Ministry of Health and Long-term Care
Exceptional Access Program (EAP)

EAP Reimbursement Criteria for Frequently Requested Drugs

Updated: December 22, 2016

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 following list of drugs and indications that will be considered for funding under the Exceptional Access Program is not exhaustive. Physicians may wish to contact the EAP directly by phone at 416-327-8109 or 1-866-811-9893 or by email at EAPFeedback.MOH@ontario.ca to see if a specific drug product and or indication not listed below may be considered for EAP funding.

The information provided in this document and website is intended for information purposes only and does not provide any medical diagnosis, symptom assessment, health counselling 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

For a drug to be considered for funding, the EAP reimbursement criteria must always be met and the request approved prior to the initiation of treatment with the drug being requested, unless otherwise specified within the criteria. This includes:

- funding for continued treatment that was previously supplied through a clinical trial, or paid for by other means (such as a third party payer)
  Note: First time applications for the funding of ongoing treatments must meet **both** initial and renewal criteria for the drug being requested (unless otherwise specified)
- funding for a renewal beyond the previously approved initial period, unless otherwise specified.

Note that the terms “fund”, “funded”, or “funding” within this document are interpreted and applied by the Ministry in accordance with the clinical evidence used to establish the reimbursement criteria. The Ministry does not distinguish between the source of the drug funding (e.g. public or private payer[s]) in administering the EAP reimbursement criteria.

Consider the following:

The “non-funding” of specific combination treatments as identified by the criteria will not be reimbursed regardless of the funding source(s) of either therapy. The funding criteria are established based on the reviewed clinical evidence through the submission process and are not to be misconstrued with the source(s) of funding.

Example 1: If drug A has approved reimbursement criteria and drug B has approved reimbursement criteria but the combination therapy of drug A plus drug B has not been reviewed through the established process and/or has no reimbursement criteria, the EAP will not fund either drug individually or as combination therapy if the intended use is for combination therapy, regardless of the actual source of funding of either drug A or drug B.

Example 2: If drug A has approved reimbursement criteria and drug B does not have approved reimbursement criteria, and drug A used in combination with drug B does not have approved reimbursement criteria, funding for drug A will not be provided if the intent is to use drug A as combination with drug B, regardless of the source of funding for drug B.

The duration of funding of a regimen identified in the criteria is in accordance with the duration of therapy supported by the clinical evidence and is not related to or dependent on source(s) of funding.

Example 1: If the approved reimbursement criteria states that “The Ministry will fund drug C for a period of 3 years” and drug C was already used by the patient for 2 years funded by another payer (e.g. private payer, manufacturer, out-of-pocket), the Ministry will only be obliged to fund drug C for the remaining one year if the request meets the approved EAP reimbursement

criteria. Such a limitation in the duration of funding is aligned with the clinical evidence provided to the Ministry at the time of the review.

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.

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 meets 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.

ANEMIA

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Darbepoetin	Aranesp	Prefilled syringes 150 mcg, 200 mcg, 300 mcg, 500 mcg	**For the treatment of anemia secondary to chronic renal disease in those who are not eligible under the Special Drugs Program**, approval can be given if the patient meets the following criteria: • Estimated glomerular filtration rate (GFR) less than 30 mL/min **AND** • Baseline hemoglobin level less than 100 g/L **AND** • Mean corpuscular volume (MCV) level between 75 fL and 120 fL All requests MUST indicate the reason why the patient is ineligible for the Special Drugs Program. **Renewals** will be provided to patients where the hemoglobin levels have improved by 15 g/L after 3 months of therapy. Renewals must specify the name of the drug and dose requested and MUST 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.	Initial: 6 months Renewals: 12 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Darbepoetin	Aranesp	Prefilled syringes 150 mcg, 200 mcg, 300 mcg, 500 mcg	**For the treatment of anemia secondary to myelodysplastic syndrome (MDS)** in patients who meet the following criteria: • MDS confirmed by the bone marrow report **AND** • With a hemoglobin count less than 100 g/L **AND** • Endogenous erythropoietin level of less than 500 U/L **AND** • Mean corpuscular volume (MCV) level between 75 fL and 120 fL. 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. **Renewals** will be provided to patients where the hemoglobin levels have improved by 15 g/L after 3 months of therapy. Renewals must specify the name of the drug and dose requested and MUST 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. _____ Requests **for the treatment of chemotherapy-induced anemia in patients with malignant cancer** DO NOT require	Initial: 6 months Renewals: 12 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			an EAP submission. Please refer to the ODB e-formulary to determine if the patient satisfies the criteria for use.	
Epoetin Alpha	Eprex	Prefilled syringes 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	**For the treatment of anemia secondary to chronic renal disease in those who are not eligible under the Special Drugs Program**, approval can be given if the patient meets the following criteria: • Estimated glomerular filtration rate (GFR) less than 30 mL/min **AND** • Baseline hemoglobin level less than 100 g/L **AND** • Mean corpuscular volume (MCV) level between 75 fL and 120 fL All requests MUST indicate the reason why the patient is ineligible for the Special Drugs Program. **Renewals** will be provided to patients where the hemoglobin levels have improved by 15 g/L after 3 months of therapy. Renewals must specify the name of the drug and dose requested and MUST 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 epoetin alpha and the date(s) that the transfusion(s) occurred.	Initial: 6 month Renewals: 12 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Epoetin Alpha	Eprex	Prefilled syringes 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	**For the treatment of anemia secondary to myelodysplastic syndrome (MDS)** in patients who meet the following criteria: • MDS confirmed by the bone marrow report **AND** • With a hemoglobin count less than 100 g/L **AND** • Endogenous erythropoietin level of less than 500 U/L **AND** Mean corpuscular volume (MCV) level between 75 fL and 120 fL. 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. **Renewals** will be provided to patients where the hemoglobin levels have improved by 15 g/L after 3 months of therapy. **Renewals** must specify the name of the drug and dose requested and MUST 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 epoetin alfa and the date(s) that the transfusion(s) occurred.	Initial: 6 month Renewals: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Epoetin Alpha	Eprex	Prefilled syringes 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	**For treatment of anemia secondary to hepatitis C therapy** in patients who meet the following criteria: • Patient is diagnosed with Hepatitis C and is undergoing treatment with pegylated interferon and ribavirin **AND** • Current hemoglobin is >100 g/L but patient has experienced a drop in hemoglobin of at least 40 g/L since treatment **OR** • Current hemoglobin count is < 100 g/L Submissions must include the following: i) Details of therapy with pegylated interferon and ribavirin (ie: Start date, duration of treatment, patient response etc) ii) Bloodwork (full CBC preferred) that includes the hemoglobin and mean corpuscular volume (MCV) as well as 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. Submissions not meeting the above criteria will be considered on a case-by-case basis. All submissions should be accompanied by • Baseline and current bloodwork (full CBC with MCV) • Baseline clinical status and current symptoms from anemia that were not present at baseline • Details of any complications from anemia	Initials: Full duration of treatment with pegylated interferon/ ribavirin treatment

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			Renewals 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.	Renewals: Full duration of treatment with pegylated interferon/ ribavirin treatment
Epoetin alpha	Eprex	Prefilled syringes 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	**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**; • Hemoglobin between 100 – 130 g/L inclusive **AND** • Mean corpuscular volume (MCV) level between 75 fL and 120 fL inclusive. Request not meeting these criteria will be assessed on a case-by-case basis.	Up to 4 doses preoperatively
			For the treatment of anemia in palliative cancer patients, individuals will be assessed on a case-by-case basis. Submissions must include the rationale for using epoetin alpha over transfusion. _____ Requests **for the treatment of chemotherapy-induced anemia in patients with malignant cancer** DO NOT require an EAP submission. Please refer to the e-formulary to determine if the patient satisfies the criteria for use.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg / 1.6 mL	**Effective July 30, 2013,** neupogen is available on the Ontario Drug Benefit Formulary with limited use criteria for the primary and secondary prophylaxis of febrile neutropenia in patients receiving chemotherapy with curative intent and for pre-stem cell transplant mobilization. Please refer to the Ministry's e-formulary for details. Requests for **neupogen for febrile neutropenia for non-curative disease** may be considered through EAP on a case-by-case basis. Please provide appropriate and adequate details in the request submission for a full assessment. Effective **December 22, 2016,** the subsequent entry biologic (SEB) filgrastim as Grastofil® will be funded under the Ontario Drug Benefit (ODB) Program as a general benefit (GB). Please refer to the e-formulary for funded strengths.	
Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg / 1.6 mL	Note: For all the listed indications in this section, the dosage approved will be based on prescriber request. Indications reviewed through the EAP submission process include: • **For the treatment of patients with an intermediate or high grade lymphoma that have relapsed after initial chemotherapy** and are to receive an autologous bone marrow during the 2 to 4 months of their pre-transplant chemotherapy.	Duration of chemotherapy

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			• **For the treatment of patients with an intermediate or high-grade lymphoma, leukemia and myeloma that have relapsed after initial chemotherapy** and are to receive a peripheral stem cell transplant/stem cell mobilization. Effective **December 22, 2016,** the subsequent entry biologic (SEB) filgrastim as Grastofil® will be funded under the Ontario Drug Benefit (ODB) Program as a general benefit (GB). Please refer to the e-formulary for funded strengths.	Duration as requested
Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg / 1.6 mL	**For the treatment of patients with HIV/AIDS** and who have: a) a persistent (> 3 month) absolute neutrophil count < 0.5 x 10^9 cells/L, **OR** b) an absolute neutrophil count between 0.5-1.0 x 10^9 cells/L with a prior history of three or more opportunistic infections and a persistently low CD4 count less than or equal to 20 x 10^6 cells/L. Note: Dosage approved will be based on prescriber request Effective **December 22, 2016,** the subsequent entry biologic (SEB) filgrastim as Grastofil® will be funded under the Ontario Drug Benefit (ODB) Program as a general benefit (GB). Please refer to the e-formulary for funded strengths.	1 year

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Filgrastim [Granulocyte colony stimulating factor (G-CSF)]	Neupogen	300 mcg/mL 480 mcg/ 1.6 mL	Note: For all the listed indications in this section, the dosage approved will be based on prescriber request. **For the treatment of patients with malignant neutropenia** with persistently low neutrophil counts (i.e. <0.5 x 10^9 cells/L for 3 months) and documented infective episodes. 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; • CBC showing neutrophil counts < 0.5 x 10^9 cells/L for 3 months prior to filgrastim therapy **AND** • A documented history of recurrent infections **AND** • A recent bone marrow examination report with cytogenetics testing **<u>Renewals</u>** for congenital neutropenia will be considered on a case-by-case basis. Submissions must include the following information; a. Updated monitoring plan b. Bloodwork (ie. WBC and ANC) with <u>corresponding</u> filgrastim (Neupogen) doses c. Recent bone marrow report with cytogenetics testing d. History of infections (if applicable) Effective **December 22, 2016,** the subsequent entry biologic (SEB) filgrastim as Grastofil® will be funded under the Ontario Drug Benefit (ODB) Program as a general benefit (GB). Please refer to the e-formulary for funded strengths.	6 months Cyclic or Idiopathic: Lifetime Initial approval for congenital neutropenia: 2 years Renewals for congenital neutropenia: 2 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Iron dextran complex	Dexiron	50 mg/mL Injectable	**For the treatment of iron-deficiency anemia** confirmed by bloodwork where the patient has a demonstrated intolerance[1] to oral iron therapy[2] OR has not responded to adequate therapy with oral iron[2]. [1]Intolerance must be described. [2]Provide name of iron salt, dose, duration of therapy, response etc. **Renewals** will be considered on a case-by-case basis.	Initial: 1 year Renewals: 2 years
Iron sucrose	Venofer	20 mg/mL Injectable	**For the treatment of iron-deficiency anemia** confirmed by bloodwork where the patient has a demonstrated intolerance[1] to oral iron therapy[2] OR has not responded to adequate therapy with oral iron[2]. [1]Intolerance must be described. [2]Provide name of iron salt, dose, duration of therapy, response etc. **Renewals** will be considered on a case-by-case basis.	Initial: 1 year Renewals: 2 years
Lenalidomide	Revlimid	5 mg, 10 mg capsule	**Treatment of anemia due to myelodysplastic syndrome (MDS)** for patients who have; • Demonstrated diagnosis of MDS on bone marrow aspiration • Presence of del[5q] documented by standard cytogenetic or fluorescence in situ hybridization • International Prognostic Scoring System (IPSS) risk category low or intermediate-1 • Transfusion-dependent symptomatic anemia	Initial: 6 months

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			Renewal will be considered for patients who are transfusion-dependent and who have demonstrated at least a fifty percent (50%) reduction in transfusion requirements. Patients with anemia due to MDS who are not transfusion-dependent will be assessed on a case-by-case basis.	Renewal: Up to 1 year

ANTICONVULSANTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Lamotrigine (chewable)	Lamictal	5 mg chewable tablet	**For the adjunctive therapy for children over 2 years of age who are suffering from refractory seizures associated with Lennox-Gastaut syndrome**, and who have previously tried other antiepileptic drugs.	1 year
Levetiracetam	Keppra and generics	250 mg, 500 mg, 750 mg tablet	**Effective July 28, 2016, Levetiracetam is made available as a Limited Use drug on the Ontario Drug Benefit Formulary.**	
Oxcarbazepine	Trileptal	150 mg, 300 mg, and 600 mg tablet 60 mg/mL	**For the treatment of partial seizures** 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. * Intolerance must be described in detail. *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: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/trileptal_hpc-cps_e.html*	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Phenobarbital	PMS-Phenobarbital	15 mg, 30 mg, 60 mg tablet; 5 mg/mL oral liquid	Treatment of seizures.	Lifetime
Rufinamide	Banzel	100 mg 200 mg 400 mg	**For the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients** who meet the following criteria: • Patient is 4 years of age or older; AND • the Patient is currently on two or more anti-epileptic drugs (AEDs) without optimal seizure control; AND • the Patient has failed an adequate trial[1] of lamotrigine AND topiramate; AND • the Patient is in the care of a physician experienced in managing seizures. [1]If an adequate trial of lamotrigine and/or topiramate is not possible due to intolerance or contraindication, a less costly AED that is listed as a benefit on the Ontario drug benefit formulary must be tried in its place. <u>Dose:</u> Maximum daily dose is 1,300 mg per day for patients less than 30 kg; and 3,200 mg per day for patients 30 kg or greater <u>Exclusion Criteria</u>. <u>Funding will not be approved for the following circumstances</u>: • Banzel used first line for LGS; OR • Treatment of partial seizures	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Stiripentol	Diacomit	250 mg capsule 250 mg/pack powder for suspension 500 mg capsule 500 mg/pack powder for suspension	**For the treatment of patients with severe myoclonic epilepsy in infancy (Dravet syndrome)** who meet the following criteria; i) the patient has refractory generalized tonic-clonic seizures; AND ii) the patient requires Diacomit (Stiripentol) for use in combination with clobazam and valproate as adjunctive therapy for the seizures; AND iii) the patient's seizures are not adequately controlled with clobazam and valproate alone; AND iv) the request is submitted by a neurologist or pediatrician. Case-by-case consideration through external review will be permitted for circumstances not meeting the above criteria.	Lifetime

ANTIDIABETIC AGENTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Pioglitazone	Actos , Generics	15 mg, 30 mg, 45 mg tablet	For the treatment of type 2 diabetes in patients who require; • Dual combination therapy of diabetes AND demonstrate inadequate glycemic control (HbA1c of >7%) on maximal doses of metformin (2000 mg/day) OR • Dual combination therapy of diabetes AND demonstrate inadequate glycemic control (HbA1c of >7%) on maximal* doses of sulfonylurea and demonstrated intolerance / contraindication to metformin OR • 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. ***Those with one or more of the following contraindications/ precautions to therapy with pioglitazone/rosiglitazone will not be considered. • Patients with type 1 diabetes • Patients who will be using this as monotherapy • Combination use with a nitrates • Combination use with insulin • Patients with any stage of heart failure (i.e. NYHA Class I, II, III, IV) • Patients at high risk for bone fracture (i.e. post-menopausal women with previously confirmed osteoporosis or osteopenia)	Initial: 5 Years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Pioglitazone	Actos , Generics	15 mg, 30 mg, 45 mg tablet	• Patients with recent history (in the past 3 months) of an ischemic cardiovascular event (myocardial infarction, unstable angina) * Note: For the purpose of the EAP submission, maximal dose of sulfonylurea is considered to be glyburide 10 mg/day, gliclazide 160mg/day OR Diamicron MR 60mg/day, OR glimepiride (Amaryl) 4 mg/day. **Note: For the purpose of the EAP submission, maximal dose of metformin is considered to be 2000 mg/day. <u>Renewals</u> 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.	Renewal: 5 Years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Repaglinide	GlucoNorm	0.5 mg, 1 mg, 2 mg tablet	**For the treatment of type 2 diabetes** in patients with: • Inadequate glycemic control (HbA1c >7%) using maximal* doses of a sulfonylurea AND metformin (2000mg/day) **OR** • Inadequate glycemic control and demonstrated intolerance or contraindication to metformin and who are on maximal* doses of a sulfonylurea **OR** • Inadequate glycemic control and demonstrated intolerance or contraindication to a sulfonylurea (glyburide, gliclazide or glimepiride) and are on maximal** doses of metformin **OR** • Demonstrated intolerance or contraindication to both a sulfonylurea (glyburide, gliclazide or glimepiride) AND metformin **OR** • Adequate glycemic control (HbA1c ≤ 7%) who develops intolerance or contraindication to sulfonylurea (glyburide, gliclazide or glimepiride) or metformin **OR** • HbA1c ≤ 7% but with greater than 50% of fasting blood glucose (FBG >7mmol/L) or post-prandial plasma glucose (PPG >10mmol/L) levels not within target range and using maximally tolerated doses of a sulfonylurea and metformin. *** Note:** For the purpose of the EAP submission, maximal dose of sulfonylurea is considered to be glyburide 10mg/day, gliclazide 160 mg/day or Diamicron MR 60 mg/day, OR glimepiride (Amaryl) 4 mg/day. ****Note**: For the purpose of the EAP submission, maximal dose of metformin is considered to be 2000 mg/day	Initial: 5 Years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Rosiglitazone	Avandia	2 mg, 4 mg, 8 mg tablet	For the treatment of type 2 diabetes mellitus in patients with: • Inadequate glycemic control (HbA1c >7%) from ALL other oral antidiabetic agents* funded through one of the Ontario Drug Benefit Programs, in monotherapy or in combination OR • Where ALL other oral antidiabetic agents are inappropriate due to contraindications or intolerance AND • The patient has refused or is not able to take insulin AND • There is no known contraindication to rosiglitazone. * Oral antidiabetics include the following agents; ○ glyburide ○ metformin ○ gliclazide (Diamicron, Diamicron MR) ○ sitagliptin (Januvia) ○ saxagliptin (Onglyza) ○ repaglinide (GlucoNorm) ○ pioglitazone (Actos) Note: A trial with acarbose is not a mandatory requirement. 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: ○ glimepiride (Amaryl) ○ nateglinide (Starlix) **<u>Renewals</u>** will be considered where patients have benefited and continue to benefit from rosiglitazone treatment as demonstrated by <u>recent</u> HbA1c levels ≤7% while on treatment with rosiglitazone AND in those who continue to have no known contraindication(s) to rosiglitazone.	Initial: 5 years Renewal: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Orlistat	Xenical	120 mg capsule	**For the treatment of type 2 diabetes** in a patient with: • Inadequate glycemic control (i.e., HbA1c > 7.0%) on <u>maximal</u> oral antidiabetic medications* **AND** • Body Mass Index ≥ 27 **AND** • Demonstrated failure to a trial of nutritional/dietary counselling and exercise programs * Note: Maximal dose of sulfonylurea is considered to be glyburide 10mg/day, gliclazide (160mg/day or Diamicron MR 60 mg/day) OR glimepiride (Amaryl) 4mg/day. Note: Maximal dose of metformin is considered to be 2000 mg/day **<u>Renewals</u>** 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 <7.0% or HbA1c reduction of more than 0.5%)	1 Year First renewal: 12 months

ANTI-INFECTIVES

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Aztreonam	Cayston	75 mg/vial powder for solution	For the treatment of chronic infection with *Pseudomonas aeruginosa* (PsA)infection in patients with a diagnosis of Cystic Fibrosis who meet all the following criteria: (a) Patient has a documented diagnosis of cystic fibrosis; (b) Patient has a chronic infection with Pseudomonas aeruginosa (PsA) that has been confirmed by 2 (two) positive sputum cultures taken at least 1 month apart that are both positive for PsA; (c) the Patient's clinical condition is deteriorating despite treatment with inhaled tobramycin; (d) the Patient has moderate to severe impairment of lung function defined by baseline FEV1 < 75% of predicted; and (e) the Patient is ≥ 6 years old. **Exclusion Criteria:** Aztreonam (Cayston) will not be funded in the following circumstances. • Aztreonam will not be funded in combination with tobramycin inhalation • Aztreonam will not be funded for bronchiectasis indications outside of proven cystic fibrosis; • Aztreonam will not be funded outside of the cystic fibrosis population • Aztreonam will not be funded for patients with mild cystic fibrosis; • Aztreonam will not be funded for the purpose of convenience	Initial: 1 year

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Aztreonam	Cayston	75 mg/vial powder for solution	Approved Dosage. The approved dosage for Aztreonam (Cayston) under the EAP is as follows: Inhale 75 mg three times daily used in a repeated 28 day cycle that involves administration of aztreonam for 4 weeks of treatment followed by 4 weeks off aztreonam therapy. **Renewals** will be considered in patients who demonstrate ongoing response to therapy.	Renewal: 1 year
Dapsone	Dapsone	100 mg tablet	**For the treatment of** the following conditions and situations; • **PCP prophylaxis in immunocompromised patients** (e.g. patients with HIV or organ transplants) with an intolerance/allergy to trimethoprim-sulfamethoxazole. • **Autoimmune diseases** (e.g. pemphigus vulgaris, pemphigoid, dermatitis herpetiformis) • Patients who have previously taken, or are currently taking, dapsone. **Renewals** are considered for patients who still require treatment with dapsone.	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Daptomycin	Cubicin	500 mg/ 10 mL powder for injection	Note that initial requests for Daptomycin may be accessed through the EAP's Telephone Request Service. **For the treatment of patients experiencing the following types of infections due to methicillin-resistant Staphylococcus aureus (MRSA) bacteria**; i) Staphylococcus aureus bloodstream (SAB) infection including right-sided Staphylococcus aureus infective endocarditis (SARIE); AND/OR ii) Osteomyelitis; AND/OR iii) Device-related osteoarticular or prosthetic joint infections; AND/OR iv) Diabetic foot infections. Additionally, the patient must have failed to adequately respond to, be intolerant[1] to, or have a contraindication to vancomycin. [1]Intolerance due to Red Man Syndrome. If the physician asserts that the patient is intolerant to vancomycin due to red man's syndrome, additional clinical details of the patient's intolerance, including rate of infusion and the use of antihistamines and other histamine blockers prior to therapy with vancomycin . **Renewals** will be considered on a case-by-case basis. (Physicians must submit adequate clinical information to justify the need for ongoing therapy with daptomycin.) Exclusion Criteria: • Daptomycin is not funded for patients with MRSA-related	Initials: Up to 8 weeks Renewals: Case-by-case

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			pneumonia; • Daptomycin is not funded for patients with skin/skin structure infections other than diabetic foot infections caused by MRSA.	
Fidaxomicin (May be accessed through the telephone request service)	Dificid	200 mg tablet	**For the treatment of Clostridium difficile infection (CDI)** in patients who meet the EAP criteria for vancomycin use, but where the patient: • has experienced a third or subsequent episode within 6 months of treatment with vancomycin for prior episode(s), with no previous trial of fidaxomicin; OR • has experienced treatment failure* with oral vancomycin for the current CDI episode; OR • has had a documented allergy (immune-mediated reaction) to oral vancomycin; OR • has experienced a severe adverse reaction or intolerance** to oral vancomycin treatment that resulted in the discontinuation of vancomycin therapy. **Treatment failure is defined as 7 days of vancomycin therapy without acceptable clinical improvement.* ***Details of severe adverse reaction or intolerance must be provided and should be clinically related to oral administration of vancomycin.* Re-treatment criteria: • Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 30 days of the completion of the most recent fidaxomicin course.	200 mg twice a day for 10 days

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			• Relapse/ recurrence occurring beyond 30 days after the completion of the most recent fidaxomicin course will require a trial with vancomycin, unless there is a documented allergy, severe adverse reaction or intolerance to prior oral vancomycin use. Note: Fecal biotherapy ("stool transplantation"), if available, should be encouraged for this patient population. Approved dose and duration: 200 mg twice a day for 10 days	
Fluconazole	Diflucan, Generics	50 mg, 100 mg, tablets 150 mg capsule 10mg/mL oral solution	**For the prevention of fungal infections post- bone marrow or stem cell transplant until engraftment**. **Renewals** will be assessed on a case-by-case basis. Note: Fluconazole is reimbursed under limited use status for the following conditions: • The treatment of thrush in immunocompromised patients (i.e. patients with malignancies and transplant recipients) who are unresponsive to nystatin or imidazole preparations • the treatment of oroesophageal candidiasis in immunocompromised patients (i.e. patients with malignancies and transplant recipients) • Patients with disseminated candidiasis • Treatment of acute cryptococcal meningitis • For the treatment of vaginal candidiasis	3 Months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Posaconazole	Posanol	40 mg/mL Suspension	**For the prophylaxis of Aspergillus and Candida infections in patients who have recently (within the past 3 months) undergone an allogeneic bone marrow transplant.**	Limited to 4 months
			For the prophylaxis of invasive fungal infections in patients who have previously (3 months or longer) undergone an allogeneic stem cell transplant and are experiencing moderate to severe graft-versus-host-disease (GVHD) will be considered on a case-by-case basis. Note: Please provide details of the patient's clinical condition including all medications used to treat the condition with your request application.	Up to 4 months
			<u>Renewals</u> will be considered on a case-by-case basis for patients who continue to experience ongoing symptoms of moderate to severe GVHD. Please provide information regarding infections that were experienced while on therapy (as applicable) including the names of medications and treatments being used to manage GVHD. .	Case-by-case
			For the treatment of invasive aspergillosis* in patients who are refractory or intolerant to voriconazole OR who have documented contraindication to voriconazole. *Invasive aspergillosis should be confirmed by fungal culture. Note: Requests without a positive fungal culture must be accompanied by a consultation note from an infectious disease expert with details of how the diagnosis was made and will be	Initial:3 months

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Posaconazole	Posanol	40 mg/mL Suspension	considered on a case-by-case basis. **Renewals** will be considered on a case-by-case basis. **For the treatment of mucormycosis**** in patients who have failed, have a contraindication to, or experienced intolerance to amphotericin B; OR **For the step-down treatment of mucormycosis**** in patients who have been initially treated with amphotericin B but cannot tolerate long-term therapy with this agent. **Mucormycosis infection must be confirmed by fungal culture. *Note: Requests without a positive fungal culture but where the diagnosis of mucormycosis is documented by an infectious diseases consult and other tools (e.g, radiology reports, histopathology, etc.) will be considered on a case-by-case basis.* **Renewals** will be considered for patients who are responding to therapy but who have not experienced clinical resolution of their condition. Note that requests for renewal must be accompanied by supporting clinical information (Infectious disease consultation/radiology report).	Initial:3 months First renewal: 3 months Subsequent renewals: case-by-case duration

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Vancomycin (May be accessed through the telephone request service)	Vancocin and other generics (Note that only specific DINs are reimbursed by the EAP)	125 mg capsules 250 mg capsules 1 g vials	**For the treatment of patients with symptomatic Clostridium difficile-associated diarrhea (CDAD)** with diagnosis confirmed by: • Positive toxin assay; *or* • Typical endoscopic appearance; *or* • Typical histologic pattern on biopsy; *or* • Pending toxin results and clinical suspicion of CDAD; *or* • Clinical suspicion and less than 30 days since last CDAD episode that was diagnosed by any of the above 3 criteria (quick relapse). AND meeting one of the below criteria: • Documentation of Severe CDAD* • 3 or more episodes in the last 6 months • Relapse within 60 days of completion of previous vancomycin therapy • Contraindication or current/previous intolerance to metronidazole • Failure (inadequate clinical response) with metronidazole for the current episode *__Indicators of Severe CDAD:__ If patient has ≥ two indicators from column 1 OR ≥ one indicator from column 2, then failure of a standard course of metronidazole is NOT required. <u>Column 1 (Two Of):</u> • Age ≥ 65 years old • Renal failure SrCr ≥ 200 umol/L • High leukocyte count <u>Column 2 (One Of):</u> • Toxic megacolon • Septic shock/hypotension • Bowel perforation • Ileus	Duration is provided based on the clinical history of the CDI infection provided.
Vancomycin (May be accessed through the telephone request service)	Vancocin and other generics (Note that only specific DINs are reimbursed by the EAP)	125 mg capsules 250 mg capsules 1 g vials		Range of 2 to 8 weeks based on clinical details which include the number of episodes for the infection.

