

## **Specialty Drugs and Approval Guidelines**

**(Special authorization drugs may vary depending on plan)**

DRUG	DISEASE	APPROVAL GUIDELINES
ADCIRCA (Tadalafil)	<ul style="list-style-type: none"> <li>- Pulmonary Hypertension</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of pulmonary arterial hypertension in patients who have failed conventional therapy (e.g. Flolan, Remodulin, etc.)</li> <li>- Coordinate with provincial government program</li> </ul>
AMEVIVE (alefacept)	<ul style="list-style-type: none"> <li>- Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
APTIVUS (tipranavir)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>
ARANESP (erythropoietin)	<ul style="list-style-type: none"> <li>- Anemia with chemotherapy</li> <li>- Chronic renal failure</li> </ul>	<ul style="list-style-type: none"> <li>- For patient with chronic renal failure under going dialysis treatment</li> <li>- For patient with anemia secondary to chemotherapy</li> <li>- Coordinate with provincial government program</li> </ul>
ATRIPLA (efavirenz emtricitabine tenofovir)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> </ul>
AVONEX AVONEX PS (interferon beta-1a)	<ul style="list-style-type: none"> <li>- Multiple sclerosis, relapsing remitting</li> <li>- Multiple sclerosis, chronic progressive</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> <li>- EDSS value required</li> </ul>
BARACLUDGE (entecavir)	<ul style="list-style-type: none"> <li>- Chronic hepatitis B</li> </ul>	<ul style="list-style-type: none"> <li>- For chronic hepatitis B patients who develop resistance to Lamivudine AND who have tried and failed combination therapy with lamivudine/adefovir or lamivudine/tenofovir</li> <li>- For chronic hepatitis B patients who have severe liver disease (e.g. cirrhosis)</li> </ul>
BETASERON (interferon beta-1a)	<ul style="list-style-type: none"> <li>- Multiple sclerosis, relapsing remitting</li> <li>- Multiple sclerosis, chronic progressive</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> <li>- EDSS value required</li> </ul>



DRUG	DISEASE	APPROVAL GUIDELINES
BOTOX (botulinum toxin type A)	<ul style="list-style-type: none"> <li>- Blepharospasm</li> <li>- Strabismus</li> <li>- Torticollis</li> <li>- Cervical dystonia</li> <li>- Cerebral palsy</li> <li>- Hyperhidrosis</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of blepharospasm and strabismus in patients 12 years of age or older</li> <li>- For the treatment of torticollis in adult patients</li> <li>- For spasticity and other approved clinical conditions</li> <li>- For axillary hyperhidrosis</li> </ul>
CAYSTON (Aztreonam)	<ul style="list-style-type: none"> <li>- Treatment of pulmonary infection with <i>Pseudomonas aeruginosa</i> in Cystic Fibrosis Patients</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- Co-ordinate with provincial programs where possible</li> </ul>
CELSENTRI (maraviroc)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>
CIMZIA (Certolizumab pegol)	<ul style="list-style-type: none"> <li>- Moderate to Severe Rheumatoid Arthritis</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
COPAXONE (glatiramer acetate)	<ul style="list-style-type: none"> <li>- Multiple sclerosis, relapsing remitting</li> <li>- Multiple sclerosis, chronic progressive</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> <li>- EDSS value required</li> </ul>
DUODOPA (levodopa/carbidopa intestinal gel)	<ul style="list-style-type: none"> <li>- Parkinson's disease</li> </ul>	<ul style="list-style-type: none"> <li>- For individuals with advanced Parkinson's disease and who have tried and failed other oral therapies for control of severe, disabling motor fluctuations</li> <li>- Individuals are being screened and managed by specialists and at appropriate centers where the individuals have responded to the drug during the test phase</li> <li>- Coordinate with provincial government program</li> </ul>
ENBREL (etanercept)	<ul style="list-style-type: none"> <li>- Moderate to Severe Rheumatoid Arthritis</li> <li>- Moderate to Severe Juvenile Rheumatoid Arthritis</li> <li>- Psoriatic arthritis</li> <li>- Ankylosing spondylitis</li> <li>- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> <li>- 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</li> </ul>



