

*Disclaimer: The information in this document is updated on a regular basis. Although we strive to ensure that all information is accurate at the time of posting, please be aware that some items may be subject to change from time-to-time.*

*The information provided in this document and website is intended for information purposes only and does not provide any medical diagnosis, symptom assessment, health counseling or medical opinion for individual users. This information also does not constitute medical advice for physicians or patients. For more detailed information on prescription drugs, please consult a qualified healthcare professional.*

## **Reimbursement Criteria for Frequently Requested Drugs and Indications**

Reimbursement criteria for select drugs and indications considered through EAP are posted below. The reimbursement criteria must always be met - even in cases where EAP drug coverage is required to provide continued treatment that was previously supplied through a clinical trial, or paid for by other means (such as a third party payer). For a limited number of requests where expert opinion is required, the requests are reviewed by an external reviewer who is a medical expert in the field.

Where available, a link has been provided to the information page containing details of the Committee to Evaluate Drugs (CED) review and subsequent the Executive Officer's funding decision for the particular drug and indication. Information on whether the drug and indication can be considered through the Telephone Request Service (TRS) is also included.

EAP requests may be submitted for numerous other drugs not listed below, or for drugs listed below but for different indications. However, EAP funding will only be considered for drugs and indications that have been reviewed by the CED and approved for funding by the Executive Officer. For more information, please refer to the main [EAP webpage](#).

Some of the drugs considered through EAP are also listed on the ODB Formulary for a different indication as Limited Use (LU) benefit. You can check whether the drug is listed by searching the [e-Formulary](#).

For details on how the EAP reimbursement criteria are developed, please refer to the main [EAP webpage](#).

To assist physicians applying for exceptional access, the ministry has developed a [standard form](#). Use of form is not mandatory but does facilitate provision of all relevant information. Where applicable, please ensure that all relevant clinical information is provided demonstrating that the patient meet the reimbursement criteria.

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*Note: The dosage form and strength of the product that has been approved for reimbursement consideration are those that have been approved by the Committee to Evaluate Drugs (CED). In most cases, these are the dosage forms and strengths submitted to the CED by the manufacturer for consideration, however, it may not be inclusive of all dosage forms and strengths available through the manufacturer.*

<b>ANEMIA</b>				
<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Darbepoetin	Aranesp	Prefilled syringes  150 mcg, 200 mcg, 300 mcg, 500 mcg	<p><b>For the treatment of anemia secondary to chronic renal disease in those who are not eligible under the Special Drugs Program</b>, approval can be given if the patient meets the following criteria:</p> <ul style="list-style-type: none"> <li>• Estimated glomerular filtration rate (GFR) less than 30 mL/min <b>AND</b></li> <li>• Baseline hemoglobin level less than 100 g/L <b>AND</b></li> <li>• Mean corpuscular volume (MCV) level between 75 fL and 120 fL</li> </ul> <p>All requests <b>MUST</b> indicate the reason why the patient is ineligible for the Special Drugs Program.</p> <p><b>Renewals</b> will be provided to patients where the hemoglobin levels have improved by 15 g/L after 3 months of therapy.</p> <p>Renewals must specify the name of the drug and dose requested and <b>MUST</b> be accompanied by bloodwork that includes a recent hemoglobin level. Also, please identify if the patient has received transfusions after the first 2 weeks of therapy with darbepoetin and the date (s) that the transfusion(s) occurred.</p>	Initial: 3 months
			<p><b>For the treatment of anemia secondary to myelodysplastic syndrome (MDS)</b> in patients who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• MDS confirmed by the bone marrow report <b>AND</b></li> <li>• With a hemoglobin count less than 100 g/L <b>AND</b></li> <li>• Endogenous erythropoietin level of less than 500 U/L <b>AND</b></li> <li>• Mean corpuscular volume (MCV) level between 75 fL and 120 fL.</li> </ul> <p>Submissions must include the date(s) for the above blood work. For patients with an MCV level below 75 fL or above 120 fL, the physician must provide a discussion of how reversible causes of anemia were ruled out to enable further consideration of the submission.</p>	Renewals: 3 months
				Initial: 3 months





			<p>Submissions not meeting the above criteria will be considered on a case-by-case basis. All submissions should be accompanied by</p> <ul style="list-style-type: none"> <li>• Baseline and current bloodwork (full CBC with MCV)</li> <li>• Baseline clinical status and current symptoms from anemia that were not present at baseline</li> <li>• Details of any complications from anemia</li> </ul> <p><b>Renewals</b> will be granted for the full period of pegylated interferon and ribavirin treatment in those who show significant response to therapy. Renewals should be accompanied by bloodwork that includes a recent hemoglobin and must identify if the patient has required transfusions after the first 2 weeks of therapy.</p>	Renewal: duration of hepatitis C therapy
Epoetin alpha	Eprex	<p>Prefilled syringes</p> <p>5,000 IU/0.5 mL, 6,000 IU/0.6 mL, 8,000 IU/0.8 mL, 10,000 IU/mL, 20,000 IU/ 0.5 mL, 40,000 IU/mL</p>	<p><b>Pre-operative use at a dose up to 40,000 IU weekly prior to single hip, double knee, or single (“redo”) knee surgery in patients who meet the following criteria;</b></p> <ul style="list-style-type: none"> <li>• Hemoglobin between 100 – 130 g/L inclusive <b>AND</b></li> <li>• Mean corpuscular volume (MCV) level between 75 fL and 120 fL inclusive.</li> </ul> <p>Request not meeting these criteria will be assessed on a case-by-case basis.</p> <p><b>For the treatment of anemia in palliative cancer patients,</b> individuals will be assessed on a case-by-case basis. Submissions must include the rationale for using epoetin alpha over transfusion.</p> <hr/> <p>Requests <b>for the treatment of chemotherapy-induced anemia in patients with malignant cancer</b> DO NOT require an EAP submission. Please refer to the formulary to determine if the patient satisfies the criteria for use. (Refer to the “Therapeutic notes” section of the formulary listing).</p> <p>To access the ODB e-formulary, click on the link below:</p> <p><b><u><a href="http://www.health.gov.on.ca/english/providers/program/drugs/odbf_eformulary.html">http://www.health.gov.on.ca/english/providers/program/drugs/odbf_eformulary.html</a></u></b></p>	Up to 4 doses preoperatively

<p>Filgrastim</p> <p>[Granulocyte colony stimulating factor (G-CSF)]</p>	<p>Neupogen</p>	<p>300 mcg/mL</p> <p>480 mcg /1.6 mL</p>	<p><i>Note: For all the listed indications in this section, the dosage approved will be based on the patient's weight (see below). Please provide the patient's weight in the submission. If the physician wishes to use a higher dosage, please provide reason(s) as these will be considered on a case-by-case.</i></p> <p><i>&lt; 90 kg – 300 mcg</i> <i>≥ 90 kg – 480 mcg</i></p> <p>Indications reviewed through the EAP submission process include:</p> <ul style="list-style-type: none"> <li>• <b>For the secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia in which the treatment has had to be delayed for at least one week) <b>in patients with cancer receiving a <u>curative chemotherapy regimen</u></b> consistent with Cancer Care Ontario guidelines. Please ensure that the “curative” therapy is consistent with the stage of cancer.</li> <li>• <b>For the primary prophylaxis of febrile neutropenia for patients undergoing adjuvant breast cancer therapy with dose-dense AC-Taxol</b> (doxorubicin-cyclophosphamide then paclitaxel administered every 2 weeks).</li> <li>• <b>For the primary prophylaxis of febrile neutropenia for patients undergoing adjuvant breast cancer therapy with TAC</b> (docetaxel/taxotere-doxorubicin-cyclophosphamide).</li> <li>• <b>For the secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia such that treatment has had to be delayed for at least one week) <b>for patients undergoing adjuvant / neoadjuvant breast cancer therapy:</b></li> <li>• <b>Primary prophylaxis of febrile neutropenia for patient 70 years and older with intermediate or high-grade lymphoma receiving CHOP/R</b> (cyclophosphamide-doxorubicin-vincristine-prednisone +/- Rituximab).</li> <li>• <b>Secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia such that treatment has had to be delayed for at least one week) <b>for patients with intermediate or high-grade lymphoma receiving CHOP/R</b> (cyclophosphamide-doxorubicin-vincristine-prednisone +/- Rituximab).</li> <li>• <b>Primary prophylaxis of febrile neutropenia for patient 70 years and older with</b></li> </ul>	<p>Duration of Chemotherapy</p>
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			<p><b>Hodgkin’s disease receiving initial treatment</b> (i.e. not for relapsed or refractory conditions) <b>with ABVD</b> (doxorubicin-bleomycin-vinblastine-dacarbazine).</p> <ul style="list-style-type: none"> <li>• <b>Secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia such that treatment has had to be delayed for at least one week) <b>for patients with Hodgkin’s disease receiving initial treatment</b> (i.e. not for relapsed or refractory conditions) <b>with ABVD</b> (doxorubicin-bleomycin-vinblastine-dacarbazine) or MOPP (nitrogen mustard-vincristine-procarbazine-prednisone) or a hybrid regimen.</li> <li>• <b>Secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia such that treatment has had to be delayed for at least one week) <b>for patients undergoing adjuvant colorectal cancer therapy with FOLFOX.</b></li> <li>• <b>Secondary prophylaxis of febrile neutropenia</b> (i.e. patient has experienced an episode of sepsis or febrile neutropenia or neutropenia such that treatment has had to be delayed for at least one week) <b>for patients with testicular or germ cell tumor receiving any combination of etoposide, cisplatin, bleomycin, vinblastine or ifosfamide</b> (i.e. BEP, EP, VIP regimens).</li> <li>• <b>For the primary prophylaxis of febrile neutropenia</b> for patients receiving docetaxel every 3 weeks for 3 cycles, as part of the FEC-D (5-fluorouracil, epirubicin, cyclophosphamide every 3 cycles followed by docetaxel every 3 weeks for 3 cycles) chemotherapy regimen for the treatment of adjuvant breast cancer. The approval period will be for the duration of the docetaxel portion of the chemotherapy (ie: 9 weeks).</li> </ul> <p>Note: Requests for non-curative disease will be considered on a case-by-case basis.</p>	
Filgrastim  [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL  480 mcg /1.6 mL	<p>Note: For all the listed indications in this section, the dosage approved will be based on prescriber request.</p> <p>Indications reviewed through the EAP submission process include:</p> <ul style="list-style-type: none"> <li>• <b>For the treatment of patients with an intermediate or high grade lymphoma that have relapsed after initial chemotherapy</b> and are to receive an autologous bone marrow during the 2 to 4 months of their pre-transplant chemotherapy.</li> </ul>	Duration of chemotherapy  Duration as

			<ul style="list-style-type: none"> <li>• <b>For the treatment of patients with an intermediate or high-grade lymphoma, leukemia and myeloma that have relapsed after initial chemotherapy</b> and are to receive a peripheral stem cell transplant/stem cell mobilization.</li> </ul>	requested
Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg /1.6 mL	<p><b>For the treatment of patients with HIV/AIDS</b> and who have:</p> <ol style="list-style-type: none"> <li>a persistent (&gt; 3 month) absolute neutrophil count &lt; <math>0.5 \times 10^9</math> cells/L, <b>OR</b></li> <li>an absolute neutrophil count between <math>0.5-1.0 \times 10^9</math> cells/L with a prior history of three or more opportunistic infections and a persistently low CD<sub>4</sub> count less than or equal to <math>20 \times 10^6</math> cells/L.</li> </ol> <p>Note: Dosage approved will be based on prescriber request</p>	1 year
Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg/1.6 mL	<p>Note: For all the listed indications in this section, the dosage approved will be based on prescriber request.</p> <p><b>For the treatment of patients with malignant neutropenia</b> with persistently low neutrophil counts (i.e. &lt; <math>0.5 \times 10^9</math> cells/L for 3 months) and documented infective episodes.</p> <p>For patients with non-malignant severe chronic neutropenia (i.e., congenital, cyclic, idiopathic). Approvals are assessed on a case-by-case basis. Chronic neutropenia is considered as;</p> <ul style="list-style-type: none"> <li>• CBC showing neutrophil counts &lt; <math>0.5 \times 10^9</math> cells/L for 3 months prior to filgrastim therapy <b>AND</b></li> <li>• A documented history of recurrent infections <b>AND</b></li> <li>• A recent bone marrow examination report with cytogenetics testing</li> </ul> <p><b>Renewals</b> for congenital neutropenia will be considered on a case-by-case basis. Submissions must include the following information;</p> <ol style="list-style-type: none"> <li>Updated monitoring plan</li> <li>Bloodwork (ie. WBC and ANC) with <u>corresponding</u> filgrastim (Neupogen) doses</li> <li>Recent bone marrow report with cytogenetics testing</li> <li>History of infections (if applicable)</li> </ol>	<p>6 months</p> <p>Cyclic or Idiopathic: Lifetime</p> <p>Initial approval for congenital neutropenia: 2 years</p> <p>Renewals for congenital neutropenia: 2 years</p>

Iron dextran complex	Dexiron Infufer	50 mg/mL	<p><b>For the treatment of iron-deficiency anemia</b> confirmed by bloodwork where the patient has a demonstrated intolerance to oral iron therapy OR has not responded to adequate therapy with oral iron.</p> <p><b>Renewals</b> will be considered on a case-by-case basis.</p>	1 year
Iron sucrose	Venofer	20 mg/mL Injectable	<p><b>For the treatment of iron-deficiency anemia as a third-line agent in patients with documented anemia</b> who have failed or are intolerant to oral iron AND iron dextran.</p>	1 year
Lenalidomide	Revlimid	5 mg, 10 mg capsule	<p><b>Treatment of anemia due to <u>myelodysplastic syndrome (MDS)</u></b> for patients who have;</p> <ul style="list-style-type: none"> <li>• Demonstrated diagnosis of MDS on bone marrow aspiration</li> <li>• Presence of del[5q] documented by standard cytogenetic or fluorescence in situ hybridization</li> <li>• International Prognostic Scoring System (IPSS) risk category low or intermediate-1</li> <li>• Transfusion-dependent symptomatic anemia</li> </ul> <p><b>Renewal</b> will be considered for patients who are transfusion-dependent and who have demonstrated at least a fifty percent (50%) reduction in transfusion requirements.</p> <p>Patients with anemia due to MDS who are not transfusion-dependent will be assessed on a case-by-case basis.</p>	<p>Initial: 6 months</p> <p>Renewal: Up to 1 year</p>

ANTICONVULSANTS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Lacosamide	Vimpat	50 mg, 100 mg, 150 mg, 200 mg tablet	<p><b>For the treatment of partial-onset seizures</b> in those who meet the following criteria;</p> <ul style="list-style-type: none"> <li>• Adult <math>\geq</math> 18 years old and currently receiving two or more anti-epileptic drugs (AEDs) for the treatment of unsatisfactorily controlled partial-onset seizures <b>AND</b></li> <li>• Have tried and failed to achieve seizure control with three less costly AEDs used either in monotherapy or in combination (e.g. phenytoin, carbamazepine, gabapentin, lamotrigine, vigabatrin, topiramate, etc.) <b>AND</b></li> <li>• Is under the care of a physician experienced in the treatment of epilepsy.</li> </ul>	Lifetime
Lamotrigine (chewable)	Lamictal	5 mg chewable tablet	<p><b>For the adjunctive therapy for children over 2 years of age who are suffering from refractory seizures associated with Lennox-Gastaut syndrome</b>, and who have previously tried other antiepileptic drugs.</p> <p>Note: Lamotrigine 25 mg, 100 mg and 150 mg tablets are reimbursed as Limited Use Benefit as add-on therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.</p>	1 year
Levetiracetam	Keppra	250 mg, 500 mg, 750 mg tablet	<p><b>For adjunctive therapy in the treatment of adults with partial seizures</b> who have had an inadequate response or have significant intolerance* to at least 2 of the following formulary anticonvulsants (prior or current use): gabapentin, lamotrigine, vigabatrin, and topiramate. * Intolerance must be described in detail.</p> <p>Note: Levetiracetam requests not meeting the above criteria may be reviewed by external medical experts.</p>	Lifetime

Oxcarbazepine	Trileptal	150 mg, 300 mg, and 600 mg tablet	<p><b>For the treatment of partial seizures</b> in adults and in children aged 6 years and older who have had an inadequate response or intolerance* to at least 3 other formulary agents (prior or current use) including carbamazepine.</p> <p>* Intolerance must be described in detail.</p> <p><i>Warning: Life-threatening dermatological reactions, including Stevens Johnson Syndrome and toxic epidermal necrolysis, and multi-organ hypersensitivity reactions have been associated with the use of oxcarbazepine. More information may be found on the Health Canada webpage:</i></p> <p><i><a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/trileptal_hpc-cps_e.html">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/trileptal_hpc-cps_e.html</a></i></p>	Lifetime
Phenobarbital	PMS-Phenobarbital	15 mg, 30 mg, and 60 mg tablet; 5 mg/mL oral liquid	Treatment of seizures.	Lifetime