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			>15x10^9 cells/L • Serum albumin < 25 g/L • Temperature > 38.3^{o}C • Need for colectomy • Treatment in the ICU <u>Approved Dose and Duration</u>: **1st episode**: ○ Severe CDAD: 125mg-250 mg four times daily for 2 weeks ○ Non-severe CDAD: 125 mg four times daily for 2 weeks **2 episodes in 6 months**: ○ Severe CDAD or Early Relapse: 125 mg-250 mg four times daily for 4 weeks ○ Non-severe CDAD: 125mg four times daily for 4 weeks **3 or more episodes in 6 months**: 125mg-250mg four times daily for 8 weeks	
Voriconazole	VFend	50 mg, 200 mg tablets 200 mg/vial injection	**For the treatment of patients who have culture positive candidemia, due to *Candida* species, AND with documented resistance to fluconazole**. 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.	1 Month

ANKYLOSING SPONDYLITIS DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	For the treatment of ankylosing spondylitis (AS) OR psoriatic spondylitis (PS) in patients who have severe active disease with: • Age of disease onset ≤ 50; **AND** • Low back pain and stiffness for > 3 months that improves with exercise and not relieved by rest; **AND** • 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** • BASDAI score of ≥ 4 for at least 4 weeks while on standard therapy; **AND** The information submitted with the request must include the following: • A list of current concomitant medications related to the AS/PS, including pain medications (if relevant). Please include dosing regimens. • Details of review of radiographic reports for severe active disease. o X-ray or CT scan report stating the presence of "SI joint fusion" or "SI joint erosion" OR o MRI report stating the presence of "inflammation" or "edema" of the SI joint o Actual radiographic reports must be submitted with the request. If the radiographic reports do not specify the above, the request will be reviewed by external medical experts. Additional information that should be provided if applicable: • Schober measurement and chest expansion measurement	Initial: 1 year
Certolizumab	Cimzia	200 mg/mL prefilled syringe		
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection		
Golimumab	Simponi	50 mg/0.5 ml prefilled syringe and autoinjector		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Infliximab	Remicade	100mg/10mL intravenous infusion	• Evidence of restricted spinal mobility • 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. **Renewal** will be considered for patients with objective evidence of at least a 50% reduction in BASDAI score or ≥ 2 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). For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided. The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of AS/PS are as follows: 1. Adalimumab 40mg every other week. 2. Certolizumab 400 mg at week 0, 2, 4 then maintenance doses of 200 mg every 2 weeks or 400 mg every 4 weeks 3. Etanercept 25mg twice weekly or 50mg once weekly 4. Golimumab 50 mg once a month 5. 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. **(Note that effective February 25, 2016, Infliximab as Remicade for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.**	First renewal: 1 year Second and subsequent renewals: 2 years

ANTI-INFLAMMATORIES

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Icabitant	Firazyr	30 mg/3 mL prefilled syringe	**For the treatment of acute attacks of type I or type II hereditary angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency** if the following conditions are met: a. Treatment of acute non-laryngeal attacks of at least moderate severity; OR b. Treatment of acute laryngeal attacks; AND c. Must be prescribed by physicians (e.g. immunologists, allergists or hematologists) with experience in the treatment of HAE. Notes: • Documentation of diagnosis (e.g. patient and family history, symptoms, lab test results) must be provided. • For acute non-laryngeal attacks, documentation of severity (frequency, location, and degree of swelling) must be provided Doses for acute treatment are limited to a single dose for self-administration per attack.	Lifetime

ASTHMA

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Leukotriene Receptor Antagonists				
Zafirlukast	Accolate	20 mg tablet	**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). OR **For the treatment of asthma in children and adolescents whose asthma cannot be controlled on ICS alone** 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 **Renewal** of requests that meet the above criteria will be provided where the following apply: • Current medications and dosages must be clearly specified; AND • Objective evidence of positive response from treatment (spirometry OR decrease in health care utilization) must be provided	Initial: 5 years Renewal: 5 years
Montelukast	Singulair	5 mg, 10 mg tablet		Initial: 5 years (up until age of 18) Renewal: 5 years (up until age of 18)
Omalizumab	Xolair	150 mg/ vial	**For the treatment of severe uncontrolled asthma** in patients who meet the following criteria: • Has required hospitalization for asthma within the past 12 months; OR • Has required two or more urgent visits for asthma to a physician or an emergency department within the past 12 months; OR	Initial: 1 Year

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Omalizumab	Xolair	150 mg/vial	• Has had two or more courses of high-dose oral corticosteroids in the past 12 months; AND • Is age 12 years or older; AND • Has demonstrated a positive skin test or in vitro reactivity to a perennial aeroallergen; AND • Has a baseline IgE level between 30 and 700 IU/mL (inclusive) ; AND • Has an actual body weight between 20 kg to 150 kg (inclusive); AND • 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 • Is deemed to be adherent and is using his/her inhaled corticosteroid and long-acting beta agonist daily as prescribed; AND • Is using proper inhaler technique (with a spacer if required); AND • 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.) * High-dose inhaled corticosteroids is considered the use of more than 1000 mcg of beclomethasone dipropionate (BDP) equivalents daily. To avoid delays in the assessment of the request, physicians should provide the following information within their request submission.	

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Omalizumab	Xolair	150 mg/vial	1. The number of hospitalizations for asthma in the past 12 months. 2. The number of asthma exacerbations requiring urgent visits to a physician or emergency department in the past 12 months. 3. The average number of night-time awakenings in a one week period. (reflective of control in last 12 months). 4. The average number of puffs/day of short-acting beta-agonists within a one week period (reflective of control in last 12 months). 5. The number of courses of prednisone (or acute increases in prednisone dose if the patient is already using chronic daily prednisone) for asthmaexacerbation in the past 12 months. 6. The FEV_1 pre and post bronchodilator. 7. Patient's actual body weight. 8. The serum IgE level. 9. Results of a positive allergy testing by skin prick test or IgE RAST. 10. A list of all of the patient's current asthma medications including drug name and doses. 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. 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.	

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Omalizumab	Xolair	150 mg/vial	**Renewal** 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: 1. The number of hospitalizations for asthma in the past 12 months 2. The number of asthma exacerbations requiring urgent visits to a physician or Emergency Department in the past 12 months 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. 4. The number of nighttime awakenings (over a several week period post-introduction of therapy) 5. The average number of puffs/day of short-acting beta-agonists used per day (over a several week period post-introduction of therapy) 6. The FEV_1 pre and post bronchodilator 7. All current asthma medications taken by the patient including drug names and dosing schedule.	Renewal: Up to 1 year

BLOOD MODIFIERS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Deferasirox	Exjade	125 mg, 250 mg, 500 mg tablet	**For the treatment of patients with chronic iron overload in transfusion-related anemia due to B-thalassemia or sickle cell disease** in patients who meet the following criteria; i) Patient is 6 years of age or older;OR ii) The patient is between 2 to 5 years of age (inclusive) and cannot be adequately treated with deferoxamine. Combination therapy (i.e., Exjade in addition to another iron chelating agent) will not be approved. Note, that therapy should be initiated and maintained by physicians experienced in the treatment of chronic iron overload due to blood transfusions. **Renewals** will be 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). The following documentation is required for renewals: • A transfusion record from the past year; AND • LIC levels – baseline (pre-treatment) and since initiation of treatment. The most recent LIC level should be from within the previous year.	Initial: 5 years Renewal: 5 years

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Deferasirox	Exjade	125 mg, 250 mg, 500 mg tablet	**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)** in patients who have a contraindication or severe intolerance to deferoxamine. Contraindications may include one or more of the following: • known or suspected hypersensitivity to deferoxamine • recurrent injection or infusion-site reactions (e.g., cellulitis) • concomitant bleeding disorder • immunocomprimised patients with a documented risk of significant infections with parenteral administration (e.g. neutropenia) **Renewals** will be considered on a case-by-case basis. Physicians must provide adequate information to support the request for renewal.	Initial: 1 year Renewal: 5 years
Deferiprone	Ferriprox	1000 mg Tablets	**For the treatment of patients with transfusional iron overload due to thalassemia syndromes** who cannot be adequately treated with deferoxamine or deferasirox. Notes: Combination iron chelation therapy with Ferriprox will be considered on a case-by-case basis. Therapy should be initiated and maintained by physicians experienced in the treatment of chronic iron overload due to blood transfusions.	Initiation: 5 years

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Deferiprone	Ferriprox	1000 mg tablets	**Renewals** will be considered for Patients who continue to require iron chelation therapy and has had a consistent response to therapy (demonstrated by a reduction in baseline LIC levels). The following documentation is required: • A transfusion record from the past year; and • LIC levels – baseline (pre-treatment) and since initiation of treatment. The most recent LIC level should be from within the previous year.	Renewals: 5 years
Eculizumab	Soliris	10 mg/mL (300 mg per vial)	**For the treatment of patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)** meeting the following criteria**:** The diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) has been made based on the following confirmatory results: • Flow cytometry/FLAER exam with granulocytes clone ≥ 10% **AND** • LDH > 1.5 ULN **AND at least one of the following:** • A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy, • Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months, • 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, • Pulmonary insufficiency: Debilitating shortness of breath and/or	Initial: 6 months

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	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, • Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73 m^2, where causes other than PNH have been excluded, • Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded. **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** **Renewals** will be considered for patients who; • Demonstrate clinical improvement while on therapy or • Where therapy has been shown to stabilize the patient's condition. Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry). **Further, subsidized treatment may continue unless one or more of the following situations apply:** 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; ii) If therapy fails to relieve the symptoms of disease that	Renewal: 1 year

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	originally resulted in the patient being approved for subsidized treatment; **Other eligibility requirements:** Note: All patients must receive meningococcal vaccination with a tetravalent vaccine at least two weeks prior to receiving the first dose of eculizumab. **Exclusion criteria for both initial and renewal requests:** i) Small granulocyte clone size - the treatment of patients with a granulocyte clone size below 10% will not be eligible for treatment; **OR** ii) Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity; **OR** 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); **OR** iv) The presence of another medical condition that might reasonably be expected to compromise a response to therapy.	

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	**Preamble:** A confirmed diagnosis of atypical hemolytic uremic syndrome (aHUS) is required for eculizumab funding. The information below is to provide clinicians with context for how a diagnosis of aHUS will be assessed for funding consideration. Details to address these issues should be provided in the funding request. While some patients may already have a confirmed aHUS diagnosis, by clinical history and/or genetic testing, the majority of patients presenting with thrombotic microangiopathy (TMA) have no prior diagnosis of aHUS. For most patients presenting with a TMA, it is not possible to confidently separate aHUS from the vast majority of other conditions causing TMA until after appropriate testing and treatment have occurred. The majority of patients who have TMA suffer from Thrombotic Thrombocytopenic Purpura (TTP) (30-40%), or a secondary form of TMA (e.g., pregnancy, HIV, collagen vascular disease, drugs, malignancy, stem cell transplant, malignant hypertension) (> 50%), or hemolytic uremic syndrome due to a Shiga toxin (>5%). In most cases, patients who suffer from TTP will have an ADAMTS-13 of less than 10%. If TTP has been ruled out and any secondary causes have been treated and the patient still has a persisting unexplained TMA with ADAMTS-13 ≥10%, the patient would be presumed to suffer from aHUS. Patients who present with ADAMTS-13 of ≥10% and who are unresponsive to plasma therapy (>4 plasma exchanges) and do not have a known secondary explanation would also be presumed to suffer from aHUS. In the absence of a confirmed diagnosis of aHUS, there is nothing	

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	in these criteria that changes the clinical expectation for appropriate use of plasma exchange/plasma infusion in the management of patients presenting with TMA. **<u>Initiation Criteria</u>** A patient must meet <u>all three</u> of the following criteria to obtain funding for initial treatment with eculizumab: 1. Confirmed diagnosis* of atypical hemolytic uremic syndrome (aHUS) at initial presentation, defined by: a. Presence of an unexplained non- disseminated intravascular coagulation thrombotic microangiopathy (TMA); AND b. Baseline ADAMTS-13 activity ≥ 10% on blood samples taken prior to plasma exchange or plasma infusion (PE/PI); Note: If the sample for ADAMTS-13 was not collected prior to PE or PI, platelet counts > 30 x 109/L and eGFR < 50 mL/min/1.73m^2 at TMA presentation will be accepted as predictive of ADAMTS-13 ≥10% in TMA patients. In this case, measurement of ADAMTS-13 can be taken 1-2 weeks following the last PE. The ADAMTS-13 result must be provided within 30 days of commencement of eculizumab and at least 1 week after the last PE. A one-month interim funding for eculizumab will be provided. AND	Initials: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eculizumab	Soliris	10mg/mL (300 mg per vial)	c. STEC-negative test in patients with a history of bloody diarrhea in the preceding two weeks; AND d. Other diagnoses and causes of TMA must be ruled out, as per preamble. 2. Evidence of ongoing active and progressing TMA as defined by: a. Thrombocytopenia (platelet count <150 x 10^9/L) that is not explained by some other cause including secondary TMA; AND hemolysis as indicated by the documentation of two of the following: red blood cell (RBC) fragmentation (schistocytes) on the blood film; low or absent haptoglobin; or lactate dehydrogenase (LDH) above normal; OR b. Tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and hemolysis. Note: Review by external clinical expert may be required to assess requests for patients with ongoing TMA that may not clearly meet the above criteria. 3. Evidence of at least one of the following documented clinical features of active organ damage or impairment: a. Kidney impairment as demonstrated by one of the following: o A decline in estimated glomerular filtration rate (eGFR) or a rise in serum creatinine (SrCr) of >20% in a patient with pre-existing renal impairment; OR	

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	○ SrCr > upper limit of normal (ULN) for age or eGFR < 60mL/min in patients who have no history of pre-existing renal impairment (i.e., who have no baseline eGFR measurement); OR ○ SrCr > the age-appropriate ULN in pediatric patients (subject to advice from a pediatric nephrologist); or ○ Renal biopsy; OR b. Onset of neurological impairment related to TMA (e.g., visual field defect, hemiparesis, sensory loss, asymmetric limb weakness, confusion, loss of consciousness/coma, new onset seizure). Note:Patients who have extra-renal complications related to TMA (e.g., TMA-related cardiac impairment, TMA-related gastrointestinal impairment, or TMA-related pulmonary impairment) will be reviewed by an external clinical expert. **<u>Continuation Criteria (at 6 months)</u>** After six months of eculizumab therapy, a further six month of funding will be considered if the patient demonstrates treatment response, defined as: • Hematological normalization (platelet count, LDH, haptoglobin); AND • An improvement or stabilization of eGFR (or SrCr); AND • Stabilization of neurological or extra-renal impairment if these complications were originally present.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eculizumab	Soliris	10 mg/mL (300 mg per vial)	Continued treatment with eculizumab will not be funded beyond six months if a patient has experienced treatment failure, defined as: • Dialysis-dependent at six months, and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR • On dialysis for ≥ four of the previous six months while receiving eculizumab and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR • Worsening of kidney function with a reduction in eGFR or increase in SrCr ≥ 25% from baseline. Approval duration: 6 months **<u>Continuation Criteria (at 12 months):</u>** 1. Ongoing treatment response as defined in the 6-month continuation criteria; AND 2. The patient has limited organ reserve defined as: • Significant cardiomyopathy, neurological, gastrointestinal or pulmonary impairment related to TMA; or • Grade 4 or 5 chronic kidney disease (eGFR <30mL/min). (Note: Patients who are dialysis- dependent with no significant extra-renal manifestations persisting are not considered). There may be other exceptional circumstances where the patient has a high risk of recurrence and in whom consequences of a relapse are significant (e.g., complement Factor H genetic	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eculizumab	Soliris	10 mg/mL (300 mg per vial)	mutation, multiple clinical presentations of active TMA). These will be reviewed on a case-by-case basis by an external clinical expert. For patients in whom a pause in therapy is recommended, funding will be left in place for 3 months so that eculizumab can be quickly restarted upon evidence of recurrence per recommencement criteria. Approval duration: 12 months **Recommencement Criteria:** A patient previously diagnosed with aHUS and who responded to treatment with eculizumab and has not failed eculizumab is eligible to restart eculizumab if the following clinical conditions are met: • Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; AND EITHER • Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count <150,000 x 109/L); OR • TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy.	

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Eculizumab	Soliris	10 mg/mL (300 mg per vial)	Note: 1. Raised LDH alone is not a sufficient reason to recommence eculizumab, but thrombocytopenia with one marker of hemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to recommence. 2. Kidney transplantation/dialysis is not a contraindication to recommencement. A patient who becomes eligible to restart eculizumab, in accordance with the above criteria, will be assessed every 6 months for treatment response or failure. Approval duration: 6 months **<u>Patients undergoing kidney transplantation:</u>** For patients with a confirmed aHUS diagnosis who are undergoing kidney transplantation, eculizumab funding will be provided for the time period immediately prior to (or at time of) transplant and for a maximum of six months after. Treatment must be started immediately prior to or at time of transplant. Approval duration: 6 months **All funding requests must come from, or be submitted in consultation with, a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.**	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eltrombopag	Revolade	25 mg, 50 mg tablet	**For the treatment of refractory chronic idiopathic thrombocytopenic purpura (ITP) with bleeding complications in patients who meet the following criteria**: • Patient has undergone a splenectomy[1]; AND • Patient has tried and is unresponsive to other treatment modalities[2]. [1]Requests for Revolade 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 physician must provide rationale for why a splenectomy cannot be considered, and where possible, to include a preoperative/surgical evaluation on the patient's surgical risks to splenectomy, to include consideration of risks of laparoscopic and open surgical interventions if these are available. This evaluation must come from a physician who is not the requesting physician. [2]Appropriate first-line treatment modalities may include: • Corticosteroids • IV anti-D • Intravenous immune globulin (IVIG) [2]Appropriate second-line treatment modalities include: • Azathioprine • Cyclosporine • Cyclophosphamide • Mycophenolate • Rituximab • Danazol • Dapsone	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eltrombopag	Revolade	25 mg, 50 mg tablet	Note: Patients need to have failed at least two of the second-line therapies listed above prior to requesting Revolade. Dosage: 50 mg once daily to a maximum of 75 mg once daily. **Renewal** of requests for Revolade will be assessed on a case-by-case basis **Note: Revolade therapy beyond 1 year of continuous treatment has not been studied. After 1 year of continuous treatment, therapeutic options should be reassessed.**	Renewal: 1 year
Romiplostim	Nplate	250 mcg/0.5 mL 500 mcg/mL	**For the treatment of refractory chronic idiopathic thrombocytopenic purpura (ITP)** with bleeding complications in patients who meet the following criteria; i) Patient has undergone a splenectomy[1] ii) Patient has tried and is unresponsive to other treatment modalities[2]. [1]Requests for romiplostin 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 physician 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. *Note:The Executive Officer (EO) may revise the criteria if the frequency of patients who are not eligible for splenectomy exceeds*	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Romiplostim	Nplate	250 mcg/ 0.5 mL 500 mcg/mL	*published estimates.* [2]Appropriate first-line treatment modalities may include; • Corticosteroids • IV anti-D • Intravenous immune globulin (IVIG) [2]Appropriate second-line treatment modalities may include; • Azathioprine • Cyclosporine • Cyclophosphamide • Mycophenolate • Rituximab • Danazol • Dapsone Patients need to have failed at least two second-line therapies prior to requesting Nplate. **Renewal** of requests will be considered in patients who have a stable platelet response and reduced symptoms of ITP-related bleeding events.	Renewal: 1 year

CARDIOLOGY DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Eplerenone	Inspra	25 mg, 50 mg tablets	**For the treatment of patients who have heart failure and left ventricular systolic dysfunction due to acute myocardial infarction**. Patients must have: • An ejection fraction ≤ 40% **AND** • Prior trial of spironolactone but experienced severe symptomatic (painful) gynecomastia	Lifetime

CENTRAL NERVOUS SYSTEM DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Modafanil	Alertec	100 mg tablet	**For the symptomatic treatment of excessive daytime sleepiness in patients with narcolepsy** who have demonstrated a lack of response to or an inability to tolerate dextroamphetamine AND methylphenidate. Note: See also Multiple Sclerosis Drugs	2 years (Intials and Renewals)
Tetrabenazine	Nitoman	25 mg tablet	**For the treatment of Hungtington's chorea, tic and Gille's de la Toureet syndrome and tardive dyskinesia** in patients meeting the following criteria: i) is prescribed by (or in consultation with) physicians who are experienced in the treatment of hyperkinetic movement disorders (e.g. specialists practicing in a Movement Disorder Clinic, neurologists, psychiatrists, physiatrists, geriatricians, pediatricians); **AND** ii) have disabling Huntington's chorea OR tic and Gille's de la Tourette syndrome and have documented evidence of failure to respond, intolerable side effects or contraindication to at least one agent presently available on the Formulary. **Note that for patients with disabling tardive dyskinesia, a trial of a Formulary *agent is NOT required (ie. tetrabenazine can be considered for use as a first-line agent)* **Renewals** will be considered for patients whose request is prescribed by (or in consultation with) physicians who are	Initial: 1 year Renewal: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Tetrabenazine	Nitoman	25 mg tablet	experienced in the treatment of hyperkinetic movement disorders (e.g. specialists practicing in a Movement Disorder Clinic, neurologists, psychiatrists, physiatrists, geriatricians, pediatricians); AND who provide written confirmation that movements and functional status are stabilized on tetrabenazine therapy. **For the treatment of Hemiballismus, senile chorea, or other disabling hyperkinetic movement disorders (HKMD) will be considered on a case-by-case basis** in patients meeting the following criteria**:** • is prescribed by (or in consultation with) physicians who are experienced in the treatment of hyperkinetic movement disorders (e.g. specialists practicing in a Movement Disorder Clinic, neurologists, psychiatrists, physiatrists, geriatricians, pediatricians); **AND** • have documented evidence of failure to respond, intolerable side effects or contraindication to at least one agent presently available on the Formulary. **Renewals** will be considered for patients whose request is prescribed by (or in consultation with) physicians who are experienced in the treatment of hyperkinetic movement disorders (e.g. specialists practicing in a Movement Disorder Clinic, neurologists, psychiatrists, physiatrists, geriatricians, pediatricians); AND who provide written confirmation that movements and functional status are stabilized on tetrabenazine therapy **Please note that information MUST BE provided about why a**	Initial: 1 year Renewal: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			patient has not tried or cannot try a formulary alternative. **Requests not meeting the above criteria for HKMD will be considered through a case-by-case review and the physician must provide adequate clinical information to enable this assessment.**	

