

DRUGS NOT CONSIDERED FOR REIMBURSEMENT THROUGH THE ODB PROGRAM

Drug products are covered under the ODB program's EAP based on recommendations and guidelines from the ministry's expert advisory committee, the Committee to Evaluate Drugs (CED). The CED makes recommendations to the Executive Officer as to whether a drug product should be listed as a Formulary benefit or designated as an interchangeable drug product (for generic drugs). The CED also makes recommendations as to whether or not drug products should be available through EAP, and may develop clinical criteria. Based on a thorough and comprehensive review, the CED may recommend that the drug product for specific indication(s) should neither be listed as a Formulary benefit nor considered through EAP. Select drug products that were recently reviewed and not recommended for funding through the ODB Program have been listed below, with the rationale for the Committee's decision. Where applicable, a link to more detailed information pertaining to the CED's review and subsequent decision on funding from the Executive Officer has been provided.

This document will be updated on a regular basis to include newly reviewed drugs and indications that are not recommended for funding and on as needed basis if any changes are made to the reimbursement status of the drugs in this list. In addition, the ministry is working with the manufacturers to address concerns raised during a review and changes may be made to the recommended criteria and/or listing status.

It should be noted that there are other drugs not listed in this document at this time that may not be considered for reimbursement through the ODB Program.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Alefacept	Amevive	15mg/0.5mL intramuscular injection	The CED noted that there are significant concerns regarding the limited efficacy, safety and cost-effectiveness data available for the use of Amevive in the treatment of moderate to severe chronic plaque psoriasis. There are no data either comparing Amevive to relevant comparators or supporting the efficacy of Amevive in patients who are refractory to standard systemic therapies. The cost-effectiveness of Amevive has not been established. Furthermore, there is a lack of long-term safety data as a higher incidence of skin cancer and serious infections were detected with various regimens.
Calcium acetate	PhosLo	667mg tablet	The CED completed two reviews of PhosLo for the treatment of hyperphosphatemia in hemodialysis patients and noted that there is no compelling evidence to support therapeutic superiority of PhosLo over standard calcium carbonate in this clinical setting. Furthermore, it was noted that PhosLo is significantly more expensive than standard calcium carbonate.
Chlorpropamide	Generic products available	100mg and 250mg tablet	The CED conducted a comprehensive review of the evidence related to treatments for blood glucose control to ensure that reimbursement of diabetes medications reflects current clinical knowledge and data on efficacy, safety, and cost-effectiveness. The committee has reviewed chlorpropamide for the treatment of type 2 diabetes and noted the increased risk of cardiovascular mortality with chlorpropamide, based on the UKPDS 33 study, where systolic and diastolic blood pressure were significantly higher throughout the study in patients assigned to the chlorpropamide group than any other treatment group.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Ciclopirox olamine	Stieprox	1.5% shampoo	Stieprox was reviewed for topical treatment and prophylaxis of dandruff and seborrheic dermatitis. There is little compelling evidence to support increased efficacy of Stieprox in comparison to ketoconazole shampoo (which is available to patients over-the-counter) or other formulary alternatives, including steroid creams and antifungals.
