

Special Authorization Drugs and Approval Guidelines

(Special authorization drugs may vary depending on plan)

| DRUG | DISEASE | APPROVAL GUIDELINES |
|--|---|--|
| ACLASTA (Zoledronic acid) | <ul style="list-style-type: none"> - Paget's disease of the bone - Postmenopausal osteoporosis | <ul style="list-style-type: none"> - For patients who have failed treatment with Bisphosphonates or have had intractable intolerance or adverse effects to Bisphosphonate therapy |
| ACULAR LS (Ketorolac 0.4% ophthalmic solution) | <ul style="list-style-type: none"> - For the reduction of ocular pain and photophobia following refractive surgery | <ul style="list-style-type: none"> - For the reduction of ocular pain and photophobia where the patient has tried Ketorolac 0.5% AND had intractable intolerance or adverse effects |
| ADDERALL XR (Dextroamphetamine and amphetamine extended release) | <ul style="list-style-type: none"> - Attention deficit hyperactivity disorder | <ul style="list-style-type: none"> - For patients who have tried and failed or had intolerable side effects to Methylphenidate (long or short acting) or Dextroamphetamine |
| ALPHAGAN P (Brimonidine 0.15% ophthalmic solution) | <ul style="list-style-type: none"> - Control of increased intra-ocular pressure related to Glaucoma | <ul style="list-style-type: none"> - For patients who have suffered adverse side-effects or failed on Brimonidine 0.2% |
| AMBISOME CANCIDAS (Caspofungin) | <ul style="list-style-type: none"> - Invasive aspergillosis | <ul style="list-style-type: none"> - For the treatment of invasive aspergillosis resistant to other therapies - Coordinate with Hospital Provincial Program |
| AMEVIVE (Alefcept) | <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 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 |
| ANDROGEL (Testosterone 1% pump) | <ul style="list-style-type: none"> - Endogenous testosterone deficiency | <ul style="list-style-type: none"> - For patients who have tried Testosterone sachets and have a physical disability that prevents them from physically opening a sachet |
| 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 |
| AREDIA (Pamidronate disodium) | <ul style="list-style-type: none"> - Tumour-induce Hypercalcemia - Bone metastases and multiple myeloma - Paget's disease of the bone | <ul style="list-style-type: none"> - Coordinate with provincial government program |
| AVODART (Dutasteride) | <ul style="list-style-type: none"> - Benign Prostatic Hyperplasia | <ul style="list-style-type: none"> - For male patients in the treatment of benign prostatic hyperplasia |
| 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 |



Drugs classified as special authorization may vary amongst plan sponsors.

Updated: July, 2009

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|--|--|--|
| 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) |
| 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) 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 |
| 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 |
| 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) 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% |



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|---|---|--|
| CYMBALTA (Duloxetine) | <ul style="list-style-type: none"> - Major Depressive Disorder - Generalized Anxiety Disorder - For treating pain associated with Peripheral Diabetic Neuropathy | <ul style="list-style-type: none"> - 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 |
| 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 |
| EBIXA (Memantine) | <ul style="list-style-type: none"> - For individuals who have Alzheimer's or related dementia | <ul style="list-style-type: none"> - Diagnosis of Alzheimer's |
| ELIDEL (Pimecrolimus 1% cream) | <ul style="list-style-type: none"> - Atopic dermatitis | <ul style="list-style-type: none"> - A confirmed diagnosis of atopic dermatitis (eczema) for individuals who have failed treatments with two or more different topical steroids |
| 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 |
| EZETROL (Ezetimibe) | <ul style="list-style-type: none"> - Hypercholesterolemia | <ul style="list-style-type: none"> - 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 |
| 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 AND - 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 : 18 months |
| FOSAMAX (Alendronate oral solution) | <ul style="list-style-type: none"> - Bone metabolism regulator | <ul style="list-style-type: none"> - 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) | <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 |
| 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 Chronic Myeloid Leukemia (CML) in blast or accelerated phase - For the treatment of Chronic Myeloid Leukemia (CML) in the chronic phase for whom interferon (+/- cytarabine) OR hydroxyurea is ineffective, contra-indicated or poorly tolerated and the patient is a candidate for stem cell transplantation - For the treatment of inoperable recurrent and/or metastatic GIST - Coordinate with provincial government program |
| GLUMETZA (Metformin extended release) | <ul style="list-style-type: none"> - Diabetes | <ul style="list-style-type: none"> - For patients who have tried and failed or had intolerable side effects to regular release Metformin |
| 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 |
| HUMATROPE (Somatropin) | <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 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. - 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 |

