

EXCEPTIONAL ACCESS PROGRAM

TELEPHONE REQUEST SERVICE

REIMBURSEMENT CRITERIA

June 1, 2009

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INTRODUCTION

The Ontario Public Drug Programs has developed these Reimbursement Criteria to provide physicians and/or their delegates with information about selected drug products that may qualify for coverage under the Exceptional Access Program (EAP). We will assess requests for coverage of these drugs through the Telephone Request Service (TRS).

The information provided in these Reimbursement Criteria should not be used as the basis for medical diagnosis or treatment. These criteria do not include diagnostic information, symptom assessment, health counselling or medical opinions. The information is intended for information purposes only, and is not designed to be used as medical advice for physicians or patients.

The Ministry reserves the right to change the list of drug products at its sole discretion. We will post changes on the Ministry's website before the date upon which the changes become effective. Physicians are reminded to monitor the Ministry's website on a regular basis.

If you have any questions or concerns regarding this new service, or if you have comments after you have used it, 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
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LIST OF DRUG PRODUCTS FOR TELEPHONE REQUEST SERVICE

NEW REQUESTS

ANTIBIOTICS				
DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Cefazolin	Generic products available	1g/vial injection	For treatment of infections susceptible to cefazolin.	As requested up to 5 years
Ciprofloxacin HCl and dexamethasone	Ciprodex	3 mg/mL ciprofloxacin and 1 mg/mL dexamethasone otic solution	<p>For the treatment of <u>otitis externa</u> where:</p> <ul style="list-style-type: none"> • 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). <p><i>NOTE: Ciprodex reimbursement is <u>not</u> considered for any other indications (e.g., otitis media).</i></p>	1 month
Dapsone	Dapsone	100mg tablet	<p>For the treatment of:</p> <ul style="list-style-type: none"> • Pneumocystis carinii pneumonia (PCP) prophylaxis in immunocompromised patients (e.g. patients with HIV or organ transplants) with an intolerance/allergy to trimethoprim-sulfamethoxazole • Autoimmune diseases, such as pemphigus vulgaris, pemphigoid, dermatitis herpetiformis, etc. 	5 years
Gentamycin	Generic products available	40mg/mL injection	For treatment of infections susceptible to gentamycin.	As requested up to 5 years

Vancomycin	Vancocin	125mg and 250mg capsules; 1g vial (for oral use)	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>EAP will approve vancomycin at a dose of 125mg to 250mg four times daily. (For a non-severe primary episode of CDAD, approval will be provided only for 125mg four times daily.)</p>	2 weeks (unless recurrent infection, where approval may be granted for up to 8 weeks)
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CHRONIC RENAL FAILURE DRUGS

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Calcium Carbonate	Generic products available	625mg 1250mg tablet	<p>For patients with hypoparathyroid disease or chronic renal failure.</p> <p><i>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.</i></p>	5 years
Sevelamer	Renagel	800mg tablet	<p>For the treatment of high serum phosphate levels (>1.8 mmol/L) in dialysis patients experiencing high serum calcium levels (>2.65 mmol/L) while on calcium-based phosphate binders. The physician must provide at least two recent serum phosphate and calcium levels.</p> <p>Renewal requests are approved for patients who have responded to therapy with serum phosphate levels ≤ 2.0mmol/L and serum calcium levels 2.15 – 2.60 mmol/L. The physician must provide the patient’s serum phosphate and calcium levels before and after therapy.</p>	5 years
Vitamin B complex with Vitamin C	Replavite	—	For patients receiving hemodialysis or peritoneal dialysis.	5 years

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. Please consult the Formulary for further details.

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Dalteparin sodium	Fragmin	10 000 IU/mL 25 000 IU /mL multidose vial pre-filled syringes	For: <ul style="list-style-type: none"> • 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. 	As requested up to a maximum of 10 days before the date of surgery plus up to 7 days after the date of hospital discharge
			For: <ul style="list-style-type: none"> • Post-operative prophylaxis of DVT for patients who had hip or knee surgery, and cannot use warfarin. 	As requested up to a maximum of 30 days starting on the day of surgery
			For: <ul style="list-style-type: none"> • Extended treatment of symptomatic acute venous thromboembolism (VTE) in patients with cancer, who cannot use warfarin. 	As requested up to 6 months

