

Telephone Request Service Reimbursement Criteria

Exceptional Access Program, Ministry of Health and Long-Term Care

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The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Table of contents

TELEPHONE REQUEST SERVICE REIMBURSEMENT CRITERIA.....	1
Exceptional Access Program, Ministry of Health and Long-Term Care	1
TABLE OF CONTENTS.....	3
INTRODUCTION.....	6
ANTIBIOTICS	7
Cefazolin	7
Ciprofloxacin HCl and Dexamethasone (Ciprodex®).....	7
Dapsone	8
Daptomycin (Cubicin®)	9
Fidaxomicin (Dificid®)	10
Gentamycin.....	11
Posaconazole	11
Posaconazole	12
Vancomycin	13
CHRONIC RENAL FAILURE DRUGS.....	14
Calcium Carbonate.....	14
Lanthanum Carbonate	14
Sevelamer hydrochloride	15
Vitamin B Complex with Vitamin C	15
LOW MOLECULAR WEIGHT HEPARIN (LMWH)	16

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dalteparin sodium	16
Enoxaparin sodium	17
Tinzaparin sodium.....	18
ORAL HYPOGLYCEMIC AGENTS	19
Pioglitazone	20
Rosiglitazone	21
PALLIATIVE CARE MEDICATIONS	22
Diazepam 5 mg/mL injection	23
Dimenhydrinate 50 mg/mL injection.....	23
Furosemide 10 mg/mL injection.....	23
Glycopyrrolate 0.2 mg/mL injection.....	23
Hyoscine 20 mg/mL injection and 10 mg tablet.....	23
Lorazepam 4 mg/mL.....	24
Methadone 1mg, 5 mg, 10 mg, 25 mg tablets; 1 mg/mL oral liquid; 10 mg/ml injection	24
Metoclopramide 10 mg/2 mL injection	24
Midazolam 5 mg/mL injection	24
Morphine 2 mg/mL, 10 mg/mL injection	24
Oxycodone 5 mg, 10 mg, 20 mg tablets	25
Oxycodone HCl Extended Release 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets	25
Phenobarbital 120 mg/mL injection	25
Phenytoin 50 mg/mL injection	25

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Scopolamine 0.4 mg/mL, 0.6 mg/mL injection	25
POST-TRANSPLANT DRUGS	26
Acyclovir	26
Acyclovir	26
Fluconazole	26
Mycophenolate mofetil	27
Sirolimus	27
Valganciclovir	28
Valganciclovir	29
Ganciclovir	29
HIV DRUGS – RENEWAL ONLY	31
Enfuvirtide	31
Tipranavir	31
MULTIPLE SCLEROSIS DRUGS – RENEWAL ONLY	32
Dimethyl Fumarate	32
Fingolimod	33
Glatiramer acetate	33
Interferon beta-1a	34
Interferon beta-1b	35
Natalizumab	36
Teriflunomide	37

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INTRODUCTION

The Ontario Public Drug Programs has developed these reimbursement criteria to provide physicians with information about selected drug products that may be considered for funding through the Exceptional Access Program's (EAP) Telephone Request Service (TRS). The TRS offers physicians another way to submit EAP requests for a group of selected drugs. This document provides a list of the drugs and their funding criteria that are considered through the TRS. In most cases, the request, the request will be assessed in "real time" with a one business day turnaround.

Physicians (or their delegates) are encouraged to review the reimbursement criteria for the drug being requested before calling the service to ensure that all of the necessary information is available during the call. Callers who wish to submit a request for drug products and indications not currently available through TRS will be asked to fax the request to EAP. If your request is approved, the physician will receive a faxes response letter notifying him/her of the funding decision.

The EAP response letter will list the specific drug, drug identification number (DIN) or product identification number (PIN), strength and dosage form that is considered for funding and physicians and pharmacists are responsible to ensure that funded products are provided to avoid unnecessary out-of-pocket costs to the patient. Note that not all generic brands are funded or interchangeable (on-formulary or off-formulary). You can refer to the formulary for a list of interchangeable drugs products.