Cinacalcet	Sensipar	30mg, 60mg, 90mg tablet	Sensipar was reviewed for the treatment of secondary hyperparathyroidism in patients with chronic renal disease. The CED noted that while Sensipar has been shown to impact parathyroid hormone and serum calcium levels, there is insufficient evidence to support the therapeutic efficacy of this product in achieving clinically important outcomes such as quality of life, symptomatic bone disease, hospitalizations, cardiovascular disease and mortality when compared to conventional therapy. Furthermore, the cost-effectiveness of Sensipar has not been established. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/sensipar.pdf
Darifenacin	Enablex	7.5mg and 15mg extended release tablet	The CED noted that published evidence has demonstrated that Enablex offers no advantage in terms of efficacy, safety, or tolerability to justify its price premium over existing formulary alternatives, such as oxybutynin. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/darifenacin.pdf
Desogestrel and ethinyl estradiol	Linessa	21-day and 28-day packs	The CED noted that Linessa provides no advantage in terms of efficacy, safety, or tolerability to justify its price premium over oral contraceptives listed in the current Formulary. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/desogestrel.pdf
Diclofenac sodium	Pennsaid	1.5% topical solution	Pennsaid was reviewed in the treatment of symptoms associated with osteoarthritis of the knee. The CED noted that there is a lack of evidence to demonstrate that Pennsaid provides superior therapeutic efficacy, safety, or cost-effectiveness over currently available alternatives listed on the Formulary.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Donepezil	Aricept RDT	5mg and 10mg orally disintegrating tablet	Aricept film-coated tablets are currently listed on the Formulary as a Limited Use (LU) benefit for the symptomatic treatment of patients with mild and moderate dementia of the Alzheimer's type. The CED noted that Alzheimer's patients with severe disease are most likely to have difficulty swallowing and may therefore benefit from Aricept RDT. However, the manufacturer has never made a submission to the Ministry for the use of Aricept RDT in the treatment of severe Alzheimer's disease. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/donepezil.pdf
Dorzolamide and timolol	Preservative-Free Cosopt	20mg/mL and 5mg/mL ophthalmic solution	In their review, the CED questioned the true incidence of hypersensitivity to preservatives in ophthalmic products. It was noted that claims of hypersensitivity may also occur in patients who only experience a slight irritation. Furthermore, there is a lack of evidence demonstrating superior tolerability or long-term safety of preservative free dorzolamide to justify its price premium.
Doxycycline hyclate	Periostat	20mg capsule	The CED noted that although this product has been shown to have efficacy in the treatment of periodontal disease, the manufacturer was unable to demonstrate cost-effectiveness given the significant cost premium over viable clinical alternatives currently available (eg. generic doxycycline).
Eletriptan	Relpax	20mg and 40mg tablet	The CED noted that there is a lack of compelling evidence demonstrating that Relpax is therapeutically superior to the other "triptans" that are currently considered for reimbursement via the EAP mechanism (i.e., sumatriptan, almotriptan, naratriptan, and rizatriptan). The cost-effectiveness of Relpax compared to the other triptans has not been clearly established. Additionally, the committee noted that eletriptan, unlike other drugs in this class, is primarily metabolized by the cytochrome P450 (CYP3A4) pathway, thus increasing its potential to cause drug interactions and adverse effects.
Enalapril maleate/hydrochlorothiazide	Vaseretic	10mg/25mg tablet	The CED noted that there is no published evidence demonstrating that this product is more effective than other ACE inhibitor/thiazide diuretic combination products already listed on the Formulary. It was further noted that Vaseretic is also more expensive than the other formulary products and the sum of the individual single ingredient products (enalapril and hydrochlorothiazide).
Erythromycin and benzoyl peroxide	Benzamycin	3% erythromycin and 5% benzoyl peroxide topical gel	The CED noted that there is no objective evidence demonstrating that Benzamycin is more effective than current formulary alternatives.
Esomeprazole	Nexium	20mg and 40mg tablet	The CED noted that there is no compelling evidence demonstrating that Nexium is more effective than the proton-pump inhibitors (PPIs) listed on the Formulary. Several PPIs are listed in the Formulary as Limited Use benefits, and Pariet (rabeprazole) 10mg and 20mg are listed as general benefits.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Etonogestrel and ethinyl estradiol	NuvaRing	Contraceptive vaginal ring	The CED noted there is no significant clinical benefit of NuvaRing versus oral contraceptives. The clinical evidence does not demonstrate any significant differences in the pregnancy rates, rates of adverse events or compliance rates of NuvaRing over oral contraceptives. In addition, Depo-Provera, which is available on the current Formulary as General Benefit, and intrauterine devices (IUD) are available alternatives for patients who are unable to use formulary oral contraceptives. The price premium of NuvaRing over these formulary alternatives has not been justified.