**ANTIDIABETIC AGENTS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Pioglitazone	Actos , Generics	15 mg, 30 mg, and 45 mg tablet	<p><b>For the treatment of type 2 diabetes</b> in patients who require;</p> <ul style="list-style-type: none"> <li>• Dual combination therapy of diabetes AND demonstrate inadequate glycemic control (HbA1c of &gt;7%) on maximal doses of metformin (2000mg/day) <b>OR</b></li> <li>• Dual combination therapy of diabetes AND demonstrate inadequate glycemic control (HbA1c of &gt;7%) on maximal* doses of sulfonylurea and demonstrated intolerance / contraindication to metformin <b>OR</b></li> <li>• Triple combination therapy of diabetes and who demonstrate inadequate glycemic control on maximal** doses of metformin and a sulfonylurea AND only if the physician has offered insulin as an alternative option first, and the patient has refused or is not able to take insulin. Note: Both the physician and patient must be aware that thiazolidinediones (TZDs), are not indicated for use in triple therapy.</li> </ul> <p>***Those with one or more of the following contraindications/precautions to therapy with pioglitazone/rosiglitazone will not be considered.</p> <ul style="list-style-type: none"> <li>• Patients with type 1 diabetes</li> <li>• Patients who will be using this as monotherapy</li> <li>• Combination use with a nitrates</li> <li>• Combination use with insulin</li> <li>• Patients with any stage of heart failure (i.e. NYHA Class I, II, III, IV)</li> <li>• Patients at high risk for bone fracture (i.e. post-menopausal women with previously confirmed osteoporosis or osteopenia)</li> <li>• Patients with recent history (in the past 3 months) of an ischemic cardiovascular event (myocardial infarction, unstable angina)</li> </ul> <p>* <b>Note:</b> For the purpose of the EAP submission, maximal dose of sulfonylurea is considered to be glyburide 10 mg/day, gliclazide 160mg/day OR Diamicon MR 60mg/day, OR glimepiride (Amaryl ) 4 mg/day.</p> <p>**<b>Note:</b> For the purpose of the EAP submission, maximal dose of metformin is considered to be 2000 mg/day.</p> <p><b>Renewals</b> as well as requests for ongoing treatment in patients previously provided these drugs by other means will be considered_ for those patients who have NOT developed a contraindication/precautionary use*** in the intervening period AND have demonstrated a recent HbA1c level ≤7% while on treatment.</p>	<p>Initial: 5 Years</p> <p>Renewal: 5 Years</p>

Repaglinide	GlucoNorm	0.5 mg, 1 mg, 2 mg tablet	<p><b>For the treatment of type 2 diabetes</b> in patients with:</p> <ul style="list-style-type: none"> <li>• Inadequate glycemic control (HbA1c &gt;7%) using <u>maximal</u>* doses of a sulfonylurea AND metformin (2000mg/day) <b>OR</b></li> <li>• Inadequate glycemic control and demonstrated intolerance or contraindication to metformin and who are on <u>maximal</u>* doses of a sulfonylurea <b>OR</b></li> <li>• Inadequate glycemic control and demonstrated intolerance or contraindication to a sulfonylurea (glyburide, gliclazide or glimepiride) and are on <u>maximal</u>** doses of metformin <b>OR</b></li> <li>• Demonstrated intolerance or contraindication to both a sulfonylurea (glyburide, gliclazide or glimepiride) AND metformin <b>OR</b></li> <li>• Adequate glycemic control (HbA1c ≤ 7%) who develops intolerance or contraindication to sulfonylurea (glyburide, gliclazide or glimepiride) or metformin <b>OR</b></li> <li>• HbA1c ≤ 7% but with greater than 50% of fasting blood glucose (FBG &gt;7mmol/L) or post-prandial plasma glucose (PPG &gt;10mmol/L) levels not within target range and using maximally tolerated doses of a sulfonylurea and metformin.</li> </ul> <p>* <b>Note:</b> For the purpose of the EAP submission, maximal dose of sulfonylurea is considered to be glyburide 10mg/day, gliclazide 160 mg/day or Diamicon MR 60 mg/day, OR glimepiride (Amaryl ) 4 mg/day.</p> <p>**<b>Note:</b> For the purpose of the EAP submission, maximal dose of metformin is considered to be 2000 mg/day</p>	Initial: 5 Years
Rosiglitazone	Avandia	2 mg, 4 mg and 8 mg tablet	<p>For the treatment of type 2 diabetes mellitus in patients with:</p> <ul style="list-style-type: none"> <li>• Inadequate glycemic control (HbA1c &gt;7%) from ALL other oral antidiabetic agents* funded through one of the Ontario Drug Benefit Programs, in monotherapy or in combination OR</li> <li>• Where ALL other oral antidiabetic agents are inappropriate due to contraindications or intolerance AND</li> <li>• The patient has refused or is not able to take insulin AND</li> <li>• There is no known contraindication to rosiglitazone.</li> </ul> <p>* Oral antidiabetics include the following agents;</p> <ul style="list-style-type: none"> <li>○ glyburide</li> <li>○ metformin</li> <li>○ gliclazide (Diamicon, Diamicon MR)</li> <li>○ sitagliptin (Januvia)</li> </ul>	Initial:5 years

			<ul style="list-style-type: none"> <li>○ repaglinide (GlucoNorm)</li> <li>○ pioglitazone (Actos)</li> </ul> <p>Note: A trial with acarbose is not a mandatory requirement.</p> <p>Note: It is <u>not</u> necessary for patients to have tried the following oral antidiabetic agents that are currently not funded by the OPDP for the purposes of obtaining rosiglitazone:</p> <ul style="list-style-type: none"> <li>○ glimepiride (Amaryl)</li> <li>○ nateglinide (Starlix)</li> <li>○ saxagliptin (Onglyza)</li> </ul> <p><b>Renewals</b> will be considered where patients have benefited and continue to benefit from rosiglitazone treatment as demonstrated by <u>recent</u> HbA1c levels <math>\leq 7\%</math> while on treatment with rosiglitazone AND in those who continue to have no known contraindication(s) to rosiglitazone.</p>	Renewal: 5 years
Orlistat	Xenical	120 mg capsule	<p><b>For the treatment of type 2 diabetes</b> in a patient with:</p> <ul style="list-style-type: none"> <li>• Inadequate glycemic control (i.e., HbA1c &gt; 7.0%) on <u>maximal</u> oral antidiabetic medications* <b>AND</b></li> <li>• Body Mass Index <math>\geq 27</math> <b>AND</b></li> <li>• Demonstrated failure to a trial of nutritional/dietary counselling and exercise programs</li> </ul> <p>* Note: Maximal dose of sulfonylurea is considered to be glyburide 10mg/day, gliclazide (160mg/day or Diamicon MR 60mg/day) OR glimepiride (Amaryl ) 4mg/day.  Note: Maximal dose of metformin is considered to be 2000 mg/day</p> <p><b>Renewals</b> will be considered for those with demonstrated response to treatment reported as at least 5% weight loss and improvement in glycemic control (i.e., HbA1c &lt;7.0% or HbA1c reduction of more than 0.5%)</p>	1 Year  First renewal: 12 months

ANTI-INFECTIVES				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Dapsone	Dapsone	100 mg tablet	<p>For the treatment of the following conditions and situations;</p> <ul style="list-style-type: none"> <li>• PCP prophylaxis in immunocompromised patients (e.g. patients with HIV or organ transplants) with an intolerance/allergy to trimethoprim-sulfamethoxazole.</li> <li>• Autoimmune diseases (e.g. pemphigus vulgaris, pemphigoid, dermatitis herpetiformis)</li> <li>• Patients who have previously taken, or are currently taking, dapsone.</li> </ul> <p>Renewals are considered for patients who still require treatment with dapsone.</p>	Lifetime
Fluconazole	Diflucan, Generics	50 mg, 100 mg, tablets 150 mg capsule 10mg/mL oral solution	<p><b>For the prevention of fungal infections post- bone marrow or stem cell transplant until engraftment.</b></p> <p><b>Renewals</b> will be assessed on a case-by-case basis.</p> <p>Note: Fluconazole is reimbursed under <u>limited use</u> status for the following conditions:</p> <ul style="list-style-type: none"> <li>• The treatment of thrush in immunocompromised patients (i.e. patients with malignancies and transplant recipients) who are unresponsive to nystatin or imidazole preparations</li> <li>• the treatment of oroesophageal candidiasis in immunocompromised patients (i.e. patients with malignancies and transplant recipients)</li> <li>• Patients with disseminated candidiasis</li> <li>• Treatment of acute cryptococcal meningitis</li> <li>• For the treatment of vaginal candidiasis</li> </ul>	3 Months
Voriconazole	VFend	50 mg, 200 mg tablets 200 mg/vial injection	<p><b>For the treatment of patients who have culture positive candidemia, due to <i>Candida</i> species, AND with documented resistance to fluconazole.</b> This will be for patients whose therapy is initiated in the hospital by a hospital physician and who require continuation of therapy when they are discharged as an outpatient. Oral tablets will be authorized for those with a properly functioning gastrointestinal (GI) tract and the parental injection will be authorized for those who do not have a properly functioning GI.</p>	1 Month

ANKYLOSING SPONDYLITIS DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p>For the treatment of ankylosing spondylitis (AS) OR psoriatic spondylitis (PS) in patients who have severe active disease with:</p> <ul style="list-style-type: none"> <li>• Age of disease onset <math>\leq</math> 50; <b>AND</b></li> <li>• Low back pain and stiffness for &gt; 3 months that improves with exercise and not relieved by rest; <b>AND</b></li> <li>• Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; <b>AND</b></li> <li>• BASDAI score of <math>\geq</math> 4 for at least 4 weeks while on standard therapy; <b>AND</b></li> </ul> <p>The information submitted with the request must include the following:</p> <ul style="list-style-type: none"> <li>• A list of current concomitant medications related to the AS/PS, including pain medications (if relevant). Please include dosing regimens.</li> <li>• Details of review of radiographic reports for severe active disease: <ul style="list-style-type: none"> <li>○ X-ray or CT scan report stating the presence of “SI joint fusion” or “SI joint erosion” OR</li> <li>○ MRI report stating the presence of “inflammation” or “edema” of the SI joint</li> <li>○ Actual radiographic reports must be submitted with the request. If the radiographic reports do not specify the above, the request will be reviewed by</li> </ul> </li> </ul>	Initial: 1 year
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection		
Golimumab	Simponi	50 mg/0.5 ml prefilled syringe and autoinjector		

Infliximab	Remicade	100mg/10mL intravenous infusion	<p>external medical experts.</p> <p>Additional information that should be provided if applicable:</p> <ul style="list-style-type: none"> <li>• Schober measurement and chest expansion measurement</li> <li>• Evidence of restricted spinal mobility</li> <li>• If the patient has AS/PS with predominantly peripheral joint involvement, additional information pertaining to trials of DMARDs must be provided, and these requests will be reviewed by external medical experts.</li> </ul> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 50% reduction in BASDAI score or <math>\geq 2</math> absolute point reduction in BASDAI score. Please provide an update on concomitant medications for AS/PS and whether there has been a reduction in pain medication for AS/PS since initiating the biologic (if applicable).</p> <p>For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of AS/PS are as follows:</p> <ol style="list-style-type: none"> <li>1. Adalimumab 40mg every other week.</li> <li>2. Etanercept 25mg twice weekly or 50mg once weekly</li> <li>3. Golimumab 50 mg once a month</li> <li>4. Infliximab 3-5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6 to 8 weeks.</li> </ol>	Renewal: 1 year
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ASTHMA				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
<b>Leukotriene Receptor Antagonists</b>				
Zafirlukast	Accolate	20 mg tablet	<p><b>For the treatment of asthma patients who cannot manage the use of an inhalation device despite assistance with a spacer (e.g. physically or mentally disabled patients or pediatric patients).</b></p> <p>OR</p> <p><b>For the treatment of asthma in children and adolescents whose asthma cannot be controlled on ICS alone</b> and where the condition remains uncontrolled despite using full doses of ICS with addition of LABA, and with assurance of good adherence and inhaler technique</p> <p><b>Renewal</b> of requests that meet the above criteria will be provided where the following apply:</p> <ul style="list-style-type: none"> <li>• Current medications and dosages must be clearly specified; AND</li> <li>• Objective evidence of positive response from treatment (spirometry OR decrease in health care utilization) must be provided</li> </ul>	<p>Initial: 5 years Renewal: 5 years</p>
Montelukast	Singulair	5 mg, 10 mg tablet	<p><b>Renewal</b> of requests that meet the above criteria will be provided where the following apply:</p> <ul style="list-style-type: none"> <li>• Current medications and dosages must be clearly specified; AND</li> <li>• Objective evidence of positive response from treatment (spirometry OR decrease in health care utilization) must be provided</li> </ul>	<p>Initial: 5 years (up until age of 18) Renewal: 5 years (up until age of 18)</p>
Omalizumab	Xolair	150 mg/ vial	<p><b>For the treatment of severe uncontrolled asthma</b> in patients who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• Has required hospitalization for asthma within the past 12 months; OR</li> <li>• Has required two or more urgent visits for asthma to a physician or an emergency department within the past 12 months; OR</li> <li>• Has had two or more courses of high-dose oral corticosteroids* in the past 12 months; AND</li> <li>• Is age 12 years or older; AND</li> <li>• Has demonstrated a positive skin test or in vitro reactivity to a perennial aeroallergen; AND</li> <li>• Has a baseline IgE level between 30 and 700 IU/mL (inclusive) ; AND</li> <li>• Has an actual body weight between 20 kg to 150 kg (inclusive); AND</li> <li>• Is receiving treatment with a high-dose inhaled corticosteroid* in addition to a long-acting inhaled beta 2-agonist. (Note: the patient can be on other concomitant therapies as well); AND</li> </ul>	<p>Initial: 1 Year</p>