The Ministry reserves the right to change the list of drug products at its sole discretion. If you have any questions or concerns regarding the TRS, please contact us at:

Exceptional Access Program – Telephone Request Service
3rd Floor, 5700 Yonge St.
North York, ON
M2M 4K5
Phone: 1-866-811-9893 or 416-327-8109
Fax: 1-866-811-9908 or 416-327-7526

E-mail: EAPFeedbackLine@ontario.ca

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

ANTIBIOTICS

Cefazolin

Dosage Form: 1 g/vial injection

Reimbursement Criteria:

For treatment of infections susceptible to cefazolin.

Standard Approval Duration: As requested up to 5 years

Ciprofloxacin HCl and Dexamethasone (Ciprodex[®])

Dosage Form: ciprofloxacin (3 mg/mL) and dexamethasone (1 mg/mL) otic solution

Reimbursement Criteria:

For the treatment of otitis externa where:

- The patient has perforated tympanic membrane, ventilation tubes, or documented pre-existing hearing impairment; or
- Chronic therapy with Ciprodex (i.e., >14 days) is required; or
- Aminoglycoside therapy has failed (and physician provides details pertaining to aminoglycoside use and concerns about a resistant pathogen).

NOTE: *Ciprodex reimbursement is not considered for any other indications (e.g., otitis media).*

Standard Approval Duration: 1 month

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dapsone

Dosage Form: 100 mg tablet

Reimbursement Criteria:

For the treatment of:

- **Pneumocystis jiroveci pneumonia (PJP) prophylaxis** in immunocompromised patients (e.g. patients with HIV or organ transplants or vascularized composite allotransplantation (VCA) for upper limbs (i.e. hand, forearm)) with an intolerance/allergy to trimethoprim-sulfamethoxazole; OR
- **Autoimmune diseases**, such as pemphigus vulgaris, pemphigoid, dermatitis herpetiformis, etc.

Standard Approval Duration: Lifetime

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Daptomycin (Cubicin[®])

Dosage Form: 500 mg/10mL injection

Reimbursement Criteria:

For the treatment of patients with one or more of the following condition(s):

- i) Osteomyelitis caused by methicillin-resistant staphylococcus aureus (MRSA);
- ii) Device-related osteoarticular or prosthetic joint infections caused by methicillin-resistant staphylococcus aureus (MRSA);
- iii) Diabetic foot infections caused by methicillin-resistant staphylococcus aureus (MRSA); AND/OR
- iv) *Staphylococcus aureus* bloodstream (SAB) infection including right-sided *Staphylococcus aureus* infective endocarditis (SARIE) infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA)

Additionally, the patient must have failed to adequately respond to, be intolerant* to, or have a contraindication to vancomycin.

*Requests involving red-man-syndrome with vancomycin must provide details of the intolerance including the rate of infusion and the use of antihistamines and other histamine blockers prior to therapy.

Standard Approval Duration: Up to maximum of 56 days

Exclusion Criteria:

Daptomycin is not funded for patients with:

- i) MRSA-related pneumonia;
- ii) skin/skin structure infections other than diabetic foot infections caused by MRSA.

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Fidaxomicin (Difacid[®])

Dosage Form: 200 mg tablet

Reimbursement Criteria:

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 episodes, 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.
- 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 Standard Approval Duration: 200 mg twice a day for 10 days

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Gentamycin

Dosage Form: 40 mg/mL injection

Reimbursement Criteria:

For treatment of infections susceptible to gentamycin.

Standard Approval Duration: As requested up to 5 years

Posaconazole

Dosage Form: 40 mg/mL Suspension, 100mg tablets

Reimbursement Criteria:

For the prophylaxis of Aspergillus and Candida infections in patients who have recently (within the past 3 months) undergone an allogeneic bone marrow (stem cell) transplant.

Standard Approval Duration: Limited to 4 months

Reimbursement Criteria:

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.

Standard Approval Duration: Limited to 4 months

Renewals 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.

Standard Approval Duration: Case-by-case

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Posaconazole

Dosage Form: 40 mg/mL suspension, 100mg tablets

Reimbursement Criteria:

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 considered on a case-by-case basis.

Standard Approval Duration: 3 months

Renewals will be considered on a case-by-case basis.