Fentanyl	Duragesic 12	12.5mcg/hr transdermal patch	The CED noted that Duragesic 12 patches were proportionately more expensive than the higher dose preparations of fentanyl transdermal patches which are currently listed as Limited Use (LU) benefits on the Formulary. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/fentanyl.pdf
Fulvestrant	Faslodex	50mg/mL prefilled syringe for intramuscular injection	The CED has completed a review of fulvestrant (Faslodex) for the treatment of metastatic breast cancer. In their review, the CED has noted that the current evidence for use of fulvestrant is second- or third-line therapy to anastrozole or exemestane for locally advanced or metastatic hormone receptor positive breast cancer in post-menopausal women. However, there is a lack of evidence demonstrating the use of fulvestrant would delay the need for intravenous chemotherapy and palliative care. As such, the Executive Officer has made the decision to not fund fulvestrant.
Gatifloxacin	Zymar	0.3% ophthalmic solution	The CED noted that in comparative trials, gatifloxacin was not shown to be superior to ofloxacin for the treatment of bacterial conjunctivitis. It was also noted that, since gatifloxacin is dosed every two hours for the first two days of therapy, the risk for patient non-compliance may compromise efficacy. Moreover, it appears that gatifloxacin has a similar side effect profile to ofloxacin. Lastly, gatifloxacin is significantly more expensive than other formulary alternatives with no added therapeutic benefit for this price premium.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Gefitinib	Iressa	250mg tablet	<p>The Canadian Expert Drug Advisory Committee (CEDAC) and the CED completed a review of Iressa in 2004 noting that, at the time, it was approved by Health Canada for third-line treatment of locally advanced or metastatic Non-Small Cell Lung Cancer, conditional upon the completion of a randomized controlled trial confirming clinical benefit compared to best supportive care. There was significant concern regarding the limited efficacy and safety data available for this new therapy and there were no data comparing this drug to placebo or relevant comparators. The CED recommended that additional data from well-designed studies were required to support reimbursement under the ODB program and that no requests for Iressa should be considered for reimbursement through EAP. At this time, the Ministry has not received such data from the manufacturer.</p> <p>Please also note that, more recently, important safety and efficacy information pertaining to Iressa was issued by Health Canada. Health Canada has further restricted the indication of Iressa to patients currently benefitting from treatment. No new patients will be permitted to begin treatment with Iressa. Iressa remains available to patients benefitting from therapy through pharmacies; however, for a continued supply of the drug, pharmacists must register the patient in the IRESSA Patient Registry by contacting 1-866-473-7720. Conditional market authorization for this product will be maintained while existing lung cancer patients continue to benefit from IRESSA. More information may be found on the Health Canada Advisories webpage: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/iressa_3_hpc-cps_e.html</p> <p>Note: Erlotinib (Tarceva), another Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor, is considered through EAP as monotherapy for the 2nd- or 3rd-line treatment of patients with clinically documented incurable progressive non-small cell lung cancer (NSCLC) despite prior chemotherapy</p>
Glimepiride	Amaryl	1mg, 2mg, and 4mg tablet	The CED noted that there is insufficient evidence to demonstrate a therapeutic advantage for Amaryl over other oral anti-diabetic agents currently listed on the Formulary. In addition, it was noted that Amaryl is more costly than other alternatives.
