

UPDATE AE
Ontario Drug Benefit
Formulary/Comparative Drug Index
No. 41
Effective February 29, 2012

SUMMARY OF CHANGES

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New Single Source Drug(s)

<u>DIN</u>	<u>PRODUCT</u>	<u>GENERIC NAME</u>	<u>MFR</u>	<u>DBP</u>
02370417	Actonel DR 35mg DR Tab	RISEDRONATE SODIUM	WAR	10.7875
02352648	Fragmin 7500IU/0.3mL Inj Pref Syr	DALTEPARIN SODIUM	PFI	15.4120

Reason for Use Code

Clinical Criteria

- 186 For acute treatment of deep venous thrombosis (DVT), for a maximum of three weeks;
LU Authorization Period: 1 year.
- 187 For DVT in pregnant or lactating females;
LU Authorization Period: 1 year.
- 188 For DVT in patients whom treatment with warfarin is not tolerated, or contraindicated;
LU Authorization Period: 1 year.
- 189 For DVT in patients who have failed treatment with warfarin.
LU Authorization Period: 1 year.

<u>DIN</u>	<u>PRODUCT</u>	<u>GENERIC NAME</u>	<u>MFR</u>	<u>DBP</u>
02333856	Janumet 500mg & 50mg Tab	METFORMIN & SITAGLIPTIN	MEK	1.5200
02333864	Janumet 850mg & 50mg Tab	METFORMIN & SITAGLIPTIN	MEK	1.5200
02333872	Janumet 1000mg & 50mg Tab	METFORMIN & SITAGLIPTIN	MEK	1.5200

Treatment of Type 2 diabetes in patients on maximal doses of metformin (2000mg/day) who have:

- Inadequate glycemic control (defined as HbA1c>0.07) and intolerance or contraindication to a sulfonylurea; or
- An HbA1c less than or equal to 0.07 and elevated 2 hour post prandial glucose (PPG > 10 mmol/L) or fasting plasma glucose (FPG > 7 mmol/L) levels and intolerance or contraindication to a sulfonylurea; or
- Inadequate glycemic control (HbA1c>0.07) and on maximal doses of a sulfonylurea and for whom insulin is not an option.

02357593	Norvir 100mg Tab	RITONAVIR	ABB	1.4671
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For the treatment of HIV/AIDS, the prescriber must be approved for the Facilitated Access mechanism.

02333554	Onglyza 5mg Tab	SAXAGLIPTIN	BQU	2.7560
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Treatment of Type 2 diabetes in patients on maximal doses of metformin (2000mg/day) who have:

- Inadequate glycemic control (defined as HbA1c>0.07) and intolerance or contraindication to a sulfonylurea; or
- An HbA1c less than or equal to 0.07 and elevated 2 hour post prandial glucose (PPG > 10 mmol/L) or fasting plasma glucose (FPG > 7 mmol/L) levels and intolerance or contraindication to a sulfonylurea.

<u>DIN</u>	<u>PRODUCT</u>	<u>GENERIC NAME</u>	<u>MFR</u>	<u>DBP</u>
02343541	Prolia (Preservative Free) 60mg/mL Inj Sol-Pref Syr	DENOSUMAB	AMG	330.0000

**Reason for
Use Code**

Clinical Criteria

428 For the treatment of osteoporosis in postmenopausal women who have experienced a further significant decline in BMD after 1 year continuous bisphosphonate therapy and meet at least two of the following criteria:

- i. Age greater than 75 years old
- ii. A bone mineral density (BMD) T-score less than or equal to -2.5
- iii. Prior fragility fracture

OR

429 For the treatment of osteoporosis in postmenopausal women who would otherwise be eligible for funding for oral bisphosphonates, but for whom bisphosphonates are contraindicated due to hypersensitivity or abnormalities of the esophagus (e.g., esophageal stricture or achalasia), **AND** have at least two of the following:

- Age greater than 75 years old
- A prior fragility fracture
- A bone mineral density (BMD) T-score less than or equal to -2.5

NOTES: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy.

The recommended dose of PROLIA (denosumab) is a single SC injection of 60mg, once every 6 months.

LU Authorization Period: Indefinite.

