUIDELINES
WAKIX* (Pitolisant)	Adults: ▪ Excessive daytime sleepiness (EDS) in narcoleptic patients ▪ Excessive daytime sleepiness (EDS) in obstructive sleep apnea (OSA) patients ▪ Cataplexy in narcoleptic patients Pediatrics: ▪ Excessive daytime sleepiness (EDS) in narcoleptic patients ▪ Cataplexy in narcoleptic patients	Adult: ▪ 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 excessive daytime sleepiness (EDS) in adult patients diagnosed with obstructive sleep apnea (OSA) who have insufficient response, intolerance or contraindication to at least 2 therapies (e.g Sunosi and generic Alertec) ▪ 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) Pediatric: • For the treatment of excessive daytime sleepiness (EDS) in pediatric patients with narcolepsy who have tried and failed or are intolerant to at least two prior therapies (e.g. generic Ritalin, generic Dexedrine) • For the treatment of cataplexy in pediatric patients with narcolepsy who have tried and failed or are intolerant to at least one prior therapy (e.g. SSRI, SNRI).
WEGOVY (Semaglutide)	▪ Weight-Management	ADULT <u>Initial Authorization Approval (1 year)</u> ▪ Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with at least one weight-related comorbidity (e.g. hypertension, type 2 diabetes, dyslipidemia, or obstructive sleep apnea) ▪ Have tried and will continue prescribed lifestyle therapy (reduced calorie diet and increased physical activity) ▪ Weight prior to initiation of treatment ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable <u>Subsequent Authorization Approval (1 year)</u> ▪ Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND ▪ Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Wegovy ▪ Current weight ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable PEDIATRIC <u>Initial Authorization Approval for Pediatric (1 year):</u> ▪ Patients 12 to less than 18 years of age with an initial BMI at the 95th percentile or greater for age and sex AND ▪ A body weight above 60kg AND ▪ Inadequate response to reduced calorie diet and increased physical activity ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable <u>Subsequent Authorization Approval for Pediatric (1 year):</u> • Patients 12 to less than 18 years of age with an initial BMI at the 95th percentile or greater for age and sex AND

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DRUG	DISEASE	APPROVAL GUIDELINES
		• Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND • Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Wegovy. • Current Weight ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable
WELLBUTRIN SR/XL and generic BUPROPION	▪ Depression	For patients with a confirmed diagnosis of depression
WEZLANA* (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 or involvement of the face, palms, soles or genital regions, 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 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
WYOST* (denosumab)	▪ Bone metastases	▪ For patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumors AND have tried and failed or experienced intolerable side effects with bisphosphates (Clasteon or Zometa)
XCOPRI (cenobamate)	▪ Partial Onset Seizures	▪ For use as adjunctive therapy in the treatment of partial onset seizures in patients 18 years and older of age who have tried and failed or experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
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

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ For patients with a confirmed diagnosis of psoriatic arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND Leflunomide or Sulfasalazine for a period of 3 months ▪ 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
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
XELODA* and generic CAPECITABINE	▪ Adjuvant treatment of stage III (Dukes' stage C) colon cancer ▪ Metastatic colorectal cancer ▪ Metastatic breast cancer	▪ For the first-line treatment of metastatic colorectal cancer ▪ For the treatment of metastatic colorectal cancer in combination with oxaliplatin after failure of irinotecan-containing combination chemotherapy ▪ For treatment of advanced or metastatic breast cancer after failure of standard therapy including a taxane unless contraindicated OR in combination with docetaxel after failure of prior anthracycline containing chemotherapy ▪ Coordinate with provincial government program
XENICAL (Orlistat)	▪ Weight management	<u>Initial Authorization Approval (1 year):</u> ▪ Body Mass Index (BMI) greater than or equal to 30 OR a BMI of 27-29 with at least one weight-related comorbidity (e.g. hypertension, type 2 diabetes, dyslipidemia, excess visceral fat) ▪ Have tried and will continue prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Xenical ▪ Weight prior to initiation of treatment ▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable <u>Subsequent Authorization Approval (1 year):</u> ▪ Demonstrate a minimum reduction of 5% of initial body weight or continue to maintain initial 5% weight reduction AND ▪ Continuation of prescribed lifestyle therapy (reduced calorie diet and increased physical activity) while using Xenical ▪ Current weight

DRUG	DISEASE	APPROVAL GUIDELINES
		▪ Maximum Lifetime Coverage to be in line with anti-obesity coverage of the plan as applicable
XEOMIN (Incobotulinumtoxin A)	▪ Blepharospasm ▪ Cervical dystonia (spasmodic torticollis) ▪ Spasticity of the upper limbs ▪ Chronic sialorrhea ▪ Spasticity of the lower limbs	▪ For the treatment of blepharospasm in patients 18 years of age or older ▪ For the treatment of torticollis in adult patients ▪ For the treatment of 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) ▪ For the treatment of post-stroke lower limb spasticity involving ankle and foot in adult patients
XGEVA and generic DENOSUMAB	▪ Bone metastases	▪ For patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumors AND have tried and failed or experienced intolerable side effects with bisphosphates (Clasteon or Zometa) ▪ For patients who are previously stabilized on Xgeva OR patients who are medically unable to use Wyost ▪ For denosumab naïve patients, Wyost will be approved
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