Idoxuridine	Herplex D	0.1% topical liquid	The CED has noted that Herplex D appears to have minimal effect in recurrent or primary herpes simplex virus (HSV) on duration of symptoms, new lesion formation, healing time, or risk of subsequent recurrence. It may be associated with complications such as local burning, generalized contact dermatitis, and vulvar carcinoma in situ.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Lanthanum carbonate hydrate	Fosrenol	250mg, 500mg, 750mg, 1000mg chewable tablet	The CED has completed a review of Fosrenol for the treatment of hyperphosphatemia associated with end-stage renal disease (ESRD) in patients undergoing dialysis. The CED noted that there is a lack of sufficient evidence to demonstrate a therapeutic or safety advantage of lanthanum over sevelamer (Renagel). Although it was noted that Fosrenol causes fewer episodes of documented hypercalcemia than calcium-based phosphate binders, it is unclear how the reduction of hypercalcemia in ESRD patients results in clinical improvements, such as a reduction in mortality or cardiovascular risks. Fosrenol is significantly more costly compared to calcium-based phosphate binders. Furthermore, both calcium-based phosphate binders and sevelamer are currently considered for reimbursement through EAP.
Levonorgestrel and ethinyl estradiol	Seasonale	0.15mg/0.03mg tablet	<p>The CED has completed a review of Seasonale for use as a long-term oral contraceptive. While the CED noted that Seasonale is equally efficacious to other oral contraceptives, the CED did note that Seasonale was not associated with increased safety, increased compliance, or improved quality of life versus comparators. In addition, it was noted that there are less costly contraceptives currently on the Formulary. In view of the above, the price premium of Seasonale is not justified.</p> <p>For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/seasonale.pdf</p>
Levothyroxine sodium	Synthroid	0.137mg	The CED has reviewed Synthroid 0.137mg tablets and the committee noted that the proposed price for the 0.137mg tablet is significantly higher than other strengths of the same medication. This would translate into a significant overall cost increase when compared to the use of the 0.15mg and 0.125mg tablets alternated daily. Therefore, there appears to be little rationale to justify the significant cost difference.
Memantine	Ebixa	10mg tablet	The CED completed a review of Ebixa for the symptomatic treatment of patients with moderate to severe dementia of the Alzheimer's type. It was noted that the evidence currently available fails to establish clinically significant benefits from the use of Ebixa; and there were no demonstrated differences in rates of hospitalization or institutionalization with Ebixa in randomized clinical trials. In addition, the Committee also noted that there are safety concerns regarding the use of Ebixa, as described in the product's monograph.
Moxifloxacin	Vigamox	0.5% ophthalmic solution	The CED noted that the majority of cases of acute bacterial conjunctivitis resolve spontaneously within 5 days regardless of therapy. It was further noted that current published medical literature did not demonstrate that Vigamox was superior to ciprofloxacin or ofloxacin eye drops, yet was significantly more expensive. The physician is reminded that ofloxacin eye drops are currently listed on the Formulary as a Limited Use (LU) benefit.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Nateglinide	Starlix	60mg and 120mg tablet	The CED found that current head to head comparisons between nateglinide and other antidiabetic agents indicate a decreased efficacy compared to glyburide in lowering fasting plasma glucose and is similar in cost to other alternatives such as repaglinide (Gluconorm).
Omalizumab	Xolair	150mg subcutaneous injection	The CED noted that Xolair is indicated for the treatment of moderate to severe persistent asthma in patients who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). The committee noted that there is a lack of evidence to demonstrate that Xolair provides superior therapeutic efficacy, safety, or cost-effectiveness over currently available formulary alternatives. Furthermore, there are no studies assessing the role of Xolair as add-on therapy to standard regimens (i.e., ICS; long-acting beta agonists (LABA) and leukotriene antagonists or ICS; or LABA and oral steroids) in refractory patients or comparing Xolair to oral steroids in patients with severe asthma. Lastly, with respect to its safety, close monitoring at injection time is mandatory due to potential of anaphylactic reactions and long term safety data are unavailable.
Oxybutynin chloride	Ditropan XL	5mg and 10mg extended release tablet	A review of the available clinical data demonstrated that Ditropan XL has similar efficacy and adverse effect profiles to regular oxybutynin which is a formulary benefit. Specifically, it was noted that there is a lack of supportive evidence demonstrating that Ditropan XL is better tolerated than regular oxybutynin. The CED is of the opinion that Ditropan XL does not provide an advantage over existing listed formulary alternatives.