Reimbursement Criteria:

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.

Standard Approval Duration: 3 months

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).

First renewal: 3 months

Subsequent renewals: Case-by-case duration

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Vancomycin

Dosage Form: 125 mg and 250 mg capsules; 1g vial (for oral use)

(Note that not all manufactured brands are reimbursed. Please refer to the EAP approval letter to confirm funded brands.)

Reimbursement Criteria:

For patients with Clostridium difficile-associated diarrhea (CDAD) confirmed by toxin assay or typical endoscopic appearance, or histologic pattern on biopsy. If toxin results are pending, clinical suspicion is required. The following information is also required:

- For the first episode, patient must have failed an adequate trial of metronidazole or have an intolerance or contraindication to metronidazole, if there are no indicators of severe CDAD.
- For subsequent episodes, physician must provide detailed history of previous CDAD infection, including dates, duration and dose of treatment used, and patient's response to treatment.
- For severe CDAD, the physician must describe the complication(s) CDAD caused, or describe multiple risk factors for developing serious complications (e.g., renal failure, high leukocyte count, low serum albumin, high fever, elderly). Examples of complication(s) are the following: toxic megacolon, septic shock, bowel perforation, need for colectomy, treatment in the ICU, and ileus.

EAP will approve vancomycin at a dose of 125 mg to 250 mg four times daily. (For a non-severe primary episode of CDAD, approval will be provided only for 125 mg four times daily.)

Standard Approval Duration: 2 weeks (unless recurrent infection, where approval may be granted for up to 8 weeks)

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

CHRONIC RENAL FAILURE DRUGS

Calcium Carbonate

Dosage Form: 625 mg, 1250 mg tablet

Reimbursement Criteria:

For patients with hypoparathyroid disease or chronic renal failure.

NOTE: Calcium supplements for patients who do not have hypoparathyroid disease or chronic renal failure are not eligible for funding consideration by the ODB program, which includes EAP.

Standard Approval Duration: 5 years

Lanthanum Carbonate

Dosage Form: 250mg, 500mg, 750mg, 1000mg Chewable tablet

Reimbursement Criteria:

- For the treatment of hyperphosphatemia associated with end-stage renal disease (ESRD) where patients are on dialysis and have a sustained serum phosphate greater than 1.8 mmol/L **AND** serum calcium greater than 2.65 mmol/L.
- For dialysis patients experiencing hyperphosphatemia (sustained serum phosphate levels >1.8mmol/L) who have calciphylaxis and/or coronary artery calcification

Exclusion criteria: Dialysis patients experiencing hyperphosphatemia (sustained serum phosphate levels >1.8mmol/L) who have other types of calcification (e.g. carotid artery, peripheral vascular, aortic, etc.) will not be considered for funding.

Standard Approval Duration: Lifetime

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Sevelamer hydrochloride

Dosage Form: 800 mg tablet

Reimbursement Criteria:

- For the treatment of hyperphosphatemia associated with end-stage renal disease (ESRD) where patients are on dialysis and have a sustained serum phosphate greater than 1.8 mmol/L **AND** serum calcium greater than 2.65 mmol/L; OR
- For dialysis patients experiencing hyperphosphatemia (sustained serum phosphate levels >1.8mmol/L) who have calciphylaxis and/or coronary artery calcification

Exclusion criteria: Dialysis patients experiencing hyperphosphatemia (sustained serum phosphate levels >1.8mmol/L) who have other types of calcification (e.g. carotid artery, peripheral vascular, aortic, etc.) will not be considered for funding.

Standard Approval Duration: Lifetime

Vitamin B Complex with Vitamin C

Dosage Form: tablet

Reimbursement Criteria:

For patients receiving hemodialysis or peritoneal dialysis.

Standard Approval Duration: 5 years

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

LOW MOLECULAR WEIGHT HEPARIN (LMWH)

NOTE: LMWHs are currently listed on the ODB Formulary as Limited Use (LU) benefits for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in certain patient groups. Consult the Formulary for further details.