DRUG	DISEASE	APPROVAL GUIDELINES
EPREX (erythropoietin)	<ul style="list-style-type: none"> <li>- Anemia with chemotherapy</li> <li>- Chronic renal failure</li> </ul>	<ul style="list-style-type: none"> <li>- For patient with chronic renal failure under going dialysis treatment</li> <li>- For patient with anemia secondary to chemotherapy</li> <li>- Coordinate with provincial government program</li> </ul>
FASLODEX (fulvestrant)	<ul style="list-style-type: none"> <li>- Hormonal treatment of locally advanced or metastatic breast cancer in postmenopausal women</li> </ul>	<ul style="list-style-type: none"> <li>- Second-line treatment for patients who have failed treatment with or have had intractable side-effects to Tamoxifen and/or Aromatase Inhibitors</li> </ul>
FLUDARA (fludarabine oral tablet)	<ul style="list-style-type: none"> <li>- Chronic Lymphocytic Leukemia (CLL)</li> </ul>	<ul style="list-style-type: none"> <li>- For patients who have failed first-line treatment and meet the following criteria:               <ol style="list-style-type: none"> <li>1. Provincial cancer drug coverage is not available for Fludarabine oral tablet in the province where the applicant resides</li> </ol>               AND               <ol style="list-style-type: none"> <li>2. Applicant has first tried I.V. / infusion Fludarabine and has developed intolerance or adverse effects to this formulation</li> </ol> </li> </ul>
FORTEO (teriparatide)	<ul style="list-style-type: none"> <li>- Osteoporosis</li> <li>- Osteoporosis associated with sustained systemic glucocorticoid therapy</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> <li>- Maximum lifetime treatment : 18 months</li> </ul>
FUZEON (enfuvirtide)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>
GLEEVEC (imatinib)	<ul style="list-style-type: none"> <li>- Chronic myeloid leukemia</li> <li>- Gastrointestinal Stromal Tumour (GIST)</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of Chronic Myeloid Leukemia (CML) in blast or accelerated phase and for those for whom interferon is ineffective, contra-indicated or poorly tolerated and the patient is a candidate for stem cell transplantation</li> <li>- For the treatment of inoperable recurrent and/or metastatic GIST</li> <li>- Coordinate with provincial government program</li> </ul>
HEPSERA (adefovir)	<ul style="list-style-type: none"> <li>- Chronic hepatitis B</li> </ul>	<ul style="list-style-type: none"> <li>- For chronic hepatitis B patients who develop resistance to Lamivudine or who have severe liver disease (e.g. cirrhosis)</li> <li>- For hepatitis B patients co-infected with HIV who do not require HAART therapy for HIV</li> </ul>



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Updated: January, 2010

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<p>HUMATROPE (somatropin)</p>	<ul style="list-style-type: none"> <li>- Dwarfism</li> <li>- Turner's syndrome</li> <li>- Adult Growth Hormone Deficiency ("Adult GHD")</li> <li>- Idiopathic Short Stature ("ISS")</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- For the treatment of patients with Turner's syndrome under 14 years of age</li> <li>- 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</li> <li>- For adults who have GHD (GH <math>\leq</math> 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</li> <li>- 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 25<sup>th</sup> percentile for bone age; and (v) patients whose epiphyses are not closed</li> <li>- Coordinate with provincial government program</li> </ul>
<p>HUMIRA (adalimumab)</p>	<ul style="list-style-type: none"> <li>- Crohn's Disease</li> <li>- Moderate to Severe Rheumatoid Arthritis</li> <li>- Psoriatic arthritis</li> <li>- Ankylosing spondylitis</li> <li>- Patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> <li>- 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</li> <li>- 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</li> </ul>
<p>INFERGEN (interferon alfacon-1)</p>	<ul style="list-style-type: none"> <li>- Hepatitis C</li> </ul>	<ul style="list-style-type: none"> <li>- For patients who have failed to respond to or relapsed after prior administration of Interferon alpha</li> </ul>
<p>INTELENCE (etravirine)</p>	<ul style="list-style-type: none"> <li>- HIV infection</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>



