

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – January 2018
Effective January 31, 2018

Drug Programs Policy and Strategy Branch
Ontario Public Drug Programs
Ministry of Health and Long-Term Care

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New Multi-Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02453908	Act Buprenorphine/Naloxone	2mg & 0.5mg	SL Tab	ACV	0.6675
02453916	Act Buprenorphine/Naloxone	8mg & 2mg	SL Tab	ACV	1.1825

(Interchangeable with Suboxone)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02457172	Mylan-Propafenone	150mg	Tab	MYL	0.2966
02457164	Mylan-Propafenone	300mg	Tab	MYL	0.5227

(Interchangeable with Rythmol)

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02459884	CCP-Letrozole	2.5mg	Tab	CCP	1.3780

(Interchangeable with Femara)

Reason For Use Code and Clinical Criteria

Code 365

For the treatment of metastatic breast cancer in hormone receptor positive post-menopausal women.

LU Authorization Period: Indefinite

Code 403

For the treatment of hormone receptor positive early breast cancer in postmenopausal women who have received 5 years of adjuvant tamoxifen therapy.

LU Authorization Period: 5 years

Code 408

As an alternative to tamoxifen for the adjuvant treatment of post-menopausal women with hormone receptor positive early breast cancer for a maximum of five years.

LU Authorization Period: 5 years

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02383381	Sandoz Moxifloxacin	400mg	Tab	SDZ	1.5230

(Interchangeable with Avelox)

Reason For Use Code and Clinical Criteria

For treatment of patients with:

Code 337

CAP with co-morbidity:

Community acquired pneumonia with co-morbid illnesses or failure to first-line therapy.

LU Authorization Period: 1 year

Code 338

COPD with risk:

Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) with risk factors*; bronchiectasis.

*Risk factors include: poor pulmonary lung function (FEV1 below 50% predicted level), age over 65 years, co-morbid medical illness (congestive heart failure, diabetes, chronic renal failure, chronic liver disease), chronic corticosteroid use, malnutrition, prolonged duration of disease or 4 or more exacerbations per year.

LU Authorization Period: 1 year

Code 339

Step-Down:

Step-down therapy after parenteral therapy or hospital / emergency department discharge.

LU Authorization Period: 1 year

Code 977

Exceptional cases of allergy or intolerance to all other appropriate therapies.

LU Authorization Period: 1 year

New Off-Formulary Interchangeable (OFI) Product

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02462486	Teva-Cyclosporine	0.05% w/v	Oph Emuls - 0.4mL Pk	TEV	2.9160

(Interchangeable with Restasis)

Transition from the Exceptional Access Program to General Benefit

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
00645575	Phenobarb Elixir	5mg/mL	Oral Elixir	PEN	0.1424/mL
00178799	Phenobarb	15mg	Tab	PEN	0.1399
00178802	Phenobarb	30mg	Tab	PEN	0.1665
00178810	Phenobarb	60mg	Tab	PEN	0.2257
00178829	Phenobarb	100mg	Tab	PEN	0.3088

Product Status Change from Palliative Care Facilitated Access to Limited Use

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/mL
02242484	Morphine Sulfate	2mg/mL	Inj Sol Amp	SDZ	2.2510
00392588	Morphine Sulfate	10mg/mL	Inj Sol Amp	SDZ	2.3860
02304090	Phenobarbital Sodium Injection USP	120mg/mL	Inj Sol-1mL Pk	SDZ	15.7000

Reason For Use Code and Clinical Criteria

Code 481

For the management of patients receiving palliative care*.

LU Authorization Period: 1 Year

*Note: The patient must have a progressive life-limiting illness and require this medication for palliative purposes.

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
09857226**	Morphine Sulfate	2mg/mL	Inj Sol Amp	SDZ
09857227**	Morphine Sulfate	10mg/mL	Inj Sol Amp	SDZ
09857296**	Phenobarbital Sodium Injection USP	120mg/mL	Inj Sol-1mL Pk	SDZ

**The use of this Palliative Care Facilitated Access (PCFA) PIN is discontinued as this product is transitioned to the Formulary as a Limited Use drug.

New and Revised Reason For Use Codes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02343541	Prolia (Preservative Free)	60mg/mL	Inj Sol-Pref Syr	AMG

New Reason For Use Codes

Code 515

To increase bone mass in males with osteoporosis who meet the following criteria:

- High risk* for fracture; and
- Failed other available osteoporosis therapy (i.e. fragility fracture OR evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence for one year.

*High fracture risk is defined as either:

- a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
- a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
- where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture

Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

LU Authorization Period: Indefinite

NOTE: 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 60 mg, once every 6 months.