Dalteparin sodium

Dosage Form: 10 000 IU/mL, 25 000 IU/mL multidose vial or pre-filled syringes

Reimbursement Criteria:

For **peri-operative bridging** for patients who require long-term warfarin therapy and must temporarily discontinue it before and after surgery, and who are at moderate- to high-risk for an embolic event while off warfarin.

Standard Approval Duration: As requested up to a maximum of **10 days** before the date of surgery **plus up to 7 days** after surgery

Reimbursement Criteria:

For **post-operative prophylaxis of DVT** for patients who had hip or knee surgery, and cannot use warfarin.

Standard Approval Duration: As requested up to a maximum of **30 days** starting on the day of surgery.

Reimbursement Criteria:

For extended treatment of symptomatic acute **venous thromboembolism (VTE)** in patients with cancer, who cannot use warfarin.

Standard Approval Duration: As requested up to 6 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Enoxaparin sodium

Dosage Form: 100 mg/mL, 150 mg/mL multidose vial or pre-filled syringes

Reimbursement Criteria:

For **peri-operative bridging** for patients who require long-term warfarin therapy and must temporarily discontinue it before and after surgery, and who are at moderate- to high-risk for an embolic event while off warfarin.

Standard Approval Duration: As requested up to a maximum of **10 days** before the date of surgery **plus up to 7 days** after the surgery

Reimbursement Criteria:

For **post-operative prophylaxis of DVT** for patients who had hip or knee surgery, and cannot use warfarin.

Standard Approval Duration: As requested up to a maximum of **30 days** starting on the day of surgery

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Tinzaparin sodium

Dosage Form: 10 000 IU/mL, 20 000 IU/mL multidose vial or pre-filled syringes

Reimbursement Criteria:

For **peri-operative bridging** for patients who require long-term warfarin therapy and must temporarily discontinue it before and after surgery, and who are at moderate- to high-risk for an embolic event while off warfarin.

Standard Approval Duration: As requested up to a maximum of **10 days** before the date of surgery **plus up to 7 days** after the surgery

Reimbursement Criteria:

For **post-operative prophylaxis of DVT** for patients who had hip or knee surgery, and cannot use warfarin.

Standard Approval Duration: As requested up to a maximum of **30 days** starting on the day of surgery

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

ORAL HYPOGLYCEMIC AGENTS

Note: Physicians do not need to make an EAP request for patients currently receiving pioglitazone or rosiglitazone through ODB. Physicians will be required to make an application for coverage for any patient new to ODB that is being started on either of these drugs or any ODB recipient who is new to using these drugs.

Requests for ongoing treatment with pioglitazone or rosiglitazone for patients who were previously covered by other means may be considered according to renewal criteria.

Funding under the EAP for pioglitazone or rosiglitazone will not be provided in the following clinical settings:

- Patients with type 1 diabetes
- Monotherapy, even if patient is intolerant or has contraindications to both metformin and sulfonylureas
- Combination use with either nitrates or insulin
- Patients with any stage of heart failure (NYHA Class I, II, III, IV)
- Patients at high risk for bone fracture (post-menopausal women with previously confirmed osteoporosis or osteopenia)
- Patients with recent history (in the past 3 months) of ischemic cardiovascular event (myocardial infarction, unstable angina)
- Patients with active bladder cancer, a history of bladder cancer or uninvestigated macroscopic haematuria

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Pioglitazone

Dosage Form: 15 mg, 30 mg, 45 mg tablet

Reimbursement Criteria:

For dual combination therapy of type 2 diabetes, in patients with:

- a) Inadequate glycemic control (HbA1c of >7%) on maximal doses of metformin (2000 mg/day); OR
- b) Inadequate glycemic control, on maximal doses of sulfonylurea (glyburide 10mg/day, gliclazide 160mg/day or gliclazide modified release (MR) 60 mg/day) or glimepiride 4 mg/day and demonstrated intolerance / contraindication to metformin

For triple combination therapy of type 2 diabetes, in patients with:

- a) Inadequate glycemic control on maximal doses of metformin and a sulfonylurea AND only if:
 - physician has offered insulin as alternative option first, and patient has refused or is not able to take insulin, AND
 - both physician and patient are aware that thiazolidinediones are not indicated for use in triple therapy.