DRUG	DISEASE	APPROVAL GUIDELINES
INTRON A (interferon alfa-2b)	<ul style="list-style-type: none"> <li>- Chronic Hepatitis</li> <li>- Chronic active hepatitis B</li> <li>- Chronic myelogenous leukemia (CML)</li> <li>- Thrombocytosis associated with CML</li> <li>- Multiple Myeloma</li> <li>- Non-Hodgkin's lymphoma</li> <li>- Malignant melanoma</li> <li>- AIDS-related Kaposi's sarcoma</li> <li>- Hairy cell leukemia</li> <li>- Basal cell carcinoma</li> <li>- Condylomata acuminata</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> </ul>
IRESSA (gefitinib)	<ul style="list-style-type: none"> <li>- Third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer ("NSCLC")</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- Coordinate with provincial government program</li> </ul>
ISENTRESS (raltegravir)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>
KINERET (anakinra)	<ul style="list-style-type: none"> <li>- Rheumatoid Arthritis</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
LUCENTIS (ranibizumab)	<ul style="list-style-type: none"> <li>- End-stage or "wet" age-related macular degeneration ("AMD")</li> </ul>	<ul style="list-style-type: none"> <li>- For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate.</li> <li>- Validate site of administration</li> <li>- Coordinate with provincial government program</li> </ul>
MACUGEN (pegaptanib)	<ul style="list-style-type: none"> <li>- End-stage or "wet" age-related macular degeneration ("AMD")</li> </ul>	<ul style="list-style-type: none"> <li>- For patient with a diagnosis of wet AMD AND where Visudyne is deemed inappropriate.</li> <li>- Validate site of administration</li> <li>- Coordinate with provincial government program</li> </ul>
NEULASTA (pegfilgrastim)	<ul style="list-style-type: none"> <li>- Neutropenia associated with chemotherapy, transplant</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- Co-ordinate with provincial government program</li> </ul>
NEUPOGEN (filgrastim)	<ul style="list-style-type: none"> <li>- Neutropenia associated with chemotherapy, transplant</li> </ul>	<ul style="list-style-type: none"> <li>- Co-ordinate with provincial government program</li> </ul>
NEXAVAR (sorafenib)	<ul style="list-style-type: none"> <li>- Metastatic renal cell (clear cell) carcinoma</li> <li>- Advanced hepatocellular carcinoma</li> </ul>	<ul style="list-style-type: none"> <li>- For patients who are refractory or resistant to treatment with cytokines</li> <li>- For patients with advanced hepatocellular carcinoma who are Child-Pugh Class A and have an ECOG of 0-2</li> <li>- Coordinate with provincial government program</li> </ul>



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NUTROPIN PROTROPIN SAIZEN (somatropin)	<ul style="list-style-type: none"> <li>- Dwarfism</li> <li>- Turner's syndrome</li> <li>- Adult Growth Hormone Deficiency ("Adult GHD")</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- For the treatment of patients with Turner's syndrome under 14 years of age</li> <li>- 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</li> <li>- For adults who have GHD (GH <math>\leq</math> 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</li> <li>- Coordinate with provincial government program</li> </ul>
OMNITROPE (Somatropin)	<ul style="list-style-type: none"> <li>- Growth Hormone Deficiency ("GHD") in children</li> <li>- Adult Growth Hormone Deficiency ("Adult GHD")</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> <li>- For adults who have GHD (GH <math>\leq</math> 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.</li> <li>- Coordinate with provincial government program</li> </ul>
ORENCIA (abatacept)	<ul style="list-style-type: none"> <li>- Rheumatoid Arthritis</li> <li>- Moderate to Severe Juvenile Rheumatoid Arthritis</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
PEGASYS, PEGASYS RBV PEGETRON PEGETRON REDIPEN REBETRON REDIPEN (peginterferon alfa-2b and ribavirin)	<ul style="list-style-type: none"> <li>- Hepatitis C</li> <li>- Hepatitis B</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> </ul>
PREZISTA (darunavir)	<ul style="list-style-type: none"> <li>- HIV anti-viral</li> </ul>	<ul style="list-style-type: none"> <li>- 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)</li> <li>- Coordinate with provincial government program</li> </ul>