Omalizumab	Xolair	150 mg/vial	<ul style="list-style-type: none"> <li>• Is deemed to be adherent and is using his/her inhaled corticosteroid and long-acting beta agonist daily as prescribed; AND</li> <li>• Is using proper inhaler technique (with a spacer if required); AND</li> <li>• The request for Xolair is made by the patient's specialist in respirology or allergy/clinical immunology. (Note: Individual consideration can be given for extenuating circumstances where access to these specialists is not possible.)</li> </ul> <p>* High-dose oral corticosteroids is considered the use of more than 1000 mcg of beclomethasone dipropionate (BDP) equivalents daily</p> <p>To avoid delays in the assessment of the request, physicians should provide the following information within their request submission.</p> <ol style="list-style-type: none"> <li>1. The number of hospitalizations for asthma in the past 12 months.</li> <li>2. The number of asthma exacerbations requiring urgent visits to a physician or emergency department in the past 12 months.</li> <li>3. The average number of night-time awakenings in a one week period (reflective of control in last 12 months).</li> <li>4. The average number of puffs/day of short-acting beta-agonists within a one week period (reflective of control in last 12 months).</li> <li>5. The number of courses of prednisone (or acute increases in prednisone dose if the patient is already using chronic daily prednisone) for asthma exacerbation in the past 12 months.</li> <li>6. The FEV<sub>1</sub> pre and post bronchodilator.</li> <li>7. Patient's actual body weight.</li> <li>8. The serum IgE level.</li> <li>9. Results of a positive allergy testing by skin prick test or IgE RAST.</li> <li>10. A list of all of the patient's current asthma medications including drug name and doses.</li> <li>11. Confirmation that the patient's asthma is currently uncontrolled despite optimal therapy (including confirmation of proper inhaler technique), patient adherence to current therapy, and the removal of allergic and environmental triggers or the reduction of such triggers to the fullest extent possible.</li> </ol> <p>Note that contraindications and intolerance to inhaled corticosteroids and/or long-acting beta agonists will not be considered as a justification to request Xolair funding.</p>	
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Omalizumab	Xolair	150 mg/vial	<p><b>Renewal</b> of requests for Xolair will be considered in patients who have a positive clinical response to the drug and who are expected to continue to do so. Renewals will be considered on a case-by-case basis and should be accompanied by the following information:</p> <ol style="list-style-type: none"> <li>1. The number of hospitalizations for asthma in the past 12 months</li> <li>2. The number of asthma exacerbations requiring urgent visits to a physician or Emergency Department in the past 12 months</li> <li>3. The number of courses of prednisone (or acute increases in prednisone dose if patient is already using chronic daily prednisone) for asthma exacerbations in the past 12 months.</li> <li>4. The number of nighttime awakenings (over a several week period post-introduction of therapy)</li> <li>5. The average number of puffs/day of short-acting beta-agonists used per day (over a several week period post-introduction of therapy)</li> <li>6. The FEV<sub>1</sub> pre and post bronchodilator</li> <li>7. All current asthma medications taken by the patient including drug names and dosing schedule.</li> </ol>	Renewal: Up to 1 year
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**BLOOD MODIFIERS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Deferasirox	Exjade	125 mg, 250 mg, 500 mg tablet	<p><b>For the treatment of patients with chronic iron overload in transfusion-related anemia due to B-thalassemia or sickle cell disease</b> in patients who meet the following criteria;</p> <ul style="list-style-type: none"> <li>i) Patient is 6 years of age or older; OR</li> <li>ii) The patient is between 2 to 5 years of age (inclusive) and cannot be adequately treated with deferoxamine.</li> </ul> <p>Combination therapy (i.e., Exjade in addition to another iron chelating agent) will not be approved.</p> <p>Note, that therapy should be initiated and maintained by physicians experienced in the treatment of chronic iron overload due to blood transfusions.</p> <p>Renewal is considered in patients who continue to require iron chelation therapy and has had a consistent response to therapy (demonstrated by a reduction in baseline LIC levels).</p> <p>The following documentation is required for renewals:</p> <ul style="list-style-type: none"> <li>• A transfusion record from the past year; AND</li> <li>• LIC levels – baseline (pre-treatment) and since initiation of treatment. The most recent LIC level should be from within the previous year.</li> </ul> <p><b>For the treatment of chronic iron overload in transfusion-dependent anemia in those with low-risk myelodysplastic syndrome (MDS) or other rare anemias (e.g. Diamond Blackfan)</b> in patients who have a contraindication or severe intolerance to deferoxamine.</p> <p>Contraindications may include one or more of the following:</p> <ul style="list-style-type: none"> <li>• known or suspected hypersensitivity to deferoxamine</li> <li>• recurrent injection or infusion-site reactions (e.g., cellulitis)</li> <li>• concomitant bleeding disorder</li> <li>• immunocompromised patients with a documented risk of significant infections with parenteral administration (e.g. neutropenia)</li> </ul> <p><b>Renewals</b> will be considered on a case-by-case basis. Physicians must provide adequate information to support the request for renewal.</p>	<p>Initial: 5 years</p> <p>Renewal: 5 years</p> <p>Initial: 5 years</p> <p>Renewal: 5 years</p>

Prasugrel	Effient	10 mg tablet	<p>For patients with Acute Coronary Syndrome (ACS) within one year of unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI), or ST elevation myocardial infarction (STEMI) treated with percutaneous coronary intervention (PCI), who have angiographically demonstrated definite stent thrombosis* while on clopidogrel OR who have true clopidogrel allergy.</p> <p>*thrombosis must be at the stent site</p> <p>The physician will be required to provide the date of the event, type of event, and a description of clopidogrel allergy (if applicable).</p> <p>Reimbursement of prasugrel will not be considered for:</p> <ul style="list-style-type: none"> <li>• Patients with intolerances or other contraindications to clopidogrel</li> <li>• Patients with prior history of stroke or transient ischemic attack (TIA)</li> <li>• Patients aged 75 years or older</li> <li>• Patients with a body weight of less than 60 kg</li> </ul> <p>No renewals after the initial approval will be considered.</p>	15 months
Romiplostim	Nplate	250 mcg/0.5 mL 500 mcg/ 1 mL	<p><b>For the treatment of refractory chronic idiopathic thrombocytopenic purpura (ITP)</b> with bleeding complications in patients who meet the following criteria;</p> <p>i) Patient has undergone a splenectomy<sup>1</sup></p> <p><sup>1</sup>Requests for romiplostim where the requesting physician has stated that the patient is not a candidate for splenectomy will be assessed on a case-by-case basis. The requesting physicians must provide rationale for why a splenectomy cannot be considered, and where possible, to include a preoperative evaluation on the patient's surgical risks to splenectomy to include consideration of risks of laparoscopic and open surgical interventions if these are available.</p> <p><i>Note: The Executive Officer (EO) may revise the criteria if the frequency of patients who are not eligible for splenectomy exceeds published estimates.</i></p> <p>ii) Patient has tried and is unresponsive to other treatment modalities*.</p> <p>*Appropriate first-line treatment modalities may include;</p> <ul style="list-style-type: none"> <li>• Corticosteroids</li> <li>• IV anti-D</li> </ul>	Initial: 1 year

			<ul style="list-style-type: none"> <li>• Intravenous immune globulin (IVIG)</li> </ul> <p>*Appropriate second-line treatment modalities may include;</p> <ul style="list-style-type: none"> <li>• Azathioprine</li> <li>• Cyclosporine</li> <li>• Cyclophosphamide</li> <li>• Mycophenolate</li> <li>• Rituximab</li> <li>• Danazol</li> <li>• Dapsone</li> </ul> <p>Patients need to have failed at least two second-line therapies prior to requesting romiplostim.</p> <p><b>Renewal</b> of requests will be considered in patients who have a stable platelet response and reduced symptoms of ITP-related bleeding events.</p>	Renewal: 1 year
Eculizumab	Soliris	10 mg/mL (300 mg per vial)	<p><b>For the treatment of patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)</b> meeting the following criteria:</p> <p>The diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) has been made based on the following confirmatory results:</p> <ul style="list-style-type: none"> <li>• Flow cytometry/FLAER exam with granulocytes clone <math>\geq 10\%</math> <b>AND</b></li> <li>• LDH &gt; 1.5 ULN</li> </ul> <p><b><u>AND at least one of the following:</u></b></p> <ul style="list-style-type: none"> <li>• A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,</li> <li>• Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,</li> <li>• Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70 g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia,</li> <li>• Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,</li> <li>• Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73 m<sup>2</sup>, where causes other than PNH have been excluded,</li> <li>• Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization</li> </ul>	Initial: 6 months

			<p>and/or narcotic analgesia, where causes other than PNH have been excluded.</p> <p><b>The dose of eculizumab that will be considered is: 600 mg once per week for the first 4 weeks, then from week five of treatment, 900 mg once every 2 weeks</b></p> <p><b>Renewals</b> will be considered for patients who;</p> <ul style="list-style-type: none"> <li>• Demonstrate clinical improvement while on therapy or</li> <li>• Where therapy has been shown to stabilize the patient’s condition.</li> </ul> <p>Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).</p> <p><b>Further, subsidized treatment may continue unless one or more of the following situations apply:</b></p> <ol style="list-style-type: none"> <li>i) The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;</li> <li>ii) If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment;</li> </ol> <p><b>Other eligibility requirements:</b> Note: All patients must receive meningococcal vaccination with a tetravalent vaccine at least two weeks prior to receiving the first dose of eculizumab.</p> <p><b>Exclusion criteria for both initial and renewal requests:</b></p> <ol style="list-style-type: none"> <li>i) Small granulocyte clone size - the treatment of patients with a granulocyte clone size below 10% will not be eligible for treatment; <b>OR</b></li> <li>ii) Aplastic anemia with two or more of the following: neutrophil count below <math>0.5 \times 10^9/L</math>, platelet count below <math>20 \times 10^9/L</math>, reticulocytes below <math>25 \times 10^9/L</math>, or severe bone marrow hypocellularity; <b>OR</b></li> <li>iii) Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); <b>OR</b></li> <li>iv) The presence of another medical condition that might reasonably be expected to compromise a response to therapy.</li> </ol>	<p>Renewal: 1 year</p>
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**CARDIOLOGY DRUGS**

<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Eplerenone	Inspra	25 mg, 50 mg tablets	<p><b>For the treatment of patients who have heart failure and left ventricular systolic dysfunction due to acute myocardial infarction.</b> Patients must have:</p> <ul style="list-style-type: none"> <li>• An ejection fraction <math>\leq</math> 40% <b>AND</b></li> <li>• Prior trial of spironolactone but experienced severe symptomatic (painful) gynecomastia</li> </ul>	Lifetime

**CENTRAL NERVOUS SYSTEM DRUGS**

<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Modafanil	Alertec	100 mg tablet	<p><b>For the symptomatic treatment of excessive daytime sleepiness in patients with narcolepsy</b> who have demonstrated a lack of response to or an inability to tolerate dextroamphetamine <b>AND</b> methylphenidate.</p> <p>Note: See also Multiple Sclerosis Drugs</p>	1 Year

CROHN'S DISEASE DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Infliximab	Remicade	100mg/10mL intravenous infusion	<p><b>Treatment of <u>fistulizing</u> Crohn's Disease</b> in patients who have:</p> <ul style="list-style-type: none"> <li>Actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of antibiotic therapy (ciprofloxacin and/or metronidazole) and immunosuppressive therapy (azathioprine or 6-mercaptopurine).</li> </ul> <p><i>Note: Any intolerance(s) or contraindication(s) to treatment with required alternative(s) must be described in detail.</i></p> <p><b>Renewal</b> will be considered for patients with resolution of fistulae.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended dose for the treatment of Crohn's Disease is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks.</p>	<p>Initial: 3 months</p> <p>Renewal: 1 year</p>
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p><b>For the treatment of fistulising Crohn's disease with concomitant luminal disease in patients who meet the following criteria;</b></p> <ul style="list-style-type: none"> <li>Patient with actively draining perianal or enterocutaneous fistula(e) that have recurred or persist despite a course of appropriate antibiotic therapy (e.g. ciprofloxacin and/or metronidazole) AND immununosuppressive therapy (e.g. azathioprine or 6-mercaptopurine) AND</li> <li>Harvey Bradshaw Index (HBI) score <math>\geq 7</math></li> </ul> <p>The dose that will be considered is Adalimumab (Humira) 160 mg at week zero, 80 mg at week two, followed by 40 mg every two weeks.</p> <p><b>Renewal</b> will be considered based on the response to therapy.</p> <p>The dose that will be considered on renewals is Adalimumab (Humira) 40 mg every two weeks. All requests for higher doses will not be approved.</p>	<p>Initial: 3 months</p> <p>Renewal: 3 months to 1 year pending fistula(e) resolution</p>

Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p><b>Treatment of moderate to severe (luminal) Crohn's Disease</b> in patients who have:</p> <ul style="list-style-type: none"> <li>• HBI (Harvey Bradshaw Index) score <math>\geq 7^*</math>; and</li> <li>• Failed to respond to conventional treatment with glucocorticoids (prednisone 40mg/day or equivalent for at least 2 weeks <u>or</u> dose cannot be tapered to below prednisone 20 mg/day or equivalent); and</li> <li>• Failed to respond to an immunosuppressive agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) tried for at least 3 months.</li> </ul> <p><i>Note: Any intolerance(s) or contraindication(s) to treatment with required alternative(s) must be described in detail.</i></p>	Initial: 3 months Renewal: 1 year
Infliximab	Remicade	100mg/10mL intravenous infusion	<p>*If the patient has HBI <math>&lt; 7</math>, the request will be reviewed by external medical experts when the following information is provided: bloodwork (with hematocrit, hemoglobin, C reactive protein, ESR, platelets, and ferritin levels); supporting endoscopy; details of weight loss; and a list of narcotic analgesics being used.</p> <p><b>Renewal</b> will be considered for patients with 50% reduction in HBI from pre-treatment as well as improvement of symptoms (e.g., absence of bloody diarrhea and weight stabilization or increase) and no longer using steroids. Biochemical improvements may also be required.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of Crohn's Disease are as follows:</p> <ul style="list-style-type: none"> <li>○ Adalimumab: 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks</li> <li>○ Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks then 5mg/kg/dose every 8 weeks</li> </ul>	

DERMATOLOGY DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Imiquimod	Aldara	5% Cream	<p><b>For the treatment of external genital and perianal warts/condyloma acuminata</b> in patients who;</p> <ul style="list-style-type: none"> <li>• Have documented failure to a trial of podophyllum resin <u>and</u> one other treatment modality (including cryotherapy, surgical excision, or electrosurgery).</li> </ul> <p><b>For the treatment of biopsy-confirmed primary superficial basal cell carcinoma</b> in patients meeting the following criteria;</p> <ul style="list-style-type: none"> <li>• Tumour diameter of <math>\leq 2</math> cm AND</li> <li>• Tumour location on the trunk, neck or extremities (excluding hands and feet) AND</li> <li>• Surgery or irradiation therapy is not medically indicated (e.g. recurrent lesions in previously irradiated area, number of lesions too numerous to irradiate or remove surgically)</li> </ul> <p><b>Renewals</b> for the same tumour will not be considered.</p>	<p>1 year (Maximum of 16 weeks for each treatment course )</p> <p>6 weeks</p>

## HEPATITIS B DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
<p><b>For the treatment of Chronic Hepatitis B</b>                      HBsAg, HBeAg, Anti-HBe, HBV DNA, and ALTs including pre-treatment and current data are required for ALL initial requests</p> <p>* Lamivudine virological breakthrough is defined as an increase in HBV DNA of <math>\geq 1 \log_{10}</math> IU/mL above the nadir, measured on two separate occasions at least one month apart, after at least three months of therapy.</p> <p>** Adefovir virological breakthrough is defined as an increase in HBV DNA of <math>\geq 1 \log_{10}</math> IU/mL above the nadir, measured on two separate occasions at least one month apart, after at least three months of therapy; <b>or</b> a HBV DNA &gt; 200 IU/mL after one year of treatment.</p> <p>*** Lamivudine resistance is defined as a HBV DNA &gt; 200 IU/mL after one year of treatment <b>or</b> the presence of lamivudine-resistant mutation (i.e. YMDD), requires copy of mutation report.</p> <p>**** Adefovir is considered contra-indicated in patients with progressive worsening of renal function despite adequate dose reduction of adefovir.</p> <p>***** Presence of lamivudine-resistant mutation (i.e. YMDD), requires copy of mutation report.</p>				
Adefovir	Hepsera	10mg tablet	For the treatment of chronic hepatitis B in patients with objective evidence of lamivudine virologic* breakthrough where failure is not due to poor adherence to therapy; AND <ul style="list-style-type: none"> <li>○ Liver biopsy showing Metavir stage 3 fibrosis or greater; OR</li> <li>○ Documented evidence of cirrhosis.</li> </ul> OR <ul style="list-style-type: none"> <li>● Patients with the presence of a lamivudine resistance mutation*****; AND</li> <li>○ Liver Biopsy showing Metavir stage 3 fibrosis or greater; OR</li> <li>○ Documented evidence of cirrhosis.</li> </ul>	1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Entecavir	Baraclude	0.5mg tablet	<p><b>For the treatment of chronic hepatitis B in lamivudine naïve patients</b> with high viral load (<math>&gt; 1 \times 10^6</math> IU/mL); AND</p> <ul style="list-style-type: none"> <li>○ Liver biopsy showing Metavir stage 4 fibrosis; OR</li> <li>○ Other documented evidence of cirrhosis.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>Patients with inadequate response to lamivudine</b> defined as: <ul style="list-style-type: none"> <li>○ Less than 2 <math>\log_{10}</math> drop in HBV DNA after three months of lamivudine therapy; <b>OR</b></li> <li>○ Incomplete suppression of viral load after six months of lamivudine therapy; <b>AND</b></li> <li>○ Documented evidence of cirrhosis</li> </ul> </li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>Patients with objective evidence of lamivudine virologic breakthrough* AND</b> documented evidence of cirrhosis; <b>AND</b> <ul style="list-style-type: none"> <li>○ Adefovir virologic breakthrough**; <b>OR</b></li> <li>○ Contraindication to adefovir therapy****.</li> </ul> </li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>Patients with the presence of a lamivudine resistance mutation*****; AND</b> documented evidence of cirrhosis; <b>AND</b> <ul style="list-style-type: none"> <li>○ Adefovir virologic breakthrough**; <b>OR</b></li> <li>○ Contraindication to adefovir therapy****.</li> </ul> </li> </ul>	1 Year
Interferon - alpha	Intron A	18 MU 30 MU 60 MU	<p><b>For the treatment of chronic hepatitis B</b> where the patient meets the following criteria:</p> <ul style="list-style-type: none"> <li>• Patients less than 50 years of age; and</li> <li>• 2 ALTs <math>&gt; 2 \times</math> ULN within the past 6 month period; and</li> <li>• HBV DNA between <math>1 \times 10^4 - 1 \times 10^7</math> IU/mL; and</li> <li>• Liver biopsy showing Metavir stage 3 fibrosis or less (i.e. no cirrhosis)</li> </ul>	HBeAg pos: 24 weeks HBeAg neg: 48 weeks

