Special Authorization Drugs and Approval Guidelines

(Special authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ABSTRAL (Fentanyl citrate)	- Management of breakthrough pain in cancer patients	- For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day - Patient should be currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) **AND** have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR
ACLASTA (Zoledronic acid)	- Paget's disease of the bone - Postmenopausal osteoporosis	- For patients who have failed treatment with Bisphosponates or have had intractable intolerance or adverse effects to Bisphosphonate therapy
ACTEMRA (Tocilizumab)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months - Coordinate with provincial government program
ACULAR LS (Ketorolac 0.4% ophthalmic solution)	- For the reduction of ocular pain and photophobia following refractive surgery	- For the reduction of ocular pain and photophobia where the patient has tried Ketorolac 0.5% AND had intractable intolerance or adverse effects
ADCIRCA (Tadalafil)	- Pulmonary Hypertension	- For patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
ADDERALL XR (Dextroamphetamine and amphetamine extended release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting), generic Concerta, or Dextroamphetamine
AFINITOR (Everolimus)	- Second-line treatment of metastatic Renal Cell Carcinoma ("RCC")	- For patients with a confirmed diagnosis of metastatic renal cell carcinoma of clear cell morphology who have tried and failed initial treatment with either sunitinib or sorafenib. - Coordinate with provincial government program
AMBISOME CANCIDAS (Caspofungin)	- Invasive aspergillosis	- For the treatment of invasive aspergillosis resistant to other therapies - Coordinate with Hospital Provincial Program
AMEVIVE (Alefacept)	- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients who are 16 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist

DRUG	DISEASE	APPROVAL GUIDELINES
ANDROGEL (Testosterone 1% pump)	- Endogenous testosterone deficiency	- For patients who have tried Testosterone sachets and have a physical disability that prevents them from physically opening a sachet
APTIVUS (Tipranavir)	- 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
ARANESP (Erythropoietin)	- Anemia with chemotherapy - Chronic renal failure	- For patient with chronic renal failure undergoing dialysis treatment - For patient with anemia secondary to chemotherapy - Coordinate with provincial government program
AREDIA (Pamidronate disodium)	- Tumour-induce Hypercalcemia - Bone metastases and multiple myeloma - Paget's disease of the bone	- Coordinate with provincial government program
AVODART (Dutasteride)	- Benign Prostatic Hyperplasia	- For male patients in the treatment of benign prostatic hyperplasia
AVONEX AVONEX PS (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
BANZEL (Rufinamide)	- Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome	- For the treatment of Lennox Gastaut Syndrome in children 4 years and older and adults, in combination with other anti-epileptic drugs (e.g. valproic acid, topiramate, lamotrigine)
BARACLUDE (Entecavir)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to lamivudine AND who have tried and failed combination therapy with lamivudine/adefovir or lamivudine/tenofovir - For chronic hepatitis B patients who have severe liver disease (e.g. cirrhosis)
BENLYSTA (Belimumab)	- Systemic Lupus Erythematosus (SLE)	- For adult patients (≥ 18 years old) with moderate-severe SLE being treated by a rheumatologist - Patient must be autoantibody positive (within last 3 months) i.e. ANA or dsDNA positive with SELENA-SLEDAI score ≥ 6 who have tried and failed or are intolerant to corticosteroid and hydroxychloroquine - Renewal based on achieving/maintain a SELENA-SLEDAI reduction of 4 points or more
BETASERON (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
BIPHENTIN CR (Methylphenidate controlled release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting), generic Concerta, or Dextroamphetamine
BOTOX (Botulinum toxin type A)	- Blepharospasm - Strabismus - Torticollis - Cervical dystonia - Cerebral palsy - Hyperhidrosis	- For the treatment of blepharospasm and strabismus in patients 12 years of age or older - For the treatment of torticollis in adult patients - For spasticity and other approved clinical conditions - For axillary hyperhidrosis in patients that have failed OR are intolerant to an aluminum chloride preparation

