

Special Authorization Drugs and Approval Guidelines

(Special authorization drugs may vary depending on plan)

DRUG	DISEASE	APPROVAL GUIDELINES
ACTEMRA (Tocilizumab)	<ul style="list-style-type: none"> - Moderate to Severe Rheumatoid Arthritis 	<ul style="list-style-type: none"> - 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
ADCIRCA (Tadalafil)	<ul style="list-style-type: none"> - Pulmonary Hypertension 	<ul style="list-style-type: none"> - 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
AFINITOR (Everlimus)	<ul style="list-style-type: none"> - Second-line treatment of metastatic Renal Cell Carcinoma ("RCC") 	<ul style="list-style-type: none"> - 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
AMEVIVE (Alefcept)	<ul style="list-style-type: none"> - Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy 	<ul style="list-style-type: none"> - 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 have tried and failed or are intolerant to at least 2 systemic therapies AND who are being treated by a dermatologist
APTIVUS (Tipranavir)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Anemia with chemotherapy - Chronic renal failure 	<ul style="list-style-type: none"> - For patient with chronic renal failure under going dialysis treatment - For patient with anemia secondary to chemotherapy - Coordinate with provincial government program
ATRIPLA (Efavirenz, Emtricitabine, Tenofovir)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - Coordinate with provincial government program



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DRUG	DISEASE	APPROVAL GUIDELINES
AVONEX AVONEX PS (Interferon beta-1a)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive 	<ul style="list-style-type: none"> - Coordinate with provincial government program - EDSS value required
BARACLUDE (Entecavir)	<ul style="list-style-type: none"> - Chronic hepatitis B 	<ul style="list-style-type: none"> - For chronic hepatitis B patients who develop resistance to Lamivudine AND who have tried and failed combination therapy with lamivudine/adeфовir or lamivudine/tenоfovir - For chronic hepatitis B patients who have severe liver disease (e.g. cirrhosis)
BENLYSTA (Belimumab)	<ul style="list-style-type: none"> - Systemic Lupus Erythematosus (SLE) 	<ul style="list-style-type: none"> - 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 hydroxychlorоquine - Renewal based on achieving/maintain a SELENA-SLEDAI reduction of 4 points or more
BETASERON (Interferon beta-1a)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive 	<ul style="list-style-type: none"> - Coordinate with provincial government program - EDSS value required
BOTOX (Botulinum toxin type A)	<ul style="list-style-type: none"> - Blepharospasm - Strabismus - Torticollis - Cervical dystonia - Cerebral palsy - Hyperhidrosis 	<ul style="list-style-type: none"> - 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
CAYSTON (Aztreonam)	<ul style="list-style-type: none"> - Treatment of pulmonary infection with <i>Pseudomonas aeruginosa</i> in Cystic Fibrosis Patients 	<ul style="list-style-type: none"> - For patients with confirmed Cystic Fibrosis and pulmonary infection with <i>Pseudomonas aeruginosa</i>, who have tried and failed or did not tolerate prior therapy with TOBI - Co-ordinate with provincial programs where possible
CELSENTRI (Maraviroc)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Moderate to Severe Rheumatoid Arthritis 	<ul style="list-style-type: none"> - 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
COPAXONE (Glatiramer acetate)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive 	<ul style="list-style-type: none"> - Coordinate with provincial government program - EDSS value required



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DUODOPA (Levodopa/carbidopa intestinal gel)	<ul style="list-style-type: none"> - Parkinson's disease 	<ul style="list-style-type: none"> - 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
ENBREL (Etanercept)	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Anemia with chemotherapy - Chronic renal failure 	<ul style="list-style-type: none"> - For patient with chronic renal failure under going dialysis treatment - For patient with anemia secondary to chemotherapy - Coordinate with provincial government program
EXTAVIA (interferon beta-1b)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive 	<ul style="list-style-type: none"> - Coordinate with provincial government program - EDSS value required
FASLODEX (Fulvestrant)	<ul style="list-style-type: none"> - Hormonal treatment of locally advanced or metastatic breast cancer in postmenopausal women 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Chronic Lymphocytic Leukemia (CLL) 	<ul style="list-style-type: none"> - 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 <p>AND</p> <ul style="list-style-type: none"> - Applicant has first tried I.V. / infusion Fludarabine and has developed intolerance or adverse effects to this formulation