Standard Approval Duration: 5 years

Renewal Criteria: EAP will renew pioglitazone only for patients who have achieved adequate glycemic control (HbA1c of $\leq 7\%$ while on therapy and who have no known contraindications to rosiglitazone.

Standard Approval Duration: 5 years

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Rosiglitazone

Dosage Form: 2 mg, 4 mg, 8 mg tablets

Reimbursement Criteria:

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 (ODB) 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 that need to be tried prior to consideration of rosiglitazone include the following agents currently reimbursed through the Ontario Public Drug Programs;

Glyburide, metformin, gliclazide (Diamicon, Diamicon MR), sitagliptin (Januvia), repaglinide (GlucNorm), pioglitazone (Actos), saxagliptin (Onglyza), linagliptin (Trajenta),

Note: A trial with acarbose is not a mandatory requirement.

Note: It is not necessary for patients to have tried the following oral antidiabetic agents that are currently not funded by the Ontario Public Drug Programs for the purposes of obtaining rosiglitazone:

glimepiride (Amaryl), nateglinide (Starlix)

Standard Approval Duration: 5 years

Renewals will be considered where patients have benefited and continue to benefit from rosiglitazone treatment as demonstrated by recent HbA1c levels $\leq 7\%$ while on treatment with rosiglitazone AND in those who continue to have no known contraindication(s) to rosiglitazone.

Standard Approval Duration: 5 years

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

PALLIATIVE CARE MEDICATIONS

NOTE: Specific products used to treat ODB-eligible patients undergoing palliative care are reimbursed under the Ontario Public Drug Programs, through its Facilitated Access process. Under this process, a select group of participating physicians are exempt from obtaining approval under EAP on a case-by-case basis. This assumes that the physician's College of Physicians and Surgeons of Ontario registration number appears on the prescription, for purposes of verification.

Palliative Care medication claims to be reimbursed by the ODB program must be prescribed in accordance with the following patient eligibility criteria: "This patient has a terminal illness and has chosen outpatient palliative treatment. Life expectancy is less than six months and the medications are being requested for symptom control for a maximum period of six months."

In order to participate in the Facilitated Access to Palliative Care Drugs process, these physicians must be registered by the Ontario Medical Association ("OMA") and must meet pre-defined criteria the OMA sets. To facilitate the reimbursement process at the pharmacy, these physicians are asked to indicate either, "Palliative" or "P.C.F.A." on the prescription.

Physicians who are not registered through this process must obtain approval through the Exceptional Access Program. A physician must provide the details of the patient's diagnosis, current clinical status, and life expectancy.

For further information regarding the list of physicians and/or the criteria physicians require to be included on the list, please contact Dr. Howard Burke, c/o Carlene Nash, Ontario Medical Association: (416) 340-2234, or via email at Carlene.Nash@oma.org.

The following products can be reimbursed for the management of patients receiving palliative care.

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Diazepam 5 mg/mL injection

Reimbursement Criteria:

For use in seizure control or anxiety when patients cannot use other dosage forms.

Standard Approval Duration: 6 months

Dimenhydrinate 50 mg/mL injection

Reimbursement Criteria:

For nausea, when patients cannot use other dosage forms.

Standard Approval Duration: 6 months

Furosemide 10 mg/mL injection

Reimbursement Criteria:

For palliative care.

Standard Approval Duration: 6 months

Glycopyrrolate 0.2 mg/mL injection

Reimbursement Criteria:

For secretion control in the very terminal stage of care.

Standard Approval Duration: 6 months

Hyoscine 20 mg/mL injection and 10 mg tablet

Reimbursement Criteria:

For abdominal spasm, pain.

Standard Approval Duration: 6 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Lorazepam 4 mg/mL

Reimbursement Criteria:

For palliative care.

Standard Approval Duration: 6 months

Methadone 1mg, 5 mg, 10 mg, 25 mg tablets; 1 mg/mL oral liquid; 10 mg/ml injection

Reimbursement Criteria:

If traditional narcotic analgesics fail to control pain or lead to side effects.