DRUG	DISEASE	APPROVAL GUIDELINES
BRILINTA (Ticagrelor)	- For the secondary prevention of atherothrombotic events in patients with Acute Coronary Syndrome	- For patients diagnosed with Acute Coronary Syndrome (unstable angina OR ST/non ST elevation Myocardial Infarction), in combination with ASA, who have tried and failed or are intolerant to anti-platelet agents (Plavix, Effient or Ticlid)
BYETTA (Exenatide)	- For the treatment of Type II Diabetes	- For use in combination with dual therapy of metformin and a sulfonylurea OR for use in combination with maximum doses of metformin alone (>2000 mg/day) when a sulfonylurea is tried and failed or not tolerated
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
CELEBREX (Celecoxib)	- Osteoarthritis - Rheumatoid Arthritis	- For patients who have failed to respond or have intolerable side-effects to Meloxicam and at least one Non-Steroidal Anti-Inflammatory Drug (NSAID) - For patients who have a documented history of clinically significant G.I. bleed or ulcer(s) and intolerable side-effects or unresponsive to Meloxicam
CELSENTRI (Maraviroc)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
CIMZIA (Certolizumab pegol)	- Moderate to Severe Rheumatoid Arthritis	- For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months
CIPRALEX (Escitalopram)	- Depression - Generalized Anxiety Disorder - Obsessive Compulsive Disorder	- For patients who have tried and failed (4 week trial minimum) OR had intolerable adverse effects to Citalopram OR at least one drug from each of the following classes: SSRI and SNRI
CONCERTA (Methylphenidate controlled release)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting), generic Concerta or Dextroamphetamine
COPAXONE (Glatiramer acetate)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
COSOPT (Dorzolamide and timolol preservative-free ophthalmic solution)	- Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	- For patients who are allergic to or cannot tolerate the formulation with the preservative
CUTIVATE (Fluticasone 0.05% cream)	- Atopic dermatitis	- For individuals who have tried and failed to respond to one other corticosteroid other than Hydrocortisone 0.5% or 1%

DRUG	DISEASE	APPROVAL GUIDELINES
CYMBALTA (Duloxetine)	- Major Depressive Disorder - Generalized Anxiety Disorder - For treating pain associated with Peripheral Diabetic Neuropathy - For treating pain associated with Fibromyalgia - Chronic Low Back Pain	- 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 - Diagnosis of Peripheral Diabetic Neuropathy - For patients with fibromyalgia who have tried and failed (4 week trial minimum) at least one drug from each of the following classes: analgesics/NSAIDs, antidepressants (amytriptiline, nortriptiline, fluoxetine, etc.), and anticonvulsants (gabalin, pregabalin, etc.) - For patients with chronic low back pain who have tried and failed at least one drug from each of the following classes: analgesics/NSAIDs, muscle relaxants and opiate analgesics
DAXAS (roflumilas)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema - Coordinate with provincial coverage if available
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
ELIDEL (Pimecrolimus 1% cream)	- Atopic dermatitis	- A confirmed diagnosis of atopic dermatitis (eczema) for individuals who have failed treatments with two or more different topical steroids
ENBREL (Etanercept)	- Moderate to Severe Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
EPREX (Erythropoietin)	- Anemia with chemotherapy - Chronic renal failure	- For patient with chronic renal failure undergoing dialysis treatment - For patient with anemia secondary to chemotherapy - Coordinate with provincial government program
EXTAVIA (Interferon beta-1b)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
EZETROL (Ezetimibe)	- Hypercholesterolemia	- For patients who cannot tolerate HMG-Co-A-Reductase Inhibitors or where these drugs are contraindicated - As adjunctive therapy for the treatment of hyperlipidemia with HMG-Co-A-Reductase Inhibitors where such drugs have not provided sufficient lipid control

DRUG	DISEASE	APPROVAL GUIDELINES
FASLODEX (Fulvestrant)	- Hormonal treatment of locally advanced or metastatic breast cancer in postmenopausal women	- Second-line treatment for patients who have failed treatment with or have had intractable side-effects to Tamoxifen and/or Aromatase Inhibitors
FLUDARA (Fludarabine oral tablet)	- Chronic Lymphocytic Leukemia (CLL)	- For patients who have failed first-line treatment and meet the following criteria: - Provincial cancer drug coverage is not available for Fludarabine oral tablet in the province where the applicant resides AND - Applicant has first tried I.V. / infusion Fludarabine and has developed intolerance or adverse effects to this formulation
FORTEO (Teriparatide)	- Osteoporosis - Osteoporosis associated with sustained systemic glucocorticoid therapy	- Severe osteoporosis where patient has a bone scan of less than -3.5 SD AND a history of non-trauma related fractures while on bisphosphonates - Severe osteoporosis where patient has a bone scan of less than -1.5 SD and a minimum of 3 months of sustained systemic glucocorticoid therapy - Maximum lifetime treatment : 24 months
FOSAMAX (Alendronate oral solution)	- Bone metabolism regulator	- For patients who have esophageal problems or who have tried and failed or have experienced intolerable side-effects to Alendronate or other oral Bisphosphonates
FUZEON (Enfuvirtide)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
GILENYA (Fingolimod)	- Multiple sclerosis, relapsing remitting	- Diagnosis of relapsing remitting multiple sclerosis - EDSS value required - Failure or intolerance to one or more therapies for multiple sclerosis treatments i.e. Avonex, Betaseron, Copaxone, Extavia, Rebif, Tysabri - Coordinate with provincial government program
GLEEVEC (Imatinib)	- Chronic myeloid leukemia - Gastrointestinal Stromal Tumour (GIST)	- For the treatment of newly diagnosed, Philadelphia-chromosome positive, CML in chronic phase OR - For the treatment adult patients with Philadelphia chromosome-positive CML in blast crisis, accelerated phase or chronic phase after failure of interferon-alpha therapy - For the treatment of C-Kit positive (CD 117) inoperable recurrent and/or metastatic GIST - Coordinate with provincial government program
GLUMETZA (Metformin extended release)	- Diabetes	- For patients who have tried and failed or had intolerable side effects to regular release Metformin
HEPSERA (Adefovir)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis) - For hepatitis B patients co-infected with HIV who do not require HAART therapy for HIV