02371022	Twynsta 40mg & 5mg Tab	TELMISARTAN & AMLODIPINE BESYLATE	BOE	0.6819
02371049	Twynsta 80mg & 5mg Tab	TELMISARTAN & AMLODIPINE BESYLATE	BOE	0.6819
02371030	Twynsta 40mg & 10mg Tab	TELMISARTAN & AMLODIPINE BESYLATE	BOE	0.6819
02371057	Twynsta 80mg & 10mg Tab	TELMISARTAN & AMLODIPINE BESYLATE	BOE	0.6819

<u>DIN</u>	<u>PRODUCT</u>	<u>GENERIC NAME</u>	<u>MFR</u>	<u>DBP</u>
02361744	Zenhale 50mcg & 5mcg Metered Dose Inh-120 Dose Pk	MOMETASONE FUROATE & FORMOTEROL FUMARATE DIHYDRATE	MEK	66.9000
02361752	Zenhale 100mcg & 5mcg Metered Dose Inh-120 Dose Pk	MOMETASONE FUROATE & FORMOTEROL FUMARATE DIHYDRATE	MEK	84.9000
02361760	Zenhale 200mcg & 5mcg Metered Dose Inh-120 Dose Pk	MOMETASONE FUROATE & FORMOTEROL FUMARATE DIHYDRATE	MEK	102.9000

Reason for Use Code Clinical Criteria

330 For the treatment of asthma in patients who are using optimum anti-inflammatory treatment and are still experiencing breakthrough symptoms

LU Authorization Period: Indefinite.

Solutions for use in nebulizers are more expensive than metered dose inhalers (MDI) and turbuhalers, and for most patients, there is no significant benefit. The only indication for this mode of administration is for selected patient groups, such as those noted in the Limited Use clinical criteria for solutions for use in nebulizers, who are unable to use other formulations. Even children who are unable to coordinate actuation of a MDI and inhalation can usually use a spacer or turbuhaler. Special fittings are available for patients with severe arthritis who have difficulty using a standard MDI.

New Multi-Source Drug(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
02229873	Apo-Acetaminophen Caplets (Interchangeable with Atasol)	325mg	Caplet	APX	0.0245
02229977	Apo-Acetaminophen Caplets (Interchangeable with Atasol Forte)	500mg	Caplet	APX	0.0285
02377608	Apo-Montelukast (Interchangeable with Singulair)	4mg	Chew Tab	APX	0.3646
	Reason for Use Code	Clinical Criteria			
	382	For the treatment of asthma in patients aged 2-5 years old. LU Authorization Period: 1 Year.			
02357194	Jamp-Amlodipine	5mg	Tab	JPC	0.3391
02357208	Jamp-Amlodipine (Interchangeable with Norvasc)	10mg	Tab	JPC	0.5031

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
02348004	PMS-Clopidogrel (Interchangeable with Plavix)	75mg	Tab	PMS	0.6576
	Reason for Use Code	Clinical Criteria			
	375	For patients immediately post-hospitalization for Acute Coronary Syndrome (ACS), in combination with ASA. ACS is defined as any myocardial infarction (MI) or unstable angina (UA). LU Authorization Period: Indefinite.			
	376	For patients immediately pre- or post-percutaneous coronary intervention (PCI).* *Therapy may be initiated up to 10 days prior to PCI LU Authorization Period: Indefinite.			
	411	For patients who experience a stroke or transient ischemic attack (TIA) while taking Aggrenox (dipyridamole and ASA) or ASA alone; or For patients experiencing ongoing severe symptomatic peripheral vascular disease (PVD) (i.e. with Ankle Brachial Index < 0.5) after a vascular event while on ASA. ASA should not be used concomitantly; or For patients requiring ASA with documented severe allergy to ASA, such as anaphylactic reaction or bronchospasm. Gastrointestinal events (GI), including GI bleeds, are excluded. LU Authorization Period: Indefinite.			
02324253	PMS-Hydrocodone (Interchangeable with Hycodan)	1mg/mL	O/L	PMS	0.0570
02370697	PMS-Risperidone ODT	3mg	Orally Disintegrating Tab	PMS	2.2913
02370700	PMS-Risperidone ODT (Interchangeable with Risperdal M-Tab)	4mg	Orally Disintegrating Tab	PMS	3.0638

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
02359316	Sandoz Clopidogrel (Interchangeable with Plavix)	75mg	Tab	SDZ	0.6576

**Reason for
Use Code**

Clinical Criteria

- 375 For patients immediately post-hospitalization for Acute Coronary Syndrome (ACS), in combination with ASA. ACS is defined as any myocardial infarction (MI) or unstable angina (UA).