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Lamivudine	Heptovir	100 mg tablet	<p><b>For the treatment of chronic hepatitis B in treatment naïve patient, age <math>\geq</math> 40 years old with HBV DNA <math>&gt;</math> 1,000IU/mL; AND</b></p> <ul style="list-style-type: none"> <li>○ Three separate ALT levels <math>\geq</math> 1.3 x ULN within the 6 month period prior to treatment; <b>OR</b></li> <li>○ Liver biopsy showing Metavir stage 3 fibrosis or greater; <b>OR</b></li> <li>○ Documented evidence of cirrhosis.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>Treatment naïve patient, age <math>&lt;</math> 40 years old with HBV DNA <math>&gt;</math> 1,000 IU/mL; AND</b></li> <li>○ Liver biopsy showing Metavir stage 3 fibrosis or greater; <b>OR</b></li> <li>○ Documented evidence of cirrhosis.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>HBsAg-positive treatment naïve patient (any age) who has received an organ transplant other than liver with a detectable viral load; AND three separate ALT levels <math>\geq</math> 1.3 x ULN within the 6 month period prior to treatment .</b></li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>HBsAg-positive treatment naïve patient (any age) who is considered to be immunosuppressed, with a detectable viral load; AND three separate ALT levels <math>\geq</math> 1.3 x ULN within the 6 month period prior to treatment.</b></li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>HBsAg-positive treatment naïve patient (any age) who is about to undergo chemotherapy. (Approval time: duration of chemo + 6 months)</b></li> </ul> <p>Requests for the addition of lamivudine to patients with adefovir resistance will be considered for patients who would have originally met the initial lamivudine criteria where HBV DNA <math>&gt;</math> 1,000 IU/mL; <b>AND</b></p> <ul style="list-style-type: none"> <li>• Three separate ALT levels <math>\geq</math> 1.3 x ULN within the 6 month period prior to treatment; <b>OR</b></li> <li>• Liver biopsy showing Metavir stage 3 fibrosis or greater; <b>OR</b></li> <li>• Documented evidence of cirrhosis.</li> </ul>	1 Year unless otherwise stated

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Tenofovir	Viread	300 mg tablet	<p><b>For the treatment of chronic hepatitis B in patients who are treatment naïve with high viral load (&gt; 1 x 10<sup>6</sup> IU/mL); AND</b></p> <ul style="list-style-type: none"> <li>○ Liver biopsy showing Metavir stage 4 fibrosis; <b>OR</b></li> <li>○ Other documented evidence of cirrhosis.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>Patients who have inadequate response to lamivudine</b> defined as: <ul style="list-style-type: none"> <li>○ Less than 2 log<sub>10</sub> drop in HBV DNA after three months of lamivudine therapy; <b>OR</b></li> <li>○ Incomplete suppression of viral load after six months of lamivudine therapy <b>AND</b></li> <li>○ Liver Biopsy showing Metavir stage 3 fibrosis or greater <b>OR</b></li> <li>○ Documented evidence of cirrhosis.</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>Patients with objective evidence of lamivudine virologic breakthrough* where failure is not due to poor adherence to therapy AND</b> <ul style="list-style-type: none"> <li>○ Liver Biopsy showing Metavir stage 3 fibrosis or greater; <b>OR</b></li> <li>○ Documented evidence of cirrhosis.</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• <b>Patients with the presence of a lamivudine resistance mutation*****AND</b> <ul style="list-style-type: none"> <li>○ Liver Biopsy showing Metavir stage 3 fibrosis or greater <b>OR</b></li> <li>○ Documented evidence of cirrhosis.</li> </ul> </li> </ul> <p>Requests for tenofovir in pregnant patients are considered on an individual case-by-case basis via external review.</p>	1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
<b>Renewals</b>				
HBsAg, HBeAg, Anti-HBe, HBVDNA, and ALTs are required for ALL renewal requests for classic patients.				
Only HBsAg and HBV DNA required for ALL renewal requests for pre-core mutant patients.				
Adefovir Entecavir Lamivudine Tenofovir	Hepsera Baraclude Heptovir Viread	10 mg tablet 0.5 mg tablet 100 mg tablet 300 mg tablet	<ul style="list-style-type: none"> <li>• <b>For patients receiving therapy (monotherapy or any combination therapy) who have not seroconverted</b> (e.g. remain HBeAg positive and anti-HBe negative) and are not demonstrating virological breakthrough.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>Initial renewal requests for patients who were initially HBeAg positive and seroconverted to anti-HBe positive.</b> (6 month renewal)</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>Subsequent renewal requests for patients who were initially HBeAg positive and seroconverted to anti-HBe positive</b> where: <ul style="list-style-type: none"> <li>○ Reactivation has occurred ( two ALTs &gt; 1.3 x ULN at least one month apart or one ALT &gt; 2.5 x ULN; AND a HBV DNA &gt; 1000 IU/mL)</li> <li>○ If no reactivation, rationale for continuing therapy must be provided and the request will be considered on an individual case-by-case basis via external review.</li> </ul> </li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• <b>For patients who were HBeAg negative initially</b> (i.e. pre-treatment with antiviral agents) <b>and continues to be HBsAg positive</b> (i.e. Pre-core mutant).</li> </ul>	1 year unless otherwise stated
<b>Pre- or Post- Liver transplant</b>				
Patients not meeting the criteria below and patients with other organ transplants will be considered on an individual case-by-case basis via external review.				
* Lamivudine virological breakthrough is defined as an increase in HBV DNA of $\geq 1 \log_{10}$ IU/mL above the nadir, measured on two separate occasions at least one month apart, after at least three months of therapy.				
** Adefovir virological breakthrough is defined as an increase in HBV DNA of $\geq 1 \log_{10}$ IU/mL above the nadir, measured on two separate occasions at least one month apart, after at least three months of therapy; <b>or</b> a HBV DNA > 200 IU/mL after one year of treatment.				
*** Lamivudine resistance is defined as a HBV DNA > 200 IU/mL after one year of treatment <b>or</b> the presence of lamivudine-resistant mutation (i.e. YMDD), requires copy of mutation report.				
**** Adefovir is considered contra-indicated in patients with progressive worsening of renal function despite adequate dose reduction of adefovir.				
Adefovir	Hepsera	10 mg tablet	<ul style="list-style-type: none"> <li>• Patients with objective evidence of lamivudine virologic breakthrough* or lamivudine resistance*** or a contraindication to lamivudine therapy; AND where failure is not due to poor adherence to therapy.</li> </ul>	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Entecavir	Baraclude	0.5 mg tablet	<ul style="list-style-type: none"> <li>• Lamivudine-naïve pre- or post-liver transplant patients with documented evidence of cirrhosis AND a high viral load (<math>&gt; 1 \times 10^6</math> IU/mL).</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Pre- or post-liver transplant patients with objective evidence of lamivudine virologic breakthrough* or lamivudine resistance*** or a contraindication to lamivudine; <b>AND</b> either adefovir virological breakthrough** or a contraindication to adefovir therapy****</li> </ul>	Lifetime
Lamivudine	Heptovir	100 mg tablet	<ul style="list-style-type: none"> <li>• Patients who are treatment naïve (any age) and HBsAg-positive.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Patients who have objective evidence of adefovir virologic breakthrough** or adefovir resistance or a contraindication to adefovir therapy****; <b>AND</b> where failure is not due to poor adherence to therapy.</li> </ul>	Lifetime
Tenofovir	Viread	300 mg tablet	<ul style="list-style-type: none"> <li>• Patients who are lamivudine-naïve with documented evidence of cirrhosis AND a high viral load (<math>&gt; 1 \times 10^6</math> IU/mL).</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Patients who have objective evidence of lamivudine virologic breakthrough* or lamivudine resistance*** or a contraindication to lamivudine therapy; <b>AND</b> where failure is not due to poor adherence to therapy.</li> </ul>	Lifetime

**HEPATITIS C DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION												
Boceprevir	<p>Victrelis</p> <p>Victrelis Triple (4 strengths)</p>	<p>200 mg capsule</p> <p>Triple combination treatment with varying strengths of peginterferon alfa-2b powder</p> <p>200 mg (B)/ 200 mg (R)/ 80 mcg (P)</p> <p>200 mg (B)/ 200 mg (R)/ 100 mcg (P)</p> <p>200 mg (B)/ 200 mg (R)/ 120 mcg (P)</p> <p>200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)</p>	<p><b>For the treatment of chronic hepatitis C in <u>treatment naïve patients</u> with genotype 1,</b> in combination with peginterferon alfa and ribavirin (PR) who meet ALL of the following:</p> <ul style="list-style-type: none"> <li>• Patient has a quantitative HCV RNA value from within the last 6 months</li> <li>• &lt; 70 years old OR ≥ 70 years old with no co-morbid conditions</li> <li>• Fibrosis stage F2 or greater (Metavir scale or equivalent)</li> <li>• No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6)</li> </ul> <p>Also please note the case-by-case<sup>1</sup> criteria and exclusion criteria<sup>2</sup> stated below.</p> <p><u>Dosing:</u></p> <p>Boceprevir(B) dosage: 800 mg three times daily</p> <ul style="list-style-type: none"> <li>○ Patients must also meet peginterferon/ribavirin criteria, as applicable (<i>Note: The PR criteria are currently under review</i>)</li> <li>○ HCV RNA laboratory values must be from within the last 6 months preceding the EAP request application.</li> </ul> <p>It is recommended that boceprevir dosing follow the response-guided therapy (RGT) as described in Table 1 and that the futility rule be followed as applicable. Boceprevir is to be initiated after a 4-week lead-in period with peginterferon alfa and ribavirin therapy:</p> <p>Table 1:</p> <table border="1" data-bbox="808 1101 1780 1338"> <thead> <tr> <th colspan="3">Response-guided therapy for <u>treatment naïve</u> patients with NO cirrhosis</th> </tr> <tr> <th>HCV RNA at Treatment Week 8</th> <th>HCV RNA at Treatment week 24</th> <th>Action</th> </tr> </thead> <tbody> <tr> <td>Undetectable</td> <td>Undetectable</td> <td>Stop all therapy at treatment week 28.</td> </tr> <tr> <td>Detectable</td> <td>Undetectable</td> <td>Stop boceprevir at treatment week 28; continue pegylated interferon/ribavirin until week 48.</td> </tr> </tbody> </table> <p><u>In treatment naïve patients with compensated cirrhosis</u> it is recommended that boceprevir is</p>	Response-guided therapy for <u>treatment naïve</u> patients with NO cirrhosis			HCV RNA at Treatment Week 8	HCV RNA at Treatment week 24	Action	Undetectable	Undetectable	Stop all therapy at treatment week 28.	Detectable	Undetectable	Stop boceprevir at treatment week 28; continue pegylated interferon/ribavirin until week 48.	<p><b>Initial Requests in Treatment Naïve:</b></p> <p><u>No Cirrhosis:</u></p> <p>24 weeks (B) 48 weeks (PR)</p> <p><u>Compensated Cirrhosis:</u></p> <p>44 weeks (B) 48 weeks (PR)</p> <p><i>Note: Extension of boceprevir beyond the stated durations above will not be considered for any patients.</i></p>
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Undetectable	Undetectable	Stop all therapy at treatment week 28.														
Detectable	Undetectable	Stop boceprevir at treatment week 28; continue pegylated interferon/ribavirin until week 48.														

			<p>initiated after a 4-week lead-in period with peginterferon alfa and ribavirin (i.e., 44 weeks of boceprevir therapy and 48 weeks of PR) and it is recommended that the futility rule be followed as applicable.</p> <p><u>Treatment Futility Rule:</u> If the patient has HCV RNA results <math>\geq 100</math> IU/mL at treatment week 12 or if the patient has confirmed detectable HCV RNA at treatment week 24, then discontinue the triple therapy regimen.</p> <p><u>Renewals</u> are not considered.</p> <p><b>For the treatment of chronic hepatitis C in <u>treatment experienced patients</u> (partial responders/non-responders or relapsers; excludes previous null responders*) with genotype 1</b> in combination with peginterferon alfa and ribavirin (PR) who meet ALL of the following:</p> <ul style="list-style-type: none"> <li>• Patient has a quantitative HCV RNA value from within the past 6 months*</li> <li>• &lt; 70 years old OR <math>\geq 70</math> years old with no co-morbid conditions</li> <li>• Fibrosis stage F2 or greater (Metavir stage or equivalent)</li> <li>• No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6)</li> </ul> <p>* Null responders are considered those with a decrease in HCV RNA of &lt; 2 logs IU/mL by week 12 on previous therapy.</p> <p><u>Dosing:</u></p> <p>Boceprevir dosage: 800 mg three times daily</p> <ul style="list-style-type: none"> <li>○ Patients must also meet peginterferon/ribavirin criteria, as applicable (<i>Note: The PR criteria are currently under review</i>)</li> <li>○ HCV RNA laboratory values must be from within the last 6 months preceding the EAP request application.</li> </ul> <p>It is recommended that boceprevir dosing follow the response-guided therapy (RGT) as described in Table 2 and that the futility rule be followed as applicable. Boceprevir is to be initiated after a 4-week lead-in period with peginterferon alfa and ribavirin therapy:</p>	<p><b>Initial Requests in Treatment Experienced:</b></p> <p><u>No Cirrhosis:</u></p> <p>32 weeks (B) 48 weeks (PR)</p> <p><u>Compensated Cirrhosis:</u></p> <p>44 weeks (B) 48 weeks (PR)</p> <p><i>Note: Extension of boceprevir beyond the stated durations above will not be considered for any patients.</i></p>
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		<p>Table 2:</p> <table border="1"> <tr> <th colspan="3">Response-guided therapy for <u>treatment experienced</u> patients with NO cirrhosis</th> </tr> <tr> <th>HCV RNA at Treatment Week 8</th> <th>HCV RNA at Treatment week 24</th> <th>Action</th> </tr> <tr> <td>Undetectable</td> <td>Undetectable</td> <td>Stop all therapy at treatment week 36.</td> </tr> <tr> <td>Detectable</td> <td>Undetectable</td> <td>Stop boceprevir at treatment week 36; continue pegylated interferon/ribavirin until week 48.</td> </tr> </table> <p><u>In treatment experienced patients with compensated cirrhosis</u> it is recommended that boceprevir is initiated after a 4-week lead-in period with peginterferon alfa and ribavirin (i.e., 44 weeks of boceprevir therapy and 48 weeks of PR) and it is recommended that the futility rule be followed as applicable.</p> <p><b><u>Treatment Futility Rule:</u></b> If the patient has HCV-RNA results <math>\geq 100</math> IU/mL at treatment week 12 or if the patient has confirmed detectable HCV-RNA at treatment week 24, then discontinue triple therapy regimen</p> <p><b><u>Renewals</u></b> are not considered.</p> <p>Also please note the case-by-case<sup>1</sup> considerations and exclusion criteria<sup>2</sup> stated below.</p> <p><sup>1</sup> <b>Case-by-case considerations:</b> Boceprevir requests will be considered on a <u>case-by-case</u> basis for patients:</p> <ul style="list-style-type: none"> <li>• Who are <math>\geq 70</math> years of age with co-morbid diagnoses that are a relative/strong contraindication (not including criteria noted above where funding will not be considered); <b>OR</b></li> <li>• Who have cirrhosis with Child Pugh Score = B (7-9); <b>OR</b></li> <li>• Who previously tried Pegatron or Pegasys RBV but were unable to finish their treatment course due to intolerance; <b>OR</b></li> <li>• Who have hepatitis B co-infection; <b>OR</b></li> <li>• Who have certain abnormal baseline hematologic and/or clinical chemistry findings.</li> </ul> <p><sup>2</sup> <b>Exclusion criteria:</b> Reimbursement will <b>NOT</b> be considered for patients who meet <i>ANY</i> of the following:</p> <ul style="list-style-type: none"> <li>• Not genotype 1</li> <li>• Null responders to previous treatment (i.e., those with a decrease in HCV RNA of <math>&lt; 2</math> logs IU/mL by week 12)</li> </ul>	Response-guided therapy for <u>treatment experienced</u> patients with NO cirrhosis			HCV RNA at Treatment Week 8	HCV RNA at Treatment week 24	Action	Undetectable	Undetectable	Stop all therapy at treatment week 36.	Detectable	Undetectable	Stop boceprevir at treatment week 36; continue pegylated interferon/ribavirin until week 48.	
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Undetectable	Undetectable	Stop all therapy at treatment week 36.													
Detectable	Undetectable	Stop boceprevir at treatment week 36; continue pegylated interferon/ribavirin until week 48.													