DRUG	DISEASE	APPROVAL GUIDELINES
HUMATROPE (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD") - Idiopathic Short Stature ("ISS")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For the treatment of patients with Turner's syndrome under 14 years of age - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - For treatment of ISS which is defined as: (i) normal birth weight; (ii) diagnostic evaluation that excludes other known causes of short stature; (iii) height at least 2.25 standard deviation scores below the mean for age and sex; (iv) height velocity below the 25th percentile for bone age; and (v) patients whose epiphyses are not closed - Coordinate with provincial government program
HUMIRA (Adalimumab)	- Crohn's Disease - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients with single or multiple draining fistulas or patients with moderate to severe Crohn's disease AND who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
ILARIS (Canakinumab)	- Cryopyrin-Associated Periodic Syndromes (CAPS) - Familial Cold Autoinflammatory Syndrome (FCAS)/Familial Cold Urticaria (FCU - Muckle-Wells Syndrome (MWS)	- For patients with a confirmed diagnosis Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS)/Familial Cold Urticaria (FCU), or Muckle-Wells Syndrome (MWS) - Coordinate with available provincial programs AND Novartis patient support program
INFERGEN (Interferon alfacon-1)	- Hepatitis C	- For patients who have failed to respond to or relapsed after prior administration of Interferon alpha

DRUG	DISEASE	APPROVAL GUIDELINES
INTELLENCE (Etravirine)	- HIV infection	- For combination antiretroviral therapy in patients who have evidence of resistance to at least one antiretroviral therapy from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
INVEGA SUSTENNA (Paliperidone injection)	- For the management of the manifestations of schizophrenia and related psychotic disorders	- For patients who are non-compliant or non-adherent with conventional oral therapy (i.e. aripiprazole, clozapine, olanzapine, quetiapine, paliperidone, risperidone, ziprasidone) resulting in multiple relapses/hospitalizations
IRESSA (Gefitinib)	- First-line treatment of locally advanced (not amenable to curative surgery) or metastatic Non-Small Cell Lung Cancer ("NSCLC")	- For patients with confirmed activating mutations of the EGFR-TK ("mutation-positive") - Coordinate with provincial government program
ISENTRESS (Raltegravir)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
JANUVIA (Sitagliptin) JANUMET (Sitagliptin/metformin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
KINERET (Anakinra)	- Rheumatoid Arthritis	- For patients with a confirmed diagnosis of moderate to severe rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months
KUVAN (Sapropterin)	- Phenylketonuria (PKU)	- Diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU) for patients 12 years of age or under - Patients must demonstrate responsiveness to 30-day trial and maintain Phe-restrictive diet during treatment - Coordinate with provincial government program
LANTUS LANTUS SoloSTAR (Insulin glargine)	- Diabetes mellitus	- For patients who have tried and failed on existing longer acting insulins AND/OR patients currently using or are candidates for insulin infusion pump therapy
LEVEMIR LEVEMIR FLEXPEN (Insulin detemir)	- Diabetes mellitus	- For patients who have tried and failed on existing longer acting insulins AND/OR patients currently using or are candidates for insulin infusion pump therapy
LIPIDIL EZ (Fenofibrate nanocrystal formulation)	- Hypercholesterolemia	- For patients who have failed to respond or have had intolerable side-effects to microcoated and/or micronized Fenofibrate
LIPITOR (Atorvastatin)	- Hypercholesterolemia	- For patients who have failed to respond to or have had intolerable side-effects to Fluvastatin OR Pravastatin OR Lovastatin OR Simvastatin OR Rosuvastatin

