

Reimbursement Criteria for Frequently Requested Drugs and Indications

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

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

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

This document will be updated on a regular basis. 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](#).

The information provided in the reimbursement criteria should not be used for medical diagnosis or treatment. This website does not provide any medical diagnosis, symptom assessment, health counseling or medical opinion for individual users. The information contained on this website is intended for information purposes only and does not constitute medical advice for physicians or patients. For more detailed information on prescription drugs, please consult a qualified healthcare professional. For details on how the EAP reimbursement criteria are developed, please refer to the main [EAP webpage](#).

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

TABLE OF CONTENTS

ANTICONVULSANTS	4
Lamotrigine (chewable).....	4
Levetiracetam.....	4
Oxcarbazepine.....	4
Phenobarbital.....	4
ANKYLOSING SPONDYLITIS DRUGS	5
Etanercept.....	5
Infliximab.....	5
CROHN'S DISEASE DRUGS	6
Infliximab.....	6
Adalimumab.....	6
JUVENILE IDIOPATHIC ARTHRITIS DRUG	7
Etanercept.....	7
MIGRAINE TREATMENT DRUGS	8
Almotriptan.....	8
Naratriptan.....	8
Rizatriptan.....	8
Sumatriptan.....	8
MULTIPLE SCLEROSIS DRUGS	9
Glatiramer acetate.....	9
Interferon beta-1a.....	9
Interferon beta-1b.....	10
Modafanil.....	11
NEUROPATHIC PAIN DRUGS	12
Cannabidiol and delta-9-tetrahydro-cannabinol.....	12
Gabapentin.....	13
Pregabalin.....	13
ONCOLOGY DRUGS	14
Erlotinib.....	14
Sorafenib.....	14
Sunitinib.....	15
OSTEOPOROSIS DRUGS	16
Alendronate.....	16
Calcitonin Salmon.....	16
Zoledronic Acid.....	16
PSORIATIC ARTHRITIS DRUGS	17
Adalimumab.....	17

Etanercept.....	17
Leflunomide.....	17
PSYCHIATRIC DRUGS	18
Lamotrigine.....	18
Topiramate.....	18
Zopiclone.....	18
Zuclopenthixol.....	19
RHEUMATOID ARTHRITIS DRUGS	20
Adalimumab.....	20
Anakinra.....	20
Etanercept.....	20
Infliximab.....	20
Rituximab.....	21
Abatacept.....	21
SPASTICITY TREATMENTS	22
Botulinum toxin type A.....	22
Tizanidine.....	22

ANTICONVULSANTS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Lamotrigine (chewable)	Lamictal	5mg chewable tablet	<p>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.</p> <p>Note: Lamotrigine 25mg, 100mg and 150mg tablets are reimbursed as Limited Use Benefit as add-on therapy in the treatment of seizure disorders where control by other listed anticonvulsants has been unsatisfactory.</p>	1 year
Levetiracetam	Keppra	250mg, 500mg, and 750mg tablet	<p>Adjunctive therapy in the treatment of adults with partial seizures who have had an inadequate response or have significant intolerance* to at least 2 of the following formulary anticonvulsants (prior or current use): gabapentin, lamotrigine, vigabatrin, and topiramate.</p> <p>* Intolerance must be described in detail.</p> <p>Note: Levetiracetam requests not meeting the above criteria may be reviewed by external medical experts.</p>	Lifetime
Oxcarbazepine	Trileptal	150mg, 300mg, and 600mg tablet	<p>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.</p> <p>* Intolerance must be described in detail.</p> <p><i>Warning: Life-threatening dermatological reactions, including Stevens Johnson Syndrome and toxic epidermal necrolysis, and multi-organ hypersensitivity reactions have been associated with the use of oxcarbazepine. More information may be found on the Health Canada webpage:</i></p> <p><i>http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/trileptal_hpc-cps_e.html</i></p>	Lifetime
Phenobarbital	PMS-Phenobarbital	15mg, 30mg, and 60 tablet; 5mg/mL oral liquid	Treatment of seizures.	Lifetime