			<ul style="list-style-type: none"> <li>Fibrosis stage less than F2 (Metavir scale or equivalent)</li> <li>Boceprevir monotherapy</li> <li>Cirrhosis with Child Pugh Score = C (10 or greater)</li> <li>&lt; 18 years of age</li> <li>Decompensated liver disease, including a history of the presence of clinical ascites, bleeding varices, or hepatic encephalopathy</li> <li>HIV co-infection</li> <li>Prior organ transplant including liver transplant</li> </ul>	
Peginterferon Alfa-2B + Ribavirin	Pegetron	Vials: 50 mcg 80 mcg 100 mcg 120 mcg 150 mcg  Redipen: 50 mcg 80 mcg 100 mcg 120 mcg 150 mcg  + 200 mg capsule	<p><i>(Note: The criteria for peginterferon alfa/ribavirin are currently under review Fall 2011)</i></p> <p><b>For the treatment of chronic hepatitis C in patients previously untreated with interferon or peginterferon therapy (i.e. naive patients):</b></p> <p><b>Genotype 2, 3:</b></p> <ul style="list-style-type: none"> <li>Positive HCV RNA. A quantitative value is required.</li> <li>&lt; 70 years old OR ≥ 70 years old with no co-morbid conditions * <b>AND</b></li> <li>No diagnosis of cirrhosis <b>OR</b> cirrhosis with a Child-Pugh score of ≤ 6.</li> </ul> <p><b>Genotype other than 2 and 3.(e.g. 1, 4, 5, 6, and others):</b></p> <ul style="list-style-type: none"> <li>HCV genotype must be provided, <b>AND</b></li> <li>Positive HCV RNA. A quantitative value is required, <b>AND</b></li> <li>At least two elevated ALT values (more than 1.5 times the upper limit of normal values) within the previous six months <b>OR</b> fibrosis on biopsy (Stage 2 or greater) (This criteria is not needed if patient has co-infection with HIV) <b>AND</b></li> <li>&lt; 70 years old OR ≥ 70 years old with no co-morbid conditions * <b>AND</b></li> <li>No diagnosis of cirrhosis <b>OR</b> cirrhosis with a Child-Pugh score of ≤ 6.</li> </ul> <p>*Note: Those ≥ 70 years old with co-morbid conditions will be assessed on a case-by-case basis.</p>	           6 months               1 year

Peginterferon Alfa-2A + Ribavirin	Pegasys RBV	180 mcg / 0.5 mL prefilled syringe OR 180 mcg / mL vial + 200 mg tablet	<p><b>For the treatment of patients with chronic hepatitis C who have had treatment failure with interferon alpha monotherapy:</b></p> <ul style="list-style-type: none"> <li>• Same criteria and approval duration as the above for naïve patients (according to genotype), <b>AND</b></li> <li>• Reason for failure should be provided.</li> </ul>	6 months or 1 year depending on genotype
Peginterferon Alfa-2A	Pegasys	180 mcg / 0.5 mL prefilled syringe OR 180 mcg/mL vial	<p><b>For the treatment of patients with Hepatitis C Virus (HCV)/Human Immunodeficiency Virus (HIV) co-infection:</b></p> <ul style="list-style-type: none"> <li>• Same criteria as the above for naïve patients (according to genotype) but genotype non-2,3 do not require ALT or fibrosis data.</li> </ul> <p><b>For the treatment of patients post-liver transplant with positive HCV RNA.</b> (Note:Please provide a quantitative value in the submission.)</p> <p><b>For the treatment of patients with chronic hepatitis C who have had treatment failure with Rebetron (interferon alfa-2B/ribavirin)* in the past:</b></p> <p>Submissions should include the following information:</p> <ul style="list-style-type: none"> <li>• Dose, duration, tolerance, and HCV RNA response of previous therapy.</li> <li>• Genotype</li> <li>• Current HCV RNA result</li> <li>• Evidence of relapse to past therapy.</li> <li>• ( Note: Relapse is defined as patient must have previously received a course of Rebetron for 6-12 months AND patient had at least one undetectable HCV RNA result after initiating therapy with Rebetron.</li> </ul> <p>*Note Rebetron is no longer available in Canada</p>	<p>1 year</p> <p>1 year</p> <p>6 months to 1 year based on genotype</p>

MIGRAINE TREATMENT DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Almotriptan	Axert	6 mg, 12.5mg tablet	<p><b>For the treatment of migraines with or without aura in patients who failed adequate trials of other medications for migraines</b> (e.g. acetaminophen, NSAIDs) and where the following information is provided:</p> <ul style="list-style-type: none"> <li>• Details of migraine prophylactic regimens (e.g. amitriptyline, beta-blockers) tried or rationale why they are inappropriate; and</li> <li>• The number of attacks, duration, and severity of migraines.</li> </ul> <p><b>Renewal</b> requests may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.</p> <p><i>Warning: The frequent use of triptans (i.e. more than three days per week for longer than three months at a time) may predispose a patient to developing triptan-induced chronic daily headaches.</i></p>	5 years
Naratriptan	Amerge	1 mg, 2.5 mg tablet		
Rizatriptan	Maxalt Maxalt RPD	5 mg, 10 mg tablet and wafer		
Sumatriptan	Imitrex	50 mg, 100 mg tablet		
Sumatriptan	Imitrex Injection	12 mg/mL subcutaneous injection	<p><b>For the treatment of migraines with or without aura in patients who failed adequate trials of other medications for migraines</b> (e.g. acetaminophen, NSAIDs) <u>and</u> has documented intolerance* to an oral triptan. The following information must also be provided:</p> <ul style="list-style-type: none"> <li>• Details of migraine prophylactic regimens (e.g. amitriptyline, beta-blockers) tried or rationale why they are inappropriate; and</li> <li>• The number of attacks, duration, and severity of migraines.</li> </ul> <p>* The nature of intolerance or why oral sumatriptan cannot be used must be specified.</p> <p><b>Renewal</b> requests for sumatriptan may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.</p> <p><i>Warning: The frequent use of triptans (i.e. more than three days per week for longer than three months at a time) may predispose a patient to developing triptan-induced chronic daily headaches.</i></p>	5 years
		Imitrex Nasal Spray		
Zolmitriptan	Zomig	2.5 mg tablet	<p><b>For the treatment of migraines with or without aura in patients who have failed an adequate trial of or experienced intolerance</b> to all other oral triptans considered under the Exceptional Access Program.</p> <p><b>Renewal</b> requests may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.</p>	5 years
		Zomig Rapimelt		

**MULTIPLE SCLEROSIS DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20 mg/mL pre-filled syringe for subcutaneous injection	<p><b>For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)</b> (see criteria in next section).</p> <p><u>For CDMS:</u> Copaxone requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and</li> <li>• EDSS score <math>\leq</math> 5.</li> </ul> <p><b>Renewal</b> requests for Copaxone can be submitted through the Telephone Request Service and will be considered for patients who have benefited from therapy and have an EDSS score <math>\leq</math> 5. The physician must provide the following information:</p> <ul style="list-style-type: none"> <li>• Description of the patient’s clinical course in the last year, including details of all attacks;</li> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• EDSS score.</li> </ul>	1 year
Interferon beta-1a	Avonex PS Avonex Pen	30 mcg/0.5mL prefilled syringe for intramuscular injection  30 mcg single-use prefilled autoinjector	<p><b>For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)</b> (see criteria in next section).</p> <p><u>For CDMS:</u> Avonex requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Details of the most recent neurological examination within the last ninety (90) days, including a description of any recent attacks (date and neurological findings)</li> <li>• The patient has experienced at least two clinical attacks including one clinical attack within the past year</li> <li>• MRI findings as applicable</li> <li>• The patient’s EDSS is less than or equal to 6.0 (please provide EDSS score)</li> </ul>	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p><b>Renewal</b> requests for Avonex can be submitted through the Telephone Request Service. The physician must provide the following information:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last ninety (90) days).</li> <li>• Patients must be stable (i.e. no relapses or attacks during the last year)</li> <li>• The patient's EDSS must be less than or equal to 6.0</li> </ul>	<p>Renewals: 1 year</p>
Interferon beta-1a	Rebif	<p>22mcg and 44mcg prefilled syringe for subcutaneous injection</p> <p>66 mcg/ml and 132mcg/ml pre-filled cartridge</p>	<p><b>For the treatment of Clinically Definite Multiple Sclerosis (CDMS)</b></p> <p><u>For CDMS:</u> Rebif requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and</li> <li>• EDSS score <math>\leq</math> 6.</li> </ul> <p><b>Renewal</b> requests for Rebif can be submitted through the Telephone Request Service and will be considered for patients who have benefited from therapy and have an EDSS score <math>\leq</math> 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> <li>• Description of the patient's clinical course in the last year, including details of all attacks;</li> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• EDSS score.</li> </ul>	<p>1 year</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Interferon beta-1b	Betaseron	0.3 mg/vial subcutaneous injection	<p><b>For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)</b> (see criteria in next section)</p> <p><u>For CDMS:</u> Betaseron requests for patients will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and</li> <li>• EDSS score <math>\leq</math> 6.</li> </ul> <p><b>Renewal</b> requests for Betaseron can be submitted through the Telephone Request Service and will be considered for patients who have benefited from therapy and have an EDSS score <math>\leq</math> 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> <li>• Description of the patient’s clinical course in the last year, including details of all attacks;</li> <li>• Date and details of the most recent neurological examination (within the last 90 days); and</li> <li>• EDSS score.</li> </ul>	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Interferon beta-1b	Extavia	0.3 mg/vial subcutaneous injection	<p><b>For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)</b> (see criteria in next section).</p> <p><u>For CDMS:</u> Extavia requests for patients will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination (within the last 90 days) AND</li> <li>• Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year AND</li> <li>• EDSS score <math>\leq</math> 6.</li> </ul> <p><b>Renewal</b> requests for Extavia can be submitted through the Telephone Request Service and will be considered for patients who have benefited from therapy and have an EDSS score <math>\leq</math> 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> <li>• Description of the patient’s clinical course in the last year, including details of all attacks AND</li> <li>• Date and details of the most recent neurological examination (within the last 90 days) AND</li> <li>• EDSS score.</li> </ul>	1 year
Natalizumab	Tysabri	300 mg/15 mL concentrate for solution for intravenous infusion	<p><b>For the treatment of Rapidly Evolving Severe Relapsing-Remitting Multiple Sclerosis (RES-RRMS)</b> according to the following criteria:</p> <ul style="list-style-type: none"> <li>• The patient’s physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND</li> </ul> <p>The patient;</p> <ul style="list-style-type: none"> <li>• Has been diagnosed with MS; AND</li> <li>• Is 18 to 65 years of age; AND</li> <li>• Has a current EDSS is less than or equal to 5.0; AND</li> <li>• Has had two or more disabling relapses (relapse associated with residual neurological deficit/ incomplete neurological recovery) in the previous year; AND</li> <li>• Has failed<sup>1</sup> an adequate trial (i.e. at least six months) of at least ONE disease modifying therapy OR has contraindications/intolerance<sup>2</sup> to at least TWO disease-modifying therapies; AND</li> <li>• Has at least ONE gadolinium-enhancing lesion on brain MRI, or significant increase in T2 lesion load compared to a previous MRI (i.e. 3 or more new lesions) and an MRI</li> </ul>	Initial: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p>report has been provided; AND</p> <ul style="list-style-type: none"> <li>• Is being followed by a neurologist experienced in the management of RRMS</li> </ul> <ol style="list-style-type: none"> <li><sup>1</sup> Failure defined as two disabling attacks AND significant new disease burden on MRI scan in the preceding six months while on therapy.</li> <li><sup>2</sup> Contraindication/intolerance per product monograph. Needle phobia is not acceptable.</li> </ol> <p><u>Required Information for Tysabri Funding Requests.</u></p> <p>It should be noted that the requesting physician must provide/submit the following information</p> <ol style="list-style-type: none"> <li>(a) Details of the most recent neurological examination within the last ninety (90) days, including a description of recent attacks, dates and all neurological findings;</li> <li>(b) MRI report;</li> <li>(c) Details of past treatment, including dates and patient response; and</li> <li>(d) Indication that the Patient is monitored by a neurologist experienced in the management of RRMS</li> </ol> <p><b>Renewal</b> requests for Tysabri can be submitted through the Telephone Request Service. The physician must provide the following information for renewal consideration of Tysabri;</p> <ol style="list-style-type: none"> <li>(a) Documentation providing the date and details of the patient’s most recent neurological examination and EDSS scores (examination must have occurred within the last ninety (90) days);</li> <li>(b) Evidence that the patient is stable and has had no relapses during the preceding approval period (NB: if the patient has had a relapse, the request will be sent for external review); and</li> <li>(c) Evidence that the patient’s EDSS is less than or equal to 5.0</li> </ol>	Renewals: 1 year
Modafanil	Alertec	100 mg tablet	<p><b>For the treatment of fatigue in patients with multiple sclerosis who have demonstrated a lack of response</b> to or an inability to tolerate amantadine.</p> <p>Note: See Additional indications and criteria under “CNS” drugs</p>	5 Years

**CLINICALLY ISOLATED SYNDROME DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20 mg/mL pre-filled syringe for subcutaneous injection	<p><b>For the treatment of Clinically Isolated Syndrome (CIS):</b> requests for patients who have experienced a single demyelinating event will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> <li>• Date and details of the most recent neurological examination which must have been conducted within the last ninety days of the request;</li> <li>• The patient’s EDSS is less than or equal to 6.0 (please provide EDSS score); AND</li> <li>• The patient’s clinically isolated syndrome occurred within the last twelve months.</li> </ul> <p><b>Renewal</b> requests will be assessed according to the following criteria:</p> <ul style="list-style-type: none"> <li>• the requesting physician provides the date and details of the patient’s most recent neurological examination and EDSS scores;</li> <li>• the patient’s neurological examination occurred within that last ninety days;</li> <li>• the patient is stable (i.e. no relapses or attacks during the last year) and</li> <li>• the patient’s EDSS is less than or equal to 6.0</li> </ul>	1 year
Interferon beta-1a	Avonex PS Avonex Pen	30 mcg/0.5mL prefilled syringe for intramuscular injection  30 mcg single-use prefilled autoinjector		
Interferon beta-1b	Betaseron	0.3 mg/vial subcutaneous injection		
Interferon beta-1b	Extavia	0.3 mg/vial subcutaneous injection		

**NEUROPATHIC PAIN DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Cannabidiol and delta-9-tetrahydrocannabinol	Sativex	25 mg/27 mg per mL buccal spray	<p><b>For the treatment of <u>neuropathic pain related to multiple sclerosis</u></b> in patients who have:</p> <ul style="list-style-type: none"> <li>• Ineffective response or intolerable side effects / contraindications to adequate trials* of a tricyclic antidepressant and gabapentin and pregabalin; and</li> <li>• Ineffective response or intolerable side effects / contraindications to adequate trials* of Cesamet (nabilone) and Marinol (delta-9-tetrahydrocannabinol); and</li> <li>• No contraindications to Sativex therapy.</li> </ul> <p>* Adequate trial is defined as 2 months unless intolerable side effect(s) occur.</p> <p>Note: Side effects and contraindications must be described in detail. Side effects should be deemed serious by the physician such that no further therapy with the agent would be warranted.</p> <p><b>Renewal</b> will be considered for patients responding to Sativex therapy as demonstrated by decreased pain and other pain-related symptoms; no initiation of new analgesics; and no increase in doses of any analgesics.</p> <p><i>Sativex is also reimbursed for the treatment of refractory pain in palliative cancer patients according to specified criteria.</i></p>	<p>Initial: 1 year</p> <p>Renewal: Lifetime</p> <hr/> <p>6 months</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Pregabalin	Lyrica	25mg, 50mg, 75mg, 150mg, 300mg capsule	<p><b>For the treatment in patients with objective evidence of <u>neuropathic pain</u> who have:</b></p> <ul style="list-style-type: none"> <li>• Ineffective response or intolerable side effects / contraindications* to adequate trials of a tricyclic antidepressant and gabapentin.</li> </ul> <p>* Side effects and contraindications must be described in detail.</p> <p>Note: The physician may be asked to provide details of investigations into the neuropathic cause of the pain.</p>	Lifetime