DRUG	DISEASE	APPROVAL GUIDELINES
LUCENTIS (Ranibizumab)	- End-stage or "wet" age-related macular degeneration ("AMD") - Treatment of macular edema following Central or Branch Retinal Vein Occlusion - Treatment of diabetic macular edema	- For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate - For patients with central retinal vein occlusion who have tried and failed Ozurdex - For patients with branch retinal vein occlusion who have tried and failed laser therapy - For patients with diabetic macular edema who have tried and failed laser therapy - Validate site of administration - Coordinate with provincial government program
MACUGEN (Pegaptanib)	- End-stage or "wet" age-related macular degeneration ("AMD")	- For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate. - Validate site of administration - Coordinate with provincial government program
METOJECT (Methotrexate)	- Treatment or maintenance of neoplastic diseases - Severe, disabling psoriasis, rheumatoid arthritis, psoriatic arthritis or other seronegative arthritides where standard therapeutic interventions have failed	- For patients who have a physical disability which prevents them from drawing-up a syringe
METVIX-PDT (Methyl Aminolevulinate)	- Primary superficial basal cell carcinoma (BCC) outside the H-zone of the face	- For the treatment of BCC - Rationale for use is identified i.e. for individuals with multiple lesions, large lesions, bleeding disorders, poor vascularization, delayed healing, body not amenable to surgery, unsuitable for invasive therapy, concerns regarding disfigurement or inadequate response to previous therapies, etc; and - Maximum annual reimbursement of $1800 per patient per year
NEULASTA (Pegfilgrastim)	- Neutropenia associated with chemotherapy, transplant	- For patients who require GCSF treatment for more than 9 consecutive days OR have tried and failed and/or had intolerable adverse effects to Neupogen - Co-ordinate with provincial government program
NEUPOGEN (Filgrastim)	- Neutropenia associated with chemotherapy, transplant	- Co-ordinate with provincial government program
NEXAVAR (Sorafenib)	- Metastatic renal cell (clear cell) carcinoma - Advanced hepatocellular carcinoma	- For patients who are refractory or resistant to treatment with cytokines - For patients with advanced hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG between 0 and 2. - Coordinate with provincial government program
NEXIUM NEXIUM GRANULES and generic ESOMEPRAZOLE (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 Pantaprazole - 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 Pantaprazole - For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole, Omeprazole and/or Pantaprazole

DRUG	DISEASE	APPROVAL GUIDELINES
NUCYNTA CR (Tapentadol)	- For the management of moderate to moderately severe pain	- Pain management in a specified chronic pain diagnosis - For patient who are unable to tolerate or receive an adequate response to the sustained release preparations of either hydromorphone, oxycodone or morphine
NUTROPIN SAIZEN SEROSTIM SOMATREM (Somatropin)	- Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For the treatment of patients with Turner's syndrome under 14 years of age - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - Coordinate with provincial government program
OMNITROPE (Somatropin)	- Growth Hormone Deficiency ("GHD") in children - Adult Growth Hormone Deficiency ("Adult GHD")	- For the treatment of children and adolescents under 17 years of age with endogenous growth hormone deficiency or with renal failure resulting in slowed growth rate - For adolescents/adults who were growth hormone-deficient during childhood and who have growth hormone deficiency syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH ≤ 5 mcg/L) due to multiple hormone deficiencies, as a result of pituitary disease (hypopituitarism); hypothalamic disease; surgery (pituitary gland tumour ablation); radiation therapy; or trauma. - Coordinate with provincial government program
ONGLYZA (Saxagliptin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
ONSOLIS (Fentanyl citrate)	- Management of breakthrough pain in cancer patients	- For cancer patients who are 18 years or older who experience up to 4 breakthrough pain episodes a day - Patient should be currently on or tolerant to opioid therapy for their persistent baseline cancer pain (i.e. at least 60mg/day morphine, or 25mcg/hr transdermal fentanyl, or 30mg/day oxycodone, or 8mg/day hydromorphone or 25mg/day oxymorphone or an equianalgesic dose of another opioid for one week or longer) **AND** have tried and failed immediate release oral opioids i.e. Dilaudid, Statex, MS-IR, Supeudol, Oxy-IR
ORENCIA (Abatacept)	- Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis	- For patients with a confirmed diagnosis of moderate to severe rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months
OXYTROL (Oxybutynin transdermal system)	- Urinary incontinence	- For individuals who have tried and failed oral anticholingerics (ex. Oxybutynin)

DRUG	DISEASE	APPROVAL GUIDELINES
OZURDEX (Dexamethasone)	- Treatment of macular edema following Central Retinal Vein Occlusion	Initial Authorization Approval: - Patient must meet the following criteria to receive 1 implant per affected eye(s) for six months: - For treatment of macular edema following Central Retinal Vein Occlusion - Validate site of administration Subsequent Authorization Approval: - Patient must have received a beneficial effect from the initial injection with a subsequent loss in visual acuity to receive an additional 1 impant per affected eye(s) for six months - Renewal will not be granted in the following circumstances: ➢ Patient experienced vision deterioration without any beneficial effect from initial injection ➢ Patient continues to benefit from initial injection and has not experienced a subsequent loss in visual acuity - Maximum lifetime approval: 6 injections in 3 years per affected eye(s) - Coordinate with provincial government plan
PAXIL CR (Paroxetine controlled release)	- Depression	- Patient must have tried and failed and/or had adverse side-effects to regular release SSRIs or extended release SNRIs or atypical antidepressants
PEGASYS, PEGASYS RBV PEGETRON PEGETRON REDIPEN (Peginterferon alfa-2b and ribavirin)	- Hepatitis C - Hepatitis B	- For all Hepatitis C patients, an initial 16 weeks will be approved. For genotypes 2 and 3, an additional 8 weeks and for all other genotypes, an additional 32 weeks will be approved if they are responsive to the initial therapy as measured by Early Viral Response (EVR) protocol - For chronic Hepatitis B patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease). An initial 16 weeks will be approved; an additional 32 weeks will be approved if there is response to the initial therapy as measured by HbeAg seroconversion or EVR protocol
PENNSAID (Diclofenac 15% topical solution)	- Osteoarthritis	- A confirmed diagnosis of osteoarthritis, where the patient failed to respond OR had intolerable side-effects to Meloxicam AND at least one Non-Steroidal Anti-Inflammatory Drug (NSAID) - A confirmed diagnosis of osteoarthritis, where the patient also has documented history of clinically significant ulcer OR GI bleed AND/OR intractable intolerance to oral Non-Steroidal Anti-inflammatory Drugs (NSAIDs) AND Meloxicam
PERIOSTAT (Doxycycline low dose)	- Periodontitis	- For patients who have tried and failed or cannot tolerate Chlorhexidine gluconate mouth rinse and/or a combination of Amoxicillin and Metronidazole therapy