ANKYLOSING SPONDYLITIS DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection	<p>Treatment of ankylosing spondylitis in patients who meet the following conditions:</p> <ul style="list-style-type: none"> • Age of disease onset ≤ 50; 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 1 month each; and • Severe active disease confirmed by radiographic report of sacroiliac joint (i.e., X-ray, CT scan, or MRI report); and • BASDAI score of ≥ 4 for at least 4 weeks while on standard therapy; and • A list of current concomitant medications with details of narcotic usage is provided. <p>Note: Other information, such as Schober measurement and chest expansion measurement, may also be helpful.</p> <p><i>If the patient has ankylosing spondylitis with peripheral joint involvement, additional information pertaining to trials of DMARDs must be provided, and these requests will be reviewed by external medical experts.</i></p> <p><u>Renewal</u> 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. There should not be an increase in the usage of narcotic or other pain medications. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of ankylosing spondylitis are as follows:</p> <ul style="list-style-type: none"> ○ Etanercept 25mg twice weekly or 50mg once weekly ○ Infliximab 3-5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3-5mg/kg/dose every 8 weeks 	<p>Initial: 6 months</p> <p>Renewal: 1 year</p>
Infliximab	Remicade	100mg/10mL intravenous infusion		

CROHN'S DISEASE DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Infliximab	Remicade	100mg/10mL intravenous infusion	<p>Treatment of <u>fistulizing</u> Crohn's Disease in patients who have:</p> <ul style="list-style-type: none"> Actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of antibiotic therapy (ciprofloxacin and/or metronidazole) and immunosuppressive therapy (azathioprine or 6-mercaptopurine). <p><i>Note: Any intolerance(s) or contraindication(s) to treatment with required alternative(s) must be described in detail.</i></p> <p><u>Renewal</u> will be considered for patients with resolution of fistulae.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended dose for the treatment of Crohn's Disease is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks.</p>	<p>Initial: 3 months</p> <p>Renewal: 1 year</p>
Infliximab	Remicade	100mg/10mL intravenous infusion	<p>Treatment of <u>moderate to severe</u> (luminal) Crohn's Disease in patients who have:</p> <ul style="list-style-type: none"> HBI (Harvey Bradshaw Index) score $\geq 7^*$; and Failed to respond to conventional treatment with glucocorticoids (prednisone 40mg/day or equivalent for at least 2 weeks <u>or</u> dose cannot be tapered to below prednisone 20 mg/day or equivalent); and Failed to respond to an immunosuppressive agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) tried for at least 3 months. <p><i>Note: Any intolerance(s) or contraindication(s) to treatment with required alternative(s) must be described in detail.</i></p> <p>*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 weight loss; and a list of narcotic analgesics being used.</p> <p><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.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of Crohn's Disease are as follows:</p> <ul style="list-style-type: none"> Adalimumab: 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks then 5mg/kg/dose every 8 weeks 	<p>Initial: 3 months</p> <p>Renewal: 1 year</p>
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p><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.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of Crohn's Disease are as follows:</p> <ul style="list-style-type: none"> Adalimumab: 160mg at week 0; 80mg at week 2; followed by 40mg every two weeks Infliximab: 5mg/kg/dose at 0, 2 and 6 weeks then 5mg/kg/dose every 8 weeks 	<p>Initial: 3 months</p> <p>Renewal: 1 year</p>

JUVENILE IDIOPATHIC ARTHRITIS DRUG

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection	<p>Treatment of juvenile idiopathic arthritis in patients who have:</p> <ul style="list-style-type: none"> • Active disease (≥ 3 swollen joints and ≥ 5 active joints) despite a trial of optimal dose of subcutaneously administered methotrexate (i.e. $15\text{mg}/\text{m}^2$ per week) for at least 3 months. <ul style="list-style-type: none"> ○ 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. <p><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.</p> <p>The planned dosing regimen should be provided. The maximum recommended dose is 50mg once weekly.</p>	1 year

MIGRAINE TREATMENT DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Almotriptan	Axert	6mg and 12.5mg tablet	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:	5 years
Naratriptan	Amerge	1mg and 2.5mg tablet	<ul style="list-style-type: none"> • 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. 	
Rizatriptan	Maxalt Maxalt RPD	5mg and 10mg tablet and wafer	<p><u>Renewal</u> requests may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.</p>	
Sumatriptan	Imitrex	50mg and 100mg tablet	<p><i>Warning: The frequent use of triptans (i.e. more than three days per week for longer than three months at a time) may predispose a patient to developing triptan-induced chronic daily headaches.</i></p>	
Sumatriptan	Imitrex Injection	12mg/mL subcutaneous injection	<p>Treatment of migraines with or without aura in patients who failed adequate trials of other medications for migraines (e.g. acetaminophen, NSAIDs) <u>and</u> has documented intolerance* to an oral triptan. The following information must also be provided:</p> <ul style="list-style-type: none"> • 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. <p>* The nature of intolerance or why oral sumatriptan cannot be used must be specified.</p>	5 years
	Imitrex Nasal Spray	5mg/dose and 20mg/dose nasal spray	<p><u>Renewal</u> requests for sumatriptan may be considered for patients who continue to benefit from treatment. The physician must provide the frequency of triptan use.</p> <p><i>Warning: The frequent use of triptans (i.e. more than three days per week for longer than three months at a time) may predispose a patient to developing triptan-induced chronic daily headaches.</i></p>	