ONCOLOGY DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Aprepitant	Emend	80 mg, 125 mg capsule, Tri-pack	<p>As part of the antiemetic regimen</p> <p>1. For patients receiving high dose cisplatin (<math>\geq 70\text{mg}/\text{m}^2</math>) as a single dose in each cycle of chemotherapy; AND</p> <p>2. The usual dose is 125 mg po on Day 1 of high dose cisplatin followed by 80 mg po on Days 2 and 3 post-chemotherapy for each cycle.</p>	Duration of chemotherapy or 1 year
Dasatinib	Sprycel	20 mg, 50 mg, 70 mg tablet	<p><b>For the treatment of patients with chronic myelogenous leukemia (CML) meeting the following criteria:</b></p> <p>(a) For second line therapy for adult patients with chronic phase CML with primary or acquired resistance to imatinib at 600 mg/day. In such patients the dasatinib dosages that can be considered is either 100 mg per day or 70 mg two times daily (dosage is not to exceed 140 mg per day); OR</p> <p>(b) For adult patients with chronic phase CML who progress to accelerated phase on imatinib at 600mg per day. In such patients, the dasatinib dosage that will be approved is not to exceed 140 mg per day; OR</p> <p>(c) For adult patients with chronic phase CML who have a blast crisis while on imatinib at 600 mg per day. In such patients, the dosage that will be approved is not to exceed 140 mg per day; OR</p> <p>(d) For adult patients with chronic, accelerated, or blast phase CML who have intolerance to imatinib at any dose where the patients have experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of imatinib therapy; OR</p> <p>(e) As an alternative for the treatment of adult patients with chronic or accelerated phase Philadelphia chromosome positive (Ph+) CML who are resistant or intolerant to imatinib therapy AND was previously initiated on second line treatment with nilotinib but are experiencing an intolerance to nilotinib therapy.</p>	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Dasatinib	Sprycel	20 mg, 50 mg, 70 mg tablet	<p><u>Definitions:</u></p> <p><u>Intolerance</u> to imatinib (at any dose) is considered as the patient has experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of therapy.</p> <p><u>Resistance</u> to imatinib resistance is defined as primary or acquired resistance to imatinib at doses of at least 600mg/day.</p> <p><b>Renewals</b> will be considered for patients who have demonstrated benefit from therapy and who are expected to continue to benefit from the therapy.</p> <p><b>Exclusion criteria:</b></p> <p>Dasatinib (Sprycel) will not be considered in patients as a sequential third line therapy in patients who experience primary or acquired resistance to nilotinib.</p>	Renewal: 1 year
			<p><b>For the treatment of patients with Philadelphia chromosome positive acute lymphoblastic leukemia ( Ph+ ALL) who meet the following criteria:</b></p> <p>For adult patients with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL) whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day) or have experienced grade 3 non-hematologic toxicity, or grade 4 hematologic toxicity persisting for more than 7 days to imatinib.</p> <p><u>Definitions:</u></p> <p><u>Intolerance</u> to imatinib (at any dose) is considered as the patient has experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of therapy.</p> <p><u>Resistance</u> to imatinib resistance is defined as primary or acquired resistance to imatinib at doses of at least 600mg/day.</p> <p><b>Renewals</b> will be considered for patients who have demonstrated benefit from therapy and who are expected to continue to benefit from the therapy.</p>	Initial: 1 year
			<p><b>Requests for dasatinib in children with acute lymphoblastic leukemia will be reviewed by external advisors.</b></p>	Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Erlotinib	Tarceva	100 mg, 150 mg tablet	<p><b>For the treatment of clinically documented incurable progressive non-small cell lung cancer (NSCLC) where:</b></p> <ul style="list-style-type: none"> <li>• Erlotinib is used as monotherapy for the 2nd- or 3rd-line treatment after failure of prior chemotherapy with cisplatin or carboplatin; or</li> <li>• Erlotinib is used as monotherapy for the 2nd- or 3rd-line treatment after failure of prior chemotherapy (any regimen) in patients 70 years of age or older.</li> </ul> <p><b>Renewal</b> will be considered for patients who respond to therapy with no evidence of disease progression. Patients should be assessed for disease status at least every two months. Erlotinib should be discontinued if there is evidence of disease progression.</p> <p><i>Note: Erlotinib is not indicated and therefore, is not considered for reimbursement as 1<sup>st</sup> line therapy in treatment of NSCLC.</i></p>	3 months at 150 mg/day
Everolimus	Afinitor	10 mg tablet	<p><b>For the treatment of metastatic renal cell carcinoma (MRCC) as second or third-line therapy in patients previously treated with sunitinib (Sutent), sorafenib (Nexavar), or both.</b></p> <p>Dose: 10mg daily</p> <p><b>Renewal</b> will be considered for those who have demonstrated benefit from therapy and is expected to continue to benefit from Afinitor therapy.</p>	1 Year
Gefitinib	Iressa	250 mg tablet	<p><b>For the first line, monotherapy treatment of locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) in patients who have activating mutations of epidermal growth factor receptor-tyrosine kinase (EGFR-TK).</b> (i.e. Patients who are EGFR Positive)</p> <p>The patient is to be assessed for disease status at least every two months and treatment will be discontinued if there is evidence of disease progression.</p> <p>Dose Reimbursed: 250 mg orally once daily.</p> <p>Iressa will not be granted funding in the following circumstances;</p> <ul style="list-style-type: none"> <li>○ Patients with EGFR wild-type mutation (i.e. negative for mutation);</li> <li>○ Patients with EGFR unknown mutation;</li> <li>○ 2<sup>nd</sup> or 3<sup>rd</sup> line or maintenance NSCLC; or</li> <li>○ Patients with unknown EGFR status who start their first chemotherapy while waiting for EGFR testing, then are found/confirmed to be EGFR positive, should</li> </ul>	6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p>continue with the current therapy and will not be eligible for gefitinib (Iressa) in this setting.</p> <ul style="list-style-type: none"> <li>○ Patients who receive gefitinib (Iressa) first line are not eligible for erlotinib in the second- or third-line in the setting of maintenance therapy of NSCLC.</li> </ul> <p><b>Renewal</b> will be considered for patients until there is any evidence of disease progression, at which point, treatment with gefitinib (Iressa) must be discontinued. Patients must have their disease status assessed at least every two months.</p> <p>Dose Reimbursed: 250 mg orally once daily.</p>	<p>Renewal: 6 months</p>
Imatinib	Gleevec	100 mg tablet	<p><b>For the treatment of Metastatic Gastrointestinal Stromal Tumours (GIST)</b> in patients who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• The tumour is not surgically resectable (metastatic or recurrent); AND</li> <li>• The pathology has been confirmed with c-kit positivity</li> </ul> <p><b>For the treatment of Adjuvant Gastrointestinal Stromal Tumours (GIST)</b> in patients who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• Patients are at intermediate to high risk of recurrence following complete resection (using Miettinen relapse risk criteria, risk &gt;/20%); AND and</li> <li>• The pathology has been confirmed with c-kit positivity.</li> </ul> <p>Note that there will be no renewals and the dosing regimen is no more than 400 mg daily.</p> <p><b>For the treatment of adult patients with with newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL)</b></p> <p><b>Renewal</b> will be considered for patients who GIST who have benefited from or continues to benefit from therapy with Gleevec and is expected to continue to do so. For patients receiving Gleevec for Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), the patient must also demonstrate a hematologic or cytogenetic response to therapy.</p> <p>Renewals will NOT be considered for patients receiving Gleevec for Adjuvant GIST.</p>	<p>Initial: 1 Year</p> <p>Renewal: 1 Year (where applicable)</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Lapatinib	Tykerb	250 mg tablet	<p>For the second-line treatment of HER2-positive metastatic breast cancer when used in combination with chemotherapy after previous exposure to trastuzumab-based treatments.</p> <p>For the treatment of HER-2 positive metastatic breast cancer when used in combination with chemotherapy after use of trastuzumab in patients who have an adverse drug reaction or contraindication to trastuzumab therapy.</p> <p>Lapatinib will not be considered in patients who meet the following exclusions:</p> <ul style="list-style-type: none"> <li>• Lapatinib (Tykerb) will not be funded in combination with trastuzumab (Herceptin) for second-line HER-2 positive metastatic breast cancer.</li> <li>• Patients who have progressed while on trastuzumab (Herceptin) for second-line treatment of HER-2 positive metastatic breast cancer, will not be eligible for funding of lapatinib (Tykerb).</li> <li>• Lapatinib (Tykerb) will not be funded in the adjuvant setting.</li> </ul> <p>Dosing schedule: 1250 mg (5 tablets) once daily in combination with capecitabine for days 1 to 14 (in a 21 day cycle) until disease progression, unacceptable toxicity, or withdrawal of consent.</p> <p>Note: Funding of second-line lapatinib for HER-2 positive metastatic breast cancer will be discontinued upon evidence of disease progression</p> <p><u>Renewal</u> will be considered for lapatinib until there is evidence of disease progression at which point the drug should be discontinued.</p>	<p>6 months</p> <p>Renewal: 6 months</p>
Lenalidomide	Revlimid	5 mg, 10 mg capsule	<p><b>For the treatment of anemia due to <u>myelodysplastic syndrome (MDS)</u></b> for patients who have;</p> <ul style="list-style-type: none"> <li>• Demonstrated diagnosis of MDS on bone marrow aspiration</li> <li>• Presence of del[5q] documented by standard cytogenetic or fluorescence in situ hybridization</li> <li>• International Prognostic Scoring System (IPSS) risk category low or intermediate-1</li> <li>• Transfusion-dependent symptomatic anemia</li> </ul>	6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p><b>Renewal</b> will be considered for patients who are transfusion-dependent and who have demonstrated at least a fifty percent (50%) reduction in transfusion requirements.</p> <p>Patients with anemia due to MDS who are not transfusion-dependent will be assessed on a case-by-case basis.</p>	<p>Renewal: Up to 1 year</p>
Lenalidomide	Revlimid	5 mg, 10 mg, 15 mg, 25 mg capsule	<p><b>For the treatment of <u>multiple myeloma</u> in combination with dexamethasone</b> for patients who are not candidates for autologous stem cell transplant for patients who are;</p> <ul style="list-style-type: none"> <li>• Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who are suitable for further chemotherapy OR</li> <li>• Have completed at least one full treatment regimen as initial therapy and has demonstrated an intolerance to their current chemotherapy.</li> </ul> <p><b>Renewals</b> will be considered for those who continue to respond to therapy.</p>	<p>Initial: 1 year</p> <p>Renewal: 1 year</p>
Nilotinib	Tasigna	200 mg capsule	<p><b>Nilotinib (Tasigna) is considered for reimbursement in the following conditions;</b></p> <ol style="list-style-type: none"> <li>i) <b>For the 2<sup>nd</sup> line treatment of patients with chronic or accelerated phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) with primary or acquired resistance to imatinib at 600 mg/day.</b></li> <li>ii) <b>For the 2<sup>nd</sup> line treatment of patients with chronic or accelerated phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who have intolerance to imatinib (at any dose) where the patients have experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of imatinib therapy.</b></li> <li>iii) <b>As an alternative for the treatment of adult patients with chronic or accelerated Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who are resistant or intolerant to imatinib therapy and who was previously initiated on second line treatment with dasatinib but are experiencing an intolerance to dasatinib therapy.</b></li> </ol> <p>Dosages of nilotinib (Tasigna) greater than 800 mg/day will not be approved.</p> <p>Definitions of intolerance and resistance:</p>	<p>Initial : 1 year</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<ul style="list-style-type: none"> <li>• Intolerance to imatinib – patient has experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of imatinib therapy.</li> <li>• Resistance to imatinib resistance – patient has experienced primary or acquired resistance to imatinib at doses of at least 600mg/day;</li> <li>• Intolerance to dasatinib – patient has experienced persistent grade 3 or 4 toxicity requiring discontinuation of dasatinib therapy.</li> </ul> <p>Renewals will be considered for patients who have demonstrated that they have benefited from and continue to benefit from therapy with nilotinib (Tasigna), and is expected to continue to do so.</p> <p>Nilotinib (Tasigna) will not be reimbursed for the following conditions.</p> <ul style="list-style-type: none"> <li>i) Blast phase chronic myelogenous leukemia (CML) with resistance or intolerance to imatinib</li> <li>ii) For Ph+ acute lymphoblastic leukemia (ALL);</li> <li>iii) As an alternative to imatinib for the first-line treatment of Ph+ CML;</li> <li>iv) As a sequential third line therapy in patients who experience primary or acquired resistance to dasatinib.</li> </ul>	Renewal: 1 year
Sorafenib	Nexavar	200 mg tablet	<p><b>For the treatment of <u>metastatic renal cell carcinoma (MRCC)</u></b> for patients who have:</p> <ul style="list-style-type: none"> <li>• Histologically confirmed metastatic clear-cell renal-cell carcinoma; and</li> <li>• Experienced disease progression after prior cytokine therapy within the previous 8 months; and</li> <li>• A performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group criteria; and</li> <li>• Intermediate-risk or low-risk status, according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score.</li> </ul> <p><b>Renewal</b> will be considered with confirmation from the physician that the patient has benefited from therapy and is expected to continue to do so.</p>	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p><b>For the treatment of <u>advanced hepatocellular carcinoma (HCC)</u></b> in patients who have:</p> <ul style="list-style-type: none"> <li>• Child-Pugh Class A disease; and</li> <li>• ECOG status 0, 1 or 2; and</li> <li>• Either progressed on transarterial chemoembolization (TACE) or are not suitable for the TACE procedure (where detailed rationale is provided).</li> </ul> <p><b>Renewal</b> will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression.</p>	3 months
Sunitinib	Sutent	12.5 mg, 25 mg, 50 mg capsule	<p><b>For the treatment of <u>gastrointestinal stromal tumour (GIST)</u> in patients with c-KIT expressing (CD117+) unresectable or metastatic/recurrent GIST</b> and where one of the following conditions are met:</p> <ul style="list-style-type: none"> <li>• Early progression (within 6 months) while on imatinib; OR</li> <li>• Progression following treatment with optimum (escalated) doses of imatinib (800mg per day); OR</li> <li>• Intolerance* to imatinib (where detailed description of intolerance is provided).</li> </ul> <p>*Definition of intolerance to imatinib – patient has experienced persistent grade 3 toxicity requiring discontinuation of therapy.</p> <p><b>Renewal</b> will be considered for patients who are stable (no disease progression) and not experiencing intolerance to sunitinib therapy.</p> <p><i>Note: Approval will be granted at a dose of 50mg per day (4 weeks on, 2 weeks off).</i></p>	6 months
			<p><b>Treatment of <u>metastatic renal cell carcinoma (MRCC)</u>:</b></p> <ul style="list-style-type: none"> <li>• <u>First-line therapy</u> for patients with MSK Prognostic Score of Favourable Risk or an Intermediate Risk OR</li> <li>• <u>Second-line therapy</u> for patients where: <ul style="list-style-type: none"> <li>○ The disease is of clear cell histology AND</li> <li>○ Documented failure to first-line cytokine-based therapy.</li> </ul> </li> </ul> <p><b>Renewal</b> will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression.</p> <p><i>Note: The prescribed dosage should be 50 mg daily for four (4) weeks, followed by two (2) weeks off the Drug Product, in repeated six (6) week cycles.</i></p>	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Temozolomide	Temodal	5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg capsule	<p><b>For the treatment of newly diagnosed glioblastoma multiforme (GBM).</b></p> <p>Temozolomide 75 mg/m<sup>2</sup> daily for up to 6 weeks during radiotherapy then adjuvant treatment of 150-200 mg/m<sup>2</sup> daily for 5 days. The course is repeated every 28 days for up to 6 months.</p>	6 to 8 months pending the treatment(s) identified

### OPIOID DEPENDENCE

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Buprenorphine/Naloxone	Suboxone	8mg/2mg sublingual tablet	<p><b>For the treatment of opioid dependence:</b></p> <ul style="list-style-type: none"> <li>In patients who have failed, have significant intolerance, have a contraindication to, or who are at high risk for toxicity with methadone*; OR</li> <li>When a methadone maintenance program is not available or accessible**</li> </ul> <p>*high risk for toxicity with methadone: use of benzodiazepines, alcohol abuse or dependence, elderly, patients who are dependent on codeine or abuse opioids on a less than daily basis, on medications that interfere with methadone metabolism, at high risk for prolonged QT interval</p> <p>**no methadone maintenance programs available in the area, or waiting list is 3 months or longer</p> <p>Note: All physicians who wish to prescribe this product to treat opioid-dependent patients should have training/education regarding use of this drug, and addiction medicine generally, prior to initiating Suboxone treatment.</p> <p>Duration of therapy: 1 year</p> <p><b>Renewal</b> requests should include the prescriber's intended treatment course, including whether tapering or discontinuation of Suboxone has been considered. Evidence of effectiveness including a reduction in opioid use (through urine drug screens or patient self-reports) should be provided.</p>	1 year