DRUG	DISEASE	APPROVAL GUIDELINES
XIIDRA (Lifitegrast)	▪ Moderate to severe dry eyes	▪ For the treatment of moderate to severe dry eye disease and for patients who had insufficient response to artificial tears
XOLAIR Pre-Filled Syringes (PFS)* (Omalizumab)	▪ Severe allergic asthma ▪ Chronic idiopathic urticaria	<u>Initial Criteria:</u> ▪ 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) o Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen o Documentation of weight and pretreatment serum IgE ▪ In all cases, must provided 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 <u>Renewal Criteria:</u> ▪ 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 ▪ 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

*Coverage Navigation through provincial government programs and other funding sources may apply, in accordance with your insurance program – ClaimSecure to assist Members with this process

DRUG	DISEASE	APPROVAL GUIDELINES
XTANDI* (Enzalutamide)	▪ Metastatic castration-resistant prostate cancer (mCRPC) ▪ Non-metastatic castration-resistant prostate cancer (nmCRPC) ▪ Metastatic castration-sensitive prostate cancer (mCSPC)	Initial Criteria (6 months): ▪ For patients with a diagnosis of metastatic CRPC who received prior chemotherapy containing docetaxel ▪ Coordinate with provincial government program Renewal criteria (6 months): ▪ Absence of disease progression Initial Criteria (6 months): ▪ In combination with Androgen depriviation Therapy (ADT) for the treatment of men with non-metastatic castrate resistant prostate cancer (nmCRPC) in patients who are at high risk of developing metastases (i.e. prostate-specific antigen (PSA) doubling time of 10 months or less during continuous ADT) AND ECOG 0-1 ▪ Coordinate with provincial government program Renewal criteria (6 months): ▪ Absence of disease progression Initial Criteria (6 months): ▪ For adult patients with a diagnosis of metastatic castration- sensitive prostate cancer (mCSPC) AND meet all the following: ECOG score of ≤ 2 AND must maintain androgen- deprivation therapy (ADT) with Lupron Depot, Firmagon, or Zoladex ▪ Coordinate with provincial government program Renewal criteria (6 months): ▪ Absence of disease progression
XULTOPHY (Insulin degludec/Liraglutide)	▪ Diabetes mellitus	▪ Trial and failure with a basal insulin (i.e. Levemir, Basaglar, Lantus, Toujeo, Tresiba) OR ▪ Trial and failure with a GLP-1 agonist (i.e. Ozempic, Victoza, Trulicity)
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	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

DRUG	DISEASE	APPROVAL GUIDELINES
	▪ Ulcerative Colitis ▪ Rheumatoid Arthritis ▪ Psoriatic arthritis ▪ Ankylosing spondylitis ▪ Chronic plaque psoriasis ▪ Hidradenitis Suppurativa ▪ Non-infectious Uveitis <u>PEDIATRIC</u> ▪ Juvenile Idiopathic Arthritis ▪ Non-infectious anterior uveitis ▪ Hidradenitis Suppurativa	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 or involvement of the face, palms, soles or genital regions,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. ▪ <u>Renewal Criteria:</u> 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 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 ▪ <u>Renewal Criteria:</u> 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

DRUG	DISEASE	APPROVAL GUIDELINES
		antibiotics (i.e. dicloxacillin, erythromycin, minocycline, tetracycline, doxycycline) AND the Abscess and Nodule count is ≥ 3. ▪ Coordinate with provincial government program
ZAXINE (Rifaximin)	▪ Irritable bowel syndrome with diarrhea (IBS-D) ▪ For reduction in risk of overt hepatic encephalopathy	▪ For treatment of irritable bowel syndrome with diarrhea (IBS-D) in adult patients who have tried and failed dietary and lifestyle measures and standard therapy (i.e. Imodium) ▪ Lifetime approval maximum of 126 tablets ▪ For adult patients susceptible to overt hepatic encephalopathy AND have tried lactulose (unless severe intolerance or contraindication) Coordinate with provincial government program
ZEPATIER* (Elbasvir/Grazoprevir)	▪ Hepatitis C Infection	▪ For treatment-naïve or treatment-experienced* adult patients with or without cirrhosis diagnosed with chronic hepatitis C genotype 1 and genotype 4 with: ▪ Quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months ▪ Fibrosis stage F2 or greater (Metavir scale or equivalent) ▪ Have failed or have a true contraindication to Maviret ▪ Retreatment requests will not be considered ▪ Coordinate with provincial government program ▪ Maximum approval 12 weeks ▪ *Treatment relapse or failure to standard peg-interferon/ribavirin OR peg-interferon/ribavirin/boceprevir, simeprevir, or telaprevir.
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)

DRUG	DISEASE	APPROVAL GUIDELINES
ZUACTA (Zucapsaicin cream)	▪ Osteoarthritis	▪ A confirmed diagnosis of osteoarthritis, where the patient failed to respond OR had intolerable side-effects to Meloxicam AND at least one Non-Steroidal Anti-Inflammatory Drug (NSAID)
ZYDELIG* (Idelalisib)	▪ Treatment of patients with relapsed Chronic Lymphocytic Leukemia (CLL)	▪ For the treatment of patients with who have relapsed CLL ▪ Who failed or are experiencing recurrent disease despite 1 prior therapy (e.g. bendamustine + rituximab, fludarabine + cyclophosphamide + rituximab, single-agent rituximab, fludarabine + rituximab, chlorambucil, fludarabine, ofatumumab, chlorambucil, etc.) ▪ Must be taken in combination with rituximab ▪ Coordinate with provincial government program
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