MULTIPLE SCLEROSIS DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20mg/mL pre-filled syringe for subcutaneous injection	<p><u>Clinically Definite Multiple Sclerosis (CDMS)</u>: Copaxone requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • 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 \leq 5. <p><u>Renewal</u> 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 \leq 5. The physician must provide the following information:</p> <ul style="list-style-type: none"> • 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 • EDSS score. 	1 year
Interferon beta-1a	Avonex Avonex PS	30 μ g/mL or 60 μ g/mL vial and 30 μ g/0.5mL prefilled syringe for intramuscular injection	<p><u>Clinically Isolated Syndrome (CIS)</u>: Avonex requests for patients who have experienced a single demyelinating event will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • Date and details of the most recent neurological examination (within the last 90 days); and • Date and description of CIS within the last 12 months; and • EDSS score \leq 6. <p><u>Clinically Definite Multiple Sclerosis (CDMS)</u>: Avonex requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • 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 \leq 6. <p><u>Renewal</u> requests for Avonex can be submitted through the Telephone Request Service and</p>	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<p>will be considered for patients who have benefited from therapy and have an EDSS score \leq 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> • 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 • EDSS score. 	
Interferon beta-1a	Rebif	22mcg and 44mcg prefilled syringe for subcutaneous injection	<p><u>Clinically Definite Multiple Sclerosis (CDMS)</u>: Rebif requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • 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 \leq 6. <p><u>Renewal</u> 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 \leq 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> • 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 • EDSS score. 	1 year
Interferon beta-1b	Betaseron	0.3 mg/vial subcutaneous injection	<p><u>Clinically Isolated Syndrome (CIS)</u>: Betaseron requests for patients who have experienced a single demyelinating event will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • Date and details of the most recent neurological examination (within the last 90 days); and • Date and description of CIS within the last 12 months; and • EDSS score \leq 6. <p><u>Clinically Definite Multiple Sclerosis (CDMS)</u>: Betaseron requests for patients with CDMS will be reviewed by external medical experts when the following information is provided:</p> <ul style="list-style-type: none"> • Date and details of the most recent neurological examination (within the last 90 days); and 	1 year

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<ul style="list-style-type: none"> • Dates and details (e.g., neurological findings) of at least two clinical attacks, including one clinical attack within the past year; and • EDSS score \leq 6. <p><u>Renewal</u> 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 \leq 6. The physician must provide the following information:</p> <ul style="list-style-type: none"> • 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 • EDSS score. 	
Modafanil	Alertec	100mg tablet	<ul style="list-style-type: none"> • Symptomatic relief of fatigue in patients with multiple sclerosis who have demonstrated a lack of response to or an inability to tolerate amantadine. 	Lifetime

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Gabapentin	Neurontin	100mg, 300mg, and 400mg capsule	<p>Treatment of <u>neuropathic pain</u> in patients with objective evidence of neuropathic pain who have:</p> <ul style="list-style-type: none"> • Ineffective response or intolerable side effects / contraindications* to an adequate trial of a tricyclic antidepressant. <p>Note: The physician may be asked to provide details of investigations into the cause of the pain.</p> <p>Treatment of <u>pain caused by trigeminal neuralgia</u> in patients who have:</p> <ul style="list-style-type: none"> • Ineffective response or intolerable side effects / contraindications* to adequate trials of at least 2 of the following agents: tricyclic antidepressant, carbamazepine, or baclofen. <p>Treatment of <u>neuropathic pain secondary to malignancy</u> in patients who have:</p> <ul style="list-style-type: none"> • Ineffective response or intolerable side effects / contraindications* to an adequate trial of a tricyclic antidepressant or to a narcotic analgesic. <p>* Side effects and contraindications must be described in detail.</p>	Lifetime
Pregabalin	Lyrica	25mg, 50mg, 75mg, 150mg, and 300mg capsule	<p>Treatment in patients with objective evidence of <u>neuropathic pain</u> who have:</p> <ul style="list-style-type: none"> • Ineffective response or intolerable side effects / contraindications* to adequate trials of a tricyclic antidepressant and gabapentin. <p>* Side effects and contraindications must be described in detail.</p> <p>Note: The physician may be asked to provide details of investigations into the neuropathic cause of the pain.</p>	Lifetime