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| HUMIRA (Adalimumab) | <ul style="list-style-type: none"> - 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 | <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 did not respond to oral corticosteroid therapy, Sulfasalazine, Mesalamine, 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 |
| INFERGEN (Interferon alfacon-1) | <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 |
| 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 |
| INTELLENCE (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 |
| 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 |
| LANTUS LANTUS SoloSTAR (Insulin glargine) | <ul style="list-style-type: none"> - Diabetes mellitus | <ul style="list-style-type: none"> - 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) | <ul style="list-style-type: none"> - Diabetes mellitus | <ul style="list-style-type: none"> - 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) | <ul style="list-style-type: none"> - Hypercholesterolemia | <ul style="list-style-type: none"> - For patients who have failed to respond or have had intolerable side-effects to microcoated and/or micronized Fenofibrate |



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|---|--|---|
| 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 |
| LUCENTIS (Ranibizumab) | - 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 |
| 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 |
| MERIDIA (Sibutramine) XENICAL (Orlistat) | - Obesity | <p><u>Initial Authorization Approval:</u> Patient must meet each of the following criteria to receive coverage for Xenical or Meridia for up to six months:</p> <ul style="list-style-type: none"> • Patient has been prescribed lifestyle therapy (diet and exercise) for six months or more prior to using Xenical or Meridia • Patient is continuing with prescribed lifestyle therapy (diet and exercise) while using Xenical or Meridia • 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: <ul style="list-style-type: none"> ➤ Hypertension and is on medication ➤ Diabetes mellitus and is on medication ➤ Hyperlipidemia and is on medication ➤ Coronary artery disease and is on medication <p><u>Subsequent Authorization Approval:</u></p> <ul style="list-style-type: none"> • Patient must meet each of the following criteria to receive additional coverage for Xenical or Meridia 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 or Meridia • 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: <ul style="list-style-type: none"> ➤ Hypertension and is on medication ➤ Diabetes mellitus and is on medication ➤ Hyperlipidemia and is on medication ➤ Coronary artery disease and is on medication <p><u>Maximum Lifetime Coverage:</u> 24 months for all anti-obesity drugs</p> |
| 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 |
| 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 |



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|--|--|---|
| 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 between 0 and 2. - Coordinate with provincial government program |
| NEXIUM NEXIUM GRANULES (Esomeprazole) | <ul style="list-style-type: none"> - Gastroesophageal Reflux Disease - Duodenal and Gastric Ulcers - Zollinger-Ellison Syndrome | <ul style="list-style-type: none"> - For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabepazole, 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: Rabepazole, Omeprazole and/or Pantaprazole - For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabepazole, Omeprazole and/or Pantaprazole |
| NUTROPIN SAIZEN SEROSTIM SOMATREM (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 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 |
| OXYTROL (Oxybutynin transdermal system) | <ul style="list-style-type: none"> - Urinary incontinence | <ul style="list-style-type: none"> - For individuals who have tried and failed oral anticholinergics (ex. Oxybutynin) |
| PAXIL CR (Paroxetine controlled release) | <ul style="list-style-type: none"> - Depression | <ul style="list-style-type: none"> - 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) | <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 |