New and Revised Reason For Use Codes (Continued)

Code 516

To increase bone mass in males with osteoporosis who meet the following criteria:

- High risk* for fracture; and
- For whom oral bisphosphonates are contraindicated due to hypersensitivity OR abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR inability to stand or sit upright for at least 30 minutes.

*High fracture risk is defined as either:

- a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
- a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
- where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture

Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

LU Authorization Period: Indefinite

NOTE: 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 60 mg, once every 6 months.

New and Revised Reason For Use Codes (Continued)

Revised Reason For Use Codes

Code 428

To increase bone mass in postmenopausal females with osteoporosis who meet the following criteria:

- High risk* for fracture; and
- Failed other available osteoporosis therapy (i.e. fragility fracture OR evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence for one year.

*High fracture risk is defined as either:

- a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
- a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
- where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture

Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

LU Authorization Period: Indefinite

NOTE: 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 60 mg, once every 6 months.

New and Revised Reason For Use Codes (Continued)

Code 429

To increase bone mass in postmenopausal females with osteoporosis who meet the following criteria:

- High risk* for fracture; and
- For whom oral bisphosphonates are contraindicated due to hypersensitivity OR abnormalities of the esophagus (e.g. esophageal stricture or achalasia) OR inability to stand or sit upright for at least 30 minutes.

*High fracture risk is defined as either:

- a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool; OR
- a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; OR
- where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture

Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

LU Authorization Period: Indefinite

NOTE: 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 60 mg, once every 6 months.

Changes to Reason For Use Content

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02426862	Aptiom	200mg	Tab	SUO
02426870	Aptiom	400mg	Tab	SUO
02426889	Aptiom	600mg	Tab	SUO
02426897	Aptiom	800mg	Tab	SUO
02404516	Fycompa	2mg	Tab	EIS
02404524	Fycompa	4mg	Tab	EIS
02404532	Fycompa	6mg	Tab	EIS
02404540	Fycompa	8mg	Tab	EIS
02404559	Fycompa	10mg	Tab	EIS
02404567	Fycompa	12mg	Tab	EIS
02357615	Vimpat	50mg	Tab	UCB
02357623	Vimpat	100mg	Tab	UCB
02357631	Vimpat	150mg	Tab	UCB
02357658	Vimpat	200mg	Tab	UCB

Revised Reason For Use Code Content

Code 430

As adjunctive therapy in the treatment of patients with partial onset seizures who have had an inadequate response or have significant intolerance to at least 3 less costly anticonvulsant therapies; AND

Patients are under the care of a physician experienced in the treatment of epilepsy.

Note: Less costly anticonvulsant therapies may include the following:

Phenytoin, Carbamazepine, Gabapentin, Lamotrigine, Vigabatrin, Topiramate, etc.

LU Authorization Period: Indefinite

Revised Therapeutic Note

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02452006	Apo-Emtricitabine-Tenofovir	200mg & 300mg	Tab	APX

(same Therapeutic Note as Truvada)

Revised Therapeutic Note

Prescribers should be informed and stay current with a drug's official indications in accordance with Health Canada's approved product monograph.

For the treatment of HIV/AIDS. The prescriber must be approved for the Facilitated Access to HIV/AIDS Drug Products mechanism.

For use as pre-exposure prophylaxis (PrEP) of HIV-1 in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults at high risk for infection, in accordance with Health Canada's approved product monograph. Approval for the Facilitated Access to HIV/AIDS Drug Products mechanism is not required.

Drug Benefit Price (DBP) Changes

DIN/PIN/ NPN	Brand Name	Strength	Dosage Form	Mfr	DBP/ Unit Price
02240521*	Maxalt	10mg	Tab	FRS	19.8854
02380242**	Zelboraf	240mg	Tab	HLR	34.5111
02247732	Concerta	18mg	SR Tab	JAN	2.3372
02250241	Concerta	27mg	SR Tab	JAN	2.6972
02247733	Concerta	36mg	SR Tab	JAN	3.0574
02247734	Concerta	54mg	SR Tab	JAN	3.7773
01968440	Cyclen	0.25mg & 0.035mg	Tab-21 Pk	JAN	25.4400
01992872	Cyclen	0.25mg & 0.035mg	Tab-28 Pk	JAN	25.4400
02243239	Eprex	20,000IU/0.5mL	Pref Syr - 0.5mL Pk	JAN	308.8300
02240722	Eprex	40,000IU/mL	Pref Syr - 1mL Pk	JAN	462.4300
02434407**	Imbruvica	140mg	Cap	JAN	94.1270
02306778	Intelence	100mg	Tab	JAN	6.1440
02375931	Intelence	200mg	Tab	JAN	12.0392
02300273	Invega	3mg	ER Tab	JAN	3.8660
02300281	Invega	6mg	ER Tab	JAN	5.7833
02300303	Invega	9mg	ER Tab	JAN	7.7080
02425483	Invokana	100mg	Tab	JAN	2.7627
02425491	Invokana	300mg	Tab	JAN	2.7627
00037605	Micronor	0.35mg	Tab-28 Pk	JAN	25.4400