LU Authorization Period: Indefinite.
- 376 For patients immediately pre- or post-percutaneous coronary intervention (PCI).*
*Therapy may be initiated up to 10 days prior to PCI

LU Authorization Period: Indefinite.
- 411 For patients who experience a stroke or transient ischemic attack (TIA) while taking Aggrenox (dipyridamole and ASA) or ASA alone; or

For patients experiencing ongoing severe symptomatic peripheral vascular disease (PVD) (i.e. with Ankle Brachial Index < 0.5) after a vascular event while on ASA. ASA should not be used concomitantly; or

For patients requiring ASA with documented severe allergy to ASA, such as anaphylactic reaction or bronchospasm. Gastrointestinal events (GI), including GI bleeds, are excluded.

LU Authorization Period: Indefinite.

02375958	Sandoz Telmisartan	40mg	Tab	SDZ	0.2824
02375966	Sandoz Telmisartan (Interchangeable with Micardis)	80mg	Tab	SDZ	0.2824
02367157	Taro-Mometasone (Interchangeable with Elocom)	0.1%	Cr	TAR	0.5263

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
02293161	Teva-Clopidogrel (Interchangeable with Plavix)	75mg	Tab	TEV	0.6576

**Reason for
Use Code**

Clinical Criteria

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|-----|---|
| 375 | <p>For patients immediately post-hospitalization for Acute Coronary Syndrome (ACS), in combination with ASA. ACS is defined as any myocardial infarction (MI) or unstable angina (UA).</p> <p>LU Authorization Period: Indefinite.</p> |
| 376 | <p>For patients immediately pre- or post-percutaneous coronary intervention (PCI).*</p> <p>*Therapy may be initiated up to 10 days prior to PCI</p> <p>LU Authorization Period: Indefinite.</p> |
| 411 | <p>For patients who experience a stroke or transient ischemic attack (TIA) while taking Aggrenox (dipyridamole and ASA) or ASA alone; or</p> <p>For patients experiencing ongoing severe symptomatic peripheral vascular disease (PVD) (i.e. with Ankle Brachial Index < 0.5) after a vascular event while on ASA. ASA should not be used concomitantly; or</p> <p>For patients requiring ASA with documented severe allergy to ASA, such as anaphylactic reaction or bronchospasm. Gastrointestinal events (GI), including GI bleeds, are excluded.</p> <p>LU Authorization Period: Indefinite.</p> |

Off Formulary Interchangeable Product(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>UNIT COST</u>
02377616	Apo-Montelukast (Interchangeable with Singulair)	5mg	Chew Tab	APX	1.2075
02355663	Apo-Repaglinide	0.5mg	Tab	APX	0.2279
02355671	Apo-Repaglinide	1mg	Tab	APX	0.2369
02355698	Apo-Repaglinide (Interchangeable with GlucoNorm)	2mg	Tab	APX	0.2461

Manufacturer Requested Discontinued Drug(s)

Please note that these discontinued products will remain on the formulary until the current stock is depleted.

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
02331071	Jamp-Amlodipine	5mg	Tab	JPC
02331098	Jamp-Amlodipine	10mg	Tab	JPC
02185830	PMS-Cefaclor	250mg	Cap	PMS
02185849	PMS-Cefaclor	500mg	Cap	PMS
02185857	PMS-Cefaclor	25mg/mL	Oral Susp	PMS
02185865	PMS-Cefaclor	50mg/mL	Oral Susp	PMS
02185873	PMS-Cefaclor	375mg/5mL	Oral Susp	PMS
00703605	PMS-Lindane	1%	Shampoo	PMS
02245286	PMS-Morphine Sulfate	60mg	SR Tab	PMS
02241332	Vagifem	25mcg	Vag Tab	NOO

Delisted Drug(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
02202441	Oxycontin	10mg	SR Tab	PFP
02202468	Oxycontin	20mg	SR Tab	PFP
02202476	Oxycontin	40mg	SR Tab	PFP
02202484	Oxycontin	80mg	SR Tab	PFP