Standard Approval Duration: 6 months

Metoclopramide 10 mg/2 mL injection

Reimbursement Criteria:

For nausea when patients cannot take oral alternatives.

Standard Approval Duration: 6 months

Midazolam 5 mg/mL injection

Reimbursement Criteria:

For use in respiratory distress or anxiety.

Standard Approval Duration: 6 months

Morphine 2 mg/mL, 10 mg/mL injection

Reimbursement Criteria:

For palliative care.

Standard Approval Duration: 6 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Oxycodone 5 mg, 10 mg, 20 mg tablets

Reimbursement Criteria:

For use when patients cannot use combination oxycodone & acetaminophen.

Standard Approval Duration: 6 months

Oxycodone HCl Extended Release 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets

Reimbursement Criteria:

For the treatment of cancer-related pain or pain in patients receiving end-of-life palliative care; AND the patient has experienced intolerance or has failed an adequate trial (for example, three months) of at least one other listed long-acting opioid product.

Standard Approval Duration: 12 months

Phenobarbital 120 mg/mL injection

Reimbursement Criteria:

For use in seizure control, sedation, when oral dosage forms cannot be used.

Standard Approval Duration: 6 months

Phenytoin 50 mg/mL injection

Reimbursement Criteria:

For use in seizure control, when patients cannot use oral dosage forms.

Standard Approval Duration: 6 months

Scopolamine 0.4 mg/mL, 0.6 mg/mL injection

Reimbursement Criteria: For secretion control in the very terminal stage of care.

Standard Approval Duration: 6 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

POST-TRANSPLANT DRUGS

Acyclovir

Dosage Form: 400mg tablets

Reimbursement Criteria:

For Herpes Simplex Virus (HSV) prophylaxis following kidney/pancreas/heart transplants.

Standard Approval Duration: 3 months

Acyclovir

Dosage Form: 200 mg, 400 mg tablets

Reimbursement Criteria:

For Herpes Simplex Virus (HSV) and varicella zoster virus (VZV) prophylaxis following stem cell transplantation.

Standard Approval Duration: As requested up to 12 months

Fluconazole

Dosage Form: 50 mg, 100 mg tablet;150 mg capsule; 10 mg/mL oral liquid

Reimbursement Criteria:

For the prevention of fungal infections post-bone marrow or stem cell transplant, until engraftment.

Standard Approval Duration: As requested up to 3 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Mycophenolate mofetil

Dosage Form: 250 mg SG capsule, 500 mg tablet, 200 mg/mL oral liquid

Reimbursement Criteria:

- Solid organ transplants other than allogenic renal, cardiac or hepatic transplants*, where patient has failed cyclosporine, (can be used in place of, or in addition to cyclosporine) or has experienced intolerable side effects to cyclosporine; OR
- Stem cell transplantation; OR
- For the prophylaxis of limb (composite tissue) rejection in patients receiving vascularized composite allotransplantation (VCA) for upper limbs (i.e. hand, forearm) who have failed or are intolerant to cyclosporine.

**NOTE: Cellcept is currently listed on the ODB Formulary as Limited Use (LU) benefit for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. Myfortic (mycophenolate sodium) is available on the formulary as a General Benefit (GB).*

Standard Approval Duration: Lifetime

Sirolimus

Dosage Form: 1 mg tablet, 1 mg/mL oral liquid

Reimbursement Criteria:

- For liver transplant recipients who require regimens that mandate calcineurin inhibitor avoidance. The physician must be able to explain clearly why the patient cannot use a calcineurin inhibitor; OR
- For the prophylaxis of limb (composite tissue) rejection in patients receiving vascularized composite allotransplantation (VCA) for upper limbs (i.e. hand, forearm) who require calcineurin inhibitor avoidance.

NOTE: Rapamune is currently listed on the ODB Formulary as a Limited Use (LU) benefit for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants.

Standard Approval Duration: Lifetime

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Valganciclovir

Dosage Form: 450 mg tablet

Reimbursement Criteria:

For prophylaxis in transplant recipients at high risk for cytomegalovirus (CMV) disease (D+/R- for any solid organ transplant; or R+ for lung or heart-lung transplant; or R+ and receiving antilymphocyte antibody products for immunosuppression). The physician must provide the following information:

- organ(s) transplanted;
- donor and recipient pre-transplant CMV serology; and
- details of treatment with antilymphocyte antibody products, if applicable.