* Off-Formulary Interchangeable (OFI) Product

** Exceptional Access Program (EAP) Product

*** Special Drug Program (SDP) Product PIN

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN/ NPN	Brand Name	Strength	Dosage Form	Mfr	DBP/ Unit Price
00789445	Pancrease MT4	4000 & 12000 & 12000 USP Units	Ent Microsph Cap	JAN	0.6928
09857784***	Pancrease MT4	4000 & 12000 & 12000 USP Units	Ent Microsph Cap	JAN	0.6928
02243796	Pariet	10mg	Tab	JAN	0.9522
02243797	Pariet	20mg	Tab	JAN	1.9047
02324024	Prezista	600mg	Tab	JAN	16.3420
02393050	Prezista	800mg	Tab	JAN	22.1720
02028700	Tri-Cyclen	3 Phase	Tab-21 Pk	JAN	25.4400
02029421	Tri-Cyclen	3 Phase	Tab-28 Pk	JAN	25.4400
02258560	Tri-Cyclen Lo	3 Phase	Tab-21 Pk	JAN	17.2000
02258587	Tri-Cyclen Lo	3 Phase	Tab-28 Pk	JAN	17.2000
02163934	Tylenol with Codeine No. 2	300mg & 15mg & 15mg	Tab	JAN	0.1243
02163926	Tylenol with Codeine No. 3	300mg & 15mg & 30mg	Tab	JAN	0.1369
02163918	Tylenol with Codeine No. 4	300mg & 60mg	Tab	JAN	0.2892
00556734	Vermox	100mg	Tab	JAN	6.0300
02239907	Topamax Sprinkle	15mg	Sprinkle Cap	JNO	1.2885
02239908	Topamax Sprinkle	25mg	Sprinkle Cap	JNO	1.3520
02240518*	Maxalt RPD	5mg	Orally Disintegrating Tab	MEK	19.8854
02240519*	Maxalt RPD	10mg	Orally Disintegrating Tab	MEK	19.8854

* Off-Formulary Interchangeable (OFI) Product

** Exceptional Access Program (EAP) Product

*** Special Drug Program (SDP) Product PIN

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN/ NPN	Brand Name	Strength	Dosage Form	Mfr	DBP/ Unit Price
02182815	Cozaar	25mg	Tab	MFC	1.7192
02182874	Cozaar	50mg	Tab	MFC	1.7192
02182882	Cozaar	100mg	Tab	MFC	1.7192
02245329	Fosamax	70mg	Tab	MFC	12.0244
02276429	Fosavance	70mg & 70mcg	Tab	MFC	5.1662
02314940	Fosavance	70mg & 140mcg	Tab	MFC	5.1662
02230047	Hyzaar	50mg & 12.5mg	Tab	MFC	1.7192
02297841	Hyzaar	100mg & 12.5mg	Tab	MFC	1.6832
02241007	Hyzaar DS	100mg & 25mg	Tab	MFC	1.7192
02010909	Proscar	5mg	Tab	MFC	2.3680
09857529	Proscar	5mg	Tab	MFC	2.3680
00708879	Vasotec	5mg	Tab	MFC	1.1827
00670901	Vasotec	10mg	Tab	MFC	1.4212
00670928	Vasotec	20mg	Tab	MFC	1.7150
02408090	Mylan-Buprenorphine/ Naloxone	2mg & 0.5mg	SL Tab	MYL	0.6675
02408104	Mylan-Buprenorphine/ Naloxone	8mg & 2mg	SL Tab	MYL	1.1825
00263818	Cotazym	8000 & 30000 & 30000 USP Units	Cap	ORG	0.2271
09857889***	Cotazym	8000 & 30000 & 30000 USP Units	Cap	ORG	0.2271
00502790	Cotazym ECS 8	8000 & 30000 & 30000 USP Units	Ent Microsph Cap	ORG	0.4099

* Off-Formulary Interchangeable (OFI) Product

** Exceptional Access Program (EAP) Product

*** Special Drug Program (SDP) Product PIN

Drug Benefit Price (DBP) Changes (Continued)