CROHN'S DISEASE DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Infliximab	Remicade	100mg/10mL intravenous infusion	**Note that effective November 30, 2016, Infliximab as Remicade for Moderate to Severe Crohn's Disase including fistulizing Crohn's Disease will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.** **Renewal** of funding of patients using Remicade for the treatment of fistulizing Crohn's Disease will be considered for patients with resolution of fistulae. 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.	Initial: 3 months First renewal: 1 year Second and subsequent renewals: 2 years
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	**For the treatment of fistulising Crohn's disease with concomitant luminal disease in patients who meet the following criteria;** • 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 • Harvey Bradshaw Index (HBI) score ≥ 7 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.	Initial: 3 months Renewal: 3 months to 1 year pending fistula(e) resolution Second Renewal: 2 years for

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			Renewal will be considered based on the response to therapy. 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.	2nd renewal of requests with complete resolution Case-by-case duration for renewal of requests with partial resolution
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	**Treatment of moderate to severe (luminal) Crohn's Disease** in patients who have: • HBI (Harvey Bradshaw Index) score ≥7*; and • Failed to respond to conventional treatment with glucocorticoids (prednisone 40mg/day or equivalent for at least 2 weeks or dose cannot be tapered to below prednisone 20 mg/day or equivalent); and • Failed to respond to an immunosuppressive agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) tried for at least 3 months. *Note:Any intolerance(s) or contraindication(s) to treatment with required alternative(s) must be described in detail.* *If the patient has HBI <7, 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	Initial: 3 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			weight loss; and a list of narcotic analgesics being used. **<u>Renewal</u>** 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. The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of Crohn's Disease are as follows: o Adalimumab: 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks o Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks then 5mg/kg/dose every 8 weeks **(Note that effective November 30, 2016, Infliximab as Remicade for Moderate to Severe Crohn's Disase including fistulizing Crohn's Disease will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.**	First renewal: 1 year Second and subsequent renewals: 2 years
Infliximab	Remicade	100mg/10mL intravenous infusion	**(Note that effective November 30, 2016, Infliximab as Remicade for Moderate to Severe Crohn's Disase including fistulizing Crohn's Disease will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.** **<u>Renewal</u>** will be considered for patients with 50% reduction in HBI	Initial: 3 months First renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			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. The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of Crohn's Disease are as follows: o Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks then 5mg/kg/dose every 8 weeks	Second and subsequent renewals: 2 years

DERMATOLOGY DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Imiquimod	Aldara	5% Cream	**For the treatment of external genital and perianal warts/condyloma acuminata** in patients who; • Have documented failure to a trial of podophyllum resin and one other treatment modality (including cryotherapy, surgical excision, or electrosurgery). **For the treatment of biopsy-confirmed primary superficial basal cell carcinoma** in patients meeting the following criteria; • Tumour diameter of ≤ 2 cm AND • Tumour location on the trunk, neck or extremities (excluding hands and feet) AND • 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) **Renewals** for the same tumour will not be considered.	1 year (Maximum of 16 weeks for each treatment course) 6 weeks
Rituximab	Rituxan	10 mg/mL intravenous injection	**For the treatment of severe pemphigus vulgaris** in patients who meet the following criteria. • Patient has failed combination therapy with high-dose systemic steroids[1] and a steroid-sparing immunosuppressant[2] trialed in combination for a minimum of 3 months. • The request must be made by a dermatologist/specialist familiar with the management of pemphigus vulgaris and with the use of rituximab in this condition. [1]Patients must have used a steroid dose equivalent to a 1	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	mg/kg prednisone dose equivalent (or a minimum of 60 mg/day for patients > 60 kg) for at least 4 to 6 weeks before attempting to taper to a lower dose. [2]Patients must try at least one of the following at therapeutic doses: azathioprine, mycophenolate, cyclophosphamide, or methotrexate (in combination with a steroid). Dose: ONE course of treatment with rituximab is considered 375 mg/m^2 administered weekly for 4 weeks (for a total of 4 doses) OR 1000 mg of rituximab administered at week 0 and week 2 (for a total of 2 doses). Re-treatment may be provided if the patient responded to rituximab therapy then experiences disease flare, as long as the request is made no less than 6 months after the last dose of the patient's last treatment course/cycle with rituximab. Rejection Criteria: • Other dermatology diagnoses, such as pemphigus foliaceus and bullous pemphigoid • Maintenance infusions (i.e. regular maintenance doses to keep disease in remission)	Maintenance Treatment is not funded. First Renewal: 1 year Subsequent Renewals after first renewal: 2 years (Rituxan is funded for course of therapy to be given at an interval of at least 6 months only upon flare of the condition.)

ENDOCRINOLOGY AGENTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Cinacalcet	Sensipar	30 mg, 60 mg, 90 mg tablets	**For the treatment of severe hyperparathyroidism* in patients with chronic kidney disease who are on dialysis** who meet the following criteria; i) the patient is refractory to other treatments; AND ii) the patient has symptoms clearly related to hyperparathyroidism that are causing significant impairment in quality of life (e.g. calciphylaxis or bone pain); AND iii) additionally, **ONE** of the following criteria is present: • the patient has been reviewed by a surgeon, anesthetist or nephrologist and has been deemed to not be a candidate for parathyroidectomy due to high surgical risk or anesthetic risk. [Please note: This must be accompanied by a clinical note explaining the high surgical risk or anesthetic risk and the patient's parathyroid hormone (PTH) level]; OR • the patient has been wait-listed for a parathyroidectomy and requires Sensipar for bridge therapy; OR • the patient is awaiting an imminent renal transplant and a nephrologist indicates a preference for pre-transplant treatment with Sensipar instead of a parathyroidectomy. *Severe hyperparathyroidism is considered to be patients with PTH levels greater than 88 pmol/L confirmed on two laboratory tests for PTH taken at	Initial : 1 year or to the estimated date of the procedure for those using for bridge therapy and awaiting surgery

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Cinacalcet	Sensipar	30 mg, 60 mg, 90 mg tablets	least 1 month apart. <u>Exclusion Criteria</u> • Patients with primary hyperparathyroidism or parathyroid carcinoma. <u>Initial Approval duration</u> i) Patients who are not a candidate for parathyroidectomy due to high surgical or anesthetic risk: 1 year ii) Patients wait-listed for a parathyroidectomy requiring bridge therapy with Sensipar or awaiting an imminent renal transplant will be approved to the estimated date of the surgery. **Renewals** will be considered for patients who are not candidates for parathyroidectomy and who continue to benefit from therapy. Requests for renewals should include the patient's PTH level. **Renewals** will NOT be considered for patients who have had a parathyroidectomy.	Renewals: 1 year

GOUT

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Febuxostat	Uloric	80 mg	**For the treatment of patients with documented severe allopurinol hypersensitivity syndrome* where lowering uric acid is recommended by clinical practice guidelines.** **For the treatment of patients with recurrent gout attacks despite treatment with allopurinol at a dose of 300 mg or more per day for at least six (6) months.** * For the purpose of the criteria severe allopurinol hypersensitivity syndrome is defined as follows; The patient has had a clear exposure to allopurinol and: (a) at least TWO of the following major clinical criteria: (i) worsening renal function; (ii) acute hepatocellular injury; (iii) a rash including either toxic epidermal necrolysis (“TEN”), Stevens-Johnson syndrome (“SJS”), erythema multiforme, generalised maculopapular exanthem or generalized exfoliative dermatitis (“GED”); OR (b) ONE of the major clinical criteria listed above and at least ONE of the following minor criteria: (i) fever (ii) eosinophilia (iii) leukocytosis. Note that an intolerance to allopurinol that does not meet the	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			above criteria will not be eligible for reimbursement. <u>Renewals</u> will be considered in patients with objective evidence to demonstrate a benefit from treatment, documented as either a reduction in gout attacks or a reduction in uric acid levels.	Renewals: 5 years

GRANULOMATOSIS WITH POLYANGIITIS OR MICROSCOPIC POLYANGIITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	For the induction of remission of severely active Granulomatosis with Polyangiitis (GPA) OR microscopic polyangiitis (MPA) as combination treatment with glucocorticoids, in patients who meet all of the following criteria: 1. The patient must have severe active disease that is life- or organ-threatening. At least one supporting laboratory and/or imaging report must be provided. The organ(s) and how the organ(s) is(are) threatened must be specified. 2. There is a positive serum assays for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided. 3. Cyclophosphamide cannot be used for the patient for at least ONE of the following reasons: i) The patient has failed a minimum of six IV pulses of cyclophosphamide; OR ii) The patient has failed three months of oral cyclophosphamide therapy; OR iii) The patient has a severe intolerance or an allergy to cyclophosphamide; OR iv) Cyclophosphamide is contraindicated; OR v) The patient has received a cumulative lifetime dose of at least 25 g of cyclophosphamide; OR vi) The patient wishes to preserve ovarian/testicular function for fertility. The initial treatment would be a once weekly infusion dosed at 375	Maintenance Treatment is not funded. First Renewal: 1 year Subsequent Renewals after first renewal: 2 years (Rituxan is funded for course of therapy to be given at an interval of at least 6 months only upon flare of the condition.)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			mg/m^2 x 4 weeks. The physician must confirm that the treatment would not be a maintenance infusion as maintenance infusions will not be funded. **Renewals** will be considered provided that, the patient meets the same criteria for initial approval and the request for retreatment is made no less than 6 months after the last does of the patient's last treatment cycle with Rituxan.	

HEPATITIS B DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
For the treatment of Chronic Hepatitis B HBsAg, HBeAg, Anti-HBe, HBV DNA, and ALTs including pre-treatment and current data are required for ALL initial requests * Lamivudine virological breakthrough is defined as an increase in HBV DNA of ≥ 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 ≥ 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; **or** 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 **or** 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. ***** Presence of lamivudine-resistant mutation (i.e. YMDD), requires copy of mutation report.				
Adefovir	Hepsera	10 mg 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 ○ Liver biopsy showing Metavir stage 3 fibrosis or greater; OR ○ Documented evidence of cirrhosis. OR • Patients with the presence of a lamivudine resistance mutation*****; AND ○ Liver Biopsy showing Metavir stage 3 fibrosis or greater; OR ○ Documented evidence of cirrhosis.	1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Entecavir	Baraclude	0.5mg tablet	**For the treatment of chronic hepatitis B in lamivudine naïve patients** with high viral load (> 1 x 10^6 IU/mL); AND ○ Liver biopsy showing Metavir stage 4 fibrosis; OR ○ Other documented evidence of cirrhosis. OR • **Patients with inadequate response to lamivudine** defined as: ○ Less than 2 $\log_{10}$ drop in HBV DNA after three months of lamivudine therapy; **OR** ○ Incomplete suppression of viral load after six months of lamivudine therapy; **AND** ○ Documented evidence of cirrhosis OR • **Patients with objective evidence of lamivudine virologic breakthrough*** **AND** documented evidence of cirrhosis; **AND** ○ Adefovir virologic breakthrough**; **OR** ○ Contraindication to adefovir therapy****. OR • **Patients with the presence of a lamivudine resistance mutation*****; **AND** documented evidence of cirrhosis; **AND** ○ Adefovir virologic breakthrough**; **OR** ○ Contraindication to adefovir therapy****.	1 Year
Interferon - alpha	Intron A	18 MU 30 MU 60 MU	**For the treatment of chronic hepatitis B** where the patient meets the following criteria: • Patients less than 50 years of age; and • 2 ALTs > 2 x ULN within the past 6 month period; and • HBV DNA between 1 x 10^4 – 1 x 10^7 IU/mL; and • Liver biopsy showing Metavir stage 3 fibrosis or less (i.e. no cirrhosis)	HBeAg pos: 24 weeks HBeAg neg: 48 weeks

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Lamivudine	Heptovir	100 mg tablet	**For the treatment of chronic hepatitis B in treatment naïve patient**, age ≥ 40 years old with HBV DNA > 1,000IU/mL; **AND** o Three separate ALT levels ≥ 1.3 x ULN within the 6 month period prior to treatment; **OR** o Liver biopsy showing Metavir stage 3 fibrosis or greater; **OR** o Documented evidence of cirrhosis. OR • **Treatment naïve patient, age < 40 years old with HBV DNA > 1,000 IU/mL**; AND o Liver biopsy showing Metavir stage 3 fibrosis or greater; **OR** o Documented evidence of cirrhosis. OR • **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 ≥ 1.3 x ULN within the 6 month period prior to treatment . OR • **HBsAg-positive, treatment naïve patient (any age) who is considered to be immunosuppressed,** with a detectable viral load; AND three separate ALT levels ≥ 1.3 x ULN within the 6 month period prior to treatment. OR • **HBsAg-positive treatment naïve patient (any age) who is about to undergo chemotherapy**. (Approval time: duration of chemo + 6 months) 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 > 1,000 IU/mL; **AND** • Three separate ALT levels ≥ 1.3 x ULN within the 6 month period prior to treatment; **OR** • Liver biopsy showing Metavir stage 3 fibrosis or greater; **OR** • Documented evidence of cirrhosis.	1 Year unless otherwise stated

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Tenofovir	Viread	300 mg tablet	**For the treatment of chronic hepatitis B in patients who are treatment naïve with high viral load (> 1 x 10^6 IU/mL)**; **AND** ○ Liver biopsy showing Metavir stage 4 fibrosis; **OR** ○ Other documented evidence of cirrhosis. OR • **Patients who have inadequate response to lamivudine** defined as: ○ Less than 2 $\log_{10}$ drop in HBV DNA after three months of lamivudine therapy; **OR** ○ Incomplete suppression of viral load after six months of lamivudine therapy **AND** ○ Liver Biopsy showing Metavir stage 3 fibrosis or greater **OR** ○ Documented evidence of cirrhosis. OR • **Patients with objective evidence of lamivudine virologic breakthrough* where failure is not due to poor adherence to therapy AND** ○ Liver Biopsy showing Metavir stage 3 fibrosis or greater; **OR** ○ Documented evidence of cirrhosis. OR • **Patients with the presence of a lamivudine resistance mutation*****AND** ○ Liver Biopsy showing Metavir stage 3 fibrosis or greater **OR** ○ Documented evidence of cirrhosis. Requests for tenofovir in pregnant patients are considered on an individual case-by-case basis via external review.	1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Renewals 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	**For patients receiving therapy (monotherapy or any combination therapy) who have not seroconverted** (e.g. remain HBeAg positive and anti-HBe negative) and are not demonstrating virological breakthrough. OR • **Initial renewal requests for patients who were initially HBeAg positive and seroconverted to anti-HBe positive**. (6 month renewal) OR • **Subsequent renewal requests for patients who were initially HBeAg positive and seroconverted to anti-HBe positive** where: o Reactivation has occurred (two ALTs > 1.3 x ULN at least one month apart or one ALT > 2.5 x ULN; AND a HBV DNA > 1000 IU/mL) o 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. OR • **For patients who were HBeAg negative initially** (i.e. pre-treatment with antiviral agents) **and continues to be HBsAg positive** (i.e. Pre-core mutant).	1 year unless otherwise stated

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Pre- or Post- Liver transplant 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 ≥ 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 ≥ 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; **or** 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 **or** 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	• 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.	Lifetime
Entecavir	Baraclude	0.5 mg tablet	• Lamivudine-naïve pre- or post-liver transplant patients with documented evidence of cirrhosis AND a high viral load (> 1 x 10^6 IU/mL). **OR** • Pre- or post-liver transplant patients with objective evidence of lamivudine virologic breakthrough* or lamivudine resistance*** or a contraindication to lamivudine; **AND** either adefovir virological breakthrough** or a contraindication to adefovir therapy****	Lifetime
Lamivudine	Heptovir	100 mg tablet	• Patients who are treatment naïve (any age) and HBsAg-positive. **OR** • Patients who have objective evidence of adefovir virologic breakthrough** or adefovir resistance or a contraindication to adefovir therapy****; AND where failure is not due to poor adherence to therapy.	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Tenofovir	Viread	300 mg tablet	• Patients who are lamivudine-naïve with documented evidence of cirrhosis AND a high viral load (> 1 x 10^6 IU/mL). **OR** • Patients who have 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.	Lifetime

HEPATITIS C DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Boceprevir	Victrelis Victrelis Triple (4 strengths)	200 mg capsule Triple combination treatment with varying strengths of peginterferon alfa-2b powder 200 mg (B)/ 200 mg (R)/ 80 mcg (P) 200 mg (B)/ 200 mg (R)/ 100 mcg (P) 200 mg (B)/ 200 mg (R)/ 120 mcg (P) 200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)	**For the treatment of chronic hepatitis C in <u>treatment naïve patients</u> with genotype 1,** in combination with peginterferon alfa and ribavirin (PR) who meet ALL of the following: • Patient has a quantitative HCV RNA value from within the last 6 months • < 70 years old OR ≥ 70 years old with no co-morbid conditions • Fibrosis stage F2 or greater (Metavir scale or equivalent) • No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6) Also please note the case-by-case[1] criteria and exclusion criteria[2] stated below. <u>Dosing:</u> Boceprevir(B) dosage: 800 mg three times daily ○ Patients must also meet peginterferon/ribavirin criteria, as applicable ○ HCV RNA laboratory values must be from within the last 6 months preceding the EAP request application. 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:	**Initial Requests in Treatment Naïve:** <u>No Cirrhosis:</u> 24 weeks (B) 48 weeks (PR) <u>Compensated Cirrhosis:</u> 44 weeks (B) 48 weeks (PR) *Extension of boceprevir beyond the stated durations above will not be considered.*

<table>
<tr>
<td>Boceprevir</td>
<td>Victrelis

Victrelis Triple (4 strengths)</td>
<td>200 mg capsule

Triple combination treatment with varying strengths of peginterferon alfa-2b powder

200 mg (B)/ 200 mg (R)/ 80 mcg (P)

200 mg (B)/ 200 mg (R)/ 100 mcg (P)

200 mg (B)/ 200 mg (R)/ 120 mcg (P)

200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)</td>
<td>Table 1:
<table>
<tr><td colspan="3">Response-guided therapy for <u>treatment naïve</u> patients with NO cirrhosis</td></tr>
<tr><td>HCV RNA at Treatment Week 8</td><td>HCV RNA at Treatment week 24</td><td>Action</td></tr>
<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>
</table>
<u>In treatment naïve 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.

<u>Treatment Futility Rule</u>: If the patient has HCV RNA results ≥ 100 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.

<u>Renewals</u> are not considered.</td>
<td></td>
</tr>
</table>

Boceprevir	Victrelis Victrelis Triple (4 strengths)	200 mg capsule Triple combination treatment with varying strengths of peginterferon alfa-2b powder 200 mg (B)/ 200 mg (R)/ 80 mcg (P) 200 mg (B)/ 200 mg (R)/ 100 mcg (P) 200 mg (B)/ 200 mg (R)/ 120 mcg (P) 200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)	**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** in combination with peginterferon alfa and ribavirin (PR) who meet ALL of the following: • Patient has a quantitative HCV RNA value from within the past 6 months* • < 70 years old OR ≥ 70 years old with no co-morbid conditions • Fibrosis stage F2 or greater (Metavir stage or equivalent) • No diagnosis of cirrhosis OR cirrhosis with a Child Pugh Score = A (5-6) * Null responders are considered those with a decrease in HCV RNA of < 2 logs IU/mL by week 12 on previous therapy. <u>Dosing:</u> Boceprevir dosage: 800 mg three times daily ○ Patients must also meet peginterferon/ribavirin criteria, as applicable. ○ HCV RNA laboratory values must be from within the last 6 months preceding the EAP request application. 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:	**Initial Requests in Treatment Experienced :** <u>No Cirrhosis:</u> 32 weeks (B) 48 weeks (PR) <u>Compensated Cirrhosis:</u> 44 weeks (B) 48 weeks (PR) *Note: Extension of boceprevir beyond the stated durations above will not be considered for any patients.*

<table>
<tr>
<td>Boceprevir</td>
<td>Victrelis

Victrelis Triple (4 strengths)</td>
<td>200 mg capsule

Triple combination treatment with varying strengths of peginterferon alfa-2b powder

200 mg (B)/ 200 mg (R)/ 80 mcg (P)

200 mg (B)/ 200 mg (R)/ 100 mcg (P)

200 mg (B)/ 200 mg (R)/ 120 mcg (P)

200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)

200 mg capsule</td>
<td>Table 2:
<table>
<tr><td colspan="3">Response-guided therapy for <u>treatment experienced</u> patients
with NO cirrhosis</td></tr>
<tr><td>HCV RNA at Treatment Week 8</td><td>HCV RNA at Treatment week 24</td><td>Action</td></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>
<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.

<u>Treatment Futility Rule</u>: If the patient has HCV-RNA results ≥ 100 IU/mL at treatment week 12 or if the patient has confirmed detectable HCV-RNA at treatment week 24, then discontinue triple therapy regimen

<u>Renewals</u> are not considered.

Also please note the case-by-case[1] considerations and exclusion criteria[2] stated below.

[1] Case-by-case considerations:</td>
<td></td>
</tr>
</table>

Boceprevir	Victrelis Victrelis Triple (4 strengths)	Triple combination treatment with varying strengths of peginterferon alfa-2b powder 200 mg (B)/ 200 mg (R)/ 80 mcg (P) 200 mg (B)/ 200 mg (R)/ 100 mcg (P) 200 mg (B)/ 200 mg (R)/ 120 mcg (P) 200 mg (B)/ 200 mg (R)/ 150 mcg (P) – Available in 2 pack sizes)	Boceprevir requests will be considered on a <u>case-by-case</u> basis for patients: • Who are **≥** 70 years of age with co-morbid diagnoses that are a relative/strong contraindication (not including criteria noted above where funding will not be considered); **OR** • Who have cirrhosis with Child Pugh Score = B (7-9); **OR** • Who previously tried Pegetron or Pegasys RBV but were unable to finish their treatment course due to intolerance; **OR** • Who have hepatitis B co-infection; **OR** • Who have HIV co-infection; **OR** • Who have certain abnormal baseline hematologic and/or clinical chemistry findings. [2] **Exclusion criteria:** Reimbursement will **NOT** be considered for patients who meet *ANY* of the following: • Not genotype 1 • Null responders to previous treatment (i.e., those with a decrease in HCV RNA of < 2 logs IU/mL by week 12) • Fibrosis stage less than F2 (Metavir scale or equivalent) • Boceprevir monotherapy • Cirrhosis with Child Pugh Score = C (10 or greater) • < 18 years of age • Decompensated liver disease, including a history of the presence of clinical ascites, bleeding varices, or hepatic encephalopathy • Prior organ transplant including liver transplant • Patients who fail, are intolerant to, or have received any prior telaprevir treatment regardless of funding source.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Ledipasvir - Sofosbuvir	Harvoni	90 mg ledipasvir / 400 mg sofosbuvir tablet	*For patients who meet the eligibility criteria outlined below clinicians are encouraged to use Harvoni as one of the preferred therapeutic option over other covered therapies (e.g., interferon-based regimens with NS3/4A protease inhibitors or polymerase inhibitors). This recommendation is based on Harvoni's advantages in some patient populations, including potentially higher sustained virological response (SVR) rates, improved tolerability, no need for concomitant interferon or ribavirin therapy, shorter course of therapy, and once daily dosing*. **For treatment-naïve and treatment-experienced[1] adult patients with chronic hepatitis C genotype 1 infections** who meet the following criteria; • Lab-confirmed hepatitis C genotype 1; AND • Patient has a quantitative Hepatitis C Virus Ribonucleic Acid (HCV RNA) value within the last 6 months; AND • Fibrosis stage F2 or greater (Metavir scale or equivalent); AND • Patient has compensated liver disease, (including compensated cirrhosis[2]); AND • Harvoni is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C) . [1] Treatment experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor. [2] Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6).	8 weeks to 24 weeks in accordance with the reimburse-ment criteria

			Duration of therapy reimbursed as follows: i) Treatment naïve, non-cirrhotic, viral load < 6 M IU/mL - 8 weeks[a] ii) Treatment naïve, non-cirrhotic, viral load ≥ 6 M IU/mL OR Treatment naïve, cirrhotic OR Treatment-experienced[1], non-cirrhotic -12 weeks iii) Treatment-experienced[1], cirrhotic - 24 weeks [a]*For this population cohort, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have borderline or severe fibrosis (F3-4) or if they are co-infected with Human immunodeficiency virus (HIV).* **Exclusion criteria** (i.e. Patients meeting the following exclusion criteria will NOT be considered for funding): • Patients currently being treated with another antiviral agent for Hepatitis C Virus • Patients who have received a previous trial of Harvoni (Re-treatment requests will **NOT** be considered) **Dosage: One tablet daily** (i.e. 90 mg/400 mg tablet) **NOTES:** • HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Ombitasvir/ Paritaprevir/ Ritonavir/ Dasabuvir	Holkira Pak	12.5 mg/ 75 mg/50 mg and 250 mg tablet	*For patients who meet the eligibility criteria outlined below clinicians will be encouraged to use Holkira Pak as one of the preferred therapeutic options over other covered therapies (e.g., interferon-based regimens with NS3/4A protease inhibitors or polymerase inhibitors). This recommendation is based on Holkira Pak's advantages in some patient populations, including potentially higher SVR rates, improved tolerability, no need for concomitant interferon, and shorter course of therapy.* **For treatment-naïve and treatment-experienced[1] adult patients with chronic hepatitis C genotype 1 infection** who meet the following criteria; • Lab-confirmed hepatitis C genotype 1, subtype 1a and 1b required • Patient has a quantitative HCV RNA value within the last 6 months • Fibrosis stage F2 or greater (Metavir scale or equivalent) • Compensated liver disease (including compensated cirrhosis[2]) • Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C – to be determined by jurisdiction). [1] Treatment experienced patients are defined as those who have previously treated with PegINF/RBV and did NOT receive adequate response. [2] Compensated cirrhosis is defined as cirrhosis with a Child	12 weeks to 24 weeks in accordance with the reimburse-ment criteria