Enoxaparin sodium	Lovenox	100 mg/mL 150 mg/mL multidose vial pre-filled syringes	For: <ul style="list-style-type: none"> • 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. 	As requested up to a maximum of 10 days before the date of surgery plus up to 7 days after the date of hospital discharge
			For: <ul style="list-style-type: none"> • Post-operative prophylaxis of DVT for patients who had hip or knee surgery, and cannot use warfarin. 	As requested up to a maximum of 30 days starting on the day of surgery
Tinzaparin sodium	Innohep	10 000 IU/mL 20 000 IU/mL multidose vial pre-filled syringes	For: <ul style="list-style-type: none"> • 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. 	As requested up to a maximum of 10 days before the date of surgery plus up to 7 days after the date of hospital discharge
			For: <ul style="list-style-type: none"> • Post-operative prophylaxis of DVT for patients who had hip or knee surgery, and cannot use warfarin. 	As requested up to a maximum of 30 days starting on the day of surgery

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)

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Pioglitazone	Generic products available	15mg 30mg 45mg tablet	<p>For dual combination therapy of type 2 diabetes, in patients with:</p> <p>a) Inadequate glycemic control (HbA1c of >7%) on maximal doses of metformin (2000mg/day); OR</p> <p>b) Inadequate glycemic control, on maximal doses of sulfonylurea (glyburide 10mg/day or gliclazide 160mg/day) and demonstrated intolerance / contraindication to metformin</p> <p>For triple combination therapy of type 2 diabetes, in patients with:</p> <p>a) Inadequate glycemic control on maximal doses of metformin and a sulfonylurea AND only if:</p> <ul style="list-style-type: none"> • physician has offered insulin as alternative option first, and patient has refused 	5 years

			<p>or is not able to take insulin, AND</p> <ul style="list-style-type: none"> • both physician and patient are aware that thiazolidinediones are not indicated for use in triple therapy. 	
Rosiglitazone	Avandia	<p>2mg 4mg 8mg tablet</p>	<p>For dual combination therapy of type 2 diabetes, in patients with:</p> <p>a) Inadequate glycemic control (HbA1c of >7%) on maximal doses of metformin (2000mg/day); OR</p> <p>b) Inadequate glycemic control, on maximal doses of sulfonylurea (glyburide 10mg/day or gliclazide 160mg/day) and demonstrated intolerance / contraindication to metformin</p> <p>For triple combination therapy of type 2 diabetes, in patients with:</p> <p>a) Inadequate glycemic control on maximal doses of metformin and a sulfonylurea AND only if:</p> <ul style="list-style-type: none"> • 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. 	5 years

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 Ina Nesbitt, Ontario Medical Association: (416) 340-2234, or via email at Ina.Nesbitt@oma.org.

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

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Diazepam	Generic products available	5mg/mL injection	For use in seizure control or anxiety when patients cannot use other dosage forms.	6 months
Dimenhydrinate	Gravol	50mg/mL injection	For nausea, when patients cannot use other dosage forms.	6 months
Furosemide	Generic products available	10mg/mL injection	For palliative care.	6 months
Gabapentin	Neurontin	100mg, 300mg, 400mg capsules	For neuropathic pain after failure of narcotic analgesics, or, if appropriate, tricyclic antidepressants.	6 months

Glycopyrolate	Generic products available	0.2mg/mL injection	For secretion control in the very terminal stage of care.	6 months
Hyoscine	Buscopan	20mg/mL injection 10mg tablet	For abdominal spasm.	6 months
Lorazepam	Generic products available	4mg/mL injection	For palliative care.	6 months
Methadone	Metadol	tablets 1mg, 5mg, 10mg, 25mg oral liquid; 1mg/mL, 10mg/mL injection	If traditional narcotic analgesics fail to control pain or lead to side effects.	6 months
Metoclopramide	Generic products available	10mg/2mL injection	For nausea when patients cannot take oral alternatives.	6 months
Midazolam	Generic products available	5mg/mL injection	For use in respiratory distress or anxiety.	6 months
Morphine	Generic products available	2mg/mL 10mg/mL injection	For palliative care.	6 months
Oxycodone	Supeudol	5mg 10mg 20mg tablets	For use when patients cannot use combination oxycodone & acetaminophen.	6 months
Phenobarbital	Generic products available	120 mg/mL injection	For use in seizure control, sedation, when oral dosage forms cannot be used.	6 months
Phenytoin	Generic products available	50mg/mL injection	For use in seizure control, when patients cannot use oral dosage forms.	6 months
Scopolamine	Generic products available	0.4mg/mL, 0.6mg/mL injection	For secretion control in the very terminal stage of care.	6 months