ONCOLOGY DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Erlotinib	Tarceva	100mg and 150mg tablet	<p>Treatment of clinically documented incurable progressive non-small cell lung cancer (NSCLC) where:</p> <ul style="list-style-type: none"> • Erlotinib is used as monotherapy for the 2nd- or 3rd-line treatment after failure of prior chemotherapy with cisplatin or carboplatin; or • 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. <p><u>Renewal</u> will be considered for patients who respond to therapy with no evidence of disease progression. Patients should be assessed for disease status at least every two months. Erlotinib should be discontinued if there is evidence of disease progression.</p> <p><i>Note: Erlotinib is not indicated and therefore, is not considered for reimbursement as 1st line therapy in treatment of NSCLC.</i></p>	3 months at 150mg/day
Sorafenib	Nexavar	200mg tablet	<p>Treatment of <u>metastatic renal cell carcinoma (MRCC)</u> for patients who have:</p> <ul style="list-style-type: none"> • 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. <p><u>Renewal</u> will be considered with confirmation from the physician that the patient has benefited from therapy and is expected to continue to do so.</p>	1 year
			<p>Treatment of <u>advanced hepatocellular carcinoma (HCC)</u> in patients who have:</p> <ul style="list-style-type: none"> • 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). <p><u>Renewal</u> will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression.</p>	3 months

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Sunitinib	Sutent	12.5mg, 25mg, and 50mg capsule	<p>Treatment of <u>gastrointestinal stromal tumour (GIST)</u> in patients with c-KIT expressing (CD117+) unresectable or metastatic/recurrent GIST and where one of the following conditions are met:</p> <ul style="list-style-type: none"> • 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). <p>Renewal will be considered for patients who are stable (no disease progression) and not experiencing intolerance to sunitinib therapy.</p> <p><i>Note: Approval will be granted at a dose of 50mg per day (4 weeks on, 2 weeks off).</i></p> <p>Treatment of <u>metastatic renal cell carcinoma (MRCC)</u>:</p> <ul style="list-style-type: none"> • <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: <ul style="list-style-type: none"> ○ The disease is of clear cell histology; and ○ Documented failure to first-line cytokine-based therapy. <p><u>Renewal</u> will be considered for patients with documentation of radiography and/or scan results indicating no diseases progression.</p> <p><i>Note: The prescribed dosage should be 50 mg daily for four (4) weeks, followed by two (2) weeks off the Drug Product, in repeated six (6) week cycles.</i></p>	<p>6 months</p> <p>1 year</p>

OSTEOPOROSIS DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Alendronate	Fosamax	70mg.75mL oral liquid	Treatment of osteoporosis confirmed by bone mineral density in patients who are unable to swallow tablets and where alendronate liquid is used as the only agent for the treatment of osteoporosis. <u>Renewals</u> will be considered for monotherapy of osteoporosis in patients who are tolerating therapy.	2 years
Calcitonin Salmon	Miacalcin	200IU/dose nasal spray	For treatment of osteoporosis in patents who have failed*; experienced intractable side effects** to; or have contraindications** to all of the available Formulary alternatives: etidronate, alendronate, risedronate and, if patient is female, raloxifene. * Failure is defined as: continued loss of bone mineral density (loss of > 3%) after two years of therapy or a new osteoporosis related fracture after one year of therapy. ** Side effects and contraindications must be described in detail. <u>Renewal</u> will be considered for patients demonstrate benefit from treatment; details of patient's concomitant medications should be provided.	2 years
Zoledronic Acid	Aclasta	5mg/100mL intravenous infusion	For the treatment of osteoporosis in ambulatory post-menopausal women and in men who are unable to absorb orally administered medications or who are unable to swallow/take any oral products. Patient must have complete inability to take oral medications i.e., patient is reliant on TPN or is NPO.	1 year or lifetime (based on whether inability to absorb/take oral products is temporary or permanent)