For prophylaxis in patients with vascularized composite allotransplantation (VCA) of the upper limbs (i.e. hand, forearm) who are at high risk for cytomegalovirus (CMV) disease.

Standard Approval Duration: 6 months (Solid organ transplant or VCA) and up to 12 months (lung or heart-lung transplant).

For the treatment of cytomegalovirus (CMV) disease following solid organ transplant, bone marrow transplant or VCA of the upper limbs in patients who meet the following criteria:

1. Objective evidence of active CMV infection determined by any one of the following methods:

- CMV antigenemia assay; OR
- CMV polymerase chain reaction (PCR); OR
- bDNA assay; OR
- Tissue biopsy with pathological changes showing intra-nuclear inclusion bodies compatible with CMV infection (i.e. Owl's eye)
- Primary Infection - positive CMV IgM antibodies; OR
- Reactivation - Positive CMV IgM antibodies with four-fold or greater increase in CMV IgG antibodies

Standard Approval Duration: Initial requests up to 3 months and up to 6 months (lung or heart-lung transplant)

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Valganciclovir

Dosage Form: 450 mg tablet

Reimbursement Criteria:

Consolidation phase of treatment (i.e. maintenance phase post-induction with IV ganciclovir) of CMV treatment in transplant patients including patients receiving vascularized composite allotransplantation (VCA) for upper limbs (i.e. hand, forearm).

Renewals will be considered for patients who continue to have active CMV infection.

Renewal requests not meeting the criteria will be considered on a case-by-case basis but the physician must submit a rationale of why ongoing treatment is necessary.

Standard Approval Duration: 3 months

Ganciclovir

Dosage Form: 500 mg/vial Injection

Reimbursement Criteria:

For the treatment of cytomegalovirus (CMV) disease following solid organ transplant, bone marrow transplant or vascularized composite allotransplantation (VCA) of the upper limbs (i.e. hand, forearm) in patients who meet the following criteria:

1. Objective evidence of active CMV infection determined by any one of the following methods:
 - CMV antigenemia assay OR
 - CMV polymerase chain reaction (PCR); OR
 - bDNA assay; OR
 - Primary Infection - positive CMV IgM antibodies; OR
 - Reactivation - Positive CMV IgM antibodies with four-fold or greater increase in CMV IgG antibodies; OR
 - Tissue biopsy with pathological changes showing intranuclear inclusion bodies compatible with CMV infection (i.e. Owl's eye)

Standard Approval Duration:

Initial requests up to 3 months and up to 6 months (lung or heart-lung transplant).

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dosage Form: 500 mg/vial Injection

Renewals will be considered for patients who continue to have active CMV infection and rationale why switching to oral step down therapy is not an alternative at this time.

Renewal requests not meeting the criteria will be considered on a case-by-case basis but the physician must submit a rationale of why ongoing treatment is necessary.

Standard Renewal duration: 3 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

HIV DRUGS – RENEWAL ONLY

Enfuvirtide

Dosage Form: 108 mg/vial injection

Reimbursement Criteria:

EAP will renew for patients who have responded to therapy and have undetectable viral load or increasing / stable CD4 count.

Standard Approval Duration: 6 months

Tipranavir

Dosage Form: 250 mg capsules

Reimbursement Criteria:

EAP will renew for patients who have responded to therapy and have undetectable viral load or increasing / stable CD4 count.

Standard Approval Duration: 12 months

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

MULTIPLE SCLEROSIS DRUGS – RENEWAL ONLY

NOTE: Avonex, Betaseron, Copaxone, Rebif, and Extavia are considered for reimbursement in patient with Clinically Definite Multiple Sclerosis (CDMS). Avonex, Betaseron, Copaxone, and Extavia are considered for reimbursement in patients with clinically isolated syndrome (CIS) (e.g., treatment of a single demyelinating event).