	Uromax	10mg and 15mg controlled release tablet	The CED noted that there is no convincing evidence to demonstrate that Uromax is therapeutically superior to immediate release (IR) oxybutynin or provides an improved adverse event profile to justify the price premium. It was also noted that the clinical evidence does not demonstrate any significant differences in quality of life between IR oxybutynin and Uromax.
Oxycodone	OxyContin	5mg slow release tablet	The CED completed multiple reviews of OxyContin 5mg tablets and noted that even in patients who are very sensitive to opioids, the 5mg tablet does not appear to afford a therapeutic advantage over other multiple short-acting and long-acting opioid analgesics currently available on the Formulary. Moreover, it was noted that the price of the 5mg tablet is proportionately more expensive than other OxyContin tablets currently listed on the Formulary (10mg, 20mg, 40mg, and 80mg). For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/oxycodone.pdf

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Pegaptanib	Macugen	0.3mg/90µL intravitreal injection	The CED completed a review of Macugen for the treatment of wet form age-related macular degeneration (AMD). While Macugen has been shown to impact visual acuity, there is insufficient evidence to support the therapeutic efficacy of this product in achieving clinically important outcomes such as quality of life when compared to a sham procedure. In addition, the committee has noted that there are concerns surrounding ophthalmic related adverse events with the use of Macugen and complications related to the intravitreal injection such as endophthalmitis, traumatic cataract, and retinal detachment. Furthermore, the cost-effectiveness of Macugen has not been clearly established.
Pegfilgrastim	Neulasta	10mg/mL subcutaneous injection	The CED noted that pegfilgrastim is therapeutically equivalent to filgrastim (Neupogen). The Committee also noted that, based on Ontario Drug Benefit utilization data, pegfilgrastim does not provide value-for-money compared to filgrastim.
Pramipexole	Mirapex	0.5mg tablet	Mirapex 0.25mg, 1mg and 1.5mg strengths are currently listed as General Benefits on the Formulary. The CED noted that the price of the 0.5mg tablet is similar to the price of the 1.0mg tablet and that the 1.0mg tablet is scored and can be split into halves. It was further noted that the 0.5mg tablet is approximately double the price of the 0.25mg tablet. Given the strengths available on the formulary, the CED concluded that there is no cost advantage in reimbursing Mirapex 0.5mg tablets.
Ramipril	Altace	15mg capsule	The CED noted that multiple strengths of generic ramipril are currently listed as General Benefits in the Formulary. In addition, it was noted that there is no evidence of clinical need or economic advantage to support the inclusion of Altace 15mg in the formulary. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/ramipril.pdf
Ramipril and felodipine	Altace Plus Felodipine	2.5mg/2.5mg and 5mg/5mg tablet	The CED reviewed Altace Plus Felodipine for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. The Committee determined that there was no compelling evidence demonstrating superior clinical efficacy, improved compliance or an improved safety profile with the fixed dose combination versus administration of the single agent components together. Moreover, the Committee noted that there is no cost-effective advantage of the fixed-dose combination over the combined use of the individual components. Lastly, the use of individual products allows for the ability to titrate and offers improved flexibility in dosing. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/ramipril_felodipine.pdf

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Risedronate	Actonel 75	75mg tablet	The CED reviewed the pertinent literature for the use of Actonel 75 mg in the prevention and treatment of osteoporosis and noted that there is no evidence that Actonel 75 mg is more efficacious than currently available Formulary alternatives. A clinical study comparing Actonel 75 mg twice monthly to Actonel 5 mg once daily found the two agents demonstrated similar efficacy and adverse event profiles. There is no published data supporting improved compliance with the 75 mg dosage and there is lack of evidence comparing Actonel 75 mg to other agents such as alendronate. Therefore, a clinically relevant comparison with formulary agents is not available.