PSORIATIC ARTHRITIS DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p>Treatment of psoriatic arthritis in patients who have:</p> <ul style="list-style-type: none"> • Severe active disease (≥ 5 swollen joints and radiographic evidence of joint erosion) despite treatment with methotrexate (20mg/week) for at least 3 months and to leflunomide (20mg/day) for at least 3 months. <ul style="list-style-type: none"> ○ If the patient has documented contraindications or intolerances to either methotrexate or leflunomide, a trial of sulfasalazine (1g twice daily) for at least 3 months is required. Details of contraindications and intolerances must also be provided. <p><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.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of psoriatic arthritis are as follows:</p> <ul style="list-style-type: none"> ○ Adalimumab 40mg every two weeks ○ Etanercept 25mg twice weekly or 50mg once weekly <p>For more details on the review of adalimumab for psoriatic arthritis, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/adalimumab.pdf</p>	1 year
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection	<p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of psoriatic arthritis are as follows:</p> <ul style="list-style-type: none"> ○ Adalimumab 40mg every two weeks ○ Etanercept 25mg twice weekly or 50mg once weekly <p>For more details on the review of adalimumab for psoriatic arthritis, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/adalimumab.pdf</p>	
Leflunomide	Arava	10mg and 20mg tablet	<p>Treatment of psoriatic arthritis in patients who failed at least a 3 month trial with methotrexate 20mg per week, or who have documented intolerance/contraindication* to methotrexate.</p> <p>* Details of contraindications and intolerances must also be provided.</p> <p><u>Renewals</u> of coverage may be considered for patients who demonstrate objective evidence of response (e.g., reduction in the number of swollen joints).</p> <p><i>Note: Leflunomide is listed on the Formulary as a Limited Use benefit for the treatment of rheumatoid arthritis in patients who have failed, or are intolerant to, one or more of the listed Disease- Modifying Anti-Rheumatic Drugs (DMARDs).</i></p>	Initial: 3 months Renewal: 5 years

PSYCHIATRIC DRUGS				
DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Lamotrigine	Lamictal	25mg, 100mg, and 150mg tablet	<p>Treatment of <u>refractory bipolar depression and the prophylaxis of bipolar disorder</u>:</p> <ul style="list-style-type: none"> In patients who have not responded to, experienced side effects* with, or have contraindications* to 2 of the following listed alternatives: lithium, divalproex sodium/valproic acid, carbamazepine. <p>Treatment of <u>rapid-cycling bipolar disorder</u>:</p> <ul style="list-style-type: none"> In patients who have not responded to an adequate trial of carbamazepine or divalproex sodium/valproic acid (or who have side effects / contraindications* to carbamazepine and divalproex sodium/valproic acid). <p>* Side effect(s) and contraindication(s) must be described in detail.</p> <p><u>Renewal</u> requests may be considered with documentation of the patient's stabilization and response to therapy. The physician must also provide an update of the patient's psychiatric diagnosis and all concomitant medications.</p>	5 years
Topiramate	Topamax	25mg, 100mg, and 200mg tablet	<p>Treatment of <u>refractory bipolar disorder</u> in patients who have:</p> <ul style="list-style-type: none"> Failed to responded to, experienced side effects* with, or have contraindications* to 2 of the following listed alternatives: lithium, divalproex sodium/valproic acid, carbamazepine; and Failed to responded to, experienced side effects* with, or have contraindications* to lamotrigine. <p>* Side effect(s) and contraindication(s) must be described in detail.</p> <p><u>Renewal</u> requests will be considered for patients who have stabilized on therapy, and the physician must provide an update of the patient's psychiatric diagnosis and all concomitant medications.</p>	5 years
Zopiclone	Imovane	5mg and 7.5mg tablet	<p>Treatment of insomnia as a single hypnotic agent where following information is provided:</p> <ul style="list-style-type: none"> Documentation of failure or a detailed description of intolerable side effects to benzodiazepines and other hypnotic agents (e.g., amitriptyline, trazodone, etc.); Documentation of failure to non-pharmacological treatment (e.g., relaxation therapy, stimulus control such as caffeine and light, sleep restriction, and cognitive behavioural therapy) or a clear rationale for why such treatment is inappropriate; and 	Initial: 1 year Renewal: 2 years

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
			<ul style="list-style-type: none"> • A list of comorbid conditions and concomitant medications (including doses and dosing frequencies). 	
Zuclopenthixol	Clopixol Depot	200mg/mL intramuscular injection	Treatment of chronic schizophrenia where the following information is provided: <ul style="list-style-type: none"> • Documentation of failure of treatment or intolerable side effects with a depot neuroleptic presently available on the Formulary; or • Details of positive clinical response to treatment with Clopixol depot, if already started. • List of concomitant medications 	Lifetime
	Clopixol Tablet	10mg and 25mg tablet	Treatment of chronic schizophrenia where the following information is provided: <ul style="list-style-type: none"> • Documentation of failure of treatment or intolerable side effects with at least two oral neuroleptic agents presently available on the Formulary. • List of concomitant medications 	