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FORTEO (Teriparatide)	<ul style="list-style-type: none"> - Osteoporosis - Osteoporosis associated with sustained systemic glucocorticoid therapy 	<ul style="list-style-type: none"> - 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
FUZEON (Enfuvirtide)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Chronic myeloid leukemia - Gastrointestinal Stromal Tumour (GIST) 	<ul style="list-style-type: none"> - 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
HEPSERA (Adefovir)	<ul style="list-style-type: none"> - Chronic hepatitis B 	<ul style="list-style-type: none"> - 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

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<p>HUMATROPE (Somatropin)</p>	<ul style="list-style-type: none"> - Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD") - Idiopathic Short Stature ("ISS") 	<ul style="list-style-type: none"> - 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 GHD syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH \leq 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
<p>HUMIRA (Adalimumab)</p>	<ul style="list-style-type: none"> - Crohn's Disease - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy 	<ul style="list-style-type: none"> - 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
<p>ILARIS (canakinumab)</p>	<ul style="list-style-type: none"> - Cryopyrin-Associated Periodic Syndromes (CAPS) - Familial Cold Autoinflammatory Syndrome (FCAS)/Familial Cold Urticaria (FCU) - Muckle-Wells Syndrome (MWS) 	<ul style="list-style-type: none"> - 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
<p>INFERGEN (Interferon alfacon-1)</p>	<ul style="list-style-type: none"> - Hepatitis C 	<ul style="list-style-type: none"> - For patients who have failed to respond to or relapsed after prior administration of Interferon alpha

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INTELENCE (Etravirine)	<ul style="list-style-type: none"> - HIV infection 	<ul style="list-style-type: none"> - 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
INTRON A (Interferon alfa-2b)	<ul style="list-style-type: none"> - Chronic Hepatitis - Chronic active hepatitis B - Chronic myelogenous leukemia (CML) - Thrombocytosis associated with CML - Multiple Myeloma - Non-Hodgkin's lymphoma - Malignant melanoma - AIDS-related Kaposi's sarcoma - Hairy cell leukemia - Basal cell carcinoma - Condylomata acuminata 	<ul style="list-style-type: none"> - Coordinate with provincial government program
IRESSA (Gefitinib)	<ul style="list-style-type: none"> - Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC") 	<ul style="list-style-type: none"> - For patients who have tried and failed first-line and second-line chemotherapy or are ineligible for second-line therapy. Treatment with platinum compounds and docetaxel must be documented. ECOG performance status must be three or less - Coordinate with provincial government program
ISENTRESS (Raltegravir)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - 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
KINERET (Anakinra)	<ul style="list-style-type: none"> - Rheumatoid Arthritis 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Phenylketonuria (PKU) 	<ul style="list-style-type: none"> - 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



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LUCENTIS (Ranibizumab)	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - End-stage or "wet" age-related macular degeneration ("AMD") 	<ul style="list-style-type: none"> - For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate. - Validate site of administration - Coordinate with provincial government program
NEULASTA (Pegfilgrastim)	<ul style="list-style-type: none"> - Neutropenia associated with chemotherapy, transplant 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Neutropenia associated with chemotherapy, transplant 	<ul style="list-style-type: none"> - Co-ordinate with provincial government program
NEXAVAR (Sorafenib)	<ul style="list-style-type: none"> - Metastatic renal cell (clear cell) carcinoma - Advanced hepatocellular carcinoma 	<ul style="list-style-type: none"> - 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 of 0-2 - Coordinate with provincial government program
NUTROPIN PROTROPIN SAIZEN (Somatropin)	<ul style="list-style-type: none"> - Dwarfism - Turner's syndrome - Adult Growth Hormone Deficiency ("Adult GHD") 	<ul style="list-style-type: none"> - 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 GHD syndrome confirmed as an adult. Use of growth hormone as a child must be documented - For adults who have GHD (GH \leq 5 mcg/L) due to multiple hormone deficiencies as a result of pituitary disease (hypopituitarism), hypothalamic disease, surgery (pituitary gland tumour ablation), radiation therapy, or trauma - Coordinate with provincial government program