OSTEOPOROSIS DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Calcitonin Salmon	Miacalcin	200 IU/dose nasal spray	<p><b>For treatment of osteoporosis in patents who have failed*; experienced intractable side effects** to; or have contraindications** to all of the available Formulary alternatives:</b> etidronate, alendronate, risedronate and, if patient is female, raloxifene.</p> <p>* Failure is defined as: continued loss of bone mineral density (loss of &gt; 3%) after two years of therapy or a new osteoporosis related fracture after one year of therapy.</p> <p>** Side effects and contraindications must be described in detail.</p> <p><b>Renewals</b> will be considered for patients demonstrate benefit from treatment; details of patient's concomitant medications should be provided.</p>	2 years
Zoledronic Acid	Aclasta	5 mg/100 mL intravenous infusion	<p><b>For the treatment of osteoporosis in ambulatory post-menopausal women and in men who are unable to absorb orally administered medications or who are unable to swallow/take any oral products.</b></p> <p>Patient must have complete inability to take oral medications i.e., patient is reliant on TPN or is NPO.</p>	1 year or lifetime (based on whether inability to absorb/take oral products is temporary or permanent)
Zoledronic Acid	Zometa Concentrate	4 mg/5 mL Vial	<p>Zoledronic acid as Zometa Concentrate will only be considered <b>for the treatment of bony metastases in those with hormone refractory prostate cancer as well as other cancers</b> through the Exceptional Access Program (EAP) <b>in those receiving outpatient care</b> who do not meet the criteria of Cancer Care Ontario (CCO).</p> <p>Zometa is considered through CCO for those receiving prostate cancer treatment from a cancer clinic.</p> <p><u>EAP criteria:</u></p> <ul style="list-style-type: none"> <li>• For the treatment of bony metastases for patients with hormone refractory prostate cancer as determined by an elevated PSA level, or evidence of progressive bony disease<sup>1</sup>, despite castrate serum testosterone levels (&lt;50 ng/dL).</li> </ul> <p><sup>1</sup>Progressive bony disease should be demonstrated by: progressive changes in</p>	Initial: 6 months

			<p>radionucleotide bone scan or clinical signs of disease progression (e.g., via radionucleotide scanning, pathologic fracture or increasing bone pain).</p> <p>Requests for patients who have undergone orchidectomy do not need to provide a serum testosterone level.</p> <ul style="list-style-type: none"> <li>• For the prevention of skeletal related events in patients who have not experienced previous skeletal related events<sup>2</sup> and who have bony metastases secondary to: <ul style="list-style-type: none"> <li>• solid tumours (e.g. renal, small cell lung, pancreatic cancers) who have good performance status<sup>3</sup> <b>OR</b></li> <li>• breast cancer or multiple myeloma who are intolerant to pamidronate.</li> </ul> </li> </ul> <p><sup>2</sup>A skeletal related event is defined as: pathologic fracture, spinal cord compression, radiation therapy to bone or surgery to bone.</p> <p><sup>3</sup>Good performance status is defined as patients that are ambulatory, capable of self care and up and about more than 50 per cent of waking hours.</p> <ul style="list-style-type: none"> <li>• For the treatment of patients with symptoms due to bony metastases secondary to breast cancer or multiple myeloma who have failed or are intolerant to pamidronate.</li> <li>• Consideration for patients who are symptomatic due to bony metastases secondary to other types of solid tumours or cancers will be considered on a case-by-case basis. The physician is asked to include information describing the patient's bone pain and use of other therapies including the use of bisphosphonates. The use of other non-pharmacologic treatment modalities such as surgery or radiation that have been tried should also be provided in the request.</li> </ul> <p><b>Renewals</b> will be considered for patients who are responding to therapy and is still deemed to require treatment.</p>	<p>Renewal: 6 months</p>
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**PARKINSONS DISEASE DRUGS**

<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Rasagiline	Azilect	0.5 mg, 1 mg tablet	<p><b>For the treatment of patients with Parkinson's disease</b></p> <ul style="list-style-type: none"> <li>• With 25% of the waking day in the off-state despite maximally tolerated doses of levodopa</li> </ul>	5 years

**PSORIATIC ARTHRITIS DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Adalimumab	Humira	40 mg/0.8 mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p><b>For the treatment of psoriatic arthritis</b> in patients who have:</p> <p>Severe active disease (<math>\geq 5</math> swollen joints and radiographic evidence of psoriatic arthritis) despite treatment with methotrexate (20mg/week) for at least 3 months and one of leflunomide (20mg/day) or sulfasalazine (1g twice daily)_for at least 3 months.</p>	Initial: 1 year
Etanercept	Enbrel	25 mg/vial and 50 mg prefilled syringe for subcutaneous injection	<p>If the patient has documented contraindications or intolerances to methotrexate, then only one of leflunomide (20 mg/day) or sulfasalazine (1 g twice daily) for at least 3 months is required. Details of contraindications and intolerances must also be provided.</p> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p>	Renewal: 1 year
Golimumab	Simponi	50 mg/0.5 ml prefilled syringe and autoinjector	<p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of psoriatic arthritis are as follows:</p> <ul style="list-style-type: none"> <li>○ Adalimumab 40mg every two weeks</li> <li>○ Etanercept 25mg twice weekly or 50mg once weekly</li> <li>○ Golimumab 50mg once a month</li> </ul>	

**PSYCHIATRIC DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Atomoxetine	Strattera	10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg	<p><b>For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)</b> according to DSM-IV criteria in patients <math>\geq</math> six years of age where symptoms are not due to other medical conditions which affect concentration, and who require 12-hour continuous coverage due to academic and/or psychosocial needs. All of the following criteria must be met:</p> <ul style="list-style-type: none"> <li>• Must be prescribed by or prescribed in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD AND</li> <li>• Patient must demonstrate significant and problematic disruptive behaviour or have problems with inattention that interfere with learning AND</li> <li>• Must have previously been treated with methylphenidate immediate release (IR) OR methylphenidate slow release (SR), OR dextroamphetamine sulfate IR OR dextroamphetamine SR with unsatisfactory results due to poor symptom control or side effects AND</li> <li>• Must have evidence of benefit from a one month trial with Atomoxetine (Strattera)</li> </ul> <p><b>Renewals</b> will be considered in those with objective evidence of on-going benefit (socially/academically) from treatment with atomoxetine and where the renewal is prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics, or a general practitioner with expertise in ADHD.</p>	<p>Initial: 1 Year</p> <p>Renewal: 5 Year</p>
Buspirone	Apo-buspirone Novo-buspirone	10 mg tablet	<p><b>For the treatment of generalized anxiety disorder.</b></p> <ul style="list-style-type: none"> <li>• Buspirone is being used as a single agent</li> <li>• Clinician provides the rationale for why listed benzodiazepines cannot be used</li> <li>• A detailed clinical history and treatment plan is provided</li> </ul> <p><b>Renewals</b> will be considered for those with evidence of response</p>	<p>Initial: 5 Years</p> <p>Renewal: 5 Years</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Dextroamphetamine	Dexedrine Spansule SRC	10 mg, 15 mg sustained-release capsules (Spansules)	<p><b>For the treatment of childhood onset Attention-Deficit/Hyperactivity Disorder (ADHD).</b></p> <ul style="list-style-type: none"> <li>• Must be diagnosed with ADHD of childhood onset AND</li> <li>• Where a more sustained effect is required following a trial with regular release dextroamphetamine or methylphenidate, particularly in situations involving; <ul style="list-style-type: none"> <li>○ Poor compliance with noon or afternoon doses</li> <li>○ Great variability in symptoms throughout the day</li> <li>○ Idiosyncratic reactions</li> <li>○ Prescribed dosage less than 60 mg AND</li> <li>○ Used as a single agent</li> </ul> </li> </ul> <p><b>Renewals</b> will be considered for patients stabilized on therapy.</p>	<p>Initial: 1 Year</p> <p>Renewal: 5 years</p>
Zopiclone	Imovane + generic brands	5 mg, 7.5 mg tablet	<p><b>For the treatment of insomnia</b> as a single hypnotic agent in patients with;</p> <ul style="list-style-type: none"> <li>• Failure to at least two benzodiazepines OR</li> <li>• Failure or documentation of intolerance to trials of at least one benzodiazepine and one other hypnotic (ie: amitriptyline, trazodone) OR</li> <li>• Documentation of failure to non-pharmacological treatment (e.g., relaxation therapy, stimulus control such as caffeine and light, sleep restriction, and cognitive behavioural therapy) or a clear rationale for why such treatment is inappropriate; and</li> <li>• A list of comorbid conditions and concomitant medications (including doses and dosing frequencies)</li> </ul> <p><b>Renewals</b> will be considered in patients using zopiclone as a single hypnotic agent who have responded to therapy and are using the same or lower dose compared to the previous year.</p>	<p>Initial: 1 year</p> <p>Renewal: 2 years</p>
Zuclopenthixol Decanoate	Clopixol Depot	200 mg/mL intramuscular injection	<p><b>For the treatment of chronic schizophrenia</b> as a single antipsychotic agent in those patients where a depot formulation is indicated where the patient has;</p> <ul style="list-style-type: none"> <li>• Documented evidence of failure to respond to at least one depot neuroleptic that is presently available on the ODB Formulary OR</li> <li>• Documented intolerable side effects secondary to at least one depot neuroleptic presently available on the ODB Formulary OR</li> <li>• Stabilized on Clopixol depot prior to applying for reimbursement through EAP</li> </ul>	<p>Initial: Lifetime</p> <p>Renewals: Lifetime</p>
Zuclopenthixol dihydrochloride	Clopixol Tablet	10 mg and 25 mg tablet	<p><b>For the treatment of chronic schizophrenia</b> as a single antipsychotic agent in patients with;</p> <ul style="list-style-type: none"> <li>• Evidence of failure to respond to at least two oral neuroleptic agents presently</li> </ul>	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p>available on the ODB Formulary OR</p> <ul style="list-style-type: none"> <li>• Intolerable side effects have been documented to at least two oral neuroleptic presently available on the ODB Formulary</li> </ul> <p><b>Renewals</b> will be considered in patients who are stable and demonstrate evidence of response to therapy.</p>	

**PULMONARY ARTERIAL HYPERTENSION (PAH) DRUGS**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Monotherapy			<ul style="list-style-type: none"> <li>• Request must be from a recognized PAH referral centre: Toronto General Hospital/UHN, Kingston General Hospital, London Health Sciences Centre, Hamilton General Hospital (HHSC), Ottawa Civic Hospital/Ottawa Heart Institute;                             <ul style="list-style-type: none"> <li>○ Requests from other physicians/centres must include a recent consult note/recommendation from a referral centre that supports the request;</li> <li>○ Out-of-province referral centre consults are acceptable (e.g., from Winnipeg for patients in N.Ont).</li> </ul> </li> <li>• Patient must have proven PAH defined as <math>\geq 25</math> mmHg mean pulmonary artery pressure (mPAP) on right heart catheterization (RHC) with normal pulmonary capillary wedge pressure (<math>\leq 15</math> mmHg) and without interstitial lung disease, COPD or left ventricular failure either systolic or diastolic.</li> <li>• Requests for pediatric patients will be reviewed on a case-by-case basis.</li> </ul>	
Ambrisentan Bosentan Epoprostenol	Volibris Tracleer Flolan	5 mg , 10 mg tablet 62.5 mg, 125 mg tablet 0.5 mg and 1mg vial	<ul style="list-style-type: none"> <li>• NYHA functional class III or IV PAH</li> <li>• Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease, congenital heart disease, or HIV.</li> </ul>	1 Year
Sildenafil	Revatio	20 mg tablet	<ul style="list-style-type: none"> <li>• NYHA functional class III PAH                             <ul style="list-style-type: none"> <li>○ Note that sildenafil is not funded for NYHA Class IV patients.</li> </ul> </li> <li>• Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease.</li> </ul>	
Tadalafil	Adcirca	20 mg tablet	<ul style="list-style-type: none"> <li>• NYHA functional class III PAH                             <ul style="list-style-type: none"> <li>○ Note that tadalafil is not funded for NYHA Class IV patients.</li> </ul> </li> <li>• Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease, congenital heart disease.</li> </ul>	
Treprostinil	Remodulin	1 mg/mL, 2.5 mg/mL, 5 mg/mL and 10 mg/mL vials	<ul style="list-style-type: none"> <li>• NYHA functional class III or IV PAH</li> <li>• Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease.</li> </ul>	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p>Information must be provided in the EAP request to demonstrate how the patient meets these criteria. The request must include RHC parameters, etiology and NYHA classification.</p> <p><b>Renewals</b> (for all above):</p> <ul style="list-style-type: none"> <li>• Patient is responding to treatment;</li> <li>• Request must be from a recognized PAH referral centre.</li> </ul>	
		Combination Therapy	<ul style="list-style-type: none"> <li>• Request must be from a recognized PAH referral centre: (see monotherapy criteria)</li> <li>• Combination therapy may be considered for patients who have not achieved treatment targets after at least three months of single agent therapy (monotherapy) with a PAH-specific drug. <ul style="list-style-type: none"> <li>○ Request should indicate that the patient has not met at least one of the following targets: <ul style="list-style-type: none"> <li>▪ Improvement to at least NYHA functional class II; OR</li> <li>▪ 6 minute walk distance &gt; 380metres; OR</li> <li>▪ Mixed venous saturation on right heart catheterization &gt; 66%</li> </ul> </li> </ul> </li> <li>• Drugs used in combination must be from different classes (i.e., ERA, PDE-5 inhibitor, prostanoid)</li> <li>• Requests for pediatric patients will be reviewed on a case-by-case basis.</li> </ul> <p>Note: Triple therapy will not be funded except to allow an overlap period of 6 months with weaning of one drug.</p>	6 Months
			<p><b>Renewals</b></p> <ul style="list-style-type: none"> <li>• Request must be from a recognized PAH referral centre.</li> </ul> <p>Note: The renewal request must discuss outcome of attempts to wean initial drug with goal of continuing monotherapy with the second drug.</p> <ul style="list-style-type: none"> <li>• If unsuccessful in weaning, ongoing combination therapy will be funded for an additional 6 months.</li> </ul>	6 Month / 1 Year
			<p><b>Subsequent Renewals</b></p> <ul style="list-style-type: none"> <li>• Request must be from a recognized PAH referral centre.</li> <li>• Renewal granted for one year for patients who have achieve treatment targets or at least improved.</li> <li>• Renewal granted for six months for patients who have not met treatment targets nor improved.</li> </ul> <p>Note: MD should discuss rationale for not changing treatment regimen.</p>	6 Month / 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
	Combination Therapy (For patients enrolled in trials or receiving other 3rd-party funding)		<p>Some requests ask for only one drug to be funded with second drug funded through other 3rd-party means. EAP criteria apply only to the drug being requested under EAP by ODB.</p> <ul style="list-style-type: none"> <li>• Request must be from a recognized PAH referral centre. (see monotherapy criteria)</li> <li>• Request will be approved for one drug if evidence is provided that the patient met the criteria for initial therapy as above; (see monotherapy criteria)</li> <li>• EAP criteria do not apply to the drug(s) being funded through other means.</li> </ul>	As above for combination therapy.