Risedronate and calcium carbonate	Actonel Plus Calcium	35 mg risedronate sodium and 1250mg calcium carbonate	<p>This is a combination/compliance package that contains one tablet of risedronate sodium 35mg and six tablets of calcium carbonate 1250mg. The CED noted that there is a lack of evidence to support therapeutic advantage of Actonel Plus Calcium over existing bisphosphonate alternatives on the formulary. It was also noted that Actonel Plus Calcium is significantly more expensive than formulary bisphosphonate alternatives. Furthermore, Actonel is currently listed on the Formulary as General Benefit.</p> <p>For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/risedronate.pdf</p>
Rivastigmine	Exelon Patch 5 Exelon Patch 10	4.6 mg/24 hours and 9.5mg/24 hours transdermal patch	In the review, the CED noted that there is a small clinical effect for rivastigmine patch versus placebo and no evidence that the patch is more effective than the oral capsules and oral liquid. Furthermore, there is no comparative data for the patch versus other acetylcholine esterase inhibitors. As rivastigmine is indicated only in the treatment of mild to moderate Alzheimer's disease, the CED has expressed concerns of misuse in the treatment of severe Alzheimer's disease.
Rosiglitazone and metformin	Avandamet	1mg/500mg, 2mg/1000mg, 2mg/500mg, 4mg/1000mg, 2mg/500mg tablet	Avandamet is a combination product containing both rosiglitazone and metformin. The CED noted that there is a lack of clinical evidence to support the therapeutic advantage of fixed-dose combinations. Furthermore, it was noted that the cost of the combination product is not significantly lower than that of the sum of the two single ingredient products at the most commonly prescribed doses.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Sitagliptin	Januvia	100mg tablet	The CED has completed a review of Januvia for the treatment of type 2 diabetes and acknowledged the effectiveness data for sitagliptin in combination with metformin to reduce HbA1c levels, fasting blood glucose (FBG), and 2 hour post-prandial glucose (PPG) levels in Type 2 diabetes patients versus metformin alone. However, the Committee was concerned with the short term trial data and the lack of clinically relevant outcomes, such as microvascular or macrovascular morbidity. There is emerging evidence that control of HbA1c does not necessarily translate to improvements in clinically relevant outcomes such as morbidity and mortality. The Committee also noted the lack of clinical and pharmacoeconomic evidence of sitagliptin for the treatment in Type 2 diabetes patients with a contraindication or intolerance to a sulfonylurea.
Solifenacin	Vesicare	5mg and 10mg tablet	The CED found no clinically significant benefits for Vesicare over existing formulary alternatives for the treatment of overactive bladder in adults with symptoms of urge urinary incontinence, urinary urgency, and urinary frequency. It was also noted that there is a lack of evidence assessing the efficacy and safety of Vesicare beyond twelve weeks of use. In addition, the CED expressed concern regarding the potential for this medication to cause serious adverse effects in the elderly, particularly delirium.
Telithromycin	Ketek	400mg tablet	The CED indicated that there is insufficient evidence to demonstrate that this product has any therapeutic advantages over other less expensive formulary alternatives, including macrolide antibiotics. In addition, the Committee has noted that there are safety concerns regarding potential drug interactions involving drug metabolism by the CYP450-3A4 pathway; and, the side effect profile includes vision disturbances which are not part of the profile associated with the macrolide antibiotics currently listed as formulary benefits.
Tolbutamide	Generic products available	500mg tablet	Due to the increased risk of cardiovascular mortality with tolbutamide compared to other equally effective formulary alternatives, the CED recommended that tolbutamide no longer be reimbursed under the Ontario Drug Benefit Program. The CED conducted a comprehensive review of the evidence related to treatments for blood glucose control to ensure that reimbursement of diabetes medications reflects current clinical knowledge and data on efficacy, safety, and cost-effectiveness. The committee reviewed the use of tolbutamide for the treatment of type 2 diabetes and noted that this agent has been associated with an increased risk of cardiovascular mortality.