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OMNITROPE (Somatropin)	<ul style="list-style-type: none"> - Growth Hormone Deficiency ("GHD") in children - Adult Growth Hormone Deficiency ("Adult GHD") 	<ul style="list-style-type: none"> - 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 \leq 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
ORENCIA (Abatacept)	<ul style="list-style-type: none"> - Rheumatoid Arthritis - Moderate to Severe Juvenile Rheumatoid Arthritis 	<ul style="list-style-type: none"> - 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
PEGASYS, PEGASYS RBV PEGETRON PEGETRON REDIPEN REBETRON REDIPEN (Peginterferon alfa-2b and ribavirin)	<ul style="list-style-type: none"> - Hepatitis C - Hepatitis B 	<ul style="list-style-type: none"> - 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
PREZISTA (Darunavir)	<ul style="list-style-type: none"> - HIV anti-viral 	<ul style="list-style-type: none"> - 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
PULMOZYME (Dornase alfa)	<ul style="list-style-type: none"> - Cystic fibrosis 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy 	<ul style="list-style-type: none"> - 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



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REBIF, REBIF MULTIDOSE CARTRIDGE (Interferon beta-1a)	<ul style="list-style-type: none"> - Multiple sclerosis, relapsing remitting - Multiple sclerosis, chronic progressive 	<ul style="list-style-type: none"> - Coordinate with provincial government program - EDSS value required
RELISTOR (methylnaltrexone)	<ul style="list-style-type: none"> - Opioid-induced constipation 	<ul style="list-style-type: none"> - Patients will advanced illness, receiving palliative care, who have tried and failed traditional laxatives and/or enemas
REMICADE (Infliximab)	<ul style="list-style-type: none"> - Crohn's Disease - Moderate to severe active Ulcerative Colitis - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis - Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy 	<ul style="list-style-type: none"> - 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
RETISERT (Fluocinolone acetoneide)	<ul style="list-style-type: none"> - For treatment of chronic Non-Infectious Posterior Uveitis 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Pulmonary Hypertension 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Multiple Myeloma 	<ul style="list-style-type: none"> - 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, Thalomid) and whose ECOG is of 2 or less. - Coordinate with provincial government program

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REVOLADE (Eltrombopag Olamine)	<ul style="list-style-type: none"> - Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP) 	<ul style="list-style-type: none"> - 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 $30 \times 10^9/L$ - Maximum approval is 1 year of continuous treatment where therapy should be discontinued thereafter should platelet count exceed $400 \times 10^9/L$
RILUTEK (Riluzole)	<ul style="list-style-type: none"> - Amyotrophic lateral sclerosis (ALS) 	<ul style="list-style-type: none"> - For the treatment of ALS in patient with symptoms of less than 5 years and still has a vital lung capacity of 60% or more in the absence of tracheotomy
RITUXAN (Rituximab)	<ul style="list-style-type: none"> - Rheumatoid Arthritis 	<ul style="list-style-type: none"> - For patients who have tried and failed or could not tolerate at least one or more anti-TNF treatment
SANDOSTATIN (Octreotide)	<ul style="list-style-type: none"> - Metastatic carcinoid and vasoactive intestinal peptide-secreting tumours (VIPomas) - Acromegaly 	<ul style="list-style-type: none"> - Coordinate with provincial government program
SATIVEX (Tetrahydro-cannabinol and cannabidiol buccal spray)	<ul style="list-style-type: none"> - For symptomatic relief of neuropathic pain in adults with multiple sclerosis 	<ul style="list-style-type: none"> - Adult MS patients with neuropathic pain who have tried other medications such as analgesics, opioids, antidepressants or anti-convulsants, with little or no effect
SENSIPAR (Cinacalcet)	<ul style="list-style-type: none"> - Hyperparathyroidism secondary to Chronic Kidney Disease 	<ul style="list-style-type: none"> - For patients with hyperparathyroidism secondary to CKD with parathyroid hormone levels greater than 33pmol/L or 300pg/mL
SIMPONI (Golimumab)	<ul style="list-style-type: none"> - Moderate to Severe Rheumatoid Arthritis - Psoriatic arthritis - Ankylosing spondylitis 	<ul style="list-style-type: none"> - 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
SOMATULINE AUTOGEL (Lanreotide)	<ul style="list-style-type: none"> - Acromegaly 	<ul style="list-style-type: none"> - Coordinate with provincial government program
SOMAVERT (Pegvisomant)	<ul style="list-style-type: none"> - Acromegaly 	<ul style="list-style-type: none"> - 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