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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)	- 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
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)	- Opioid-induced constipation	- Patients will advanced illness, receiving palliative care, who have tried and failed traditional laxatives and/or enemas
REMICADE (infliximab)	- 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	- 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 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)	- Pulmonary Hypertension	- For the treatment of pulmonary arterial hypertension who have failed conventional therapy (e.g. Flolan, Remodulin, etc.) - Coordinate with provincial government program
RILUTEK (riluzole)	- Amyotrophic lateral sclerosis (ALS)	- 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)	- Rheumatoid Arthritis	- For patients who have tried and failed or could not tolerate at least one or more anti-TNF treatment



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SANDOSTATIN (octreotide)	<ul style="list-style-type: none"> <li>- Metastatic carcinoid and vasoactive intestinal peptide-secreting tumours (VIPomas)</li> <li>- Acromegaly</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> </ul>
SATIVEX (tetrahydro-cannabinol and cannabidiol buccal spray)	<ul style="list-style-type: none"> <li>- For symptomatic relief of neuropathic pain in adults with multiple sclerosis</li> </ul>	<ul style="list-style-type: none"> <li>- Adult MS patients with neuropathic pain who have tried other medications such as analgesics, opioids, antidepressants or anti-convulsants, with little or no effect</li> </ul>
SENSIPAR (cinacalcet)	<ul style="list-style-type: none"> <li>- Hyperparathyroidism secondary to Chronic Kidney Disease</li> </ul>	<ul style="list-style-type: none"> <li>- For patients with hyperparathyroidism secondary to CKD with parathyroid hormone levels greater than 33pmol/L or 300pg/mL</li> </ul>
SIMPONI (Golimumab)	<ul style="list-style-type: none"> <li>- Moderate to Severe Rheumatoid Arthritis</li> <li>- Psoriatic arthritis</li> <li>- Ankylosing spondylitis</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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</li> </ul>
SOMATULINE AUTOGEL (lanreotide)	<ul style="list-style-type: none"> <li>- Acromegaly</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> </ul>
SOMAVERT (pegvisomant)	<ul style="list-style-type: none"> <li>- Acromegaly</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
SPRIAFIL (posaconazole)	<ul style="list-style-type: none"> <li>- Invasive aspergillosis</li> <li>- Prophylaxis or prevention of aspergillus or candida infections in patients with prolonged neutropenia or stem cell transplant recipients</li> <li>- Oropharyngeal candidiasis</li> </ul>	<ul style="list-style-type: none"> <li>- For patients with invasive aspergillosis who have failed or cannot tolerate Amphotericin B or Itraconazole</li> <li>- For prophylaxis or prevention of <i>aspergillus</i> or <i>candida</i> infections in patients who have failed or cannot tolerate Fluconazole</li> <li>- For treatment of oropharyngeal candidiasis in patients who have failed or cannot tolerate Fluconazole or Itraconazole</li> </ul>
SPRYCEL (dasatinib)	<ul style="list-style-type: none"> <li>- Chronic myeloid leukemia</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of Chronic Myeloid Leukemia (CML) for patients who have tried and failed Gleevec</li> <li>- Coordinate with provincial government program</li> </ul>
STELARA (ustekinumab)	<ul style="list-style-type: none"> <li>- For treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for phototherapy and systemic therapy</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> </ul>
SUTENT (sunitinib)	<ul style="list-style-type: none"> <li>- Gastrointestinal Stromal Tumour (GIST)</li> <li>- First-line treatment of metastatic Renal Cell Carcinoma ("RCC")</li> </ul>	<ul style="list-style-type: none"> <li>- For GIST patients who have tried and failed or had no response to imatinib</li> <li>- Diagnosis of metastatic RCC. ECOG of two or less must be documented</li> <li>- Coordinate with provincial government program</li> </ul>