DRUG	DISEASE	APPROVAL GUIDELINES
PREVACID FASTAB (Lansoprazole)	- Gastroesophageal Reflux Disease - Duodenal and Gastric Ulcers - Zollinger-Ellison Syndrome	- For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole - For the treatment of H. Pylori positive (verified by serology or endoscopy or breath-test) Peptic ulcers unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole - For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Lansoprazole (regular formulation), Omeprazole and/or Pantoprazole
PREZISTA (Darunavir)	- HIV anti-viral	- For patients who have tried at least one anti-retroviral from each of the following sub-classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) and Protease Inhibitors (PI) - Coordinate with provincial government program
PRISTIQ (Desvenlafaxine)	- Major Depressive Disorder	- For patients who have tried and failed (4 week trial minimum) or cannot tolerate or have a contraindication to Venlafaxine or other extended release SNRIs
PROLIA (Denosumab)	- Postmenopausal osteoporosis	- For patients who have failed treatment with oral bisphosponates (alendronate, etidronate, risedronate) or have had intractable intolerance or adverse effects to Bisphosphonate therapy
PROSCAR (Finasteride)	- Benign Prostatic Hyperplasia	- For male patients in 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%
RAPTIVA (Efalizumab)	- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
REBIF REBIF MULTIDOSE CARTRIDGE (Interferon beta-1a)	- Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive	- Coordinate with provincial government program - EDSS value required
RELISTOR (methylnaltrexone bromide)	- Opiod-Induced Constipation (OIC)	- For patients with Opiod-Induced Constipation (OIC) receiving palliative care, who have tried and failed traditional laxatives and/or enemas

DRUG	DISEASE	APPROVAL GUIDELINES
REMICADE (Infliximab)	- Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients with single or multiple draining fistulas or patients with moderate to severe Crohn's disease AND who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy AND 5-ASA products AND/OR immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) - For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months - For patients with confirmed diagnosis of active ankylosing spondylitis where symptoms are uncontrolled by NSAIDS and the BASDAI score is greater than or equal to 4 - For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND who have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
RESTASIS (cyclosporine 0.05%)	- For treatment of moderate to moderately severe dry eyes	- For patients characterized with moderate to moderately severe ocular staining, reduction in tear production and fluctuating visual symptoms, such as blurred vision AND who have tried and failed artificial tears
RETISERT (Fluocinolone acetonide)	- For treatment of chronic Non-Infectious Posterior Uveitis	- For the treatment of chronic Non-Infectious Posterior Uveitis in patients who have tried and failed oral prednisone or an equivalent corticosteroid alone and/or an immunosuppressive agent (cyclosporine, azathioprine, methotrexate etc.)
REVATIO and generic SILDENAFIL (Sildenafil low dose)	- Pulmonary Hypertension	- For patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
REVLIMID (Lenalidomide)	- Multiple Myeloma	- For the treatment of refractory or recurrent multiple myeloma, in combination with dexamethasone, in patients who have tried and failed at least two therapies (e.g. Bortezomib, Melphalan and Prednisone, Thalomide) and whose ECOG is of 2 or less. - Coordinate with provincial government program
REVOLADE (Eltrombopag Olamine)	- Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP)	- For patients who are splenectomized and have tried and failed corticosteroids and immunoglobulins - For patients who are non-splenectomized (where surgery is contraindicated) and have tried and failed corticosteroids and immunoglobulins - Platelet counts less than 30 x 10^9/L - Maximum approval is 1 year of continuous treatment where therapy should be discontinued thereafter should platelet count exceed 400 x 10^9/L
RILUTEK (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 (6 months per authorization)