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|---|--|---|
| PENNSAID (Diclofenac 15% topical solution) | - Osteoarthritis | <ul style="list-style-type: none"> - 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 | <ul style="list-style-type: none"> - For patients who have tried and failed or cannot tolerate Chlorhexidine gluconate mouth rinse and/or a combination of Amoxicillin and Metronidazole therapy |
| PREVACID, PREVACID FASTAB (Lansoprazole) | <ul style="list-style-type: none"> - Gastroesophageal Reflux Disease - Duodenal and Gastric Ulcers - Zollinger-Ellison Syndrome | <ul style="list-style-type: none"> - For the treatment of Moderate to Severe Gastroesophageal Reflux Disease or Peptic Ulcers unresponsive to two of the following: Rabeprazole, 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, Omeprazole and/or Pantoprazole - For the treatment of pathological hypersecretory conditions (i.e. Zollinger-Ellison syndrome) unresponsive to two of the following: Rabeprazole, Omeprazole and/or Pantoprazole |
| PREZISTA (Darunavir) | - 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 |
| PRISTIQ (Desvenlafaxine) | - Major Depressive Disorder | <ul style="list-style-type: none"> - 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 |
| PROSCAR (Finasteride) | - Benign Prostatic Hyperplasia | <ul style="list-style-type: none"> - For male patients in the treatment of benign prostatic hyperplasia |
| PULMOZYME (Dornase alfa) | - 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) | - 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 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) | <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 bromide) | - Opioid-Induced Constipation (OIC) | <ul style="list-style-type: none"> - For patients with Opioid-Induced Constipation (OIC) receiving palliative care, who have tried and failed traditional laxatives and/or enemas |

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|---|--|---|
| 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 - 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"> - Patients with single or multiple draining fistulas or patient with moderate to severe Crohn's disease AND who did not respond to oral corticosteroid therapy, Sulfasalazine, Mesalamine, Azathioprine, 6-mercaptopurine, Methotrexate, or Cyclosporine - Patients with active ulcerative colitis who failed or are intolerant to oral corticosteroid therapy, 5-ASA products and/or immunosuppressants - 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 |
| REVATIO (Sildenafil low dose) | <ul style="list-style-type: none"> - Pulmonary Hypertension | <ul style="list-style-type: none"> - For the treatment of pulmonary arterial hypertension in patients who have failed conventional therapy (e.g. Flolan, Remodulin, etc.) - Coordinate with provincial government program |
| RILUTEK (Riluzole) | <ul style="list-style-type: none"> - Amyotrophic lateral sclerosis (ALS) | <ul style="list-style-type: none"> - 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) |
| 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 |
| RISPERIDAL CONSTA (Risperidone injection) | <ul style="list-style-type: none"> - For the management of the manifestations of schizophrenia and related psychotic disorders | <ul style="list-style-type: none"> - Reserved for patients who are non-compliant or non-adherent with conventional oral therapy, resulting in multiple relapses/hospitalizations |
| SATIVEX (Tetrahydrocannabinol 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 |
| SEBIVO (Telbivudine) | <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) |
| SENSIPAR (Cinacalcet) | <ul style="list-style-type: none"> - Hyperparathyroidism secondary to Chronic Kidney Disease ("CKD") | <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 |
| SOMAVERT (Pegvisomant) | <ul style="list-style-type: none"> - Treatment of 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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| DRUG | DISEASE | APPROVAL GUIDELINES |
|--|---|--|
| 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 <i>aspergillus</i> or <i>candida</i> 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 <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) | - Chronic myeloid leukemia | - For the treatment of Chronic Myeloid Leukemia (CML) for patients who have tried and failed Gleevec - Coordinate with provincial government program |
| 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 (Atomoxetine) | - Attention deficit hyperactivity disorder | - individuals who have tried and failed or had intolerable side-effects to Methylphenidate or Dextroamphetamine OR - those individuals who have had history or a propensity to abuse other stimulants such as Methylphenidate 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 imatinib Gleevec - Diagnosis of metastatic RCC. ECOG of two or less must be documented - Coordinate with provincial government program |
| TARCEVA (Erlotinib) | - Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC") | - 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 |
| TASIGNA (Nilotinib) | - Second-line treatment of accelerated phase of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) | - For adult patients 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 glioblastoma multiforme concurrently with radiation and post radiation |
| THELIN (Sitaxsentan) | - Pulmonary Hypertension | - For the treatment of pulmonary arterial hypertension in patients who have failed conventional therapy (e.g. Flolan, Remodulin, etc.) - 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 have tried or cannot tolerate Thyroid Hormone Suppression Therapy (THST) withdrawal (i.e. withholding of exogenous thyroxine - Eltroxin, Synthroid) - Validate site of administration |