			Pugh Score =A (5-6). Duration of therapy reimbursed as follows: i) Treatment naïve and experienced Genotype 1b, non-cirrhotic[3] - 12 weeks ii) Treatment naïve and experienced Genotype 1a, non-cirrhotic - 12 weeks [in combination with RBV (Moderiba[4])] iii) Treatment naïve and experienced Genotype1b, cirrhotic – 12 weeks [in combination with RBV (Moderiba[4])] iv) Treatment naïve and experienced (prior relapsers and prior partial responders) Genotype 1a, cirrhotic – 12 weeks [in combination with RBV (Moderiba[4])] v) Treatment experienced Genotype 1a, with cirrhosis, and who have had a previous null response to pegIFN and RBV - 24 weeks [in combination with RBV (Moderiba[4])] *[3]HOLKIRA™ PAK with ribavirin is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.* *[4]Abbvie Canada has launched a standalone RBV, Moderiba. For patients who require ribavirin Moderiba as outlined above, it will be provided by Abbvie Canada free of charge in combination with Holkira Pak. For clarity, Moderiba will only be provided by AbbVie when Holkira Pak is prescribed; AbbVie has no obligation to supply Moderiba other than in combination with Holkira Pak.*	12 weeks to 24 weeks in accordance with the reimburse-ment criteria

			Exclusion criteria: ▪ Patients currently being treated with another HCV antiviral agent ▪ Patients who have received a previous trial of Holkira Pak (Re-treatment requests will **NOT** be considered) ▪ Decompensated patients ▪ No funding for other Genotypes except as noted in the above funding criteria for Genotype 1 ▪ Patients who have received previous NS3/4A protease inhibitor-based regimens (i.e., boceprevir, telaprevir, and simeprevir-based regimens). ▪ Patients who have received previous sofosbuvir-based regimens, including ledispasvir/sofosbuvir **NOTES:** • HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above.	12 weeks to 24 weeks in accordance with the reimburse-ment criteria
Peginterferon Alfa-2B + Ribavirin	Pegetron	Vials: 50 mcg 80 mcg 100 mcg 120 mcg 150 mcg Clearclick: 50 mcg 80 mcg 100 mcg 120 mcg 150 mcg	**For the treatment of chronic hepatitis C in patients previously untreated with interferon or peginterferon therapy (i.e. naive patients):** **Genotype 2, 3**: • Positive HCV RNA. A quantitative value is required. • < 70 years old OR ≥ 70 years old with no co-morbid conditions * **AND** • No diagnosis of cirrhosis **OR** cirrhosis with a Child-Pugh score of ≤ 6. **Genotype other than 2 and 3.(e.g. 1, 4, 5, 6, and others)**: • HCV genotype must be provided, **AND**	6 months (Genotype 2,3) 1 year (Genotype other than 2

		+ 200 mg Capsule (Packaged in varying quantities of capsules)	• Positive HCV RNA. A quantitative value is required, **AND** • At least two elevated ALT values (more than 1.5 times the upper limit of normal values) within the previous six months **OR** fibrosis on biopsy (Stage 2 or greater) (This criteria is not needed if patient has co-infection with HIV) **AND** • < 70 years old OR ≥ 70 years old with no co-morbid conditions * **AND** • No diagnosis of cirrhosis **OR** cirrhosis with a Child-Pugh score of ≤ 6. ***Note:** Those ≥ 70 years old with co-morbid conditions will be assessed on a case-by-case basis.	and 3)
Peginterferon Alfa-2A + Ribavirin	Pegasys RBV Pegasys RBV ProClick Autoinjector	1 pk kit - 180 mcg prefilled syringe with 28 x 200 mg tablets 1 pk kit - 180 mcg prefilled syringe with 35 x 200 mg tablets 1 pk kit - 180 mcg prefilled syringe with 42 x 200 mg tablets	**For the treatment of patients with chronic hepatitis C who have had treatment failure with interferon alpha monotherapy:** • Same criteria and approval duration as the above for naïve patients (according to genotype), **AND** • Reason for failure should be provided. **For the treatment of patients with Hepatitis C Virus (HCV)/Human Immunodeficiency Virus (HIV) co-infection:** • Same criteria as the above for naïve patients (according to genotype) but genotype non-2,3 do not require ALT or fibrosis data. **For the treatment of patients post-liver transplant with positive HCV RNA.** (Note: Please provide a quantitative value in the submission.) **For the treatment of patients with chronic hepatitis C who have had treatment failure with Rebetron (interferon alfa-2B/ribavirin)* in the past:**	6 months or 1 year depending on genotype 1 year 1 year 6 months to 1 year based on genotype

		4 pk kit - 180mcg prefilled syringe with 196 x 200 mg tablets	Submissions should include the following information: • Dose, duration, tolerance, and HCV RNA response of previous therapy. • Genotype • Current HCV RNA result • Evidence of relapse to past therapy. • (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. *Note Rebetron is no longer available in Canada	
Peginterferon Alfa-2A	Pegasys	180 mcg / 0.5 mL prefilled syringe		
Ribavirin	Ibavyr	200 mg, 400 mg, 600 mg tablet	**For use within a combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria[1].** [1]The regimen for the use of ribavirin must comply with the criteria for funding of the hepatitis C regimen in which it is being administered. Note: The requesting physician is a hepatologist, gastroenterologist or an infectious disease specialist, or otherwise experienced in treating hepatitis C	Duration as specified by the criteria for the hepatitis C regimen.

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Simeprevir	Galexos	150 mg capsule	**For the treatment of chronic hepatitis C genotype 1,** in combination with peginterferon alfa and ribavirin (PR) in patients who meet ALL of the following: • the patient has a quantitative HCV RNA value that is taken within the 6 months preceding the date of the EAP request; AND • the patient is younger than 70 years of age OR is 70 years of age or older with no co-morbid conditions; AND • the patient has fibrosis at stage F2 or greater (Metavir stage or equivalent); AND • the patient has compensated liver disease; AND • the patient has either no diagnosis of cirrhosis OR has may have cirrhosis with a Child Pugh Score = A(5-6); AND • if the patient has genotype 1a, the patient must have tested negative for NS3 Q80K polymorphism. **Exclusion Criteria**: Patients who meet any of the following exclusion criteria will NOT be considered for reimbursement; • the patient has NS3 Q80K polymorphism; • the patient is not genotype 1; • the patient is using simeprevir as monotherapy; • the patient has cirrhosis with Child Pugh Score = C (10 or greater); • the patient is under 18 years of age; • the patient has decompensated liver disease, including a history of the presence of clinical ascites, bleeding varices	12 weeks Note that there will be no extensions or renewals for Galexos funding. A 12 week approval duration is the maximum of funding granted for any request.

Simeprevir	Galexos	150 mg capsule	or hepatic encephalopathy; • the patient has received a prior treatment with boceprevir or telaprevir in combination with peginterferon alfa and ribavirin and did not receive an adequate response; • the patient's fibrosis stage is less than F2 (metavir scale or equivalent); and • the patient has prior organ transplant including liver transplant. **Case-by-Case Consideration** will be considered for requests with the following circumstances; i) Patient who are ≥ 70 years of age with co-morbid conditions; OR ii) Patients who have certain abnormal baseline hematologic findings, clinical chemistry findings, or both; OR iii) Patients with cirrhosis with Child Pugh Score = B (7-9); OR iv) Patients who have HIV co-infection; OR v) Patients who have Hepatitis B co-infection **Therapy Requirements**: Simeprevir is to be administered to patients with peginterferon alfa and ribavirin ("PR") during the first 12 weeks of commencing therapy with simeprevir. As per the table below, treatment-naïve patients or prior relapsers who have undetectable HCV RNA at weeks 4 of simeprevir/PR combination therapy may receive additional 12 weeks of therapy with PR (total treatment duration of 24 weeks) while those with detectable HCV RNA (less than 25 IU/mL) at weeks 4 may benefit with PR therapy continuing for	

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<td>Simeprevir</td>
<td>Galexos</td>
<td>150 mg capsule</td>
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an additional 36 weeks (total treatment duration of 48 weeks).

Prior non-responders (including partial and null responders) who have undetectable HCV RNA or detectable HCV RNA (less than 25 IU/mL) at weeks 4 may benefit with PR therapy continuing for an additional 36 weeks (total treatment duration of 48 weeks).

Also refer to Treatment Stopping Rule for early discontinuation of therapy with Galexos.

<table>
<tr><th>Patient Group</th><th>HCV RNA at Week 4</th><th>Triple Therapy GALEXOS Peg-interferon alfa and Ribavirin</th><th>Dual Therapy Peg-interferon alfa and Ribavirin</th><th>Total Treat-ment Duration</th></tr>
<tr><td rowspan="2">Treatment-Naive and Prior Relapsers</td><td>Unde-tectable</td><td>First 12 weeks</td><td>Additional 12 weeks</td><td>24 weeks</td></tr>
<tr><td><25 IU/mL detectable</td><td>First 12 weeks</td><td>Additional 36 weeks</td><td>48 weeks</td></tr>
<tr><td>Prior Non-Responder (Including Partial and Null Responder)</td><td>Unde-tectable or <25 IU/mL detectable</td><td>First 12 weeks</td><td>Additional 36 weeks</td><td>48 weeks</td></tr>
</table>

<u>Treatment Stopping Rule</u>.
Discontinuation of treatment is recommended in patients with inadequate on-treatment virologic response since it is unlikely
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<td>Simeprevir</td>
<td>Galexos</td>
<td>150 mg capsule</td>
<td>that they will achieve a sustained virologic response (SVR) and may develop treatment-emergent resistance.

<table>
<tr><th>HCV RNA</th><th>Action</th></tr>
<tr><td>Treatment Week 4: ≥25 IU/mL</td><td>Discontinue GALEXOS™, peginterferon alfa and ribavirin</td></tr>
<tr><td>Treatment Week 12: detectable</td><td>Discontinue peginterferon alfa and ribavirin (treatment with GALEXOS™ is complete at Week 12)</td></tr>
<tr><td>Treatment Week 24: detectable</td><td>Discontinue peginterferon alfa and ribavirin</td></tr>
</table>

Please refer to the product monograph for full prescribing information.</td>
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Simeprevir	Galexos	150 mg capsule		
Sofosbuvir	Sovaldi	400 mg tablet	**For the treatment of adult patients 18 years of age or older with chronic hepatitis C infection with compensated liver disease, (including compensated cirrhosis)[1] in the following patients:** **A)Treatment-naïve patients with Genotype 1 who meet all the following criteria**: i) Patient has lab-confirmed hepatitis C for genotype 1; AND ii) Patient has a quantitative Hepatitis C Virus (HCV) ribonucleic acid (RNA) value within the last 6 months; AND iii) Fibrosis stage F2 or greater (Metavir scale or equivalent); AND iv) Sovaldi must be used in a triple therapy combination with Pegylated interferon(PegIFN) and Ribavirin(RBV);. AND v) Sovaldi is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C).	12 weeks

Sofosbuvir	Sovaldi	400 mg tablet	Exclusion criteria: (i.e. Patients meeting any of the following exclusion criteria will NOT be considered for funding): • Patients currently being treated with another HCV antiviral agent;AND/OR • Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered). Dosing regimen: Sovaldi will be funded for 12 weeks in combination with PegIFN/ RBV. **B) Treatment- naïve patients with Genotype 2 who meet all the following criteria:** i) Patient has lab-confirmed hepatitis C for genotype 2; AND ii) Patient has a quantitative HCV RNA value within the last 6 months;AND iii) Fibrosis stage F2 or greater (Metavir scale or equivalent);AND iv) Sovaldi is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C); AND v) Interferon (IFN) is medically contraindicated[2]. Exclusion criteria: (i.e. Patients meeting any of the following exclusion criteria will NOT be considered for funding): • Patients currently being treated with another HCV antiviral agent;AND/OR • Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered).	12 weeks

Sofosbuvir	Sovaldi	400 mg tablet	Dosing regimen: Sovaldi for 12 weeks in combination with RBV. **C) Patients with Genotype 2 who are treatment experienced (previously used PEGIFN/RBV[3]) who meet all the following criteria:** i) Patient has lab-confirmed hepatitis C for genotype 2; AND ii) Patient has a quantitative HCV RNA value within the last 6 months; AND iii) Fibrosis stage F2 or greater (Metavir scale or equivalent) iv) Sovaldi is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C). Exclusion criteria: (i.e. Patients meeting any of the following exclusion criteria will NOT be considered for funding): • Patients currently being treated with another HCV antiviral agent; AND/OR • Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered). Dosing regimen: Sovaldi for 12 weeks in combination with RBV **D) Treatment-naïve patients with Genotype 3 who meet all the following criteria:** i) Patient has lab-confirmed hepatitis C for genotype 3; AND ii) Patient has a quantitative HCV RNA value within the last 6 months; AND iii) Fibrosis stage F2 or greater (Metavir scale or equivalent);	12 weeks 24 weeks

Sofosbuvir	Sovaldi	400 mg tablet	AND iv) Sovaldi is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C); AND v) Interferon (IFN) is medically contraindicated[2]. Exclusion criteria: (i.e. Patients meeting any of the following exclusion criteria will NOT be considered for funding): • Patients currently being treated with another HCV antiviral agent; AND/OR • Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered). Dosing regimen: Sovaldi for 24 weeks in combination with RBV **E) Patients with Genotype 3 who are treatment experienced (previously used PEGIFN/RBV[3]) who meet all the following criteria:** i) Patient has lab-confirmed hepatitis C for genotype 3; AND ii) Patient has a quantitative HCV RNA value within the last 6 months; AND iii) Fibrosis stage F2 or greater (Metavir scale or equivalent); AND iv) Sovaldi is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C). Exclusion criteria: (i.e. Patients meeting any of the following exclusion criteria will NOT be considered for funding):	24 weeks

Sofosbuvir	Sovaldi	400 mg tablet	• Patients currently being treated with another HCV antiviral agent; AND OR • Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered). Dosing regimen: Sovaldi for 24 weeks in combination with RBV. [1] Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6) [2] Medical contraindication to IFN is defined as hypersensitivity to peginterferon or interferon alfa-2a or 2b, polyethylene glycol or any component of the formulation resulting in discontinuation of therapy; **OR** presence of significant clinical comorbidities which are deemed to have a high risk of worsening with IFN treatment. (Note: Details are required regarding patient's contraindications and/or risk of worsening significant comorbidities.) [3]Treatment-experienced patients (with Genotype 2 or 3) are defined as patients who have previously been treated with PegIFN/RBV and did NOT receive adequate response. **Additional Notes**: • HIV-HCV co-infected Patients may be considered. • Treatment of decompensated HCV may be considered on an exceptional case by case basis.	

METABOLIC MODIFIERS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sapropterin	Kuvan	100 mg tablet	**Ongoing funding of sapropterin (Kuvan) will be considered through the EAP for non-pregnant patients and patients actively planning pregnancy who have a diagnosis of Phenylketonuria(PKU) and who have demonstrated a response to the initial 6 month trial of sapropterin [reimbursed through the manufacturer (see details below)] and** who meet **ALL** of the following criteria: 1. Compliance with low protein diet, formulas, and treatment with sapropterin; AND 2. Has achieved a) normal sustained blood phenylalanine (Phe) levels [Greater than 120 µmol/L and less than 360 µmol/L] (At least 2 levels measured at least 1 month apart); OR b) sustained blood Phe reduction of at least 30% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is less than 1200 µmol/L; OR c) sustained blood Phe reduction of at least 50% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is greater than 1200 µmol/L; AND 3. Demonstrated increase of dietary protein tolerance based on targets set between the clinician and patient; AND 4. Clinically meaningful age-appropriate improvement in: a) neurobehavioural or neurocognitive function or impairment for patients with such impairments as determined by peer	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sapropterin	Kuvan	100 mg tablet	reviewed clinically validated scales; OR b) demonstrated improvement in Quality of Life using peer reviewed validated scales; AND 5. Managed by a physician specialized in metabolic/biochemical diseases. Please note that sapropterin is only considered through the EAP for responders to an initial 6 month trial period funded through the manufacturer (described in the next 2 pages). The exclusion criteria for initial funding of sapropterin also applies to funding through the EAP. (see next page)	Initial: 6 months in non-pregnant and patients planning a pregnancy (Funded by the manufacturer)
			THE INITIAL 6 MONTHS OF FUNDING OF SAPROPTERIN (KUVAN) IS PROVIDED BY THE MANUFACTURER, BIOMARIN PHARMACEUTICAL CANADA INC. THE CRITERIA FOR INITIAL COVERAGE ARE DESCRIBED BELOW.	
			Initial funding of sapropterin will be considered by the manufacturer for the management of non-pregnant patients and patients actively planning pregnancy who have a diagnosis of Phenylketonuria (PKU) and who meet **ALL** of the following criteria: 1. Compliance with a low protein diet and formulas. 2. Baseline blood phenylalanine (Phe) levels are greater than 360 µmol/L despite compliance with low protein diet (require at least 2 levels during 3 to 6 month time frame) 5. Baseline protein intake assessment by a dietitian. 6. Ability to comply with medication regimen.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sapropterin	Kuvan	100 mg tablet	7. Managed by a physician specialized in metabolic/ biochemical diseases. **Initial funding of sapropterin will also be considered by the manufacturer for the management of pregnant patients who have a diagnosis of Phenylketonuria (PKU)** and who meet **ALL** of the following criteria: • Managed by a physician specialized in metabolic/ biochemical diseases. • Baseline blood phenylalanine (Phe) levels > 360 µmol/L despite compliance with all recommendations for dietary intervention and monitoring **Funding will not be considered for patients meeting any of the following exclusion criteria:** • Known hypersensitivity to sapropterin or its excipients • Any other contraindications • Baseline Phe Levels less than 360 µmol/L in a non-pregnant patient • Baseline Phe Levels less than 360 µmol/L in a pregnant patient • Women who are nursing/breast feeding • Patients who are not on the special diet or who are not compliant with their special diet Note that sapropterin should be used with caution when the patient is taking medication known to inhibit folate synthesis (e.g, methotrexate) and/or has any condition that requires treatment with levodopa or any phosphodiesterase type 5 (PDE-5) inhibitor. Additionally, consider for initial funding of sapropterin requires that	Approval duration in pregnant patients: 6 months or to end of pregnancy (Funded through the manufacturer)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sapropterin	Kuvan	100 mg tablet	the patient completes an eligibility test called the "72 hour Kuvan Challenge" described below. **<u>Test for Eligiblility: 72 hour "Kuvan" Challenge</u>** • 72 hour challenge with sapropterin at 20 mg/kg/day • Blood Phe concentrations are measured at 48 hours, 24 hours, and time "0" PRIOR TO the sapropterin dose and THEREAFTER at 4, 12, 24, 48, and 72 hours following the dose;OR as per clinic's protocol Note that the recommended dose of sapropterin to establish clinical benefit is 20 mg/kg/day **<u>Responders to the 72 hour "Kuvan" Challenge</u>** For Non-Pregnant patients and patients actively planning pregnancy, responders to the Kuvan challenge are those who meet the following criteria: • Reduction in Phe blood level of at least 30% compared to baseline; AND • Patient must have a baseline assessment of neurobehavioural or neurocognitive impairment* and quality of life assessment due to PKU after the 72 hr Kuvan challenge but before start of Kuvan therapy (this assessment does not apply to pregnant women) Note: A baseline Phe tolerance level must be documented and Phe tolerance levels must be documented at months 1 to 2 and 4 to 6 during the initial 6 months of therapy. * For children less than 4 years of age, clinically validated age-	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sapropterin	Kuvan	100 mg tablet	appropriate neurobehavioural, neurocognitive, or developmental tests may be selected at the clinician's discretion rather than PKU specific tests For pregnant patients and patients actively planning pregnancy, responders to the Kuvan challenge are those who meet the following criteria: • Reduction in Phe blood level of at least 30% compared to baseline after 72 hours Pregnant patients who meet the "responder" definition to the 72 hour Kuvan Challenge, may be eligible for Kuvan funding if the following criteria are met: • A decrease in Phe concentration to less than 360 µmol/L is to be maintained for the duration of pregnancy to be eligible for continued funding **Renewals** for sapropterin in pregnant patients will not be considered.	

MIGRAINE TREATMENT DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Onabotulinum Toxin A	Botox	50 U/Vial 100 U/Vial 200 U/vial	For the **prophylaxis of headaches** in adults meeting the following criteria for funding: • Patient with chronic migraine (defined as ≥15 days per month with continuous headache lasting ≥4 hours AND at least 4 distinct headache episodes each lasting ≥4 hours); AND • Patient has failed[1] three or more prior oral prophylactic medications[2]; AND • Request for Botox to treat migraine must be provided by a physician with specialty training in the management of headache. Administration should only be given by physicians with the appropriate qualifications and experience in the treatment, use, and proper administration of Botox for headaches. [1]Failure is defined as no therapeutic or unsatisfactory effect (Less than a 30% reduction in frequency of headache days) to an adequate dose and duration of 3 prophylactic therapies[2] where two treatments must be of different types/classes. Contraindication or intolerable side effects necessitating discontinuation will be considered for 1 of the 3 drugs only. [2]Prophylactic therapies to be considered include: - Beta blockers - Tricyclic antidepressants - Verapamil or flunarizine - Sodium valproate (or divalproex sodium)	Initials: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Onabotulinum Toxin A	Botox	50 U/Vial 100 U/Vial 200 U/vial	- Topiramate - Gabapentin Requests should contain the following information: - Objective measure of baseline headache days and response to other prophylactic medications (i.e. headache diary) - List of previously tried prophylactic medications, including doses and duration as well as why they were discontinued - Confirmation of specialty training in the management of headache. Dosing: As per product monograph Notes regarding continued therapy with “Botox”: i) Patients who have not obtained an adequate treatment response after 2 treatment cycles should be discontinued from further therapy. ii) Patients who obtain an adequate response and who transition from chronic migraine to episodic migraine should be discontinued from therapy within 3 months of that transition. An adequate treatment response is defined as a ≥ 50% reduction in frequency of headache days per month **Renewal criteria:** • Objective evidence (i.e. headache diary) that the patient has obtained an adequate treatment response defined as a ≥	Renewals: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			50% reduction in frequency of headache days per month; AND • Confirmation that the patient has not transitioned from chronic migraine to episodic migraine. Therapy will be reimbursed for a maximum of 3 months after transition from chronic migraine to episodic migraine. • Consideration will be given for renewals in patients who had an initial adequate response to Botox, discontinued therapy and subsequently transitioned back to chronic migraine status.	
Almotriptan	Axert	6 mg, 12.5mg tablet	**For the treatment of migraines with or without aura in patients who failed adequate trials of other medications for migraines** (e.g. acetaminophen, NSAIDs) and where the following information is provided: • Details of migraine prophylactic regimens (e.g. amitriptyline, beta-blockers) tried or rationale why they are inappropriate; and • The number of attacks, duration, and severity of migraines. **<u>Renewal</u>** requests may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use. *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.*	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		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sumatriptan	Imitrex Injection	12 mg/mL subcutaneous injection	**For the treatment of migraines with or without aura in patients who failed adequate trials of other medications for migraines** (e.g. acetaminophen, NSAIDs) and has documented intolerance* to an oral triptan. The following information must also be provided: • Details of migraine prophylactic regimens (e.g. amitriptyline, beta-blockers) tried or rationale why they are inappropriate; and • The number of attacks, duration, and severity of migraines. * The nature of intolerance or why oral sumatriptan cannot be used must be specified. **Renewal** requests for sumatriptan may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use. *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.*	5 years
	Imitrex Nasal Spray	5 mg/dose and 20 mg/dose nasal spray		
Zolmitriptan	Zomig	2.5 mg tablet	**For the treatment of migraines with or without aura in patients who have failed an adequate trial of or experienced intolerance** to all other oral triptans considered under the Exceptional Access Program. **Renewal** requests may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.	5 years
	Zomig Rapimelt	2.5 mg dispersible tablet		

MULTIPLE SCLEROSIS DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Alemtuzumab	Lemtrada	12 mg/ 1.2 mL Solution for IV infusion	**For the treatment of Relapsing–Remitting Multiple Sclerosis (RRMS) as monotherapy** in patients who meet all of the following criteria**:** • The patient's physician provides documentation setting out the details of the patient's most recent neurological examination (which must have been conducted within ninety [90] days of the request, including a description of any recent attacks, the dates of attacks, and neurological findings); AND • Patient has failed to respond[1] to full and adequate courses of at least ONE of the following therapies: interferon, glatiramer acetate, dimethyl fumarate, or teriflunomide or has had a documented intolerance or contraindication to TWO or more of the listed therapies; AND • Patient has experienced one (1) or more clinically disabling relapses in the previous year; AND • Patient has had a significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) OR at least one gadolinium-enhancing lesion; • Patient is being followed by a neurologist experienced in the management of relapsing–remitting multiple sclerosis (RRMS); AND • The patient has a current Expanded Disability Status Scale (EDSS) score less than or equal to 5.0. [1] "Failed to respond to full and adequate courses" of certain therapies means that the patient has received a trial of at least 6 months of interferon, glatiramer acetate, dimethyl fumarate	2 treatment courses

