Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – April 2018

Effective April 30, 2018

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

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Ontario

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New Single Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02459779	Repatha	120mg/mL	Inj Sol-Pref Cart	EVOLOCUMAB	AMG	545.8000
02446057	Repatha	140mg/mL	Inj Sol-Pref Inj	EVOLOCUMAB	AMG	251.9100

Reason For Use Code and Clinical Criteria

Code 527

For the treatment of Heterozygous Familial Hypercholesterolemia (HeFH) in patients 18 years of age or older who meet the following criteria:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing;

AND

- Unable to reach Low Density Lipoprotein Cholesterol (LDL-C) target (i.e., LDL-C less than 2.0 mmol/L for secondary prevention) or at least a 50% reduction in LDL-C from untreated baseline despite:
  A. Confirmed adherence to high dose statin (e.g., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least a total of 3 months;

OR

  B. Confirmed adherence to ezetimibe for at least a total of 3 months and inability to tolerate high dose statin defined as:
    i. Inability to tolerate at least 2 statins with at least one started at the lowest starting daily dose; AND
    ii. For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) greater than 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether; AND
    iii. For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarker (creatine kinase (CK) greater than 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate; AND
    iv. One of the following:

New Single Source Products (Continued)

I. Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out; OR
II. Patient developed confirmed and documented rhabdomyolysis; OR
III. Patient is statin contraindicated i.e. active liver disease, unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal

Treatment with Repatha should be discontinued if the patient does not meet all of the following:

1. Patient is adherent to therapy.
2. Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of Repatha).
3. Patient continues to have a significant reduction in LDL-C (with continuation of Repatha) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months).

Patients prescribed Repatha 140mg every two weeks are limited to 26 prefilled syringes (PFS) per year. Patients prescribed Repatha 420mg every month must use the automated mini doser (AMD) and are limited to 12 AMD per year.

LU Authorization Period: 1 year

New Multi-Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02465949	Teva-Budesonide	0.125mg/mL	Inh Susp	TEV	0.1714

(Interchangeable with Pulmicort Nebuamp)

Reason For Use Code and Clinical Criteria

For the vast majority of patients, a metered dose inhaler is the preferred therapy. Nebulizer therapy will be reimbursed for patients who are unable to use a metered dose inhaler, including an inhaler with a spacer attachment, or a turbuhaler.

Code 260

Children aged 6 years or less.

LU Authorization Period: Indefinite

Code 261

Patients who have a tracheostomy.

LU Authorization Period: Indefinite

Code 262

Patients with cystic fibrosis in whom nebulizer therapy is indicated.

LU Authorization Period: Indefinite

Code 263

Patients with severe mental or physical disabilities.

LU Authorization Period: Indefinite

Code 264

Patients who have previously used nebulizer therapy within the last 12 month period.

LU Authorization Period: Indefinite

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02448319	Act Dextroamphetamine SR	10mg	SR Cap	ACV	0.8096
02448327	Act Dextroamphetamine SR	15mg	SR Cap	ACV	0.9898

(Interchangeable with Dexedrine Spansules)

Therapeutic Note

Stimulant medication should only be used when diagnostic criteria for narcolepsy or attention deficit disorder have been met and when stimulant medication has been demonstrated to produce clinical benefits. The use of conventional-release medication should almost always precede the use of extended-release preparations.

Notes: Patients greater than 6 years of age diagnosed with ADHD according to DSM-IV criteria and where symptoms are not due to other medical conditions which affect concentration, and who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following:

1) Patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; AND
2) Prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD; AND
3) Have been tried on methylphenidate immediate release (IR) or methylphenidate slow release (SR) or Dexedrine IR, and have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers, or societal barriers.

Administrative barriers include:

- inability of a school to dose the child at lunch;
- the school lunch hour does not coincide with the dosing schedule;
- poor compliance with noon or afternoon doses;
- the patient is unable to swallow tablets.

Societal barriers include:

- the patient or patient's caregiver(s) has(have) a history of substance abuse or diversion of listed immediate-release alternatives;
- the patient or patient's caregiver(s) is/are at risk of substance abuse or diversion of listed immediate-release alternatives

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02468840	Mint-Acitretin	10mg	Cap	MIN	1.2965
02468859	Mint-Acitretin	25mg	Cap	MIN	2.2770

(Interchangeable with Soriatane)

Therapeutic Note

This drug should be used with extreme caution in females of childbearing potential due to its teratogenicity. Effective contraception must be practised for at least 2 years following discontinuation.

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02289261	Apo-Perindopril	2mg	Tab	APX	0.1632
02459817	Auro-Perindopril	2mg	Tab	AUR	0.1632
02470675	PMS-Perindopril	2mg	Tab	PMS	0.1632
02470225	Sandoz Perindopril Erbumine	2mg	Tab	SDZ	0.1632
02464985	Teva-Perindopril	2mg	Tab	TEV	0.1632

(Interchangeable with Coversyl)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02289288	Apo-Perindopril	4mg	Tab	APX	0.2042
02459825	Auro-Perindopril	4mg	Tab	AUR	0.2042
02470683	PMS-Perindopril	4mg	Tab	PMS	0.2042
02470233	Sandoz Perindopril Erbumine	4mg	Tab	SDZ	0.2042
02464993	Teva-Perindopril	4mg	Tab	TEV	0.2042