POST-TRANSPLANT DRUGS

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Acyclovir	Zovirax	200mg, 400mg, 800mg tablets	For: <ul style="list-style-type: none"> • Cytomegalovirus (CMV) prophylaxis following heart, lung, or liver transplants in patients at high risk (D+/R- or D+/R+, or receiving antilymphocyte antibody products for immunosuppression) for CMV disease where the following information is provided: <ul style="list-style-type: none"> ○ Donor and recipient pre-transplant CMV serology; and ○ Details of treatment with antilymphocyte antibody products, if applicable. 	3 months
			<ul style="list-style-type: none"> • Herpes Simplex Virus (HSV) prophylaxis following kidney/pancreas/heart transplants. 	3 months
			<ul style="list-style-type: none"> • Herpes Simplex Virus (HSV) and varicella zoster virus (VZV) prophylaxis following stem cell transplantation. 	As requested up to 12 months
Fluconazole	Diflucan	50mg, 100mg tablet; 150mg capsule 10mg/mL oral liquid	For the prevention of fungal infections post-transplant, until engraftment.	As requested up to 3 months

Mycophenolate mofetil	Cellcept	250mg SG capsule 500mg tablet 200 mg/mL oral liquid	<p>For:</p> <ul style="list-style-type: none"> • Solid organ transplants other than allogeneic 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. <p><i>*NOTE: Cellcept is currently listed on the ODB Formulary as <u>Limited Use (LU)</u> 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 <u>General Benefit (GB)</u>.</i></p>	5 years
Rapamune	Rapamycin, Sirolimus	1mg tablet 1mg/mL oral liquid	<p>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.</p> <p><i>NOTE: Rapamune is currently listed on the ODB Formulary as a <u>Limited Use (LU)</u> benefit for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants.</i></p>	5 years
Valganciclovir	Valcyte	450mg tablet	<p>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:</p>	3 months

			<ul style="list-style-type: none">• organ(s) transplanted;• donor and recipient pre-transplant CMV serology; and• details of treatment with antilymphocyte antibody products, if applicable.	
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RENEWALS

HIV DRUGS – RENEWAL ONLY				
DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Enfuvirtide	Fuzeon	108 mg/vial injection	EAP will renew for patients who have responded to therapy and have undetectable viral load or increasing / stable CD4 count.	6 months
Raltegravir	Isentress	400 mg tablet	EAP will renew for patients who have responded to therapy and have undetectable viral load or increasing / stable CD4 count.	12 months
Tipranavir	Aptivus	250mg capsules	EAP will renew for patients who have responded to therapy and have undetectable viral load or increasing / stable CD4 count.	12 months
MULTIPLE SCLEROSIS DRUGS – RENEWAL ONLY				
<p><i>NOTE: All medications are considered for reimbursement in patient with Clinically Definite Multiple Sclerosis (CDMS). Avonex and Betaseron are considered for reimbursement only in patients with clinically isolated syndrome (e.g., treatment of a single demyelinating event).</i></p>				
DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Glatiramer acetate	Copaxone	20 mg/mL injection	<p>EAP will renew Copaxone for patients who have benefited from therapy and have an EDSS score ≤ 5.</p> <p>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 	12 months

			<ul style="list-style-type: none"> • EDSS score. 	
Interferon beta-1a	Avonex, Rebif	<p>Avonex: 30 or 60 µg per mL injection and 30 µg per 0.5 mL prefilled syringe</p> <p>Rebif: 22mcg/syringe and 44mcg/syringe injection</p>	<p>EAP will renew Avonex or Rebif only for patients who have benefited from therapy and have an EDSS score ≤ 6.</p> <p>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. 	12 months
Interferon beta-1b	Betaseron	0.3 mg/vial injection	<p>EAP will renew Betaseron only for patients who have benefited from therapy and have an EDSS score ≤ 6.</p> <p>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. 	12 months

ORAL HYPOGLYCEMIC AGENTS – RENEWALS

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

Funding under the EAP for pioglitazone or rosiglitazone will not be provided where the following clinical circumstances have developed while on therapy during the intervening period:

- *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)*

DRUG PRODUCT	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA	STANDARD APPROVAL DURATION
Pioglitazone	Generic products available	15mg 30mg 45mg tablet	EAP will renew pioglitazone only for patients who have achieved adequate glycemic control (HbA1c of $\leq 7\%$ while on therapy)	5 years
Rosiglitazone	Avandia	2mg 4mg 8mg tablet	EAP will renew rosiglitazone only for patients who have achieved adequate glycemic control (HbA1c of $\leq 7\%$) while on therapy	5 years