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			therapy, or teriflunomide; AND has experienced at least one disabling relapse (attack) while on such therapy. **Exclusion Criteria**: No reimbursement if the patient satisfies any of the following exclusion criteria: • the patient is receiving combination therapy of Lemtrada with other disease modifying therapies, such as Aubagio, Avonex, Betaseron, Copaxone, Extavia, Rebif, Extavia, Tysabri, Gilenya and Tecfidera; OR • the patient has an EDSS score greater than 5.0; OR • the patient is younger than 18 years old. **Dosage**: 12 mg per day for two treatment courses. Initial course: 12 mg per day for 5 consecutive days (60mg total dose). Second course: 12 mg per day for 3 consecutive days (36mg total dose) administered 12 months after the initial treatment course. Retreatment beyond two cycles (eight vials) may be considered. **Note:** MRI reports are NOT mandatory to submit with the initial request.	
Dimethyl fumarate	Tecfidera	120 mg delayed-release capsule	**For the treatment of Relapsing–Remitting Multiple Sclerosis (RRMS)** in patients who meet all of the following criteria**:** • The patient's physician provides documentation setting out the details of the patient's most recent neurological examination (which must have been conducted within ninety [90] days of the request, including a description of any recent attacks, the	Initial requests: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Dimethyl fumarate	Tecfidera	120 mg delayed-release capsule	dates of attacks, and neurological findings). • Patient has had one (1) or more clinical relapses in the previous year. • The drug is requested by and followed by a neurologist experienced in the management of RRMS. • The patient has a recent Expanded Disability Status Scale (EDSS) score ≤ 5. Dosage: Initial: 120 mg twice daily Maintenance: 240 mg twice daily **Renewal** requests will be considered. Renewals for Tecfidera can be submitted through the Telephone Request Service. • The 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); **AND** • The patient must be stable or experienced no more than one clinical relapse* in the past year; **AND** • The patient has a recent EDSS score ≤ 5. Dosage: 120 mg twice daily. Maintenance: 240 mg twice daily ***Renewal** requests where patients have experienced more than one (1) clinical relapse in the past year are to be externally reviewed.	First Renewal: 2 years Second and subsequent renewals: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Fingolimod	Gilenya	0.5 mg capsule	**As monotherapy for the treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS)** who meet all of the following criteria: • The patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attack(s), the date(s) of the attack(s), and the neurological findings; AND • Failure to respond to full and adequate courses[1] of at least one of interferon **OR** glatiramer acetate **OR** dimethyl fumarate; **OR** teriflunomide **OR** documented intolerance or contraindication to 2 of the above listed therapies; AND • Experienced one or more clinically disabling relapses in the previous year; AND • Has had a significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) **OR** at least one gadolinium-enhancing lesion. • Is being followed by a neurologist experienced in the management of RRMS. • Has a current EDSS of less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance). **Exclusion Criteria** (Patients meeting any of the following exclusion criteria will not be funded)**:** • Patient's receiving combination therapy of Gilenya with other disease modifying therapies (e.g. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Rebif, Extavia, Tysabri,	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Fingolimod	Gilenya	0.5 mg capsule	and Tecfidera). • Patients with EDSS greater than 5.5 • Patients who have had a heart attack or stroke in the last 6 months of the funding request, history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure. • Patients younger than 18 years of age. • Patients requesting Gilenya due to needle phobia or preference for oral therapy over injection who do not have a clinical contraindication to interferon or glatiramer therapy. • Skin reactions at the site of injection do NOT qualify as a contraindication to interferon or glatiramer therapy. Dosage: 0.5 mg once daily [1]Failure to respond to full and adequate courses: defined as having received a trial of at least 6 months of interferon or glatiramer or dimethyl fumarate therapy or teriflunomide **AND** experienced at least one disabling relapse (attack) while on interferon or glatiramer or dimethyl fumarate or teriflunomide. MRI reports do NOT need to be submitted with the initial request. **Renewals** are considered. Renewals can be submitted through the Telephone Request Service and will be considered for patients who have benefited from therapy.	First Renewal: 2 years Second and

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Fingolimod	Gilenya	0.5 mg capsule	Physicians must provide the following information: • Documentation providing the date and details of the Patient's most recent neurological examination and EDSS scores (exam must have occurred within the last ninety (90) days); AND • Evidence that the patient is stable and has experienced no more than one (1) disabling attack/relapse in the past year. (Note: If the Patient has had more than one attack/relapse, the request will be sent for external review. Please include details of the attack(s) including the dates on which they occurred); AND • A recent Expanded Disability Status Scale (EDSS) that is less than or equal to 5.5 (Note: Requests with an EDSS greater than 5.5 will not be funded.). Dosage: 0.5 mg once daily.	subsequent renewals: 5 years
Glatiramer acetate	Copaxone	20 mg/mL pre-filled syringe for subcutaneous injection	**For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)** (see criteria in next section). For CDMS: Copaxone requests for patients with CDMS will be reviewed by external medical experts when the following information is provided: • Date and details of the most recent neurological examination (within the last 90 days); and	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20 mg/mL pre-filled syringe for subcutaneous injection	• Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and • EDSS score ≤ 5. **Renewal** 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 ≤ 5. The physician must provide the following information: • Description of the patient's clinical course in the last year, including details of all attacks; • Date and details of the most recent neurological examination (within the last 90 days); and • The patient's most recent EDSS score.	First Renewal: 2 years Second and subsequent renewals: 5 years
Interferon beta-1a	Avonex PS Avonex Pen	30 mcg/ 0.5mL prefilled syringe for intramuscular injection	**For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)** (see CIS criteria in next section). For CDMS: Avonex requests for patients with CDMS will be reviewed by external medical experts when the following information is provided: • Details of the most recent neurological examination within the last ninety (90) days, including a description of any recent attacks (date and neurological findings) • The patient has experienced at least two clinical attacks including one clinical attack within the past year • MRI findings as applicable	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Interferon beta-1a	Avonex PS Avonex Pen	30 mcg single-use prefilled autoinjector 30 mcg/ 0.5mL prefilled syringe for intramuscular injection 30 mcg single-use prefilled autoinjector	• The patient's EDSS is less than or equal to 6.0 **Renewal** requests for Avonex can be submitted through the Telephone Request Service. Avonex renewals will be considered for patients who have benefited from therapy. Patients must be stable (i.e. no relapses or attacks during the last year) and the patient's EDSS must be less than or equal to 6.0 The physician must provide the following information: • Description of the patient's clinical course in the last year, including details of all attacks; • Date and details of the most recent neurological examination (within the last 90 days); and • The patient's most recent EDSS score.	First Renewal: 2 years Second and subsequent renewals: 5 years
Interferon beta-1a	Rebif	22 mcg and 44 mcg prefilled syringe for subcutaneous injection 66 mcg/ml and 132 mcg/ml pre-filled cartridge 22 mcg and 44 mcg prefilled syringe for	**For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)** (see CIS criteria in next section). For CDMS: Rebif requests for patients with CDMS will be reviewed by external medical experts when the following information is provided: • Date and details of the most recent neurological examination (within the last 90 days); and • Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and • EDSS score ≤ 6.	Initial: 1 year First

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Interferon beta-1a	Rebif	subcutaneous injection 66 mcg/ml and 132 mcg/ml pre-filled cartridge	**Renewal** 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 ≤ 6. The physician must provide the following information: • Description of the patient's clinical course in the last year, including details of all attacks; • Date and details of the most recent neurological examination (within the last 90 days); and • The patient's most recent EDSS score.	Renewal: 2 years Second and subsequent renewals: 5 years
Interferon beta-1b	Betaseron	0.3 mg/vial subcutaneous injection	**For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)** (see criteria in next section) For CDMS: Betaseron requests for patients will be reviewed by external medical experts when the following information is provided: • Date and details of the most recent neurological examination (within the last 90 days); AND • Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; ANd • EDSS score ≤ 6. **Renewal** 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 ≤ 6. The physician must provide the following information:	Initial: 1 year First Renewal: 2 years Second and subsequent renewals: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			• Description of the patient's clinical course in the last year, including details of all attacks;AND • Date and details of the most recent neurological examination (within the last 90 days); AND • The patient's most recent EDSS score.	
Interferon beta-1b	Extavia	0.3 mg/vial subcutaneous injection	**For the treatment of Clinically Definite Multiple Sclerosis (CDMS) or Clinically Isolated Syndrome (CIS)** (see criteria in next section). For CDMS: Extavia requests for patients will be reviewed by external medical experts when the following information is provided: • Date and details of the most recent neurological examination (within the last 90 days) AND • Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year AND • EDSS score ≤ 6. **Renewal** 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 ≤ 6. The physician must provide the following information: • Description of the patient's clinical course in the last year, including details of all attacks; • Date and details of the most recent neurological examination (within the last 90 days); and • The patient's most recent EDSS score.	Initial: 1 year First Renewal: 2 years Second and subsequent renewals: 5 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Natalizumab	Tysabri	300 mg/15 mL concentrate for solution for intravenous infusion	**Initial Request**: **As monotherapy for the treatment of Rapidly Evolving Severe Relapsing-Remitting Multiple Sclerosis (RES-RRMS)** for the patient who meets all the following: a) The patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, including the corresponding dates, and the neurological findings; AND b) Has been diagnosed with MS; AND c) Is 18 to 65 years of age; AND d) Has a current EDSS of less than or equal to 5.0; AND e) Has had ONE of the following types of relapses in the past year: • The occurrence of one relapse with partial recovery during the past year AND 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); OR • The occurrence of two or more relapses with partial recovery during the past year; OR	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Natalizumab	Tysabri	300 mg/15 mL concentrate for solution for intravenous infusion	• The occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI; (f) has failed to respond to full and adequate courses[1] of at least one of interferon **OR** glatiramer acetate **OR** dimethyl fumarate; **OR** teriflunomide **OR** documented intolerance or contraindication to 2 of the 3 therapies. (Note that needle phobia is not acceptable.) (g) is being followed by a neurologist experienced in the management of RRMS (h) details of past treatment, including dates and Patient response; *[1]Failure to respond to a full and adequate course: defined as a trial of at least 6 months of interferon or glatiramer therapy or dimethyl fumarate AND experienced at least one disabling relapse (attack) while on interferon or glatiramer or dimethyl fumarate.* MRI reports do NOT need to be submitted with the initial request. **Renewals** will be considered for requests meeting the following; (a) Documentation providing the date and details of the patient's most recent neurological examination and EDSS scores	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Natalizumab	Tysabri	300 mg/ 15 mL concentrate for solution for intravenous infusion	(exam must have occurred within the last ninety (90) days); AND (b) Evidence that the Patient is stable and has experienced no more than one (1) disabling attack/relapse in the past year (Note: if the Patient has had more than one attack/relapse, the request will be sent for external review); AND (c) A recent Expanded Disability Status Scale (EDSS) that is less than or equal to 5.0 (Note that the request will be rejected if the EDSS is greater than 5.0).	First Renewal: 2 years Second and subsequent renewals: 5 years
Modafanil	Alertec	100 mg tablet	**For the treatment of fatigue in patients with multiple sclerosis who have demonstrated a lack of response** to or an inability to tolerate amantadine. Note: See additional indications and criteria under “CNS” drugs	Lifetime
Teriflunomide	Aubagio	14 mg tablet	**For the treatment of relapsing-remitting multiple sclerosis (RRMS)** in patients who meet the following criteria; i) the physician making the request on behalf of the patient is a neurologist who is experienced in the management of RRMS; AND ii) the physician provides documentation of the patient’s most recent neurological examination which must have been conducted within ninety (90) days preceding the submission of the EAP request. This must include a description and dates of any recent attacks and other pertinent neurological	Initials:1 year
Teriflunomide	Aubagio	14 mg tablet		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			findings; AND iii) the patient's diagnosis is confirmed to be RRMS; AND ix) the patient has experienced one or more clinical attacks/relapses in the year preceding the request; AND x) the patient has a recent Expanded Disability Status Scale (EDSS) score that is equal to or less than 5.0 prior to starting therapy with teriflunomide. Dosage: 14 mg once daily **<u>Renewals</u>** for the funding of teriflunomide will be considered in patients who meet the following criteria; i) the physician provides documentation of the date and details of the patient's most recent neurological examination and EDSS scores (the examination must have occurred within the last ninety [90] days preceding the submission of the renewal request); AND ii) the physician confirms that the Patient is stable and has experienced no more than one (1) clinical relapse in the past year[1]; AND iii) the patient's most recent EDSS score while on teriflunomide is less than or equal to 5.0. [1]Renewal requests where the patient has experienced more than 1 clinical relapse in the past year will be considered on a case-by-case basis with the assistance of external medical consultants. .Dosage: 14 mg once daily.	Renewals: 2 years

CLINICALLY ISOLATED SYNDROME DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20 mg/mL pre-filled syringe for subcutaneous injection	**For the treatment of Clinically Isolated Syndrome (CIS)**: requests for patients who have experienced a single demyelinating event will be reviewed by external medical experts when the following information is provided: • Date and details of the most recent neurological examination which must have been conducted within the last ninety days of the request; • The patient's EDSS is less than or equal to 6.0 (please provide EDSS score); AND • The patient's clinically isolated syndrome occurred within the last twelve months. **Renewal** requests will be assessed according to the following criteria: • the requesting physician provides the date and details of the patient's most recent neurological examination and EDSS scores; • the patient's neurological examination occurred within that last ninety days; • the patient is stable (i.e. no relapses or attacks during the last year) and • the patient's EDSS is less than or equal to 6.0	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-1a	Rebif	22 mcg and 44 mcg prefilled syringe for subcutaneous injection 66 mcg/ml and 132 mcg/ml pre-filled cartridge		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
		22 mcg and 44 mcg prefilled syringe for subcutaneous injection 66 mcg/ml and 132 mcg/ml pre-filled cartridge		
Interferon beta-1b	Betaseron	0.3 mg/vial subcutaneous injection		
Interferon beta-1b	Extavia	0.3 mg/vial subcutaneous injection		

OCULAR DRUG TREATMENTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Mycophenolate Mofetil	Cellcept and generics	250 mg capsules 500 mg tablets 200mg/mL oral suspension	**For the treatment of non-infectious ocular inflammation (e.g., uveitis, scleritis and ocular mucous membrane pemphigoid)** in patients meeting the following criteria; • Experienced failure, intolerance, or contraindication to at least one Formulary immunosuppressant; OR • First-line use for the treatment of <u>severe</u> non-infectious ocular inflammation • Patient must be followed by a uveitis specialist, a retina specialist familiar with ocular inflammatory diseases, or a pediatric ophthalmologist. **Renewals** will be considered for requests where consultation notes or a letter is provided by the requesting physician to confirm that treatment has resulted in improvement/stability of vision and other treatment goals (e.g., remission from/control of ocular inflammation) have been met.	Initials: 1 year Renewals: 2 years
Infliximab	Remicade	100 mg/ 10 mL Injection for intravenous infusion	**For the treatment of severe non-infectious ocular inflammatory disease (OID)** in patients meeting one of the following criteria; o Experienced failure, intolerance, or contraindication to oral corticosteroid (or topical corticosteroid for anterior uveitis) and failure or intolerance to at least one immunosuppressive therapy; OR o For the treatment of chronic Juvenile Idiopathic Arthritis (JIA)-associated uveitis after failure or intolerance to a first-line immunosuppressive agent; OR	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			• For patients who have immediately vision-threatening OID and do not meet the above criteria, where consultation notes/ letter from an ophthalmologist expert specializing in OIDs (who may be the requesting physician) confirm the severity of the patient's condition and indicate detailed rationale for an immediate biologic therapy (e.g. ocular inflammation associated with Behcet's disease; severe non-necrotizing scleritis; necrotizing scleritis; etc.); AND • Patient must be followed by a uveitis specialist, a retina specialist familiar with ocular inflammatory diseases, or a pediatric ophthalmologist. **Approved Dose:** Infliximab 5-10 mg/kg IV at weeks 0, 2, 6 and maintenance every 4-8 weeks **Renewals** will be considered for requests where consultation notes or a letter is provided by the requesting physician to confirm that treatment has resulted in improvement/stability of vision and other treatment goals (e.g., remission from/control of ocular inflammation) have been met.	Renewals: 2 years
Adalimumab	Humira	40 mg per 0.8 mL Injection	**For the treatment of severe non-infectious ocular inflammatory disease (OID)** in patients meeting one of the following criteria; • Experienced failure, intolerance, or contraindication to oral corticosteroid (or topical corticosteroid for anterior uveitis) and failure or intolerance to at least one immunosuppressive therapy; OR • For the treatment of chronic Juvenile Idiopathic Arthritis (JIA)-	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Adalimumab	Humira	40 mg per 0.8 mL Injection	associated uveitis after failure or intolerance to a first-line immunosuppressive agent; OR • For patients who have immediately vision-threatening OID and do not meet the above criteria, where consultation notes/ letter from an ophthalmologist expert specializing in OIDs (who may be the requesting physician) confirm the severity of the patient's condition and indicate detailed rationale for an immediate biologic therapy (e.g. ocular inflammation associated with Behcet's disease; severe non-necrotizing scleritis; necrotizing scleritis; etc.); AND • Patient must be followed by a uveitis specialist, a retina specialist familiar with ocular inflammatory diseases, or a pediatric ophthalmologist. **Approved Dose:** Adalimumab 40 mg subcutaneous every 1 to 2 weeks. **Renewals** will be considered for requests where consultation notes or a letter is provided by the requesting physician to confirm that treatment has resulted in improvement/stability of vision and other treatment goals (e.g., remission from/control of ocular inflammation) have been met.	Renewals: 2 years
Rituximab	Rituxan	10 mg/mL intravenous injection	**For the treatment of severe non-infectious ocular inflammatory disease (OID)** in patients failed or did not tolerate treatment with infliximab or adalimumab; OR has contraindication to anti-TNF therapy AND who meet one of the following criteria; • Experienced failure, intolerance, or contraindication to oral corticosteroid (or topical corticosteroid for anterior uveitis) and	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	failure or intolerance to at least one immunosuppressive therapy; OR • For the treatment of chronic Juvenile Idiopathic Arthritis (JIA)-associated uveitis after failure or intolerance to a first-line immunosuppressive agent; OR • For patients who have immediately vision-threatening OID and do not meet the above criteria, where consultation notes/ letter from an ophthalmologist expert specializing in OIDs (who may be the requesting physician) confirm the severity of the patient's condition and indicate detailed rationale for an immediate biologic therapy (e.g. ocular inflammation associated with Behcet's disease; severe non-necrotizing scleritis; necrotizing scleritis; etc.); AND • Patient must be followed by a uveitis specialist, a retina specialist familiar with ocular inflammatory diseases, or a pediatric ophthalmologist. **Approved Dose:** Rituximab up to 1000 mg IV per infusion at days 1 & 15 and 3rd infusion at 6-12 months. Note that maintenance rituximab infusions are not funded. **Renewals** will be considered for requests where; • Consultation notes or a letter is provided by the requesting physician to confirm that treatment has resulted in improvement/stability of vision and other treatment goals (e.g., remission from/control of ocular inflammation) have been met; AND • Patients must also have demonstrated subsequent deterioration of symptoms, at least 6 months from the last dose of rituximab.	Renewals: 2 years

ONCOLOGY DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Abiraterone	Zytiga	250 mg tablet	Reimbursement criteria for Zytiga in patients who have not trialed docetaxel. **For the treatment of metastatic castrate-resistant prostate cancer (mCRPC)** in patients who meet the following criteria: • Zytiga is being used in combination with prednisone; AND • The patient is asymptomatic or mildly symptomatic after failure of androgen deprivation therapy; AND • The patient has an ECOG* ≤ 1; AND • The Patient must not meet any of the exclusion[1] criteria stated below. *ECOG = Eastern Cooperative Oncology Group Status *(Please provide clinical information as objective evidence that the above criteria are met (e.g. castrate testosterone level, prostate surface antigen levels, evidence of metastatic disease such as presence and location of lesions, surgical procedures related to the condition, and name(s), date, duration of androgen deprivation therapy used details of the response to therapy, labwork or clinical confirmation to support that the patient does not meet any of the exclusion criteria.)* **Approved dosage**: 1000 mg once daily will be funded until there is evidence of disease progression.	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Abiraterone	Zytiga	250 mg tablet	**Renewals** will be considered in patients with evidence of not having had disease progression while on Zytiga therapy. [1]**Exclusion Criteria**: Funding for Zytiga will NOT be approved in patients who meet any ONE (or more) of the following exclusion criteria: • the Patient has viral hepatitis or chronic liver disease; OR • the Patient has clinically significant heart disease; OR • Zytiga is being prescribed for combination use with Jevtana or Xtandi for mCRPC; OR • The patient has received prior chemotherapy for mCRPC. Reimbursement criteria for Zytiga in patients who are requesting Zytiga after a trial of docetaxel. **For the treatment of metastatic castrate-resistant prostate cancer (mCRPC)** in patients who meet the following criteria: • Zytiga is being used in combination with prednisone; AND • The patient's cancer has progressed after having received prior docetaxel containing therapy; AND • The patient has ECOG* ≤ 2. • Patients must not meet ANY of the exclusion[2] criteria for funding stated below. *ECOG = Eastern Cooperative Oncology Group Status	Renewals: 1 year Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Abiraterone	Zytiga	250 mg tablet	Requests for patients who initiated Jevtana (cabazitaxel) or Xtandi (enzalutamide) therapy within the three (3) months preceding the EAP request for Zytiga and who have not had disease progression, will be considered on a case-by-case basis. **Approved dosage**: 1000 mg once daily will be funded until there is evidence of disease progression. **Renewals** will be considered in patients with evidence of not having had disease progression while on Zytiga therapy. **Exclusion Criteria**: Funding for Zytiga will NOT be approved in patients who meet any ONE (or more) of the following exclusion criteria: • the Patient has viral hepatitis or chronic liver disease;OR • the Patient has clinically significant heart disease;OR • Zytiga is being prescribed for combination use with Jevtana or Xtandi for mCRPC; OR • the Patient has already used Zytiga in the pre-docetaxel setting.	Renewals: 1 year
Afatinib	Giotrif	20 mg, 30 mg, 40 mg tablet	**Initial requests:** **For the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC)** who meet the following criteria; • Afatanib is being used as first line therapy; AND • Afatanib is being used as monotherapy; AND • Patient's cancer is EGFR positive	Initials: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Afatinib	Giotrif	20 mg, 30 mg, 40 mg tablet	Dose: 40 mg orally once daily **Exclusion Criteria:** • Patients with EGFR wild-type, negative, or unknown mutation. • Afatinib will not be considered for funding in patients who have progressed on a prior EGFR TKI targeted therapy. • Not funded for 2nd or 3rd line or maintenance NSCLC. Notes: • Patients should be assessed for disease status at least every two months. Afatinib may be continued until evidence of disease progression or development of unacceptable toxicity requiring discontinuation of afatinib. • Patients who receive afatinib 1st line are NOT eligible for erlotinib in the 2nd or 3rd line or maintenance NSCLC setting. • Requests for afatinib for patients who have initiated another EGFR TKI therapy (i.e. Iressa [gefitinib]) in the first line setting and who have not had disease progression will be considered on a case-by-case basis. **Renewal requests** will be considered based on the following; Afatinib 40 mg once daily may be continued until evidence of disease progression or development of unacceptable toxicity at which point the drug should be discontinued. Patients should have their disease status assessed at least every two months. **Exclusion Criteria:** • Patients with EGFR wild-type, negative, or unknown mutation. • Afatinib will not be considered for funding in patients who have	Renewals: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			progressed on a prior EGFR TKI targeted therapy. • Not funded for 2nd or 3rd line or maintenance NSCLC.	
Axitinib	Inlyta	1 mg, 5 mg tablet	**For the treatment of with metastatic clear cell renal carcinoma** in patients meeting the following criteria; • Inlyta is being used as a second-line treatment • Inlyta is being used for patients who, based on the mutual assessment of the treating physician and patient, are unable to tolerate ongoing use of an effective dose of everolimus(Afinitor) or who have a contraindication to everolimus (Afinitor). Dosage: The usual starting dose is 5 mg twice a day. (Dose titration based on individual response and tolerability will be funded.) **Renewals** will be considered for those who have demonstrated benefit from Inlyta therapy and are expected to continue to benefit do so.	1 year (Initials and Renewals)
Bosutinib	Bosulif	100 mg, 500 mg tablet	**Chronic phase chronic myelogenous leukemia (CML)**: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented resistance/disease progression to 2 (two) prior oral tyrosine kinase inhibitors (TKI) (imatinib, dasatinib or nilotinib), where bosutinib would be the third or fourth line TKI; **OR** ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented intolerance to 1 (one) prior oral TKI (imatinib, dasatinib or nilotinib) where subsequent treatment with an alternative oral TKI (imatinib, dasatinib or nilotinib) is not clinically appropriate.	Initials: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Bosutinib		100 mg, 500 mg tablet	Dosing recommendation: 500 mg per day. **Renewals** will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so. Dosing recommendation: 500 mg per day. **<u>Accelerated Phase CML</u>**: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented resistance/disease progression to 2 (Two) prior oral TKIs (imatinib, dasatinib or nilotinib), where bosutinib would be the third or fourth line TKI; OR ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented intolerance to 1(One) prior oral TKI (imatinib, dasatinib or nilotinib) where subsequent treatment with an alternative oral TKI (imatinib, dasatinib or nilotinib) is not clinically appropriate. Dosing recommendation: 500 mg per day. **Renewals** will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so. Dosing recommendation: 500 mg per day.	Renewals: 1 year Initials: 1 Year Renewals: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Bosutinib	Bosulif	100 mg, 500 mg tablet	**Blast Phase CML**: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented resistance/disease progression to 2 prior oral TKIs (imatinib or dasatinib), where bosutinib would be the third or fourth line TKI; OR ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented intolerance to 1 (ONE) prior oral TKI (imatinib or dasatinib) where subsequent treatment with an alternative oral TKI (imatinib or dasatinib) is not clinically appropriate. Dosing recommendation: 500 mg per day. Renewal criteria: Confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so Dosing recommendation: 500 mg per day.	Initials: 1 year Renewals: 1 year
Crizotinib	Xalkori	200 mg, 250 mg capsule	Reimbursement as **first-line therapy[1] to treat patients with advanced non-small cell lung cancer (NSCLC)** who meet the following criteria: i) ALK-positive ii) ECOG* performance status ≤ 2 *ECOG = Eastern Cooperative Oncology Group Status	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Crizotinib	Xalkori	200 mg, 250 mg capsule	**Renewals** will be considered for patients who have not experienced disease progression as stated by the physician. Reimbursement as **second-line therapy[1] to treat patients with advanced non-small cell lung cancer (NSCLC)** who meet the following criteria: i) ALK-positive ii) ECOG* performance status ≤ 2 *ECOG = Eastern Cooperative Oncology Group Status **Renewals** will be considered for patients who have not experienced disease progression as stated by the physician. Dosing: 250 mg orally twice a day. [1]Exclusion Criteria: Patients who have progressed during or following first-line therapy with crizotinib are not eligible to receive crizotinib as a second-line therapy.	Initials: 1 year Renewals: 1 year.
Dabrafenib	Tafinlar	50 mg, 75 mg capsule	Initial requests: For the mutation-targeted treatment of patients with BRAF V600 mutation-positive unresectable melanoma or metastatic melanoma meeting the following criteria: • As first-line monotherapy; OR • As first-line combination therapy with trametinib; OR • As second-line monotherapy in which the disease has progressed	Initials: 6 months (Patients should have their disease status assessed at least every 3 months)