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|---|--|--|
| TRACLEER (Bosentan) | - Pulmonary Hypertension | <ul style="list-style-type: none"> - For the treatment of pulmonary arterial hypertension in patients who have failed conventional therapy (e.g. Flolan, Remodulin, etc.) - Coordinate with provincial government program |
| 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 | <ul style="list-style-type: none"> - 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 | <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 |
| VALCYTE VALCYTE POS (Valganciclovir) | - Cytomegalovirus Retinitis | - For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients |
| VIAGRA (Sildenafil) CIALIS (Tadalafil) LEVITRA (Vardenafil) | - Erectile Dysfunction | <p>Erectile dysfunction related to one of the following conditions:</p> <ul style="list-style-type: none"> ▪ 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) <p><u>Annual maximum: \$1000 per year</u></p> |
| VISUDYNE (Verteporfin) | <ul style="list-style-type: none"> - 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 |
| VFEND (Voriconazole) | <ul style="list-style-type: none"> - Treatment of invasive aspergillosis - Treatment of Candidemia in non-neutropenic patients and <i>Candida</i> infections | <ul style="list-style-type: none"> - For the treatment of invasive aspergillosis resistant to other therapies - For patients with candidemia who have failed or cannot tolerate Amphotericin B and Fluconazole or who have infections with Fluconazole-resistant <i>Candida</i> species - Coordinate with provincial government program |



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|---|---|---|
| VOLIBRIS (Ambrisentan) | - Pulmonary arterial hypertension (PAH) | <ul style="list-style-type: none"> - Treatment of primary pulmonary arterial hypertension (PAH) or pulmonary hypertension secondary to connective tissue disease AND - No response to conventional therapy in WHO functional class III and in WHO functional class II with no response to conventional therapy and no alternative treatment - Coordinate with provincial government program |
| WELLBUTRIN SR/XL (Bupropion) | - Depression | <ul style="list-style-type: none"> - Diagnosis of depression and previous or concomitant use of any other antidepressants |
| XEOMIN (Botulinum toxin type A) | <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 |
| XOLAIR (Omalizumab) | - 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 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 |
| XYREM (Sodium oxybate) | - Treatment of cataplexy (sudden loss of muscle strength) in narcoleptic patients | <ul style="list-style-type: none"> - Diagnosis of narcolepsy with chronic symptoms of cataplexy |
| ZADITOR (Ketotifen preservative-free ophthalmic solution) | - Temporary relief of itching from allergic conjunctivitis | <ul style="list-style-type: none"> - For patients who are allergic to or cannot tolerate the formulation with the preservative |
| ZENAPAX (Daclizumab) | - For kidney transplant patients receiving immunosuppressants | <ul style="list-style-type: none"> - For the prophylaxis of acute rejection in kidney transplant patients |
| ZOMETA (Zoledronic acid) | <ul style="list-style-type: none"> - Tumour-induce Hypercalcemia - Bone metastases and multiple myeloma - Paget's disease of the bone | <ul style="list-style-type: none"> - Coordinate with provincial government program |



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