(Interchangeable with Coversyl)

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02289296	Apo-Perindopril	8mg	Tab	APX	0.2831
02459833	Auro-Perindopril	8mg	Tab	AUR	0.2831
02470691	PMS-Perindopril	8mg	Tab	PMS	0.2831
02470241	Sandoz Perindopril Erbumine	8mg	Tab	SDZ	0.2831
02465000	Teva-Perindopril	8mg	Tab	TEV	0.2831

(Interchangeable with Coversyl)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02470411	Sandoz Perindopril Erbumine/ Indapamide LD	2mg & 0.625mg	Tab	SDZ	0.6338

(Interchangeable with Coversyl Plus LD)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02470438	Sandoz Perindopril Erbumine/ Indapamide	4mg & 1.25mg	Tab	SDZ	0.5113
02464020	Teva-Perindopril/Indapamide	4mg & 1.25mg	Tab	TEV	0.5113

(Interchangeable with Coversyl Plus)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02470446	Sandoz Perindopril Erbumine/ Indapamide HD	8mg & 2.5mg	Tab	SDZ	0.5718
02464039	Teva-Perindopril/Indapamide	8mg & 2.5mg	Tab	TEV	0.5718

(Interchangeable with Coversyl Plus HD)

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02442760	Auro-Risedronate	150mg	Tab	AUR	11.1875
(Interchangeable with Actonel)					

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02469987	Pharma-Simvastatin	10mg	Tab	PMS	0.2023
(Interchangeable with Zocor)					

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02231328	Apo-Fluoxetine	20mg/5mL	Oral Sol with Preservative	APX	0.5859

(Interchangeable with Prozac)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02463113	Reddy-Progesterone	100mg	Cap	DRR	1.4358

(Interchangeable with Prometrium)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02462788	Mar-Rizatriptan ODT	5mg	Orally Disintegrating Tab	MAR	11.1150
02462796	Mar-Rizatriptan ODT	10mg	Orally Disintegrating Tab	MAR	11.1150

(Interchangeable with Maxalt RPD)

Product Status Changes

Transition from the Exceptional Access Program to General Benefits

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02139375	Vancomycin Hydrochloride for Injection, USP	500mg/Vial	Inj-500mg Vial Pk	FKC	31.0500

(Interchangeable with Vancocin)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02139383	Vancomycin Hydrochloride for Injection, USP	1g/Vial	Inj-Vial Pk	FKC	58.9900

(Interchangeable with Vancocin)

Limited Use Criteria Changed and Facilitated Access HIV/AIDS Restriction Removed

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02024152	Diflucan P.O.S.	10mg/mL	O/L	PFI

Removed Reason For Use Codes

Current LU codes 274, 275, 276 and 277 are removed.

New Reason For Use Code and Clinical Criteria

Code 528

For patients who are unable to swallow or tolerate solid oral dosage forms.

LU Authorization Period: 12 months

Product Status Changes (Continued)

Transition Limited Use to General Benefit and Facilitated Access HIV/AIDS Restriction Removed

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02237370	Apo-Fluconazole	50mg	Tab	APX
02281260	Co Fluconazole	50mg	Tab	COB
02245292	Mylan-Fluconazole	50mg	Tab	MYL
02245643	PMS-Fluconazole	50mg	Tab	PMS
02236978	Teva-Fluconazole	50mg	Tab	TEV

(Interchangeable with Diflucan)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02237371	Apo-Fluconazole	100mg	Tab	APX
02281279	Co Fluconazole	100mg	Tab	COB
02245293	Mylan-Fluconazole	100mg	Tab	MYL
02245644	PMS-Fluconazole	100mg	Tab	PMS
02236979	Teva-Fluconazole	100mg	Tab	TEV

(Interchangeable with Diflucan)

Removed Reason For Use Codes

Current LU codes 202, 203, 204 and 205 are removed.

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
02424851	Teva-Buprenorphine/ Naloxone	TEV	PMS-Buprenorphine-Naloxone	PMS	2mg & 0.5mg	SL Tab
02424878	Teva-Buprenorphine/ Naloxone	TEV	PMS-Buprenorphine-Naloxone	PMS	8mg & 2mg	SL Tab

Drug Benefit Price (DBP) Changes

To view the DBP changes by DIN/PIN, the ministry has posted an Excel file with the details of the listing changes for download and review (Edition 43: Summary of Changes – Drug Benefit Price Changes – April 30, 2018). It is accessible from the ministry's website: http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx.

Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02416441*	Galexos	150mg	Cap	JAN
02278359	Mylan-Azithromycin	250mg	Tab	MYL
02351536	Mylan-Clopidogrel	75mg	Tab	MYL
02359480	Mylan-Donepezil	10mg	Tab	MYL
02245372	Mylan-Propafenone	150mg	Tab	MYL
02245373	Mylan-Propafenone	300mg	Tab	MYL
02242520	Mylan-Sertraline	50mg	Cap	MYL

* Exceptional Access Program (EAP) Product

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02237886	Mylan-Acebutolol (Type S)	200mg	Tab	MYL
02229813*	Mylan-Alprazolam	1mg	Tab	MYL
02397471*	Mylan-Gabapentin	600mg	Tab	MYL
02397498*	Mylan-Gabapentin	800mg	Tab	MYL

* Off-Formulary Interchangeable (OFI) Product


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