RHEUMATOID ARTHRITIS DRUGS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Adalimumab	Humira	40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection	<p>Treatment of rheumatoid arthritis in patients who have:</p> <ul style="list-style-type: none"> • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid joint damage) despite the optimal use of various formulary disease-modifying anti-rheumatic drugs (DMARDs)*. <p>* Optimal use of DMARDs include:</p> <ul style="list-style-type: none"> • Methotrexate (20mg/week) for at least 3 months and leflunomide (20mg/day) for at least 3 months in addition to an adequate trial (3 months) of at least one combination of DMARDs; or • Methotrexate (20mg/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. <p><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.</p> <p>The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of rheumatoid arthritis are as follows:</p> <ul style="list-style-type: none"> ○ Adalimumab 40mg every two weeks ○ Anakinra 100mg per day ○ Etanercept 25mg twice weekly or 50mg once weekly ○ 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 	1 year
Anakinra	Kineret	150 mg/mL subcutaneous injection		
Etanercept	Enbrel	25mg/vial and 50mg prefilled syringe for subcutaneous injection		
Infliximab	Remicade	100mg/10mL intravenous infusion		

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	<p>Initial treatment of rheumatoid arthritis in adult patients with:</p> <ul style="list-style-type: none"> • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid joint damage); and • Failure to respond to optimal use of DMARDs or documented intolerance to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); and • Failure to respond to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab). <p><u>Re-treatment</u> will be considered only after an interval of ≥ 6 months since the previous treatment in patients who achieved a response followed by a subsequent loss of effect.</p> <p>Note: Rituximab should not be used concomitantly with other anti-TNF agents.</p> <p>For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/rituxan.pdf</p>	1000 mg dose followed two weeks later by the second 1000 mg dose
Abatacept	Orencia	250mg/15 mL intravenous injection	<p>Treatment of rheumatoid arthritis in adult patients with:</p> <ul style="list-style-type: none"> • Severe active disease (≥ 5 swollen joints and rheumatoid factor positive and/or radiographic evidence of rheumatoid joint damage); and • Failure to respond to optimal use of DMARDs or documented intolerance to DMARDs (per current EAP reimbursement criteria for anti-TNF agents); and • Failure to respond to an adequate trial of at least TWO anti-TNF agents (e.g., adalimumab, etanercept, infliximab). <p>Only the following dose will be approved to be administered at 0, 2 and 4 weeks, then every 4 weeks thereafter: 500mg for patients <60 kg; 750mg for patients 60-100 kg; and 1000mg for patients >100 kg.</p> <p><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.</p> <p>Note: Abatacept should not be used concomitantly with anti-TNF agents.</p> <p>For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/orencia.pdf</p>	1 year

SPASTICITY TREATMENTS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Botulinum toxin type A	Botox	100 unit/vial intramuscular injection	<p>The treatment of focal spastic dystonia secondary to:</p> <ul style="list-style-type: none"> • Cerebral palsy in patients 2 years of age or older; or • Stroke; or • Spinal cord / brain injury. <p>Botox must be administered personally by a pediatrician, neurologist or physical medicine specialist or a physician with equivalent post-graduate training and experience with neuromuscular disorders.</p>	Lifetime
Tizanidine	Zanaflex	4mg tablet	<p>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.</p> <p>* Side effect(s) must be described in detail.</p>	Lifetime

INDEX OF DRUGS

Abatacept	21	Leflunomide	17
Adalimumab	6, 17, 20	Levetiracetam	4
Alendronate	16	Modafanil	11
Almotriptan	8	Naratriptan	8
Anakinra	20	Oxcarbazepine	4
Botulinum toxin type A	22	Phenobarbital	4
Calcitonin Salmon	16	Pregabalin	13
Cannabidiol and delta-9-tetrahydro-cannabinol	12	Rituximab	21
Erlotinib	14	Rizatriptan	8
Etanercept	5, 7, 17, 20	Sorafenib	14
Gabapentin	13	Sumatriptan	8
Glatiramer acetate	9	Sunitinib	15
Infliximab	5, 6, 20	Tizanidine	22
Interferon beta-1a	9, 10	Topiramate	18
Interferon beta-1b	11	Zoledronic Acid	16
Lamotrigine	18	Zopiclone	19
Lamotrigine (chewable)	4	Zuclophenthixol	19