Aubagio, Gilenya and Tecfidera are considered for reimbursement only in patients with Relapsing-Remitting Multiple Sclerosis (RRMS)

Tysabri is considered for reimbursement only in patients with Rapidly Evolving Severe Relapsing-Remitting Multiple Sclerosis (RES-RRMS).

Dimethyl Fumarate

Dosage Form:

120 mg and 240 mg capsule

Reimbursement Criteria:

EAP will renew Tecfidera for patients with RRMS who have benefited from therapy and have an EDSS score ≤ 5 .

The physician must provide the following information:

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days); and
- Patient is stable or has experienced no more than 1 clinical relapse in the past year (NB: if the Patient has had more than one attack/relapse, the request will be sent for external review); and
- The patient's most recent EDSS score.

Standard Approval Duration:

2 years for initial approvals and 5 years for subsequent approvals

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Fingolimod

Dosage Form:

0.5 mg capsule

Reimbursement Criteria:

EAP will renew Gilenya for patients with RRMS who have benefited from therapy and have an EDSS score ≤ 5.5 . Gilenya will not be funded in combination with other disease modifying therapies (e.g. Avonex, Betaseron, Copaxone, Rebif, Extavia, Tysabri, Aubagio and Tecfidera).

The physician 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 (NB: if the Patient has had more than one attack/relapse, the request will be sent for external review); AND
- The patient's most recent EDSS score.

Standard Approval Duration:

2 years for initial renewal approval and 5 years for subsequent approvals

Glatiramer acetate

Dosage Form: 20 mg/mL injection

Reimbursement Criteria:**CDMS:**

EAP will renew Copaxone for patients with CDMS 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 EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dosage Form: 20 mg/mL injection

- The patient's most recent EDSS score.

CIS:

EAP will renew Copaxone for patients with CIS who have benefited from therapy and have an EDSS score \leq 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.

Standard Approval Duration:

2 years for initial renewal approval and 5 years for subsequent approvals

Interferon beta-1a

Dosage Form:

Avonex: 30 mcg/0.5mL prefilled syringe for intramuscular injection 30 mcg single-use prefilled autoinjector

Rebif: 22 mcg/syringe and 44 mcg/syringe injection 66 mcg/pre-filled cartridge; 132 mcg/pre-filled cartridge

Reimbursement Criteria:

CDMS:

EAP will renew Avonex or Rebif for patients with CDMS who have benefited from therapy and have an EDSS score \leq 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.

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dosage Form:

Avonex: 30 mcg/0.5mL prefilled syringe for intramuscular injection 30 mcg single-use prefilled autoinjector

Rebif: 22 mcg/syringe and 44 mcg/syringe injection 66 mcg/pre-filled cartridge; 132 mcg/pre-filled cartridge

CIS:

EAP will renew Avonex for patients with CIS 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

Standard Approval Duration:

2 years for initial renewal approval and 5 years for subsequent approvals

Interferon beta-1b

Dosage Form:

Betaseron: 9.6 MIU=0.3 mg Injection

Extavia: 0.3 mg vial for Injection

Reimbursement Criteria:**CDMS and CIS:**

EAP will renew Betaseron or Extavia 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.

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Dosage Form:

Betaseron: 9.6 MIU=0.3 mg Injection

Extavia: 0.3 mg vial for Injection

Standard Approval Duration:

2 years for initial renewal approval and 5 years for subsequent approvals

Natalizumab

Dosage Form: 300 mg/15 mL Injection

Reimbursement Criteria:

EAP will renew Tysabri for patients with RES-RRMS 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.

Standard Approval Duration:

2 years for initial renewal approval and 5 years for subsequent approvals

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

Teriflunomide

Dosage Form:

14 mg tablet

Reimbursement Criteria:

EAP will renew Aubagio for patients with RRMS who have benefited from therapy and have an EDSS score ≤ 5.5 .

The physician must provide the following information:

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days); and
- Patient is stable or has experienced no more than 1 clinical relapse in the past year; and
- The patient's most recent EDSS score.

Standard Approval Duration: 2 years

The EAP response letter will list the specific drug, strength and dosage form that will be approved. Refer to the formulary for a list of interchangeable drug products that may be dispensed.