DRUG	DISEASE	APPROVAL GUIDELINES
RITUXAN (Rituximab)	- Rheumatoid Arthritis	- For patients who have tried and failed or could not tolerate at least one or more anti-TNF treatment
RISPERIDAL CONSTA (Risperidone injection)	- For the management of the manifestations of schizophrenia and related psychotic disorders	- Reserved for patients who are non-compliant or non-adherent with conventional oral therapy, resulting in multiple relapses/hospitalizations
SATIVEX (Tetrahydro-cannabinol and cannabidiol buccal spray)	- For symptomatic relief of neuropathic pain in adults with multiple sclerosis	- Adult MS patients with neuropathic pain who have tried other medications such analgesics, opioids, antidepressants or anti-convulsants, with little or no effect
SEBIVO (Telbivudine)	- Chronic hepatitis B	- For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis)
SENSIPAR (Cinacalcet)	- Hyperparathyroidism secondary to Chronic Kidney Disease (“CKD”)	- For patients with hyperparathyroidism secondary to CKD with parathyroid hormone levels greater than 33pmol/L or 300pg/mL
SIMPONI (Golimumab)	- Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis	- For patients with a confirmed diagnosis of arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND Leflunomide for a period of 3 months - 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
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
SPIRIVA (Tiotropium Bromide)	- Chronic Obstructive Pulmonary Disease (COPD)	- Diagnosis of COPD, including chronic bronchitis and emphysema
SPRIAFIL (Posaconazole)	- Treatment of invasive aspergillosis - Prophylaxis or prevention of *aspergillus* or *candida* infections in patients with prolonged neutropenia or stem cell transplant recipients - Treatment of oropharyngeal candidiasis	- For patients with invasive aspergillosis who have failed or cannot tolerate Amphotericin B or Itraconazole - For prophylaxis or prevention of *aspergillus* or *candida* infections in patients who have failed or cannot tolerate Fluconazole - For treatment of oropharyngeal candidiasis in patients who have failed or cannot tolerate Fluconazole or Itraconazole
SPRYCEL (Dasatinib)	- Chronic myeloid leukemia - Acute Lymphoblastic Leukemia	- For the treatment of adults with Philadelphia chromosome positive (Ph+) chronic, accelerated, or blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate - For the treatment of adults with Philadelphia chromosome positive (Ph+) Acute Lymphoblatic Leukemia (ALL),resistant or intolerant to prior therapy - Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
STELARA (Ustekinumab)	- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy	- For patients who are 18 years and older with moderate to severe chronic plaque psoriasis with at least 10% body involvement AND who have tried and failed phototherapy AND have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
STRATTERA and generic ATOMOXETINE (Atomoxetine)	- Attention deficit hyperactivity disorder	- individuals who have tried and failed or had intolerable side-effects to Methylphenidate, generic Concerta, or Dextroamphetamine OR - those individuals who have had history or a propensity to abuse other stimulants such as Methylphenidate, generic Concerta or Dextroamphetamine
SUTENT (Sunitinib)	- Gastrointestinal Stromal Tumour (GIST) - First-line treatment of metastatic Renal Cell Carcinoma ("RCC")	- For GIST patients who have tried and failed or had no response to Gleevec (imatinib) - Diagnosis of metastatic RCC. ECOG of two or less must be documented - Coordinate with provincial government program
TARCEVA (Erlotinib)	- Second or Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC") - Maintenance treatment of locally advanced or metastatic NSCLC	- For patients who have tried and failed first-line and second-line chemotherapy or are ineligible for second-line therapy. Treatment with cisplatin or carboplatin must be documented. ECOG performance status must be three or less - Maintenance treatment in patients with stable disease after 4 cycles of standard platinum based first line chemotherapy. ECOG performance status must be one or less - Coordinate with provincial government program
TASIGNA (Nilotinib)	- For treatment of newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase - Second-line treatment of accelerated phase of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML)	- For adult patients with accelerated phase Ph+CML resistant to OR intolerant of at least one prior therapy including imatinib - Coordinate with provincial government program
TEMODAL (Temozolomide)	- Tumours, Brain, Astrocytoma	- For the second-line treatment of glioblastoma multiforme or astrocytoma - For the treatment of newly diagnosed gioblastoma multiforme concurrently with radiation and post radiation
THALOMID (Thalomide)	- Multiple myeloma	- For patients ≥ 65 years of age who are not eligible for autologous stem cell transplantation - For use in combination with dexamethasone OR melphalan and prednisone - ECOG ≤ 2 - Coordinate with provincial government program
THYROGEN (Thyrotropin alpha injection)	- Adjunctive therapy to radioiodine imaging of thyroid cancer	- Patient(s) must have well-differentiated thyroid cancer AND cannot tolerate Thyroid Hormone Suppression Therapy (THST) withdrawal - Validate site of administration