Drug Benefit Price(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
02245345	Androgel	1%	2.5g Foil Packet	SPH	2.1710
02245346	Androgel	1%	5.0g Foil Packet	SPH	3.8390
09857395	Avonex Pen	30mcg/0.5mL	Pref AutoInj Pen	BIG	393.9400
02269201	Avonex PS	30mcg/0.5mL	Pref Syr	BIG	393.9400
02146908	Biaxin	125mg/5mL	Ped Gran	ABB	0.2924
01984853	Biaxin	250mg	Tab	ABB	1.6833
00443840	Depakene	250mg	Cap	ABB	0.5723
00443832	Depakene	50mg/mL	O/L	ABB	0.1192
00596418	Epival	125mg	Ent Tab	ABB	0.3033
00596426	Epival	250mg	Ent Tab	ABB	0.5453
00596434	Epival	500mg	Ent Tab	ABB	1.0910
02238525	Hp-PAC	30mg & 500mg & 500mg	Tab/Cap Pk	ABB	84.2700
09857294	Humira	40mg/0.8mL	Inj Sol-Pref Pen Pk	ABB	729.4200
02258595	Humira	40mg/0.8mL	Inj Sol-Pref Syr Pk	ABB	729.4200
00818658	Hytrin	1mg	Tab	ABB	0.7690
00818682	Hytrin	2mg	Tab	ABB	0.9774
00818666	Hytrin	5mg	Tab	ABB	1.3274
00818674	Hytrin	10mg	Tab	ABB	1.9431
01934317	Isoptin SR	180mg	LA Tab	ABB	1.5945
00742554	Isoptin SR	240mg	LA Tab	ABB	2.1264
02242163	Kadian	10mg	SR Cap	ABB	0.3680
02184435	Kadian	20mg	SR Cap	ABB	0.7151
02184443	Kadian	50mg	SR Cap	ABB	1.3526
02184451	Kadian	100mg	SR Cap	ABB	2.3592
02269074	Lipidil EZ	48mg	Tab	FOU	0.4187
02269082	Lipidil EZ	145mg	Tab	FOU	1.0720
02241602	Lipidil Supra	160mg	Tab	SPH	1.2823
00884502	Lupron Depot PDS	3.75mg	Inj-Kit	ABB	347.1800
02239834	Lupron Depot PDS	11.25mg	Inj-Kit	ABB	1034.4100
01919342	Luvox	50mg	Tab	SPH	0.8750
01919369	Luvox	100mg	Tab	SPH	1.5730
00716863	Lyderm	0.05%	Cr	TAR	0.2378
02236997	Lyderm	0.05%	Gel	TAR	0.3076
02236996	Lyderm	0.05%	Oint	TAR	0.3035
00611190	Marinol	2.5mg	Cap	SPH	2.0737
00611204	Marinol	5mg	Cap	SPH	4.1472
00389218	Novo-Gesic	325mg	Tab	NOP	0.0245
00482323	Novo-Gesic Forte	500mg	Tab	NOP	0.0285
00589861	Novo-Naprox	500mg	Tab	NOP	0.2244
00713449	Novo-Peridol	10mg	Tab	NOP	0.1792
00629324	Novo-Profen	200mg	Tab	NOP	0.0264
00629340	Novo-Profen	400mg	Tab	NOP	0.0468
00629359	Novo-Profen	600mg	Tab	NOP	0.1313
00603708	Rythmol	150mg	Tab	ABB	1.2426

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
00603716	Rythmol	300mg	Tab	ABB	2.1902
02172143	Synthroid	0.2mg	Tab	ABB	0.0837
02242680	Taro-Warfarin	1mg	Tab	TAR	0.0796
02242681	Taro-Warfarin	2mg	Tab	TAR	0.0841
02242682	Taro-Warfarin	2.5mg	Tab	TAR	0.0674
02242683	Taro-Warfarin	3mg	Tab	TAR	0.1043
02242684	Taro-Warfarin	4mg	Tab	TAR	0.1043
02242685	Taro-Warfarin	5mg	Tab	TAR	0.0675
02242687	Taro-Warfarin	10mg	Tab	TAR	0.1211
02243942	Teveten	600mg	Tab	SPH	1.0836
02253631	Teveten Plus	600mg & 12.5mg	Tab	SPH	1.0836
00598933	Tiamol	0.05%	Emol Cr	TAR	0.1980

New Manufacturer Name(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
00004715	Alkeran	2mg	Tab	TRT
02245828	Clasteon	400mg	Cap	SUO
00004626	Leukeran	2mg	Tab	TRT
00004618	Myleran	2mg	Tab	TRT
00602957	Ortho 7/7/7	3 Phase	Tab-21 Pk	JAN
00602965	Ortho 7/7/7	3 Phase	Tab-28 Pk	JAN
00894729	Terazol 7	0.4%	Cr	JAN
02275066	Trosec	20mg	Tab	SUO

Not-A-Benefit Drug(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
01934392	Amatine	2.5mg	Tab	SHI
01934406	Amatine	5mg	Tab	SHI
00579378	Desyrel	100mg	Tab	BQU
01937383	Duragesic 25	25mcg/hr	Trans Patch	JNO
01937391	Duragesic 50	50mcg/hr	Trans Patch	JNO
01937405	Duragesic 75	75mcg/hr	Trans Patch	JNO
01937413	Duragesic 100	100mcg/hr	Trans Patch	JNO
00030945	Provera	100mg	Tab	PFI