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Dabrafenib	Tafinlar	50 mg, 75 mg capsule	after receiving treatment in the first line setting; OR • As second-line combination therapy with trametinib in which the disease has progressed after receiving treatment in the first line setting; AND • If brain metastases are present, they should be asymptomatic or stable Recommended Dose as Monotherapy: 150 mg twice until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib Recommended Dose as combination dual therapy with trametinib: Dabrafenib 150 mg twice daily and trametinib 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation. Renewal requests: Therapy as monotherapy OR as combination dual therapy (as above) may be continued until evidence of disease progression[1] or development of unacceptable toxicity requiring discontinuation. [1] Letter from physician outlining radiological and clinical benefit requiring continuation of the drug and verification of no disease progression must be submitted. Approval duration (both initial and renewal requests): 6 months (patients should have their disease status assessed at least every 6 months.	Renewals: 6 months (Patients should have their disease status assessed at least every 3 months)

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Dabrafenib	Tafinlar	50 mg, 75 mg capsule	Case by case: Requests in patients who have initiated another single-agent BRAF or MEK inhibitor therapy will be considered on a case-by-case basis ONLY IF there has been no disease progression. Exclusion Criteria: • BRAF V600 negative, or wild type tumors, or unknown status will not be funded • Dabrafenib therapy (as monotherapy or in combination with trametinib) will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy used as monotherapy or in combination.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Dasatinib	Sprycel	20 mg, 50 mg, 70 mg, 100 mg tablet	**For the treatment of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in the chronic phase**.[1] Dosing recommendation: 100 mg per day. **Renewals** will be considered for patients who have experienced hematologic and/or cytogenic response and is expected to continue to do so. **<u>Exclusion criteria</u>**: Combination treatment with any two or more of the oral tyrosine-kinase inhibitors (TKI) (i.e. imatinib, nilotinib or dasatinib) will not be funded. [1]Note: Funding is only considered for any two oral TKIs* per patient in a lifetime for chronic phase CML (*TKIs: imatinib, nilotinib, or dasatinib). If a patient develops grade 3 or grade 4 toxicity on one of the listed TKI's within 3 months of initiating therapy, funding for a third oral TKI will be allowed. **For the treatment of patients with accelerated phase or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) with documented resistance[1] or intolerance[2] (as defined below) to imatinib therapy** Dosing recommendation: 140 mg per day. Definitions of resistance and intolerance: [1]Imatinib resistance is defined as primary or acquired resistance to imatinib at doses of at least 600 mg/day or through a mutational analysis report.	Initial: 1 year Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Dasatanib	Sprycel	20 mg, 50 mg, 70 mg, 100 mg tablet	[2]Intolerance to imatinib (at any dose) is defined as persistent grade 3 or grade 4 toxicity requiring discontinuation of therapy. **Renewals** will be considered for patients who have experienced hematologic and/or cytogenic response and is expected to continue to do so. **<u>Exclusion criteria</u>:** • Combination treatment with any 2 or more of the oral TKIs (i.e. imatinib, nilotinib or dasatinib) will not be funded. • Dasatinib is not funded as a sequential third line therapy in patients who experience primary or acquired resistance (not including mutational resistance) to nilotinib.	Initial: 1 year Renewal: 1 year
			For the treatment of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in patients meeting the following criteria: i) An adult patient with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL); AND ii) Patient's disease is resistant[1] to imatinib-containing chemotherapy (patient must have tried 600 mg/day); O iii) Patient has experienced intolerance[2] to imatinib therapy. [1]Imatinib resistance is defined as primary or acquired resistance to imatinib at doses of at least 600 mg/day or through a mutational analysis report. [2]Intolerance to imatinib (at any dose) is defined as the patient has experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of therapy.	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Dasatanib	Sprycel	20 mg, 50 mg, 70 mg, 100 mg tablet	**Renewals** will be considered after confirmation from the patient's physician that the patient has benefited or continues to benefit from therapy with Sprycel and is expected to continue to do so.	Renewal: 1 year
			Reimbursement of dasatinib for children with acute lymphoblastic leukemia will be considered on a case-by-case basis.	
Enzalutamide	Xtandi	40 mg capsule	*Reimbursement criteria for Xtandi in patients who have not received prior chemotherapy*: **For the treatment of metastatic castrate-resistant prostate cancer (mCRPC)** in patients who meet the following criteria: • The patient is asymptomatic or mildly symptomatic after failure of androgen deprivation therapy; **AND** • The patient has an ECOG* ≤ 1; **AND** • The patient must not meet any of the exclusion criteria[1] stated below. *ECOG = Eastern Cooperative Oncology Group Status [1] Exclusion Criteria: Xtandi will NOT be approved for funding in patients who meet any ONE (or more) of the following exclusion criteria: • The patient has risk factors for seizures; • The patient is using Xtandi in combination with Zytiga (abiraterone) for metastatic castration-resistant prostate cancer; • The patient has used and experienced disease progression on	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Enzalutamide	Xtandi	40 mg capsule	Zytiga; OR • The patient has received prior chemotherapy for mCRPC. **Renewal** of funding requests for Xtandi in patients who initiated Zytiga therapy and who have not had disease progression while on Zytiga will be considered on a case-by-case basis. *Reimbursement criteria for Xtandi in patients in the post-docetaxel setting:* **For the treatment of metastatic castration resistant prostate cancer** in patients who meet the following criteria; • Xtandi is being used in patients who have progressed on docetaxel-based chemotherapy; **AND** • Patient has an ECOG* ≤ 2 (prior to the start of Xtandi therapy). *ECOG = Eastern Cooperative Oncology Group Status Requests for Xtandi for patients who meet the above criteria and who have initiated therapy with Jevtana or Zytiga (abiraterone) during the three months prior to the request for reimbursement of Xtandi and who have not had disease progression will be considered. Note: Xtandi will only be considered as an alternative to Zytiga(abiraterone) for patients in the post-docetaxel setting but will not be considered as an add-on therapy to Zytiga (abiraterone) treatment.	Renewals: 1 year Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			Exclusion criteria: Xtandi will not be funded in patients who meet any ONE (or more) of the following exclusion criteria; • Patient has risk factors for seizures; • Patient is using Xtandi in combination with Jevtana (cabazitaxel) or Zytiga (abiraterone) for metastatic castration-resistant prostate cancer; *Patient's requesting Xtandi for 1st line metastatic castration-resistant prostate cancer, refer to criteria in pre-docetaxel / pre-chemotherapy setting above.* **Renewal** of funding requests will be considered in patients who have not experienced disease progression while on Xtandi.	Renewals: 1 year
Erlotinib	Tarceva	25 mg, 100 mg, 150 mg tablet	**For the treatment of clinically documented incurable progressive non-small cell lung cancer (NSCLC)** where: • 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. • Erlotinib is used as monotherapy for the 2nd- or 3rd-line treatment of patients with clinically documented incurable progressive non-small cell lung cancer (NSCLC) despite prior chemotherapy including both docetaxel and a platinum-based treatment (i.e. cisplatin or carboplatin). • Erlotinib is used as monotherapy for the 3rd-line treatment of patients with clinically documented incurable progressive non-small cell lung cancer (NSCLC) despite prior chemotherapy including	Initials: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Erlotinib	Tarceva	25 mg, 100 mg, 150 mg tablet	both a platinum-based therapy (i.e. cisplatin or carboplatin) AND either pemetrexed or topotecan. • Erlotinib is used as monotherapy for 2nd line treatment of NSCLC after 1st line platinum-based therapy, where no other chemotherapy will be given and erlotinib is used as the last treatment for the patient Patients should be assessed for disease status at least every two months. Erlotinib should be discontinued if there is evidence of disease progression. Note that erlotinib is not indicated and therefore, is not considered for reimbursement as 1st line therapy in treatment of NSCLC. Requests for 2nd-line and 3rd-line use of erlotinib in patients 70 years of age or older and have not received treatment with either platinum-based combinations will be considered on a case-by-case basis. Approved dosage: 150 mg/day **Renewal** 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.	Renewal: 6 months
Everolimus	Afinitor	2.5 mg, 5 mg, 10 mg tablet	**For the treatment of metastatic renal cell carcinoma (mRCC) as second or third line therapy in patients previously treated for mRCC with a funded tyrosine kinase inhibitor (TKI).** [Note: Funded TKIs include sunitinib (Sutent), sorafenib (Nexavar), and pazopanib (Votrient).]	1 Year (Initials and Renewals)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Everolimus	Afinitor	2.5 mg, 5 mg, 10 mg tablet	Exclusion criteria: Use in the 4th line setting or later in the treatment course of their disease Dosage: 10 mg daily **Renewal** will be considered for those who have demonstrated benefit from Afinitor therapy (i.e. no disease progression) and is expected to continue to do so. **For the treatment of patients who have progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET)**. Patient must have an ECOG* ≤ 2 (prior to the start of Afinitor therapy). *ECOG = Eastern Cooperative Oncology Group Status Exclusion criteria: the patient's disease progressed while taking sunitinib (Sutent) to treat pNET. Dosage: 10 mg daily **Renewal** will be considered for those who have benefited from Afinitor therapy (i.e. no disease progression) and is expected to continue to do so. Reimbursement of Afinitor will be considered until disease progression occurs on Afinitor.	1 Year (Initials and Renewals) 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Everolimus	Afinitor	2.5 mg, 5 mg, 10 mg tablet	**For the treatment of postmenopausal women with hormone-receptor positive, HER2 negative advanced breast cancer** meeting the following criteria: • Afinitor is to be used in combination with exemestane; AND • Patient must have an ECOG* ≤ 2 after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI). *ECOG = Eastern Cooperative Oncology Group Status Dosage: 10 mg daily (dose titration is allowed). **Renewals** will be considered for patients who have benefited or continues to benefit from therapy with Afinitor and is expected to continue to do so. **For the treatment of renal angiomyolipoma (AML) associated with tuberous sclerosis complex (TSC)** in patients who meet all the following conditions: (i) Presence of coalescent or multifocal AMLs in either one or both kidneys; AND (ii) AML progression despite previous embolization and/or surgery; AND (iii) Further embolization and/or surgery is not recommended due to a documented clinical reason (Note: The physician must submit a clinical note with the request outlining/detailing why invasive therapy cannot be considered); The approved dosage: 10 mg orally once daily.	(Initials and Renewals) Initial: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Everolimus	Afinitor	2.5 mg, 5 mg, 10 mg tablet	Case-by-Case consideration will be considered in patients who have never been treated with invasive procedures such as embolization and/or surgery. The physician must provide detailed clinical rationale (e.g., from clinical consultation notes) as to why embolization and/or nephrectomy would be medically contraindicated for the patient. **Renewals** will be considered in patients with the following documented benefits from therapy; • No AML progression (i.e. no significant new lesions and increase in kidney volume, as well as no significant AML related bleeding); **AND** • There is a reduction in volume of AMLs identified prior to treatment with the everolimus. **For the treatment of Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC)** for whom surgical resection cannot be considered* for reasons such as: • Location, size, and/or distribution of tumour(s); OR • SEGA progression despite previous surgical interventions; OR • Neurocognitive problems/ other complications secondary to previous surgical interventions. • *Requests must provide details/ consultation notes outlining why the patient cannot be considered for surgical treatment. Renewals will be considered in patients with the following documented benefits from therapy: • Stabilization of SEGA progression (based on assessment of SEGA volume and/or appearance of new lesions); AND	Renewals: 2 years Initials: 1 year Renewals: 2 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			• Improvement of symptoms (e.g., reduced seizure frequency and decreased need for neurosurgical intervention).	
Gefitinib	Iressa	250 mg tablet	**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).** (i.e. Patients who are EGFR Positive) 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. Dose Reimbursed: 250 mg orally once daily. Iressa will not be granted funding in the following circumstances; ○ Patients with EGFR wild-type mutation (i.e. negative for mutation); ○ Patients with EGFR unknown mutation; ○ 2nd or 3rd line or maintenance NSCLC; or ○ Patients with unknown EGFR status who start their first chemotherapy while waiting for EGFR testing, then are found/confirmed to be EGFR positive, should continue with the current therapy and will not be eligible for gefitinib (Iressa) in this setting. ○ 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. Requests for gefitinib for patients who have initiated another EGFR TKI therapy (i.e. Afatanib [Giotrif]) in the first line setting and who have not	Initial: 6 months Renewal: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			had disease progression will be considered on a case-by-case basis. **Renewal** 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. Dose Reimbursed: 250 mg orally once daily.	
Ibrutinib	Imbruvica	140 mg capsule	**For the treatment of patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** who meet the following criteria; i) Patient has received at least one prior therapy to treat CLL/SLL; AND ii) Patient's prescriber has deemed that it would be inappropriate for the patient to receive treatment or retreatment with a fludarabine-based regimen. Exclusion criteria: Patients whose disease has progressed on idelalisib therapy in the relapsed setting are not eligible to receive iburitinib. **Renewals** will be considered for patients who have not experienced disease progression while on ibrutinib (Imbruvica) therapy.	Initial: 1 year Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Idelalisib	Zydelig	100 mg, 150 mg Tablets	For **the treatment of patients with relapsed chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL)** in combination with Rituximab. Exclusion criteria: Patients whose disease has progressed on ibrutinib therapy in the relapsed setting are not eligible to receive idelalisib. Note: Patients who have experienced intolerance but not disease progression to ibrutinib in the relapsed setting may switch to idelalisib. Documentation on the nature of the intolerance is required. **Renewals** will be considered for patient who has not experienced disease progression while on idelalisb (Zydelig) therapy. Funded Dose: Idelalisib will be funded in combination with up to 8 cycles of rituximab at the recommended dose of 150 mg orally twice daily and will continue following the completion of the rituximab portion of the regimen.	Initial: 1 year Renewals: 1 year
Imatinib	Gleevec + generics (see below for billing information)	100 mg tablet 400 mg tablet	**For the treatment of Metastatic Gastrointestinal Stromal Tumours (GIST)** in patients with a tumour deemed to be NOT surgically resectable (metastatic or recurrent) **Renewal** will be considered for patients with GIST who have benefited from or continues to benefit from therapy with Gleevec and is expected to continue to do so.	Initial: 1 Year Renewal: 1 Year

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			For the Adjuvant treatment of Gastrointestinal Stromal Tumours (GIST) in patients who meet the following criteria: • Patients are at intermediate to high risk of recurrence following complete resection (using Miettinen relapse risk criteria, risk ≥ 20%) or has had tumor rupture before surgery or at surgery; AND • The pathology has been confirmed with c-kit positivity. Note that the dosing regimen covered is no more than 400 mg daily. **Renewals** will NOT be considered for patients receiving Gleevec for Adjuvant GIST. (i.e. Funding for adjuvant GIST is approved for up to 3 years. Longer coverage durations are not considered.)	Initial: Up to 3 years (Funding beyond 3 years is not considered for adjuvant GIST)
			For the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) **Renewal** will be considered for patients receiving Gleevec for Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) who demonstrate a hematologic or cytogenetic response to therapy.	Initial: 1 Year Renewal: 1 Year

As of June 15, 2013, EAP approval letters will indicate PINs to be used for billing purposes. The PINs will allow the full price of each product to be submitted for reimbursement of EAP approved requests. Pharmacists should refer to the respective product monograph(s) for prescribing information and approved indications.

	imatinab mesylate 100mg	imatinab mesylate 400mg
Gleevec	09857447	09857448
Apo-Imatinib	09857444	09857446
Teva-Imatinib	09857449	09857450

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Co-Imatinib (Added June 26, 2014)		09857468	09857469	
Lapatinib	Tykerb	250 mg tablet	**For the second-line treatment of HER2-positive metastatic breast cancer when used in combination with chemotherapy after previous exposure to trastuzumab-based treatments**. **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**. Lapatinib will not be considered in patients who meet the following exclusions: • Lapatinib (Tykerb) will not be funded in combination with trastuzumab (Herceptin) for second-line HER-2 positive metastatic breast cancer. • 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). • Lapatinib (Tykerb) will not be funded in the adjuvant settting. 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,	Initial: 6 months

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			or withdrawal of consent. Note: Funding of second-line lapatinib for HER-2 positive metastatic breast cancer will be discontinued upon evidence of disease progression **Renewal** will be considered for lapatinib until there is evidence of disease progression at which point the drug should be discontinued.	Renewal: 6 months
Lenalidomide	Revlimid	5 mg, 10 mg, capsule	**For the treatment of anemia due to myelodysplastic syndrome (MDS)** for patients who meet all the following clinical criteria; • Demonstrated diagnosis of MDS on bone marrow aspiration; AND • Presence of del[5q] documented by standard cytogenetic or fluorescence in situ hybridization; AND • International Prognostic Scoring System (IPSS) risk category low or intermediate-1; AND • Transfusion-dependent symptomatic anemia. **Renewal** will be considered for patients who are transfusion-dependent and who have demonstrated at least a fifty percent (50%) reduction in transfusion requirements. Note: Patients with anemia due to MDS who are not transfusion-dependent will be assessed on a case-by-case basis. o Physicians submitting initial requests for non-transfusion-dependent patients must provide clinical evidence of symptomatic anemia affecting the patient's quality of life and the rationale for why transfusions are not being used. o Renewal requests for non-transfusion-dependent patients will be	Initial: 6 months Renewal: Up to 1 year

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			considered on a case-by-case basis. In such cases, the requesting physician will be required to provide the patient's serial clinical blood culture (CBC) pre- and post-lenalidomide therapy in addition to any other objective evidence of the patient's response to lenalidomide therapy.	
Lenalidomide	Revlimid	5 mg, 10 mg, 15 mg, 25 mg capsule	**For the treatment of <u>multiple myeloma</u> in combination with dexamethasone** for patients who are not candidates for autologous stem cell transplant for patients who are; • Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who are suitable for further chemotherapy OR • Have completed at least one full treatment regimen as initial therapy and has demonstrated an intolerance to their current chemotherapy. **<u>Renewals</u>** will be considered for those who continue to respond to therapy.	Initial: 1 year Renewal: 1 year
Lenalidomide	Revlimid	5 mg, 10 mg, 15 mg, 25 mg capsule	**For the maintenance treatment of patients with newly diagnosed <u>multiple myeloma following autologous stem-cell transplantation</u>** who have stable or improved disease, and with no evidence of disease progression. <u>Recommended Dosage</u>: Initial dose of 10 mg daily. Dose adjustments of 5 mg to 15 mg may be necessary based on individual patient characteristics and responses to lenalidomide.	Initial: 1 year

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			Renewals will be considered for patients with no evidence of disease progression or development of unacceptable toxicity to lenalidomide requiring discontinuation of therapy.	Renewal: 1 year
Nilotinib	Tasigna	150 mg, 200 mg capsule	**For the treatment of patients with chronic phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML)**. *Note: Ministry will only fund any TWO of the oral Tyrosine Kinase inhibitors (TKIs) * used for chronic phase CML per patient in a lifetime. (* TKIs: imatinib, nilotinib, or dasatinib)* *If the patient develops grade 3 or 4 toxicity on one of the above TKI's within 3 months of initiating therapy, access to a 3rd oral TKI will be funded for that patient.* Approved dose: 300 mg twice daily but not exceeding 800 mg/day	Initial : 1 year
Nilotinib	Tasigna	150 mg, 200 mg capsule	**For the treatment of patients with accelerated phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) with documented intolerance[1] or resistance[2] to imatinib therapy**. *[1]Intolerance to imatinib at any dose occurs where the Patient has experienced persistent grade 3 or grade 4 toxicity requiring discontinuation of imatinib therapy; or* *[2]Imatinib resistance occurs where the Patient has primary or acquired*	

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			resistance to imatinib at doses of at least 600mg/day or via a mutational analysis report. Exclusion Criteria – Patients with the following exclusion criteria will not be funded: a) blast phase CML; b) for Ph+ acute lymphocytic leukemia (ALL); c) combination treatment with any two or more oral TKIS's (imatinib, nilotinib, or dasatinib) will not be funded d) For accelerated phase CML, nilotinib is not funded as a sequential third line therapy in patients who experience primary or acquired resistance (not including mutational resistance) to dasatinib. Approved dosage: Up to 800 mg/day but doses above 800 mg per day will not be considered **Renewals** are considered for patients who experience hematologic and/or cytogenic response to therapy, is expected to continue to do benefit from therapy with Tasigna.	Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Pazopanib	Votrient	200 mg tablet	For first-line treatment of advanced or metastatic renal cell carcinoma of clear cell histology in patients with good performance status (ECOG* ≤ 1) ECOG = Eastern Cooperative Oncology Group Performance Status The approved dosage is 800 mg once daily. **Renewals** will be considered for patients who have benefited from therapy (i.e. no disease progression) and are expected to continue to do so. Exclusion criteria: Funding for Votrient will not be approved for patients who demonstrate disease progression while on sunitinib, sorafenib, temsirolimus, everolimus or other drugs approved for treatment of metastatic renal cell carcinoma.	Initial: 1 year Renewal: 1 year
Pomalidomide	Pomalyst	1 mg, 2 mg, 3 mg, 4 mg capsules	**For the treatment of patients with relapsed and/or refractory multiple myeloma (MM)** who meet the following criteria; i) Patient has failed lenalidomide[1]; AND ii) Patient has previously failed[2] OR may have a contraindication OR demonstrated an intolerance[3] to bortezomib; AND iii) Patient has demonstrated disease progression following the last treatment[4] used for MM. [1]Failure to lenalidomide may include failure to treatment received during the maintenance setting. [2]Failure to bortezomib can include patients who have received a course of bortezomib during which there was no disease progression, however, at the time of relapse of the patient's MM, the patient is no longer eligible for retreatment with bortezomib.	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			[3]Details of the patient's intolerance(s) to bortezomib must be provided on the funding application to EAP. [4]The patient's last treatment may be a regimen other than one containing lenalidomide or bortezomib. **Renewals** will be considered for patients who continue to respond to therapy (i.e. is not refractory and has not relapsed).	Renewals: 1 year
Ponatinib	Inclusig	15 mg, 45 mg tablets	**Chronic Phase CML**: a. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase and documented T315i mutation; OR b. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib, dasatinib or nilotinib), where ponatinib would be the third or fourth line TKI. **Accelerated Phase CML**: a. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase and documented T315i mutation; OR b. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib, dasatinib or nilotinib), where ponatinib would be the third or fourth line TKI.	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			Blast Phase CML: a. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase and documented T315i mutation; OR b. For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib and dasatinib), where ponatinib would be the third or fourth line TKI. **For Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL):** a. For the treatment of patients with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL) and documented T315i mutation; OR b. For the treatment of patients with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL) with documented resistance/disease progression or intolerance to imatinib and dasatinib, where ponatinib would be the third line TKI. **Renewals** will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so.	Initials: 1 year Renewals: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Regorafenib	Stivarga	40 mg tablets	For the treatment of metastatic and/or unresectable gastrointestinal stromal tumors (GIST) in patients who have had disease progression on, or intolerance to, imatinib and sunitinib Dosage: 160 mg once daily for 3 weeks followed by 1 week of no therapy to comprise a cycle of 4 weeks. Reimbursement of Stivarga will be considered as long as benefit is observed or until unacceptable toxicity occurs. **Renewals** will be considered in patients who continue to derive benefit from therapy.	Initial: 6 months Renewal: 6 months
Ruxolitinib	Jakavi	5 mg, 15 mg, 20 mg tablets	For the treatment of intermediate to high risk symptomatic Myelofibrosis (MF) in patients meeting the following criteria; i) MF is assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus; or the patient has symptomatic splenomegaly ii)Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 3 iii) Patient is previously untreated or refractory to other treatment Dosing regimen: 5 mg to 25 mg twice a day **Initial Renewals** are considered for patients who: • Have confirmation of either a reduction in spleen size or documented improvement of disease symptoms within 6 months of initiating therapy with Jakavi.	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
			Second and subsequent Renewals are considered for patients who continue to benefit from therapy with Jakavi.	
Sorafenib	Nexavar	200 mg tablet	**For the treatment of metastatic renal cell carcinoma (MRCC) as second-line treatment** for patients who have: • Histologically confirmed metastatic clear-cell renal-cell carcinoma; and • Experienced disease progression after prior cytokine therapy within the previous 8 months; and • A performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group criteria; and • Intermediate-risk or low-risk status, according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score. **Renewals** will be considered with confirmation from the physician that the patient has benefited from therapy and is expected to continue to do so.	1 year
			For the treatment of advanced hepatocellular carcinoma (HCC) in patients who have: • Child-Pugh Class A disease; and • ECOG* status 0, 1 or 2; and • Either progressed on transarterial chemoembolization (TACE) or are not suitable for the TACE procedure (where detailed rationale is provided). *ECOG = Eastern Cooperative Oncology Group Performance Status **Renewal** will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression.	3 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sunitinib	Sutent	12.5 mg, 25 mg, 50 mg capsule	**For the treatment of gastrointestinal stromal tumour (GIST) in patients with unresectable or metastatic/recurrent GIST** where one of the following conditions is met: • Early progression (within 6 months) while on imatinib; OR • Progression following treatment with optimum (escalated) doses of imatinib (800mg per day); OR • Intolerance* to imatinib (where detailed description of intolerance is provided). *Definition of intolerance to imatinib – patient has experienced persistent grade 3 toxicity requiring discontinuation of therapy. **Renewal** will be considered for patients who are stable (no disease progression) and not experiencing intolerance to sunitinib therapy. *Note: Approval will be granted at a dose of 50mg per day (4 weeks on, 2 weeks off).*	6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Sunitinib	Sutent	12.5 mg, 25 mg, 50 mg capsule	**For the treatment of <u>metastatic renal cell carcinoma (MRCC)</u>**: • <u>First-line therapy</u> for patients with MSK Prognostic Score of Favourable Risk or an Intermediate Risk OR • <u>Second-line therapy</u> for patients where: ○ The disease is of clear cell histology AND ○ Documented failure to first-line cytokine-based therapy. **<u>Renewal</u>** will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression. *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.* **For the treatment of progressive, unresectable, well-differentiated or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors ("pNET") with good performance status (ECOG ≤ 2), until disease progression.** Exclusion criteria: Sutent will not be approved for second-line sequential therapy after everolimus failure in the first-line setting. Dosing: 37.5 mg daily	1 year 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Thalidomide	Thalomid	50 mg capsule 100 mg capsule 200 mg capsule	**For the treatment of Multiple Myeloma** in patients 65 years of age or older meeting the following criteria; • Thalidomide is being used in combination with melphalan and prednisone; AND • The patient has not previously received other treatments[1] for multiple myeloma; AND • The patient is deemed to be unsuitable for stem cell transplantation; AND [1]Exception is for those meeting bortezomib criteria as described below. It should be noted that funding of thalidomide will be considered on a case-by-case basis for patients who have developed severe (grade III/IV) thrombocytopenia during the first 1 to 2 cycles of treatment with bortezomib and who have not experienced disease progression on bortezomib. Exclusion criteria: Funding will not be considered for patients who are using thalidomide as second-line treatment of multiple myeloma.	A maximum of 12 six-week cycles.