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SPRIAFIL (Posaconazole)	<ul style="list-style-type: none"> - Invasive aspergillosis - Prophylaxis or prevention of aspergillus or candida infections in patients with prolonged neutropenia or stem cell transplant recipients - Oropharyngeal candidiasis 	<ul style="list-style-type: none"> - For patients with invasive aspergillosis who have failed or cannot tolerate Amphotericin B or Itraconazole - For prophylaxis or prevention of <i>aspergillus</i> or <i>candida</i> 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)	<ul style="list-style-type: none"> - Chronic myeloid leukemia - Acute Lymphoblastic Leukemia 	<ul style="list-style-type: none"> - 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 Lymphoblastic Leukemia (ALL), resistant or intolerant to prior therapy - Coordinate with provincial government program
STELARA (Ustekinumab)	<ul style="list-style-type: none"> - For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy 	<ul style="list-style-type: none"> - 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
SUTENT (Sunitinib)	<ul style="list-style-type: none"> - Gastrointestinal Stromal Tumour (GIST) - First-line treatment of metastatic Renal Cell Carcinoma ("RCC") 	<ul style="list-style-type: none"> - For GIST patients who have tried and failed or had no response to imatinib - Diagnosis of metastatic RCC. ECOG of two or less must be documented - Coordinate with provincial government program
TARCEVA (Erlotinib)	<ul style="list-style-type: none"> - Second or Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC") - Maintenance treatment of locally advanced or metastatic NSCLC 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - 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) 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Tumours, Brain, Astrocytoma 	<ul style="list-style-type: none"> - For the second-line treatment of glioblastoma multiforme or astrocytoma - For the treatment of newly diagnosed glioblastoma multiforme concurrently with radiation and post radiation.
THALOMID (Thalimide)	<ul style="list-style-type: none"> - Multiple myeloma 	<ul style="list-style-type: none"> - 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



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DRUG	DISEASE	APPROVAL GUIDELINES
<p>THYROGEN (Thyrotropin alpha injection)</p>	<ul style="list-style-type: none"> - Adjunctive therapy to radioiodine imaging of thyroid cancer 	<ul style="list-style-type: none"> - Patient(s) must have well-differentiated thyroid cancer AND cannot tolerate Thyroid Hormone Suppression Therapy (THST) withdrawal - Validate site of administration
<p>TOBI PODHALER (Tobramycin)</p>	<ul style="list-style-type: none"> - Cystic fibrosis 	<ul style="list-style-type: none"> - For management of cystic fibrosis patients, aged 6 years or older, with chronic pulmonary Pseudomonas aeruginosa infections - Coordinate with provincial government
<p>TOCTINO (Alitretinoin)</p>	<ul style="list-style-type: none"> - Chronic Hand Eczema (CHE) 	<ul style="list-style-type: none"> - 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)
<p>TRACLEER (Bosentan)</p>	<ul style="list-style-type: none"> - Pulmonary Hypertension 	<ul style="list-style-type: none"> - 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
<p>TYKERB (Lapatinib)</p>	<ul style="list-style-type: none"> - Advanced or metastatic breast cancer 	<ul style="list-style-type: none"> - In combination with Xeloda, for the treatment of patients with advanced or metastatic HER2-positive breast cancer who have tried and failed taxanes, anthracyclines and trastuzumab - Coordinate with provincial government program
<p>TYSABRI (Natalizumab)</p>	<ul style="list-style-type: none"> - Relapsing-Remitting Multiple Sclerosis (RRMS) in patients who have had an inadequate response to, or are unable to tolerate, other MS therapies 	<ul style="list-style-type: none"> - 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
<p>VALCYTE VALCYTE POS (Valganciclovir)</p>	<ul style="list-style-type: none"> - Cytomegalovirus Retinitis 	<ul style="list-style-type: none"> - 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