DRUG NAME	BRANDS	DOSAGE FORM/ STRENGTH	RATIONALE
Teriparatide	Forteo	250µG/mL subcutaneous injection	The CED completed multiple reviews of Forteo for the treatment of osteoporosis. Given the large cost differential between teriparatide and anti-resorptive therapies and the current clinical information available, it was felt that teriparatide has not been shown to be cost-effective for the first-line treatment of osteoporosis. In addition, the CED is unaware of any evidence to support Forteo's efficacy for patients who continue to fracture despite adequate anti-resorptive therapy. It was felt that this evidence was required to determine whether a switch to teriparatide would offer any advantage over continued bisphosphonate treatment in these patients.
Testosterone	Androderm	24.3mg transdermal patch	The CED noted that there is a lack of evidence demonstrating dose proportional bioequivalence between the 24.3mg patch and the 12.2mg patch formulation, which is currently available as a Limited Use (LU) benefit on the Formulary.
Tramadol	Ralivia	100mg, 200mg, and 300mg extended release tablet	The CED has reviewed Ralivia and noted that there is no evidence that tramadol offers a therapeutic advantage over existing formulary alternatives. The majority of clinical studies compared Ralivia to placebo and there is minimal data comparing the drug to long-acting narcotics. Therefore, a clinically relevant comparison with many formulary alternatives is not available.
	Zytram XL	150mg, 200mg, 300mg, and 400mg controlled release tablet	The CED noted that there is no evidence that tramadol offers a therapeutic advantage over formulary alternatives, including a codeine/acetaminophen combination and nonsteroidal anti-inflammatory drugs (NSAIDs). Zytram XL was not compared to long-acting narcotics in clinical trials and therefore a clinically relevant comparison with many formulary long-acting narcotic alternatives is not available. Furthermore, there is a lack of clinical safety and efficacy data to support the long-term use of Zytram XL beyond 28 days.
Trospium	Trosec	20mg tablet	The CED noted that there is no compelling evidence demonstrating improved efficacy compared to oxybutynin, which is available as a general benefit. In addition, the promoted advantage of fewer CNS side effects with Trosec has not been demonstrated in clinical trials. Furthermore, Trosec does not offer any therapeutic or cost-effective advantage over alternative agents currently considered for reimbursement under the Ontario Drug Benefit (ODB) program. For more information, please go to: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/trospium.pdf

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Valsartan	Diovan	40mg tablet	<p>The CED has reviewed Diovan 40mg tablets to be used as an initial dosing regimen for the reduction of cardiovascular mortality in patients with signs and symptoms of left ventricular dysfunction in conjunction with acute myocardial infarction, when the use of an angiotensin converting enzyme (ACE) inhibitor is not appropriate. The Committee determined that there is no compelling evidence from clinical trials demonstrating clinical superiority of Diovan versus an ACE inhibitor for this indication. Moreover, the Committee noted that there is no cost-effective advantage for Diovan 40mg tablets over alternative formulary agents.</p> <p>Please note that Diovan 80mg, 160mg, and 320mg as well as Diovan-HCT 80mg/12.5mg, 160mg/12.5mg, and 150mg/25mg are listed on the Formulary as General Benefit.</p>
Verapamil and trandolapril	Tarka	2/240mg and 4/240mg tablet	<p>The CED noted that it offers no additional therapeutic value over available Formulary alternatives for the treatment of hypertension. There were no studies that demonstrate benefit in outcomes (i.e. mortality and cardiovascular events) from treatment with Tarka. Both verapamil and trandolapril are currently listed on the Formulary as single agents. Furthermore, there are other more appropriate combination products available on the market that are less expensive than Tarka.</p>

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