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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 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	- Patients must have well-differentiated thyroid cancer AND have tried or cannot tolerate Thyroid Hormone Suppression Therapy (THST) withdrawal (i.e. withholding of exogenous thyroxine i.e. Eltroxin, Synthroid) - Validate site of administration
TRACLEER (bosentan)	- Pulmonary Hypertension	- For the treatment of pulmonary arterial hypertension who have failed conventional therapy (e.g. Flolan, Remodulin, etc.) - Coordinate with provincial government program
TYKERB (lapatinib)	- Advanced or metastatic breast cancer	- 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
TYSABRI (natalizumab)	- 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
VALCYTE VALCYTE POS (valganciclovir)	- Cytomegalovirus Retinitis	- For the treatment of retinitis caused by the cytomegalovirus (CMV) in HIV or immunocompromised patients



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Updated: January, 2010

DRUG	DISEASE	APPROVAL GUIDELINES
VFEND (voriconazole)	<ul style="list-style-type: none"> <li>- Invasive aspergillosis</li> <li>- Candidemia in non-neutropenic patients and Candida infections</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of invasive aspergillosis resistant to other therapies</li> <li>- 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</li> <li>- Coordinate with provincial government program</li> </ul>
VISUDYNE (verteporfina)	<ul style="list-style-type: none"> <li>- Age related macular degeneration</li> <li>- Pathological myopia</li> </ul>	<ul style="list-style-type: none"> <li>- 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.</li> </ul>
VOLIBRIS (ambrisentan)	<ul style="list-style-type: none"> <li>- Pulmonary Hypertension</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of pulmonary arterial hypertension who have failed conventional therapy (e.g. Flolan, Remodulin, etc.)</li> <li>- Coordinate with provincial government program</li> </ul>
XELODA (capecitabine)	<ul style="list-style-type: none"> <li>- Metastatic colorectal cancer</li> <li>- Adjuvant therapy of Dukes' C colon cancer</li> <li>- Metastatic breast cancer</li> </ul>	<ul style="list-style-type: none"> <li>- Coordinate with provincial government program</li> </ul>
XEOMIN (botulinum toxin type A)	<ul style="list-style-type: none"> <li>- Blepharospasm</li> <li>- Cervical dystonia (spasmodic torticollis)</li> <li>- Post-stroke spasticity of the upper limbs</li> </ul>	<ul style="list-style-type: none"> <li>- For the treatment of blepharospasm in patients 18 years of age or older</li> <li>- For the treatment of torticollis in adult patients</li> <li>- For the treatment of post-stroke spasticity of the upper limbs in adult patients</li> </ul>
XOLAIR (omalizumab)	<ul style="list-style-type: none"> <li>- For adults and adolescents (12 years and older) with moderate to severe persistent asthma who have a positive skin test</li> </ul>	<ul style="list-style-type: none"> <li>- 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")</li> <li>OR</li> <li>- 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.</li> </ul>
XYREM (sodium oxybate)	<ul style="list-style-type: none"> <li>- Cataplexy (sudden loss of muscle strength) in narcoleptic patients</li> </ul>	<ul style="list-style-type: none"> <li>- Diagnosis of narcolepsy with chronic symptoms of cataplexy</li> </ul>



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