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VFEND (Voriconazole)	<ul style="list-style-type: none"> - Invasive aspergillosis - Candidemia in non-neutropenic patients and Candida infections 	<ul style="list-style-type: none"> - 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
VICTRELIS (Boceprevir)	<ul style="list-style-type: none"> - Hepatitis C 	<p>Initial Criteria:</p> <ul style="list-style-type: none"> - 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 <p>Renewal Criteria:</p> <ul style="list-style-type: none"> - The authorization will be renewed if the HCV-RNA is \leq 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
VICTRELIS TRIPLE (Boceprevir/Ribavirin/ Peginterferon alfa-2b)	<ul style="list-style-type: none"> - Hepatitis C 	<p>Initial Criteria:</p> <ul style="list-style-type: none"> - For adults with chronic hepatitis C genotype 1 infection - An initial 12 weeks of Victrelis Triple will be approved <p>Renewal Criteria:</p> <ul style="list-style-type: none"> - The authorization will be renewed if the HCV-RNA is \leq 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
VISUDYNE (Verteporfin)	<ul style="list-style-type: none"> - Age related macular degeneration - Pathological myopia 	<ul style="list-style-type: none"> - 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.
VOLIBRIS (Ambrisentan)	<ul style="list-style-type: none"> - Pulmonary Hypertension 	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - Metastatic renal cell (clear cell) carcinoma (mRCC) 	<ul style="list-style-type: none"> - For patients who have received no prior systemic therapies OR who have documented failure to first line cytokine based therapy - Coordinate with provincial government program
XELODA (Capecitabine)	<ul style="list-style-type: none"> - Metastatic colorectal cancer - Adjuvant therapy of Dukes' C colon cancer - Metastatic breast cancer 	<ul style="list-style-type: none"> - Coordinate with provincial government program



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DRUG	DISEASE	APPROVAL GUIDELINES
<p>XEOMIN (Botulinum toxin type A)</p>	<ul style="list-style-type: none"> - Blepharospasm - Cervical dystonia (spasmodic torticollis) - Post-stroke spasticity of the upper limbs 	<ul style="list-style-type: none"> - 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
<p>XOLAIR (Omalizumab)</p>	<ul style="list-style-type: none"> - For adults and adolescents (12 years and older) with moderate to severe persistent asthma who have a positive skin test 	<ul style="list-style-type: none"> - 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-Receptor Agonists ("LRA") <p>OR</p> <ul style="list-style-type: none"> - If use of a previous mentioned drug cannot be used concomitantly, a combination of three of the four following drugs: ICS, LABA, LRA, and/or long-acting Theophylline.
<p>XYREM (Sodium oxybate)</p>	<ul style="list-style-type: none"> - Cataplexy (sudden loss of muscle strength) in narcoleptic patients 	<ul style="list-style-type: none"> - Diagnosis of narcolepsy with chronic symptoms of cataplexy
<p>ZYTIGA (Abiraterone acetate)</p>	<ul style="list-style-type: none"> - For treatment of metastatic prostate cancer (castration resistant prostate cancer – CRPC) 	<ul style="list-style-type: none"> - For treatment of CRPC in combination with prednisone in patients who have received prior chemotherapy containing docetaxel - Coordinate with provincial government program