<b>POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS</b>				
<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Etanercept	Enbrel	25 mg/vial, 50 mg prefilled syringe for subcutaneous injection	<p><b>For the first-line treatment of polyarticular-course juvenile idiopathic arthritis in patients</b> who have:</p> <ul style="list-style-type: none"> <li>Active disease (<math>\geq 3</math> swollen joints and <math>\geq 5</math> active joints) despite a trial of optimal dose of subcutaneously administered methotrexate (i.e. <math>15 \text{ mg/m}^2</math> per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication must be described in detail.</li> </ul> <p><u><b>Renewal</b></u> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>The planned dosing regimen should be provided. The maximum recommended dose is 50mg once weekly.</p>	<p>Initial: 1 year</p> <p>Renewal: 1 year</p>

Adalimumab	Humira	40 mg/0.8mL prefilled syringe and 40 mg/0.8mL prefilled pen for subcutaneous injection	<p><b>For the second- or third-line treatment of polyarticular-course juvenile idiopathic arthritis</b> in patients who meet the following criteria;</p> <ul style="list-style-type: none"> <li>• Patient has had an inadequate response to a three month course of methotrexate administered subcutaneously at a dosage of at least 15mg/m<sup>2</sup> per week for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication must be described in detail; AND Patient must have had an inadequate response to a three month course of etanercept (Enbrel). If the patient is unable to tolerate or has a contraindication to etanercept, the nature of the intolerance or contraindication must be described in detail; AND</li> <li>• Patient must have a minimum of 3 (three) swollen joints and a total of 5 (five) active joints.</li> </ul>	Initial: 1 year
Infliximab	Remicade	100 mg/vial	<p>Humira (adalimumab) will not be approved for the first-line biologic treatment of polyarticular-course juvenile idiopathic arthritis.</p> <p>Remicade (infliximab) will not be approved for the first-line biologic treatment of polyarticular-course juvenile idiopathic arthritis.</p> <p>Requests that do not meet these criteria will undergo external review.</p> <p>Adalimumab Dosing: Dose: 24 mg/m<sup>2</sup> (maximum 40 mg) every two weeks; OR &lt; 30 kg 20 mg every two weeks ≥ 30 kg 40 mg every two weeks</p> <p>Infliximab dosing: Up to 6 mg/kg/dose at weeks 0, 2, and 6, followed by maintenance of up to 6 mg/kg/dose every 8 weeks.</p> <p>Renewal Criteria: Objective evidence of at least a 20% reduction in swollen joint count. For renewals beyond the second year, objective evidence of the preservation of treatment effect should be provided (i.e. the current joint count should be compared to the count prior to initiating treatment with the biologic agent).</p> <p>Requests that do not meet these criteria will undergo external review.</p>	Renewal: 1 year

RHEUMATOID ARTHRITIS DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Adalimumab	Humira	40 mg/0.8mL prefilled syringe and 40 mg/0.8mL prefilled pen for subcutaneous injection	<p><b>For the treatment of rheumatoid arthritis</b> in patients who have:</p> <ul style="list-style-type: none"> <li>Severe active disease (<math>\geq 5</math> swollen joints and rheumatoid factor positive and/or radiographic evidence of <u>rheumatoid arthritis</u>) despite the optimal use of various formulary disease-modifying anti-rheumatic drugs (DMARDs)*.</li> </ul> <p>*Optimal use of DMARDs include:</p> <ul style="list-style-type: none"> <li>Methotrexate (20 mg/week) for at least 3 months and leflunomide (20 mg/day) for at least 3 months in addition to an adequate trial (3 months) of at least one combination of DMARDs; or</li> <li>Methotrexate (20 mg/week) for at least 3 months and leflunomide in combination with methotrexate for at least 3 months.</li> </ul> <p>• If the patient could not receive adequate trial(s) of methotrexate and/or leflunomide due to contraindication(s) or intolerance(s), the nature of contraindication(s) or intolerance(s) must be provided along with details of trials of other DMARDs or clear rationale why other DMARDs cannot be considered.</p> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of rheumatoid arthritis are as follows:</p> <ul style="list-style-type: none"> <li>Adalimumab 40mg every two weeks</li> <li>Anakinra 100mg per day</li> <li>Certolizumab pegol 400mg at 0, 2 and 4 weeks followed by maintenance therapy of 200 mg every 2 weeks. For maintenance dosing, 400mg every 4 weeks may be considered</li> <li>Etanercept 25mg twice weekly or 50mg once weekly</li> <li>Golimumab 50mg once a month</li> <li>Infliximab 3mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3mg/kg/dose every 8 weeks up to a maximum of six maintenance doses per year</li> </ul>	Initial: 1 year
Anakinra	Kineret	150 mg/mL subcutaneous injection		
Certolizumab pegol	Cimzia	200 mg/mL prefilled syringe		
Etanercept	Enbrel	25 mg/vial and 50mg prefilled syringe for subcutaneous injection		
Golimumab	Simponi	50 mg/0.5 mL prefilled syringe and autoinjector		
Infliximab	Remicade	100 mg/10 mL intravenous infusion		
				Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	<p><b>First course of Rituxan for the treatment of rheumatoid arthritis</b> in adult patients with:</p> <ul style="list-style-type: none"> <li>• Severe active disease (<math>\geq 5</math> swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid arthritis); <b>AND</b></li> <li>• Failure to respond to optimal use of DMARDs or documented intolerance or contraindications to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); <b>AND</b></li> <li>• Failure to respond to, <b>OR</b> the patient has intolerance or contraindications to, an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, <u>golimumab, certolizumab pegol</u>)</li> </ul> <p>Initial approval: One year: <u>One course</u> of treatment is 1000 mg followed two weeks later by the second 1000mg dose. <u>Two courses</u> will be approved each year (courses should be at least 6 months apart with second course being given only AFTER loss of effect as noted in the re-treatment guidelines below). Second course is not approved for “maintenance” therapy.</p> <p><b>Renewal criteria:</b> A joint count at 3-4 months indicating at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints, should be recorded to indicate a response, and then re-treatment can be given after an interval of at least 6 months AND after a loss of effect. Details of all courses given and the subsequent response should be provided in the renewal request.</p> <p>Renewal approval: 1 year (2 courses). One course of treatment is 1000 mg followed two weeks later by the second 1000mg dose. Repeated courses are not approved for maintenance therapy.</p> <p>Note: Rituximab should not be used concomitantly with other anti-TNF agents.</p> <p>For more information, please go to:  <a href="http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/rituxan.pdf">http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/rituxan.pdf</a></p>	<p>Initial: 1 year</p> <p>(2 courses given at least 6 months apart with initiation of 2<sup>nd</sup> course only after loss of effect)</p> <p>Renewal: 1 year</p> <p>(2 courses given at least 6 months apart with initiation of 2<sup>nd</sup> course only after loss of effect)</p>

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Abatacept	Orencia	250 mg/15 mL intravenous injection	<p><b>For the treatment of rheumatoid arthritis</b> in adult patients with:</p> <ul style="list-style-type: none"> <li>Severe active disease (<math>\geq 5</math> swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid arthritis); <b>AND</b></li> <li>Failure to respond to optimal use of DMARDs or documented intolerance or contraindication to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); <b>AND</b></li> <li>Failure to respond to, OR the patient is intolerant to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, <u>golimumab</u>, <u>certolizumab pegol</u>)</li> </ul> <p>Only the following dose will be approved to be administered at 0, 2 and 4 weeks, then every 4 weeks thereafter: 500 mg for patients &lt; 60 kg; 750 mg for patients 60-100 kg; and 1000 mg for patients &gt;100 kg.</p> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>Note: Abatacept should not be used concomitantly with anti-TNF agents.</p> <p>For more information, please go to:  <a href="http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/orencia.pdf">http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/orencia.pdf</a></p>	Initial: 1 year  Renewal: 1 year
Tocilizumab	Actemra	80 mg / 4 mL 200 mg / 10 mL 400 mg/ 20 mL	<p><b>For the treatment of rheumatoid arthritis</b> in adult patients with:</p> <ul style="list-style-type: none"> <li>Severe active disease (<math>\geq 5</math> swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid arthritis); <b>AND</b></li> <li>Failure to respond to optimal use of DMARDs or documented intolerance or contraindication to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); <b>AND</b></li> <li>Failure to respond to, OR the patient is intolerant to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, <u>golimumab</u>, <u>certolizumab pegol</u>)</li> </ul> <ul style="list-style-type: none"> <li></li> </ul> <p>*Optimal use of DMARDs include:</p> <ul style="list-style-type: none"> <li>Methotrexate (20 mg/week) for at least 3 months and leflunomide (20 mg/day) for at least 3 months in addition to an adequate trial (3 months) of at least one combination of DMARDs; or</li> </ul>	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<ul style="list-style-type: none"> <li>• Methotrexate (20 mg/week) for at least 3 months and leflunomide in combination with methotrexate for at least 3 months.</li> <li>• If the patient could not receive adequate trial(s) of methotrexate and/or leflunomide due to contraindication(s) or intolerance(s), the nature of contraindication(s) or intolerance(s) must be provided along with details of trials of other DMARDs or clear rationale why other DMARDs cannot be considered.</li> </ul> <p>The requesting physician is required to provide the planned dosing regimen on the request.</p> <p>The following is the recommended dose for tocilizumab (Actemra) for rheumatoid arthritis:</p> <p>4 mg/kg/dose once every 4 weeks followed by an increase to 8 mg/kg/dose based on clinical response. For individuals whose body weight is more than 100kg, doses exceeding 800mg per infusion are not recommended.</p> <p>Note that doses greater than 8 mg/kg will not be approved.</p> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p>	<p>Renewal: 1 year</p>

**SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS DRUG**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Tocilizumab	Actemra	80 mg / 4 mL 200 mg / 10 mL 400 mg/ 20 mL	<p><b>For the treatment of systemic juvenile idiopathic arthritis in patients</b> who meet the following criteria;</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of sJIA with fever ( &gt;38 degrees Celsius) for at least 2 weeks AND at least ONE of the following:               <ul style="list-style-type: none"> <li>○ rash of systemic JIA</li> <li>○ serositis (e.g. pericarditis , pleuritis, or peritonitis)</li> <li>○ lymphadenopathy (e.g. cervical, axillary, inguinal)</li> <li>○ hepatomegaly</li> <li>○ splenomegaly</li> </ul> </li> <li>• The physician has ruled out other potential etiologies (e.g. malignancies, serious clinical infections, and other inflammatory or connective tissue diseases); AND</li> <li>• Age of disease onset is younger than 16 years of age. (Note: the physician must specify age of disease onset in the request); AND</li> <li>• Systemic corticosteroids cannot be used for at least ONE of the following reasons (please specify name and current dose of corticosteroid, if applicable):               <ul style="list-style-type: none"> <li>○ The patient is unresponsive and/or refractory to systemic corticosteroids; OR</li> <li>○ The patient has experienced a systemic reaction (e.g. fever, rash of sJIA, serositis, lymphadenopathy, hepatomegaly or splenomegaly) while on tapering doses of systemic corticosteroids (i.e. the patient is corticosteroid dependent); OR</li> <li>○ The patient has experienced an adverse drug reaction to a systemic corticosteroid; OR</li> <li>○ The use of systemic corticosteroids is contraindicated in this patient.</li> </ul> </li> </ul> <p>Note: The following requests will undergo external review on a case-by-case basis:</p> <ul style="list-style-type: none"> <li>• Patients with Macrophage Activation Syndrome</li> <li>• Patients who meet initial sJIA criteria and are currently 16 years of age or older</li> <li>• Patients who meet initial sJIA criteria and are requesting higher dosing regimens (Please provide rationale for the higher dosing regimen with your request)</li> </ul>	Initial: 1 year

			<p>Dosing: For those less than 30 kg, 12 mg/kg IV every 2 weeks  For those greater than or the same as 30 kg 8 mg/kg IV every 2 weeks  Note: Recommended maximum adult dose is 800mg.</p> <p><b>Renewal</b> will be considered for patients demonstrating at least a 50% reduction in corticosteroid dose (unless contraindicated, not tolerated, unresponsive or refractory at the time of initial request) and no evidence of active systemic disease. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>The following renewal requests will undergo external review:</p> <ul style="list-style-type: none"> <li>• Evidence of active systemic disease</li> <li>• Requests for higher dosing regimens (Please provide rationale for the higher dosing regimen with your request)</li> <li>• Patient is currently 16 years of age or older</li> </ul>	Renewal: 1 year
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**JUVENILE SPONDYLOARTHRITIS or ENTHESITIS-RELATED ARTHRITIS**

<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Etanercept Enbrel	25mg/vial	50 mg prefilled syringe for subcutaneous injection	<p><b>For the treatment of juvenile spondyloarthritis (JSpA) or enthesitis-related arthritis (ERA) in patients who meet the following criteria for either axial or peripheral disease:</b></p> <p><b>Axial Disease</b></p> <ul style="list-style-type: none"> <li>• Age of disease onset ≤ 16 years; AND</li> <li>• Low back pain and stiffness for &gt; 3 months that improve with exercise and not relieved by rest; AND</li> <li>• Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; AND</li> <li>• BASDAI score of ≥ 4 after at least 4 weeks of standard NSAID therapy; AND</li> <li>• Radiographic evidence of severe active disease by X-ray, CT scan or MRI *</li> </ul> <p>*The details of radiographic reports for severe active disease must provide the following;</p> <ul style="list-style-type: none"> <li>○ X-ray or CT scan report stating the presence of “SI joint fusion” or “SI joint erosion” OR</li> <li>○ MRI report stating the presence of “inflammation” or “edema” or “erosion” of the SI joint</li> </ul>	Initial: 1 year
Infliximab	Remicade	100 mg/vial	<p>Actual radiographic reports must be submitted with the request. If the radiographic reports do not specify the above findings, the request will be reviewed by external medical experts. The radiographic interpretation report from the radiologist or rheumatologist may be submitted along with radiographic report.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended dose for the treatment of JSpA/ERA is as follows:</p> <ul style="list-style-type: none"> <li>• Etanercept 0.4mg/kg (max 25 mg) twice weekly or 0.8mg/kg (max 50 mg) once weekly</li> <li>• Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6-8 weeks</li> </ul>	

			<p>Higher dosing will undergo external review.</p> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 50% reduction in BASDAI score or <math>\geq 2</math> absolute point reduction in BASDAI score. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p><b>Peripheral Disease</b></p> <ul style="list-style-type: none"> <li>• Age of disease onset <math>\leq 16</math> years; and</li> <li>• Patients must have a minimum of 3 (three) swollen joints and 5 (five) active joints; and</li> <li>• Evidence of enthesitis in at least 2 locations; and</li> <li>• Failure to respond to or documented intolerance to trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each AND at least one of either sulfasalazine (50 mg/kg/day-maximum 2 grams per day) or methotrexate (15mg/m<sup>2</sup> per week subcutaneously-maximum 25 mg per week) for 3 months.</li> </ul> <p><b>Renewal</b> will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. There should also be an improvement in number of enthesitis sites. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>Requests that do not meet these criteria will undergo external review.</p>	<p>Renewal: 1 year</p>
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**SPASTICITY TREATMENTS**

<b>DRUG NAME</b>	<b>BRANDS REIMBURSED</b>	<b>DOSAGE FORM/ STRENGTH</b>	<b>REIMBURSEMENT CRITERIA</b>	<b>STANDARD APPROVAL DURATION</b>
Tizanidine	Zanaflex	4 mg tablet	<p><b>For the treatment of spasticity in patients who have failed and/or cannot tolerate at least two of the following available alternatives:</b> baclofen, diazepam and dantrolene.</p> <ul style="list-style-type: none"> <li>• Submission must describe the intolerance experienced.</li> </ul>	Lifetime

**ULCERATIVE COLITIS DRUG**

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Infliximab	Remicade	100 mg/10 mL intravenous infusion	<p>Treatment of <u>Ulcerative Colitis</u> Disease in patients who meet the following criteria:  <u>Induction</u></p> <ol style="list-style-type: none"> <li>1. <b>Mild disease</b> <ol style="list-style-type: none"> <li>a. Mayo score &lt;6 AND</li> <li>b. Patients with mild disease will be considered on a case-by-case basis BUT submission must include the rationale for coverage</li> </ol> </li> <li>2. <b>Moderate disease</b> <ol style="list-style-type: none"> <li>a. Mayo score between 6 and 10 (inclusive) AND</li> <li>b. *Endoscopic subscore of 2 AND</li> <li>c. Failed 2 weeks of oral prednisone <math>\geq</math> 40mg (or IV equivalent for at least 1 week) AND 3 months of Azathioprine (AZA)/6-Mercaptopurine (6MP) (or where the use of immunosuppressants is contraindicated)</li> </ol> <p>OR</p> <li>d. Stabilized with 2 weeks of oral prednisone <math>\geq</math> 40mg (or a 1 week course of IV equivalent) but the prednisone dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated)</li> </li></ol> <li>3. <b>Severe disease</b> <ol style="list-style-type: none"> <li>a. Mayo score &gt;10 AND</li> <li>b. *Endoscopy subscore <math>\geq</math> 2</li> <li>c. Failed 2 weeks of oral prednisone <math>\geq</math> 40mg (or 1 week IV equivalent)</li> </ol> <p>OR</p> <li>d. Stabilized with 2 weeks of oral prednisone <math>\geq</math> 40mg (or 1 week of IV equivalent) but the prednisone dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated)</li> <p>*The endoscopy procedure must be done within the last year but does not have to be full endoscopy.</p> </li>	Initial: 3 months 5mg/kg/dose at 0, 2 and 6 weeks

			<p><u>Maintenance</u></p> <p>1. After <b>3 loading doses</b> of Remicade:</p> <ul style="list-style-type: none"><li>a. Mayo score &lt; 6 AND</li><li>b. 50% reduction in prednisone from the starting dose</li></ul> <p><i>Approval: 3 months at 5mg/kg/dose every 8 weeks</i></p> <ul style="list-style-type: none"><li>c. if pt is completely off steroids:</li></ul> <p><i>Approval: 12 months at 5mg/kg/dose every 8 weeks</i></p> <p>2. Subsequent renewals:</p> <ul style="list-style-type: none"><li>a. Mayo score &lt; 6 AND</li><li>b. must be off steroids (Patients who remain on steroids will be considered on a case-by-case basis)</li></ul> <p><i>Approval: 12 months at 5mg/kg/dose every 8 weeks</i></p>	
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