Therapeutic Note Change(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
02303922	Januvia	100mg	Tab	MFC

Treatment of Type 2 diabetes in patients on maximal doses of metformin (2000mg/day) who have:

- Inadequate glycemic control (defined as HbA1c>0.07) and intolerance or contraindication to a sulfonylurea; or
- An HbA1c less than or equal to 0.07 and elevated 2 hour post prandial glucose (PPG > 10 mmol/L) or fasting plasma glucose (FPG > 7 mmol/L) levels and intolerance or contraindication to a sulfonylurea; or
- Inadequate glycemic control (HbA1c>0.07) and on maximal doses of a sulfonylurea and for whom insulin is not an option.

02302063	Rasilez	150mg	Tab	NOV
02302071	Rasilez	300mg	Tab	NOV

NOTE: For patients with moderate hypertension who have not achieved blood pressure targets while on maximally optimized therapy with a thiazide-diuretic AND an Angiotensin Converting Enzyme Inhibitor (ACE-I) or a thiazide-diuretic AND Angiotensin II Receptor Blocker (ARB).

Rasilez (ALISKIREN) must not be used with the other classes of medications for the treatment of hypertension called Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin Receptor Blockers (ARBs) in patients with type 2 diabetes.

Discontinued Drug(s) (Removed From Payment & Listing)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
02230263	Apo-Cefaclor	250mg	Cap	APX
02230264	Apo-Cefaclor	500mg	Cap	APX
00370568	Benoxyl	10%	Lot	STI
00720933	Euglucon	2.5mg	Tab	PMS
02043033	Ovral	0.05mg & 0.25mg	Tab-21 Pk	WAY
02014270	Phyllocontin	225mg	SR Tab	PFP
02014289	Phyllocontin-350	350mg	SR Tab	PFP
02240331	PMS-Bezafibrate	200mg	Tab	PMS
09857306	PMS-Pamidronate	3mg/mL	Inj Sol-10mL Vial	PMS
02091186	PMS-Salbutamol	0.4mg/mL	O/L	PMS
02284057	Prezista	300mg	Tab	JAN
00622141	Zanosar		Inj Pd-1g Pk	PFI

Not-A-Benefit Drug(s) (Removed From Listing)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
02084082	Bezalip	200mg	Tab	HLR
02245998	PMS-Pamidronate	3mg/mL	Inj Sol-10mL Vial	PMS
02212390	Ventolin	0.4mg/mL	O/L	GSK

Palliative Care Drug(s)

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>
09857408	OxyNEO	10mg	CR Tab	PFP
09857409	OxyNEO	15mg	CR Tab	PFP
09857410	OxyNEO	20mg	CR Tab	PFP
09857411	OxyNEO	30mg	CR Tab	PFP
09857412	OxyNEO	40mg	CR Tab	PFP
09857413	OxyNEO	80mg	CR Tab	PFP

OxyNEO 10mg, 15mg, 20mg, 30mg, 40mg and 80mg tablets for cancer patients or palliative care patients for whom the prescriber is registered on the Palliative Care Facilitated Access List will be funded with the following 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, 3 months) of at least one other listed long-acting opioid product.

Note: For reimbursement of OxyNEO via the Facilitated Access mechanism, prescribers must be registered on the Palliative Care Facilitated Access List. To facilitate the reimbursement process at the pharmacy, the prescriber is asked to indicate "Cancer", "Palliative" or "P.C.F.A.", on the prescription to signify that the patient meets the above-noted eligibility criteria. This would be an indication to the pharmacist that these medications may be reimbursed under this mechanism.

Note: If prescriber is not registered on the Palliative Care Facilitated Access List, a request for funding of OxyNEO must be made through the EAP process based on the EAP criteria noted above.

Note: OxyNEO 60mg tablets are not funded.

Approval Period: 1 Year

Additional information on the Facilitated Access Mechanism can be found on Part VI of the ODB Formulary.

Status Change(s) from Not-A-Benefit to General Benefit.

<u>DIN</u>	<u>BRAND</u>	<u>STRENGTH</u>	<u>DOSAGE FORM</u>	<u>MFR</u>	<u>DBP</u>
00583413	Novo-Lexin	250mg	Tab	NOP	0.2250
00583421	Novo-Lexin	500mg	Tab	NOP	0.4500