DIN/PIN/ NPN	Brand Name	Strength	Dosage Form	Mfr	DBP/ Unit Price
09857779***	Cotazym ECS 8	8000 & 30000 & 30000 USP Units	Ent Microsph Cap	ORG	0.4099
00821373	Cotazym ECS 20	20000 & 55000 & 55000 USP Units	Ent Microsph Cap	ORG	1.0749
09857780***	Cotazym ECS 20	20000 & 55000 & 55000 USP Units	Ent Microsph Cap	ORG	1.0749
02243910	Remeron	30mg	Tab	ORG	1.7460
02248542	Remeron RD	15mg	Orally Disintegrating Tab	ORG	0.5084
02248543	Remeron RD	30mg	Orally Disintegrating Tab	ORG	1.0163
02248544	Remeron RD	45mg	Orally Disintegrating Tab	ORG	1.5248
00323071	Diprosone	0.05%	Cr	SCH	0.2109
00344923	Diprosone	0.05%	Oint	SCH	0.2217
00417246	Diprosone	0.05%	Lot	SCH	0.2039
02318660	Olmotec	20mg	Tab	SCP	1.2437
02318679	Olmotec	40mg	Tab	SCP	1.2437
02319616	Olmotec Plus	20mg & 12.5mg	Tab	SCP	1.2437
02319624	Olmotec Plus	40mg & 12.5mg	Tab	SCP	1.2437
02319632	Olmotec Plus	40mg & 25mg	Tab	SCP	1.2437
02424851	Teva- Buprenorphine/ Naloxone	2mg & 0.5mg	SL Tab	TEV	0.6675
02424878	Teva- Buprenorphine/ Naloxone	8mg & 2mg	SL Tab	TEV	1.1825

* Off-Formulary Interchangeable (OFI) Product

** Exceptional Access Program (EAP) Product

*** Special Drug Program (SDP) Product PIN

Discontinued Products

(Some products will remain on Formulary for six months to facilitate depletion of supply)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02137534	Mylan-Alprazolam	0.25mg	Tab	MYL
02347512	Mylan-Carvedilol	3.125mg	Tab	MYL
02347520	Mylan-Carvedilol	6.25mg	Tab	MYL
02347555	Mylan-Carvedilol	12.5mg	Tab	MYL
02245649	Mylan-Ciprofloxacin	750mg	Tab	MYL
02230950	Mylan-Clonazepam	0.5mg	Tab	MYL
02248261	Mylan-Gabapentin	400mg	Cap	MYL
02229519	Mylan-Gliclazide	80mg	Tab	MYL
02368226	Mylan-Montelukast	10mg	Tab	MYL
02408392	Mylan-Rabeprazole	10mg	Tab	MYL
00369810	Tegretol	100mg	Chew Tab	NOV
00607762	Ratio-Morphine	1mg/mL	O/L	RPH
00607770	Ratio-Morphine	5mg/mL	O/L	RPH
00690783	Ratio-Morphine	10mg/mL	O/L	RPH
00690791	Ratio-Morphine	20mg/mL	O/L	RPH
02242067	Trileptal	150mg	Tab	NOV
02285827	Gd-Gabapentin	300mg	Cap	GEM

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
00000841	Isopto Carpine	1%	Oph Sol	ALC
02244816	Co Clomipramine	10mg	Tab	COB
02244817	Co Clomipramine	25mg	Tab	COB
02244818	Co Clomipramine	50mg	Tab	COB
02397145	Co Diclo-Miso	50mg & 200mcg	Tab	COB
02397153	Co Diclo-Miso	75mg & 200mcg	Tab	COB
02023725	Diocarpine	1%	Oph Sol	DKT
02248206	MetroLotion	0.75%	Top Lot	GAC
02285835	Gd-Gabapentin	400mg	Cap	GEM
02083558*	Relafen	750mg	Tab	GSK
02268094	Risperdal M-Tab	4mg	Orally Disintegrating Tab	JAN
00894729	Terazol 7	0.4%	Vag Cr	JAN
02239746	Novo-Moclobemide	100mg	Tab	NOP
02239747	Novo-Moclobemide	150mg	Tab	NOP
02240868*	Novo-Nabumetone	750mg	Tab	NOP
02061562	Lescol	20mg	Cap	NOV
02061570	Lescol	40mg	Cap	NOV
02147793	Klean-Prep		Pd-1 Kit	RIV
02287692	Ratio-Ramipril Cap	1.25mg	Cap	RPH
09857479**	Midazolam Inj. SDZ (Preservative Free)	5mg/mL	Inj Sol-1mL Pk	SDZ

* Off-Formulary Interchangeable (OFI) Product

** Palliative Care Facilitated Access (PCFA) PIN