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Trametinib	Mekinist	0.5 mg, 2 mg tablet	Initial requests: For the mutation-targeted treatment of patients with BRAF V600 mutation-positive unresectable melanoma or metastatic melanoma meeting the following criteria: • As first-line monotherapy; OR • As first-line combination therapy with dabrafenib; OR • As second-line monotherapy in which the disease has progressed after receiving treatment in the first line setting; OR • As second-line combination therapy with dabrafenib in which the disease has progressed after receiving treatment in the first line setting; AND • If brain metastases are present, they should be asymptomatic or stable Recommended Dose as Monotherapy: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib Recommended Dose as combination dual therapy with Dabrafenib: Trametinib 2 mg once daily and Dabrabenib 150 mg twice daily, until disease progression or development of unacceptable toxicity requiring discontinuation.	Initials: 6 months (Patients should have their disease status assessed at least every 3 months)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Trametinib	Mekinist	0.5 mg, 2 mg tablet	Renewal requests: Therapy as monotherapy OR as combination dual therapy (as above) may be continued until evidence of disease progression[1] or development of unacceptable toxicity requiring discontinuation. [1] Letter from physician outlining radiological and clinical benefit requiring continuation of the drug and verification of no disease progression must be submitted. Approval duration (both initial and renewal requests): 6 months (patients should have their disease status assessed at least every 6 months Case by case: Requests in patients who have initiated another single-agent BRAF or MEK inhibitor therapy will be considered on a case-by-case basis ONLY IF there has been no disease progression. Exclusion Criteria: • BRAF V600 negative, or wild type tumors, or unknown status will not be funded • Trametinib therapy (as monotherapy or in combination with dabrafenib) will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy used as monotherapy or in combination.	Renewals: 6 months (Patients should have their disease status assessed at least every 3 months)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Vemurafenib	Zelboraf	240 mg tablet	**Vemurafenib is funded when used as monotherapy for the 1st line treatment of patients with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or metastatic disease.** The recommended dose for vemurafenib in the 1st line setting is 960 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib. **Exclusion Criteria** • Vemurafenib is not funded in patients with BRAF V600 negative mutation • Vemurafenib is not funded in patients with wild type tumours; • Vemurafenib is not funded in patients with unknown mutational status • Vemurafenib will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy used as monotherapy or in combination. **Renewals** will be considered for requests for requests where the patient's physician provides documentation outlining; • the radiological and clinical benefit requiring continuation of the patient on vemurafenib; AND • verifying that there has been no disease progression or development of unacceptable toxicity in the patient.	Initials : 6 months (Note that patients should have their disease status assessed at least every 3 months) Renewals: 6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Vemurafenib	Zelboraf	240 mg tablet	**Vemurafenib is funded when used as monotherapy in the 2nd line treatment of patients with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or metastatic disease which has progressed after receiving treatment in the 1st line setting.** The recommended dose for vemurafenib in the 2nd line setting is 960 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib. **Exclusion Criteria** • Vemurafenib is not funded in patients with BRAF V600 negative mutation. • Vemurafenib is not funded in patients with wild type tumours; • Vemurafenib is not funded in patients with unknown mutational status • Vemurafenib will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy used as monotherapy or in combination. Requests for Zelboraf for patients who have initiated another BRAF therapy [i.e. Mekinist (trametinib), Tafinlar (dabrafenib)] and who have not had disease progression will be considered on a case-by-case basis. **Renewals** will be considered for requests for requests where the patient's physician provides documentation outlining; • the radiological and clinical benefit requiring continuation of the patient on vemurafenib; AND • verifying that there has been no disease progression or development of unacceptable toxicity in the patient.	Initials : 6 months Renewals: 6 months (Note that patients should have their disease status assessed at least every 3 months)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Vismodegib	Erivedge	150 mg tablet	**For the treatment of metastatic basal cell carcinoma (BCC) or locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome)** in patients who meet the following criteria; • Patient must have measurable metastatic disease or locally advanced disease; AND • Patient's disease must be considered inoperable or inappropriate for surgery[1]; AND • Patient's disease must be considered inappropriate for radiotherapy[2]; AND • Patient is 18 years or age or older; AND • Patient has an ECOG ≤ 2 Dose: 150 mg orally once daily taken until disease progression or unacceptable toxicity. Requests must include the following information: Physicians must provide rationale for why surgery AND radiation cannot be considered • The request must include a surgical consult note that provides a preoperative/surgical evaluation why surgery is not appropriate for the patient; AND • A consult note as to why radiation therapy is not appropriate for the patient; AND • Both of the above evaluations must come from a physician who is not the requesting physician; AND • The request must include confirmation that the patient has been discussed at a multi-disciplinary cancer conference (MCC) or equivalent.	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 and 3 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Vismodegib	Erivedge	150 mg tablet	[1]Considered inoperable or inappropriate for surgery for at least ONE of the following reasons: • Technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible); OR • Recurrence of BCC after two or more surgical procedures and curative resection unlikely; OR • Substantial deformity and/or morbidity anticipated from surgery. [2]Considered inappropriate for radiation for at least ONE of the following reasons: • Contraindication to radiation (e.g. Gorlin syndrome); OR • Prior radiation to lesion; OR • Suboptimal outcomes expected due to size/location/invasiveness of BCC. **Note: Patient preference for oral therapy will not be considered** **Renewals** will be considered where the physician has confirmed that the patient has not experienced disease progression while on Erivedge therapy.	Renewals: 1 year

ONCOLOGY- RELATED MANAGEMENT

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Aprepitant	Emend	80 mg, 125 mg capsule, Tri-pack	Effective September 25, 2014, Emend transitioned to the ODB formulary for reimbursement in patients who meet the Limited Use criteria.	
Denosumab	Xgeva	120 mg per vial for subcutaneous injection	**For the treatment of bony metastases in patients with hormone refractory prostate cancer.** Xgeva is considered through CCO for those receiving prostate cancer treatment from a cancer clinic. Hormone refractory prostate cancer is determined using the following criteria: i) Patient has an elevated PSA level or evidence of progressive bony disease[1], despite castrate serum testosterone levels (Less than 1.7 nmol/L or less than 50 ng/dL)[2]. [1] Progressive bony disease is defined as progressive changes in radionucleotide bone scan or clinical signs of disease profession, such as pathologic fracture or increasing bone pain. [2]Note: Patients who have undergone orchidectomy do not need to provide a serum testosterone level in the request submission. Approved Dosing. 120 mg subcutaneously every four (4)	Initial: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			weeks **Renewals** will be considered for patient responding to treatment with Xgeva and who still requires treatment.	 Renewal: 1 Year
Zoledronic Acid	Zometa Concentrate	4 mg/ 5 mL Vial	Zoledronic acid as Zometa Concentrate will only be considered **for the treatment of bony metastases in those with hormone refractory prostate cancer as well as other cancers** through the Exceptional Access Program (EAP) **in those receiving outpatient care** who do not meet the criteria of Cancer Care Ontario (CCO). Zometa is considered through CCO for those receiving prostate cancer treatment from a cancer clinic.	Initial: 6 months
			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[1], despite castrate serum testosterone levels (<50 ng/dL). [1]Progressive bony disease should be demonstrated by: progressive changes in radionucleotide bone scan or clinical signs of disease progression (e.g., via radionucleotide scanning, pathologic fracture or increasing bone pain).	Initial: 6 months
Zoledronic Acid	Zometa Concentrate	4 mg/ 5 mL Vial	Requests for patients who have undergone orchidectomy do not need to provide a serum testosterone level.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION

			• For the prevention of skeletal related events in patients who have not experienced previous skeletal related events[2] and who have bony metastases secondary to:
			  • solid tumours (e.g. renal, small cell lung, pancreatic cancers) who have good performance status[3] **OR**
			  • breast cancer or multiple myeloma who are intolerant to pamidronate.
			
			[2]A skeletal related event is defined as: pathologic fracture, spinal cord compression, radiation therapy to bone or surgery to bone.
			[3]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.
			
			• 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.
			
			• 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 be provided in the request.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Renewals will be considered for patients who are responding to therapy and is still deemed to require treatment.	Renewal: 6 months

OSTEOPOROSIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Teriparatide	Forteo	250 mcg/mL - 3 mL prefilled pen 250 mcg/mL 2.4 mL prefilled pen	For the treatment of osteoporosis in patients who meet the following criteria; • 65 years of age or older who are mobile; **AND** • Patient is at high risk of fragility fractures*; **AND** • Patient who has osteonecrosis of the jaw due to an anti-resorptive agent **OR** who has atypical femur fracture due to an anti-resorptive agent. (Note: One of the two conditions must be present.)[1] *High risk for fragility fractures is defined as : • A bone mineral density (BMD) T-score less than or equal to -3; AND • Prior fragility fracture Note: Requesting physicians must include a copy of the BMD report with the EAP request Requests meeting criteria will be funded for 24 months. It should be noted that renewals are NOT considered. (*As noted in the product monograph, the maximum life time exposure to an individual patient is 24 months)* [1]No other contraindications to anti-resorptive therapies will be considered for funding.	Total approval duration of 24 months will be provided. Renewals are not considered.

PAIN MANAGEMENT

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Cannabidiol and delta-9-tetrahydro-cannabinol	Sativex	25 mg/27 mg per mL buccal spray	**For the treatment of <u>neuropathic pain related to multiple sclerosis</u>** in patients who have: • Ineffective response or intolerable side effects / contraindications to adequate trials* of a tricyclic antidepressant and gabapentin and pregabalin; and • Ineffective response or intolerable side effects / contraindications to adequate trials* of Cesamet (nabilone) and Marinol (delta-9-tetrahydrocannabinol); and • No contraindications to Sativex therapy. * Adequate trial is defined as 2 months unless intolerable side effect(s) occur. 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. **<u>Renewal</u>** 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.	Initial: 1 year Renewal: Lifetime
			Sativex is also reimbursed for the treatment of refractory pain in palliative cancer patients according to specified criteria.	6 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Methadone	Metadol	1 mg, 5 mg, 10 mg, 25 mg tablets 1 mg/mL oral solution 10 mg/mL oral concentrate solution	**For the treatment of cancer and non-cancer pain in patients who cannot tolerate, or have failed treatment with a listed long-acting opioid**. The CED noted that there is a potential for drug interactions with the use of methadone resulting from inhibition of drug metabolism (via CYP 3A4 inhibition; e.g. QT prolongation with certain antibiotics). The requesting physician is asked to ensure that this issue is addressed with the patient. **Renewals** will be considered on a case-by-case basis. For renewals, the requesting physician is asked to provide details of the patient's clinical response to therapy and additional information pertaining to the current medications and addition or stoppage of other pain medications in the prior year of methadone use. Please specify the dosages and dosing frequency of current medications and provide reasons for any changes in the medication regimen.	1 year
Oxycodone Controlled Release Tablet	OxyNeo	10 mg CR 15 mg CR 20 mg CR 30 mg CR 40 mg CR	**For the treatment of chronic pain in patients who have experienced intolerance or have failed an adequate trial (for example, three months) of at least one other listed long-acting opioid product**. **Note:** Physicians should consider best practice guidelines for the safe and effective use of opioids in chronic non-cancer pain, such as the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain.	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Oxycodone Controlled Release Tablet	OxyNeo	10 mg CR 15 mg CR 20 mg CR 30 mg CR 40 mg CR	Please include the following information in your request: iv) The diagnosis for which the pain management is required must be documented. v) All concomitant pain medication therapy must be documented. vi) Other medications with potential for abuse or interaction with opioid therapy should be documented. <u>Renewals</u> will be considered if treatment continues to be appropriate for the management of the patient's chronic pain. Please include the following information on your renewal request: i) All concomitant pain medication therapy must be documented. ii) Other medications with potential for abuse or interaction with opioid therapy should be documented. **Note: OxyNEO 60mg and 80mg tablets are <u>not</u> funded.** **Note: Physicians registered on the Ontario Medical Association's Palliative Care Facilitated Access List can access OxyNeo for chronic pain management of their palliative care patient for an initial duration of one year without approval through the Exceptional Access Program.**	Renewals: 1 year

PARKINSON'S DISEASE DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Levodopa 20 mg/mL and Carbidopa 5 mg/mL Intestinal gel	Duodopa	Intestinal Gel containing Levodopa 20 mg/mL – Carbidopa 5 mg/mL (100 mL cassette)	**For the treatment of Parkinson's disease in patients who meet the following criteria;** • Experiences at least 25% of the waking day in the off state; **AND** • Has severe disability while in the off-state as assessed by a Movement Disorder Specialist; **AND** • Has received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response; **AND** • Has failed adequate trials of other adjunctive medications (entacapone, dopamine agonists, monoamine oxidase-B [MAO-B] inhibitors) if not contraindicated. Note that if a contraindication is deemed to be applicable to the patient, the requesting physician must state the contraindication and provide the rationale why it is considered a contraindication for the patient). Clinical details pertaining to the severity of the patient's disability while in the off-state as well as a complete history of all previous and current medications (e.g., name, start date and duration of therapy, doses used, side effects, and response) must be included. Requests for treatment initiation will be limited to the physicians practicing in the following specialized movement disorder clinics: Ottawa, London, Toronto Western, Kingston, Baycrest and Hamilton.	Initials: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Exclusion criteria (Patients who meet the following criteria will NOT be considered): • Patients who have a contraindication to insertion of a percutaneous endoscopic gastrostomy (PEG) tube • Severe psychosis or dementia **Renewals** will be considered in patients who continue to benefit from treatment. The patient should continue to demonstrate a significant reduction in the time spent in the off state and an improvement in the severity of the disability in the off state.	Renewals: 1 year
Rasagiline	Azilect	0.5 mg, 1 mg tablet	**For the treatment of patients with Parkinson's disease who experience about 25% of the waking day in the off-state despite maximally tolerated doses of levodopa.**	5 years (Initials and Renewals)

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	**For the treatment of psoriatic arthritis** in patients who have: Severe active disease (≥ 5 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. 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. **Renewal** 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. The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of psoriatic arthritis are as follows: o Adalimumab 40mg every two weeks o Certolizumab 400 mg at week 0, 2, 4 then maintenance doses of 200 mg every 2 weeks or 400 mg every 4 weeks o Etanercept 25mg twice weekly or 50mg once weekly o Golimumab 50mg once a month	Initial: 1 year First Renewal: 1 year Second and subsequent renewals: 2 years
Certolizumab	Cimzia	200 mg/mL prefilled syringe		
Etanercept	Enbrel	25 mg/vial and 50 mg prefilled syringe for subcutaneous injection		
Golimumab	Simponi	50 mg/0.5 ml prefilled syringe and autoinjector		

PSYCHIATRY DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Atomoxetine	Strattera and generics	10 mg, 18 mg, 25 mg, 40 mg, 60 mg, Capsules	**For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)** according to DSM-IV criteria in patients ≥ 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: • Must be prescribed by or prescribed in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD AND • Patient must demonstrate significant and problematic disruptive behaviour or have problems with inattention that interfere with learning AND • 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 • Must have evidence of benefit from a one month trial with Atomoxetine (Strattera) **Renewals** 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.	Initial: 1 Year Renewal: 5 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Buspirone	Apo-buspirone Novo-buspirone	10 mg tablet	**For the treatment of generalized anxiety disorder**.in patients who meet the following criteria; • Patient has had an inadequate response to a trial of a first line agent* (escitalopram, paroxetine, sertraline or venlafaxine). *If the patient has experienced intolerance or has a contraindication to a first line agent, another first line agent must be tried unless the patient is concurrently taking an irreversible monoamine oxidase inhibitor (MAOI) or has a co-diagnosis of bipolar disorder. **Renewals** will be considered for patients who are continuing to respond to therapy.	Initial: 5 Years Renewal: 5 Years
Zopiclone	Imovane + generic brands	5 mg, 7.5 mg tablet	**For the treatment of insomnia** as a single hypnotic agent in patients who meet the following criteria; • Have failed at least two benzodiazepines; OR • Have failed or experienced intolerance to at least one benzodiazepine and one other hypnotic (i.e., amitriptyline, trazodone, etc…) **For the treatment of insomnia if patient has an identified psychiatric diagnosis**. **Renewals** will be considered in patients who are responding to therapy AND who continues to require therapy AND who are using zopiclone as a single agent.	Initial: 2 year Renewal: 2 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Zuclo-penthixol Decanoate	Clopixol Depot	200 mg/mL intra-muscular injection	**For the treatment of chronic schizophrenia** as a single antipsychotic agent in those patients where a depot formulation is indicated where the patient has; • Documented evidence of failure to respond to at least one depot neuroleptic that is presently available on the ODB Formulary OR • Documented intolerable side effects secondary to at least one depot neuroleptic presently available on the ODB Formulary OR • Stabilized on Clopixol depot prior to applying for reimbursement through EAP	Lifetime
Zuclo-penthixol Dihydro-chloride	Clopixol Tablet	10 mg, 25 mg tablet	**For the treatment of chronic schizophrenia** as a single antipsychotic agent in patients with; • Evidence of failure to respond to at least two oral neuroleptic agents presently available on the ODB Formulary OR • Intolerable side effects have been documented to at least two oral neuroleptic presently available on the ODB Formulary **Renewals** will be considered in patients who are stable and demonstrate evidence of response to therapy	

PULMONARY ARTERIAL HYPERTENSION

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Monotherapy			• Request must be from a recognized Pulmonary Arterial Hypertension (PAH) referral centre: Toronto General Hospital/UHN, Kingston General Hospital, London Health Sciences Centre, Hamilton General Hospital (HHSC), Ottawa Civic Hospital/Ottawa Heart Institute; ○ Requests from other physicians/centres must include a recent consult note/recommendation from a referral centre that supports the request; ○ Out-of-province referral centre consults are acceptable (e.g. from Winnipeg for patients in Northern Ontario). • Patient must have proven PAH defined as ≥ 25 mmHg mean pulmonary artery pressure (mPAP) on right heart catheterization (RHC) with normal pulmonary capillary wedge pressure (≤ 15 mmHg) and without interstitial lung disease, COPD or left ventricular failure either systolic or diastolic. • Requests for pediatric patients will be reviewed on a case-by-case basis.	
Ambrisentan	Volibris	5 mg, 10 mg tablet	• NYHA functional class III or IV PAH • Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease, congenital heart disease, or HIV.	Initial: 1 year
Bosentan	Tracleer, Generics (Co-, Mylan-. PMS-, Sandoz-)	62.5 mg, 125 mg tablet		
Epoprostenol	Flolan	0.5 mg and 1mg vial		
Epoprostenol	Caripul	0.5 mg and 1.5 mg vial		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Sildenafil	Revatio	20 mg tablet	• NYHA functional class III PAH ○ Note that sildenafil is not funded for NYHA Class IV patients. • Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease.	First Renewal: 1 year Subsequent Renewals: 5 years
Tadalafil	Adcirca	20 mg tablet	• NYHA functional class III PAH ○ Note that tadalafil is not funded for NYHA Class IV patients. • Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease, congenital heart disease.	
Treprostinil	Remodulin	1 mg/mL, 2.5 mg/mL, 5 mg/mL and 10 mg/mL vials	• NYHA functional class III or IV PAH • Idiopathic (primary) PAH, familial (heritable) PAH, anorexigen-induced PAH, or PAH secondary to connective tissue disease.	
Combination Therapy			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. **<u>Renewals</u>** (for all above): • Patient is responding to treatment; • Request must be from a recognized PAH referral centre.	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Combination Therapy			• Request must be from a recognized PAH referral centre: (see monotherapy criteria) • 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. • Request should indicate that the patient has not met at least one of the following targets: - Improvement to at least NYHA functional class II; OR - 6 minute walk distance > 380 metres; OR - Mixed venous saturation on right heart catheterization > 66% • Drugs used in combination must be from different classes (i.e. ERA, PDE-5 inhibitor, prostanoid) • Requests for pediatric patients will be reviewed on a case-by-case basis. Note: Triple therapy will not be funded except to allow an overlap period of 6 months with weaning of one drug.	Initial: 6 Months
			<u>Renewals</u> • Request must be from a recognized PAH referral centre. Note: The renewal request must discuss outcome of attempts to wean initial drug with goal of continuing monotherapy with the second drug. • If unsuccessful in weaning, ongoing combination therapy will be funded for an additional 6 months.	First Renewal: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Subsequent Renewals • Request must be from a recognized PAH referral centre. • Renewal granted for one year for patients who have achieve treatment targets or at least improved. • Renewal granted for six months for patients who have not met treatment targets nor improved. Note:MD should discuss rationale for not changing treatment regimen.	5 Year
Combination Therapy (For patients enrolled in trials or receiving other 3rd-party funding)			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. • Request must be from a recognized PAH referral centre. (see monotherapy criteria) • 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) • EAP criteria do not apply to the drug(s) being funded through other means.	As above for combination therapy.