DRUG	DISEASE	APPROVAL GUIDELINES
TOBI PODHALER (Tobramycin)	- Cystic fibrosis	- For management of cystic fibrosis patients, aged 6 years or older, with chronic pulmonary Pseudomonas aeruginosa infections - Coordinate with provincial government
TOCTINO (Alitretinoin)	- Chronic Hand Eczema (CHE)	- Diagnosis of severe CHE characterized by fissures, vesicles, bumps, edema, exudation, scaling or lichenification - Trial of at least 2 of the following high potency topical steroids: amcinonide (Cyclocort), desoximetasone (Topicort), fluocinonide (Lyderm, Tiamol), betamethasone dipropionate (Diprosone), clobetasol propionate (Clobex)
TRACLEER (Bosentan)	- Pulmonary Hypertension	- For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND who have tried and failed Revatio or Adcirca - For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
TRAGENTA (Linagliptin)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
TRUSOPT (Dorzolamide (preservative-free ophthalmic solution)	- Treatment of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension	- For patients who are allergic to or cannot tolerate the formulation with the preservative
TYKERB (Lapatinib)	- Advanced or metastatic breast cancer	- In combination with Xeloda, for patients with tumours over-expressing ErbB2 (HER2) who have tried and failed taxanes, anthracyclines and trastuzumab - Coordinate with provincial government program
TYSABRI (Natalizumab)	- Treatment of Relapsing-Remitting Multiple Sclerosis (RRMS)in patients who have had an inadequate response to, or are unable to tolerate, other MS therapies	- For RRMS - patients have had an inadequate response to, or are unable to tolerate, other therapies. Patients should have evidence of lesions on their MRI scan, an EDSS value less than 6 and have had at least one relapse in previous year - For patients with rapidly evolving severe MS, they must have had two or more disabling relapses in one year and at least nine T2-hyperintense lesions in their cranial MRI or at least one gadolinium-enhancing (Gd-enhancing) lesion - Coordinate with provincial government program
ULORIC (Cebuxostat)	- To lower serum uric acid levels in patients with gout	- For patients who have tried and failed or had intolerable side effects to allopurinol
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

DRUG	DISEASE	APPROVAL GUIDELINES
VALCYTE VALCYTE POS (Valganciclovir)	- Cytomegalovirus Retinitis	- For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients - For the prevention of CMV disease in solid organ transplant patients at risk (i.e. risk is defined as donor +ve/recipient -ve for CMV, or recipient +ve post-active treatment of CMV disease with IV ganciclovir, or recipient +ve in patients receiving antilymphocyte antibody [ALA]). - Coordinate with provincial government program
VFEND (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
VIAGRA (Sildenafil) CIALIS (Tadalafil) LEVITRA (Vardenafil)	- Erectile Dysfunction	Erectile dysfunction related to one of the following conditions: ▪ Adverse side-effect to prescription drugs (e.g., beta blockers, etc.). Medical documentation must be present to validate the drug as causing the problem (up to one year approval) ▪ Diabetes mellitus and is on medication(s) and/or insulin (Lifetime approval) ▪ Aorta-iliac disease with evidence of decreased blood flow (e.g., abnormal Doppler studies or absent pulses) (Lifetime approval) ▪ Post radical prostatectomy and radiation of the prostate (Lifetime approval) ▪ Neurological injury or disease (e.g. Multiple Sclerosis, spinal cord injury) (Lifetime approval) ▪ Endocrine abnormalities (i.e. specifically low testosterone levels not responding to testosterone treatment) (Lifetime approval) ▪ Psychiatric disorder for which the patient is receiving medication or treatment from a psychiatrist (up to one year approval) <u>Annual maximum</u>: $1000 per year
VICTOZA (Liraglutide)	- Diabetes mellitus	- For patients who have tried and failed or did not tolerate maximum doses of metformin (>2000 mg)
VICTRELIS (Boceprevir)	- Hepatitis C	Initial Criteria: - For adults with chronic hepatitis C genotype 1 infection in combination with peginterferon alpha/ribavirin (Pegetron) - An initial 12 weeks of Victrelis will be approved Renewal Criteria: - The authorization will be renewed if the HCV-RNA is ≤ 100 IU/ml at week 8 of Victrelis therapy (week 12 of total treatment) - The maximum duration of treatment will be 44 weeks of Victrelis therapy - Coordinate with available provincial plans