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Riociguat	Adempas	0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg tablet	**For the treatment of chronic thromboembolic pulmonary hypertension (CTEPH)** in patients who meet the following criteria; • the physician making the request is a clinician with experience in the diagnosis and treatment of CTEPH[1]; AND • the patient is diagnosed with inoperable CTEPH (World Health Organization [WHO] Group 4); OR persistent or recurrent CTEPH after surgical treatment in adult patients (18 years of age or older) with WHO Functional Class (FC) II or III pulmonary hypertension. [1]Request should come from a clinician from a Pulmonary Hypertension referral centre (See Pulmonary Arterial Hypertension referral clinics above). **Renewal** of funding will be considered for patients who continue to respond to therapy with riociguat. When submitting a request for renewal of funding, the physician should submit clinical information to support that the patient is deriving benefit from the treatment compared to before they started the treatment. The physician should provide confirmation of improvement of any ONE or more reasonable clinical parameters which supports the response of the patient's CTEPH to riociguat. **Requests for subsequent funding renewals** (i.e. beyond the first two years of treatment) will be considered when a physician provides written confirmation that the patient continues to respond to therapy with riociguat. The physician should provide confirmation of improvement of any ONE or more reasonable clinical parameters which supports the response of the patient's CTEPH to riociguat compared to baseline or that supports that the patient's condition is stable while on riociguat.	Initials: 1 year First Renewal: 1 year Subsequent Renewals: 5 year

RESPIROLOGY THERAPIES

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Ivacaftor	Kalydeco	150 mg tablets	**For the treatment of cystic fibrosis** in patients who meet the following criteria: • Age 6 years and older; **AND** • Patient has documented G551D mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. Initial renewal criteria[1]: **<u>Renewals</u>** will be considered in patients with documented response to treatment (after at least 6 months of therapy), as evidenced by the following: In cases where the patient's sweat chloride levels prior to commencing therapy were <u>above</u> 60 mmol/litre: i) the Patient's sweat chloride level fell below 60 mmol/litre; **OR** ii) the Patient's sweat chloride level is 30% lower than the level reported in a previous test; In cases where the patient's sweat chloride levels prior to commencing therapy were <u>below</u> 60 mmol/litre: i) the patient's sweat chloride level is 30% lower than the level reported in a previous test; **OR** ii) the patient demonstrates a sustained absolute improvement in FEV1 of at least 5% when compared to the FEV1 test	Initial: 1 Year Renewals: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Ivacaftor	Kalydeco	150 mg tablets	conducted prior to the commencement of therapy. Subsequent renewal criteria after the patient has met the initial renewal criteria: The Patient is continuing to benefit from therapy with Kalydeco. [1]It should be noted that, while baseline sweat chloride levels and FEV1 are not required to meet initial approval criteria for Kalydeco, these parameters may be used to evaluate the effect of Kalydeco upon renewal of the request. It is important that the physician measures baseline sweat chloride levels and FEV1 and provides this information upon renewal to avoid delays in the assessment of the renewal funding decision as these measurements may be required to evaluate renewal requests.	
Nintedanib	Ofev	100 mg, 150 mg capsules	**Initial approval criteria:** For the treatment of adult patients with a diagnosis of **mild to moderate idiopathic pulmonary fibrosis (IPF):** • Diagnosis confirmed by a respirologist and a high-resolution CT scan. • All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded. • Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted. • Patient is under the care of a physician with experience in IPF.	Initial approval period: 7 months (allows 4 weeks for repeat pulmonary function tests)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests) **Initial renewal criteria (at 6 months):** Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later. **Second and subsequent renewals (at 12 months and thereafter):** Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later. Approval period: 12 months *Documentation/information required:* • *If high-resolution CT scan is not available, lung biopsy may be provided to support the diagnosis of IPF as applicable and available* • *Full pulmonary function test results.*	Initial renewal duration: 6 month Second renewal duration: 12 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Exclusion Criteria: Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.	
Pirfenidone	Esbriet	267 mg capsule	**Initial approval criteria:** For the treatment of adult patients with a diagnosis of **mild to moderate idiopathic pulmonary fibrosis (IPF):** • Diagnosis confirmed by a respirologist and a high-resolution CT scan. • All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded. • Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted. • Patient is under the care of a physician with experience in IPF. Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests) **Initial renewal criteria (at 6 months):** Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory	Initial approval period: 7 months (allows 4 weeks for repeat pulmonary function tests) Initial renewal duration: 6 month Second renewal duration:

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Pirfenidone	Esbriet	267 mg capsule	pulmonary function test conducted 4 weeks later. Approval period: 6 months **Second and subsequent renewals (at 12 months and thereafter):** Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later. Approval period: 12 months *Documentation/information required:* • *If high-resolution CT scan is not available, lung biopsy may be provided to support the diagnosis of IPF as applicable and available* • *Full pulmonary function test results.* **Exclusion Criteria:** Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.	12 months

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Abatacept	Orencia	250 mg/ 15 mL vial	**For the treatment of polyarticular-course juvenile idiopathic arthritis in patients meeting the following criteria**; • Patient has active disease (a minimum of 3 (three) swollen joints and a total of 5 active joints); AND • Patient has had an inadequate response to a three month course of methotrexate administered subcutaneously at a dosage of at least 15 mg/m^2 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 has had an inadequate response to a three month course of etanercept (Enbrel) OR adalimumab (Humira) OR tociluzumab (Actemra). If the patient is unable to tolerate or has a contraindication to etanercept OR adalimumab OR tociluzumab (Actemra), the nature of the intolerance or contraindication must be described in detail. **Renewals** will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count. For renewals beyond the second year, objective evidence of 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)	Initial: 1 year Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Etanercept	Enbrel	25 mg/vial, 50 mg prefilled syringe for subcutaneous injection	**For the first-line treatment of polyarticular-course juvenile idiopathic arthritis in patients** meeting the following criteria: • Patient has active disease (≥ 3 swollen joints and ≥ 5 active joints) despite a trial of optimal dose of subcutaneously administered methotrexate (i.e. 15 mg/m^2 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. **Renewal** 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. Dosing for Etanercept (Enbrel): The planned dosing regimen should be provided. The maximum recommended dose is 50mg once weekly. Recommended Dosing for Adalimumab (Humira): a) 24 mg/m^2 (maximum 40 mg) every two weeks; OR b) 20 mg every 2 weeks, if the Patient weighs less than 30 kg; OR c) 40 mg every 2 weeks, if the Patient weighs more than 30 kg. Recommended dosing for tocilizumab (Actemra): (a) 10 mg/kg every 4 weeks, if the Patient weighs less than 30kg; OR (b) 8 mg/kg every 4 weeks, if the Patient weighs more than or equal to 30kg.	Initial: 1 year Renewal: 1 year
Adalimumab	Humira	40 mg/0.8mL prefilled syringe and 40 mg/0.8mL prefilled pen for subcutaneous injection		
Tociluzumab	Actemra	80 mg / 4 mL Vial 200 mg / 10 mL Vial 400 mg/ 20 mL Vial		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Infliximab	Remicade	100 mg/vial	**For the treatment of polyarticular-course juvenile idiopathic arthritis in patients meeting the following criteria**; • Patient has active disease (a minimum of 3 (three) swollen joints and a total of 5 active joints); AND • Patient has had an inadequate response to a three month course of methotrexate administered subcutaneously at a dosage of at least 15 mg/m^2 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 has had an inadequate response to a three month course of etanercept (Enbrel) OR adalimumab (Humira). If the patient is unable to tolerate or has a contraindication to etanercept OR adalimumab, the nature of the intolerance or contraindication must be described in detail. <u>Infliximab dosing</u>: 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. **<u>Renewals</u>** will be considered for patients with objective evidence of at least a 20% reduction in swollen joint count. For renewals beyond the second year, objective evidence of 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). **Initial and Renewal requests that do not meet the stated criteria will undergo external review.**w.	Initial: 1 year Renewal: 1 year

RHEUMATOID ARTHRITIS

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	**For the treatment of rheumatoid arthritis** in patients who have: • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) despite the optimal use of various formulary disease-modifying anti-rheumatic drugs (DMARDs)*. *Optimal use of DMARDs include: • 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 • Methotrexate (20 mg/week) for at least 3 months and leflunomide in combination with methotrexate for at least 3 months. • 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. **OR** • Methotrexate (20mg/week), sulfasalazine (2 GM/day) and hydroxychloroquine (400mg/day)* for at least 3 months. If the patient could not receive an adequate trial of methotrexate, sulfasalazine and hydroxychloroquine due to intolerance, then the above DMARD trial criteria must be met.	Initial: 1 year
Anakinra	Kineret	100 mg / 0.67 mL subcutaneous injection		
Certolizumab pegol	Cimzia	200 mg/mL prefilled syringe		
Etanercept	Enbrel	25 mg/vial and 50mg prefilled syringe for subcutaneous		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
		injection	Hydroxychloroquine is based by weight up to 400 mg per day **<u>Renewal</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. The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of rheumatoid arthritis are as follows: o Adalimumab 40mg every two weeks o Anakinra 100mg per day o 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 o Etanercept 25mg twice weekly or 50mg once weekly o Golimumab 50mg once a month o 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 *(Note that effective December 22, 2016, Tofacitinib (Xeljanz) 5 mg is available on the ODB Formulary in patients meeting the Limited Use criteria)*	First renewal: 1 year Second and subsequent renewals: 5 years
Golimumab	Simponi	50 mg/0.5 mL prefilled syringe and autoinjector		
Infliximab	Remicade	100 mg/ 10 mL intravenous infusion		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	**First course of Rituxan for the treatment of rheumatoid arthritis** in adult patients with: • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid arthritis); **AND** • Failure to respond to optimal use of DMARDs or documented intolerance or contraindications to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); **AND** • Failure to respond to, or the patient has intolerance or contraindications to, an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol) Initial approval: One year: One course of treatment is 1000 mg followed two weeks later by the second 1000mg dose. Two courses 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. **Renewal criteria**: 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. Renewal approval: 1 year (2 courses). One course of treatment is	Initial: 1 year (2 courses given at least 6 months apart with initiation of 2nd course only after loss of effect) First Renewal: 1 year Subsequent Renewals: 2 years (For all renewals, the use is for after loss of effect with the course of therapy

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	1000 mg followed two weeks later by the second 1000mg dose. Repeated courses are not approved for maintenance therapy. Note: Rituximab should not be used concomitantly with other anti-TNF agents. More information describing one of the Committee to Evaluate Drugs' review of rituximab can be found on the Ministry website.	given at an interval that is at least 6 months apart)
Abatacept	Orencia	250 mg/15 mL intravenous injection 125 mg/mL pre-filled syringe for subcutaneous injection 250 mg/ 15 mL intravenous injection 125 mg/mL pre-filled syringe for subcutaneous injection	**For the treatment of adult patients with severe active rheumatoid arthritis who meet the following criteria:** The Patient has severe active disease as demonstrated by; • ≥ 5 swollen joints; AND • rheumatoid factor positive; AND/OR • having radiographic evidence of rheumatoid arthritis Despite the optimal* use of various disease-modifying anti-rheumatic drugs ("DMARDs"). *For the purpose of the criteria, the optimal use of DMARDs is defined as; • use of methotrexate (dosed at 20 mg per week) for at least 3 months; AND • use of leflunomide (dosed at 20 mg per day) for at least 3 months; AND • an adequate trial (3 months) of at least one combination of DMARDs; OR • use of methotrexate (dosed at 20 mg per week) for at least 3 months; AND	Initial: 1 year

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<tr><th>DRUG NAME</th><th>BRANDS REIMBURSED</th><th>DOSAGE FORM/ STRENGTH</th><th>REIMBURSEMENT CRITERIA</th><th>STANDARD APPROVAL DURATION</th></tr>
<tr><td>Abatacept</td><td>Orencia</td><td>250 mg/ 15 mL intravenous injection

125 mg/mL pre-filled syringe for subcutaneous injection</td><td>• leflunomide in combination with methotrexate for at least 3 months.

Note: If the patient cannot be treated with adequate trial(s) of methotrexate and/ or leflunomide due to contraindication(s) or intolerance(s), the nature of the 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.
For patients who have failed treatment with an anti-TNF therapy due to lack of efficacy or toxicity, prescribers should consider use of a biologic with a different mechanism of action.

<u>Approved Dosing</u>:

IV use: The initial dose is administered at 0, 2, and 4 weeks then every 4 weeks thereafter. Note that funding for higher doses will not be considered.

<table><tr><th>Body weight of patient</th><th>Dose</th></tr><tr><td>< 60 kg</td><td>500 mg</td></tr><tr><td>60-100 kg</td><td>750 mg</td></tr><tr><td>>100 kg</td><td>1 gram</td></tr></table>
SC use: 125 mg SC weekly. Note that an IV loading dose of 750 mg may be given prior to initiating the weekly SC dosing. (Please refer to the Orencia product monograph for further details.)

<u>Renewals</u> will be considered in patients with objective evidence of</td><td>First</td></tr>
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DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			at least a twenty percent (20%) reduction in swollen joint count and a minimum of improvement in two (2) swollen joints over the previous year. For renewals beyond the second year, objective evidence of the preservation of treatment effect must be provided by the requesting physician.	renewal: 1 year Second and subsequent renewals: 5 years
Tocilizumab	Actemra	80 mg / 4 mL Vial 200 mg / 10 mL Vial 400 mg/ 20 mL Vial 162 mg/0.9 mL solution for injection	**For the treatment of rheumatoid arthritis** in adult patients with; • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or anti-CCP positive and/or has radiographic evidence of rheumatoid arthritis); **AND** • Failure to respond to optimal use[1] of DMARDs or with documented intolerance to DMARDs (per current EAP reimbursement criteria for anti-TNF agents). Optimal use of DMARDs (hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, cyclosporine, azathioprine, penicillamine, chloroquine and gold compounds) defined as: • 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** • Methotrexate (20 mg/week) for at least 3 months AND leflunomide in combination with methotrexate for at least 3 months; **OR**	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Tocilizumab	Actemra	80 mg / 4 mL Vial 200 mg / 10 mL Vial 400 mg/ 20 mL Vial 162 mg/0.9 mL solution for injection	[1]Note: If the patient could not receive adequate trial(s) of methotrexate and/or leflunomide due to contraindication(s) or intolerance(s), the nature of the contraindication(s) or intolerance(s) must be provided along with details of trials of other DMARDs or clear rationale as to why other DMARDs cannot be considered. • Methotrexate (20 mg/week), sulfasalazine (2 G/day) and hydroxychloroquine (400 mg/day)[2] for at least 3 months. If the patient could not receive an adequate trial of methotrexate, sulfasalazine and hydroxychloroquine due to intolerance, then the above DMARD trial criteria must be met. [2]Hydroxychloroquine is based by weight up to 400 mg per day The requesting physician is required to provide the planned dosing regimen on the request. The following are the recommended doses for tocilizumab (Actemra) IV and SC for rheumatoid arthritis: **IV recommended dose**: - Approval for 4mg/kg/dose once every 4 weeks followed by an increase to 8mg/kg/dose based on clinical response; even for individuals whose body weight is more than 100kg, doses exceeding 800mg per infusion are not recommended	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Tocilizumab	Actemra	80 mg / 4 mL Vial 200 mg / 10 mL Vial 400 mg/ 20 mL Vial 162 mg/0.9 mL solution for injection	**SC recommended dose** : For patients < 100 kg weight, starting dose of 162 mg every other week, followed by an increase to every week based on clinical response. For patients at or above 100 kg weight, 162 mg every week. **Renewal** 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 joints over the previous year. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.	First renewal: 1 year Second and subsequent renewals: 5 years

SUBSTANCE DEPENDENCE

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Acamprosate Calcium	Campral	333 mg tablet	**For the management of alcohol dependence** in patients meeting the following criteria; • The request is from a physician who specializes in the treatment of addictions; • The patient has been abstinent from alcohol for at least four days; • The patient is receiving psychosocial intervention; AND • The patient has contraindications to naltrexone (e.g: currently receiving opioids, acute hepatitis, or liver failure). Renewals are to be considered on a case-by-case basis, via external review.	Initial: 6 months Renewal: 6 months
Methadone Compounded Solution			**Effective September 1, 2014** **Reimbursement of Compounded Methadone solution for the treatment of opioid dependence will be considered for patients who meet the following criteria;** Patient has demonstrated that they have experienced a true allergy to both commercially available Methadose formulations (i.e., Methadose 10 mg/mL oral cherry flavoured concentrate AND Methadose 10 mg/mL dye-free, sugar-free, unflavoured oral concentrate).	1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			The request must be accompanied by a completed Health Canada adverse drug reaction form (Canada Vigilance Adverse Reaction Reporting Form) and include a detailed description of the allergic reaction to each Methadose product, a description of the circumstances in which the reactions occurred, and demonstration that the allergy is unlikely to be related to any diluent in which Methadose was mixed, but rather, that it was caused by the excipients within the Methadose formulation.	
Naltrexone	Revia	50 mg tablet	**For the treatment of alcohol dependence as a component of an alcohol counseling program.** **Renewal** will be considered on a case-by-case basis.	Initial : 6 months Renewal: 6 months

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Anakinra	Kineret	100mg/0.67mL pre-filled syringe	**For the treatment of systemic juvenile idiopathic arthritis in patients** who meet the following criteria; • Patient must have a diagnosis of sJIA with fever (>38 degrees Celsius) for at least 2 weeks AND at least ONE of the following: o rash of systemic JIA o serositis (e.g. pericarditis , pleuritis, or peritonitis) o lymphadenopathy (e.g. cervical, axillary, inguinal) o hepatomegaly o splenomegaly • The physician making the request has ruled out other potential etiologies (e.g. malignancies, serious clinical infections, and other inflammatory or connective tissue diseases); AND • Age of disease onset is younger than 16 years of age. (Note: the physician must specify age of disease onset in the request); AND • Systemic corticosteroids cannot be used for at least ONE of the following reasons (please specify name and current dose of corticosteroid, if applicable): o The patient is unresponsive and/or refractory to systemic corticosteroids; OR o The patient has experienced a systemic reaction (e.g.	Initial: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Anakinra	Kineret	100mg/0.67mL pre-filled syringe	fever, rash of sJIA, serositis, lymphadenopathy, hepatomegaly or splenomegaly) while on tapering doses of systemic corticosteroids (i.e. the patient is corticosteroid dependent); OR ○ The patient has experienced an adverse drug reaction to a systemic corticosteroid; OR ○ The use of systemic corticosteroids is contraindicated in this patient. Note: The following requests will undergo external review on a case-by-case basis: • Patients with Macrophage Activation Syndrome • Patients who meet initial sJIA criteria and are currently 16 years of age or older • Patients who meet initial sJIA criteria and are requesting higher dosing regimens (Please provide rationale for the higher dosing regimen with your request) Dosing: 1-2 mg/kg subcutaneously once daily. **Renewal** 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. The following renewal requests will undergo external review: • Evidence of active systemic disease • Requests for higher dosing regimens (Please provide	Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			rationale for the higher dosing regimen with your request) • Patient is currently 16 years of age or older	
Tocilizumab	Actemra	80 mg / 4 mL 200 mg / 10 mL 400 mg/ 20 mL	**For the treatment of systemic juvenile idiopathic arthritis in patients** who meet the following criteria; • Patient must have a diagnosis of sJIA with fever (>38 degrees Celsius) for at least 2 weeks AND at least ONE of the following: o rash of systemic JIA o serositis (e.g. pericarditis , pleuritis, or peritonitis) o lymphadenopathy (e.g. cervical, axillary, inguinal) o hepatomegaly o splenomegaly • The physician has ruled out other potential etiologies (e.g. malignancies, serious clinical infections, and other inflammatory or connective tissue diseases); AND • Age of disease onset is younger than 16 years of age. (Note: the physician must specify age of disease onset in the request); AND • Systemic corticosteroids cannot be used for at least ONE of the following reasons (please specify name and current dose of corticosteroid, if applicable): o The patient is unresponsive and/or refractory to systemic corticosteroids; OR o The patient has experienced a systemic reaction (e.g. fever, rash of sJIA, serositis, lymphadenopathy, hepatomegaly or splenomegaly) while on tapering doses of systemic cortico-steroids (i.e. the patient is corticosteroid dependent); OR	1 year (Initials and renewals)

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	○ The patient has experienced an adverse drug reaction to a systemic corticosteroid; OR ○ The use of systemic corticosteroids is contraindicated in this patient. Note: The following requests will undergo external review on a case-by-case basis: • Patients with Macrophage Activation Syndrome • Patients who meet initial sJIA criteria and are currently 16 years of age or older • Patients who meet initial sJIA criteria and are requesting higher dosing regimens (Please provide rationale for the higher dosing regimen with your request) 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. **Renewal** 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. The following renewal requests will undergo external review: • Evidence of active systemic disease • Requests for higher dosing regimens (Please provide	Renewal: 1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			rationale for the higher dosing regimen with your request) • Patient is currently 16 years of age or older	

JUVENILE SPONDYLOARTHRITIS OR ENTHESITIS-RELATED ARTHRITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Etanercept Infliximab	Enbrel Remicade	25mg/vial 50 mg prefilled syringe for subcutaneous injection 100 mg/vial	**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**: **Axial Disease** • Age of disease onset ≤ 16 years; AND • Low back pain and stiffness for > 3 months that improve with exercise and not relieved by rest; AND • 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 • BASDAI score of ≥ 4 after at least 4 weeks of standard NSAID therapy; AND • Radiographic evidence of severe active disease by X-ray, CT scan or MRI * *The details of radiographic reports for severe active disease must provide the following; ○ X-ray or CT scan report stating the presence of "SI joint fusion" or "SI joint erosion" OR ○ MRI report stating the presence of "inflammation" or "edema" or "erosion" of the SI joint. 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	Initial and Renewals: 1 Year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Etanercept Infliximab	Enbrel Remicade	25mg/vial 50 mg prefilled syringe for subcutaneous injection 100 mg/vial	medical experts. The radiographic interpretation report from the radiologist or rheumatologist may be submitted along with radiographic report. The planned dosing regimen for the requested biologic should be provided. The recommended dose for the treatment of JSpA/ERA is as follows: • Etanercept 0.4mg/kg (max 25 mg) twice weekly or 0.8mg/kg (max 50 mg) once weekly • Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6-8 weeks Higher dosing will undergo external review. **Renewal** will be considered for patients with objective evidence of at least a 50% reduction in BASDAI score or ≥ 2 absolute point reduction in BASDAI score. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided. **Peripheral Disease** • Age of disease onset ≤ 16 years; and • Patients must have a minimum of 3 (three) swollen joints and 5 (five) active joints; and • Evidence of enthesitis in at least 2 locations; and • Failure to respond to or documented intolerance to trials of 2 non-steroidal anti-inflammatory drugs	

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			(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^2 per week subcutaneously-maximum 25 mg per week) for 3 months. **Renewal** 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. Requests that do not meet these criteria will undergo external review.	

SPASTICITY TREATMENTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Tizanidine	Zanaflex	4 mg tablet	**For the treatment of spasticity in patients who have failed and/or cannot tolerate at least two of the following available alternatives**: baclofen, diazepam and dantrolene. • Submission must describe the intolerance experienced.	Lifetime

ULCERATIVE COLITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Golimumab	Simponi	50 mg/0.5mL Pre-Filled Syringe Or Auto-Injector 100 mg/ mL Pre-filled Syringe or Auto-Injector	**For the treatment of ulcerative colitis disease** in patients who meet the following criteria: **Induction Criteria** Mild disease a. Mayo score <6 AND b. Patients with mild disease will be considered on a case-by-case basis BUT submission must include the rationale for coverage Moderate disease a. Mayo score between 6 and 10 (inclusive) AND b. Endoscopic subscore of 2 AND c. Failed 2 weeks of oral prednisone ≥40mg (or a 1 week course of IV equivalent) but the prednisone dose cannot be tapered despite 3 months azathioprine(AZA)/6-mercaptopurine(6MP) (or where the use of immunosuppressants is contraindicated) OR d. Stabilized with 2 weeks of oral prednisone ≥ 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)	Initial: 6 months *200 mg initially administered at week 0, followed by 100 mg at week 2, and then 50 mg (or 100 mg) every 4 weeks thereafter.*

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Golimumab	Simponi	50 mg/0.5mL Pre-Filled Syringe Or Auto-Injector 100 mg/ mL Pre-filled Syringe or Auto-Injector	Severe disease a. Mayo score >10 AND b. Endoscopy subscore of ≥2 AND c. Failed 2 weeks of oral prednisone ≥ 40mg (or 1 week IV equivalent) OR d. Stabilized with 2 weeks oral prednisone ≥ 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) *Initial Approval: 6 months at 200 mg initially administered at week 0, followed by 100mg at week 2, and then 50 mg every 4 weeks thereafter. The maintenance dose of 100mg every 4 weeks can be considered at the discretion of the treating physician* **Maintenance Criteria** After 4 loading doses of Simponi: a. Mayo score <6 AND b. 50% reduction in prednisone from the starting dose Approval: 6 months at 50 mg or 100 mg every 4 weeks If patient is completely off steroids. Approval: 12 months at 50 mg or 100 mg every 4 weeks.	Renewal duration: 6 months to 1 year (Pending if patient continues on steroids.) Second and subsequent renewal 2 years (for those off steroids:

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			Subsequent renewals: a. Mayo score <6; AND b. Must be off steroids (Patients who remain on steroids will be considered on a case-by-case basis) Approval: 2 years at 50 mg or 100 mg every 4 weeks.	
Infliximab	Remicade	100 mg/ 10 mL intravenous infusion	**Note that effective November 30, 2016, Infliximab as Remicade for Ulcerative Colitis will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.** **Initial induction requests for infliximab for patients with mild Ulcerative Colitis (Mayo score < 6) may be considered for Infliximab as Inflectra on a case-by-case basis through EAP but the submission must include the rationale for coverage.** **Renewal** requests for Maintenance therapy of Ulcerative Colitis will be considered for Remicade in patients meeting the following criteria: **<u>Maintenance Criteria:</u>** 1. After **3 loading doses** of Remicade: a. Mayo score[1] < 6 AND b. 50% reduction in prednisone from the starting dose *Approval: 3 months at 5 mg/kg/dose every 8 weeks*	Initial: 6 months 5mg/kg/dose at 0, 2 and 6 weeks Renewal duration: 6 months to 1 year (Pending if patient continues on steroids.) Second and subsequent renewal 2 years (for those off steroids)

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Infliximab	Remicade	100 mg/ 10 mL Intravenous infusion	If patient is completely off steroids. *Approval: 12 months at 5 mg/kg/dose every 8 weeks* 2. Subsequent renewals: a. Mayo[1] score < 6; AND b. Must be off steroids (Patients who remain on steroids will be considered on a case-by-case basis) *Approval: 12 months at 5 mg/kg/dose every 8 weeks* [1]Note that the endoscopy procedure must be done within the last year but does not have to be full endoscopy.	

URINARY ANTISPASMODICS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Oxybutynin Transdermal System	Oxytrol	36 mg transdermal patch (3.9 mg/day system)	The treatment of urinary frequency, urgency or urge incontinence in patients who are unable to take oral treatments (e.g. inability to swallow or who are unable to absorb (e.g. short gut syndrome). Adverse effects to oral therapy (e.g. dizziness) are not acceptable.	5 years