DRUG	DISEASE	APPROVAL GUIDELINES
VICTRELIS TRIPLE (Boceprevir/Ribavirin/ Peginterferon alfa-2b)	- Hepatitis C	Initial Criteria: - For adults with chronic hepatitis C genotype 1 infection - An initial 12 weeks of Victrelis Triple will be approved Renewal Criteria: - The authorization will be renewed if the HCV-RNA is ≤ 100 IU/ml at week 8 of Victrelis Triple therapy (week 12 of total treatment) - The maximum duration of treatment will be 44 weeks of Victrelis Triple therapy - Coordinate with available provincial plans
VIMOVO (Naproxen/Esomperazole)	- Osteoarthritis - Rheumatoid Arthritis - Ankylosing Spondylitis	- For patients who are unresponsive to one of the following: Rabeprazole, Lansoprazole, Omeprazole, Esomeprazole and/or Pantaprazole
VIMPAT (lacosamide)	- Adjunctive therapy for partial onset seizures	- For patients with a diagnosis of partial onset seizures AND - Tried, failed or have experienced intolerant side effects to 2 or more standard care drugs i.e. carbamazepine, lamotrigine, levetiracetam, topiramate, phenytoin, valproic acid/divalproex, gabapentin, Phenobarbital, oxcarbazepine, clobazam, primidone, vigabatrin
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, where no provincial coverage is available
VOLIBRIS (Ambrisentan)	- Pulmonary Hypertension	- For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class II or III AND who have tried and failed Revatio or Adcirca - For the treatment of patients with a confirmed diagnosis of pulmonary arterial hypertension functional class IV - Failure to conventional therapy (including calcium channel blockers, anticoagulation with warfarin to maintain INR 1.5-2.5, loop diuretics, digoxin, supplemental oxygen) - Coordinate with provincial government program
VOTRIENT (Pazopanib Hydrochloride)	- Metastatic renal cell (clear cell) carcinoma (mRCC)	- For patients who have received no prior systemic therapies OR who have documented failure to first line cytokine based therapy - Coordinate with provincial government program
VYVANSE (Lisdexamfetamine)	- Attention deficit hyperactivity disorder	- For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting), generic Concerta, or Dextroamphetamine
WELLBUTRIN SR/XL (Buproprion)	- Depression	- Diagnosis of depression and previous or concomitant use of any other antidepressants
XELODA (Capecitabine)	- Metastatic colorectal cancer - Adjuvant therapy of Dukes' C colon cancer - Metastatic breast cancer	- Coordinate with provincial government program

DRUG	DISEASE	APPROVAL GUIDELINES
XENICAL (Orlistat)	- Obesity	Initial Authorization Approval: Patient must meet each of the following criteria to receive coverage for Xenical for up to six months: • Patient has been prescribed lifestyle therapy (diet and exercise) for six months or more prior to using Xenical • Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Xenical • Patient with a Body Mass Index (BMI) greater than or equal to 30 OR • Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ➢ Hypertension and is on medication ➢ Diabetes mellitus and is on medication ➢ Hyperlipidemia and is on medication ➢ Coronary artery disease and is on medication Subsequent Authorization Approval: • Patient must meet each of the following criteria to receive additional coverage for Xenical for up to six months: • Patient must achieve and continuously maintain a minimum reduction of 6% of initial body weight. Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Xenical • Patient with a Body Mass Index (BMI) greater than or equal to 30 OR • Patient with a Body Mass Index (BMI) greater than or equal to 27, but less than 30, suffers from at least one of the following disease conditions: ➢ Hypertension and is on medication ➢ Diabetes mellitus and is on medication ➢ Hyperlipidemia and is on medication ➢ Coronary artery disease and is on medication Maximum Lifetime Coverage: 24 months for all anti-obesity drugs
XEOMIN (Botulinum toxin type A)	- Blepharospasm - Cervical dystonia (spasmodic torticollis) - Post-stroke spasticity of the upper limbs	- For the treatment of blepharospasm in patients 18 years of age or older - For the treatment of torticollis in adult patients - For the treatment of post-stroke spasticity of the upper limbs in adult patients
XGEVA (Denosumab)	- Bone metastases	- For patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumors - For patients who have tried and failed or experienced intolerable side effects with bisphosphates (Clasteon, Bonefos, Zometa or Aredia)
XOLAIR (Omalizumab)	- For adults and adolescents (12 years and older) with moderate to severe persistent asthma who have a positive skin test	- Moderate to severe asthmatics who are skin test positive or have in-vitro reactivity to a perennial aeroallergen with a baseline IgE level within 30-700IU/ml and who are not adequately controlled by a concomitant therapy of Inhaled Corticosteroids (“ICS”) and Long-Acting Beta-Agonists (“LABA”) and Leukotriene-Recepetor Agonists (“LRA”) OR - If any of the previously mentioned drugs cannot be used concomitantly, a combination of three of the four following drugs: ICS, LABA, LRA, and/or long-acting Theophylline

DRUG	DISEASE	APPROVAL GUIDELINES
XYREM (Sodium oxybate)	- Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients	- Diagnosis of narcolepsy with chronic symptoms of cataplexy
ZADITOR (Ketotifen preservative-free ophthalmic solution)	- Temporary relief of itching from allergic conjunctivis	- For patients who are allergic to or cannot tolerate the formulation with the preservative
ZENAPAX (Daclizumab)	- For kidney transplant patients receiving immunosuppressants	- For the prophylaxis of acute rejection in kidney transplant patients
ZOMETA (Zoledronic acid)	- Tumour-induce Hypercalcemia - Bone metastases and multiple myeloma - Paget's disease of the bone	- Coordinate with provincial government program
ZYTIGA (Abiraterone acetate)	- For treatment of metastatic prostate cancer (castration resistant prostate cancer – CRPC)	- For treatment of CRPC in combination with prednisone in patients who have received prior chemotherapy containing docetaxel - Coordinate with provincial government program