Ministry of Health and Long-Term Care

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – April 2019

Effective April 30, 2019

Drug Programs Policy and Strategy Branch
Drugs and Devices Division
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
02461749	Rexulti	0.25mg	Tab	BREXPIPRAZOLE	OTS	3.5000
02461757	Rexulti	0.5mg	Tab	BREXPIPRAZOLE	OTS	3.5000
02461765	Rexulti	1mg	Tab	BREXPIPRAZOLE	OTS	3.5000
02461773	Rexulti	2mg	Tab	BREXPIPRAZOLE	OTS	3.5000
02461781	Rexulti	3mg	Tab	BREXPIPRAZOLE	OTS	3.5000
02461803	Rexulti	4mg	Tab	BREXPIPRAZOLE	OTS	3.5000

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02473623	Siliq	210mg/1.5mL	Inj Sol Pref Syr	BRODALUMAB	VAL	645.000

Reason For Use Code and Clinical Criteria

Code 553

For the treatment of severe (see Note 1 below) plaque psoriasis in patients 18 years of age or older who have experienced failure, intolerance, or have a contraindication to adequate trials of several standard therapies (see Note 2 below).

Claims for the first 6 months must be written by a dermatologist. Monitoring of patients is required to determine if continuation of therapy beyond 12 weeks is required. Patients not responding adequately at 12 weeks should have treatment discontinued.

Approvals will only allow for standard dosing for Siliq 210mg subcutaneously at weeks 0, 1 and 2, and then every 2 weeks. If the patient has not responded adequately after 12 weeks of treatment at the Health Canada approved dose, higher doses are not recommended and the physician should consider switching to an alternative biologic agent.

New Single Source Products (Continued)

Note 1: Definition of severe plaque psoriasis:

- Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, AND
- Psoriasis Area and Severity Index (PASI) score of at least 10 (not required if there is involvement of the face, hands, feet or genital regions), AND
- Dermatology Life Quality Index (DLQI) score of at least 10.

Note 2: Definition of failure, intolerance or contraindication to adequate trials of standard therapies:

- 6 month trial of at least 3 topical agents including vitamin D analogues and steroids, AND
- 12 week trial of phototherapy (unless not accessible), AND
- 6 month trial of at least 2 systemic, oral agents used alone or in combination
    - Methotrexate 15-30mg per week
    - Acitretin (could have been used with phototherapy)
    - Cyclosporine

Maintenance/Renewal:

After 3 months of therapy, patients who respond to therapy should have:

- at least 50% reduction in PASI, AND
- at least 50% reduction in BSA involvement, AND
- at least a 5 point reduction in DLQI score

LU Authorization Period: 1 Year

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02475774	Juluca	50mg & 25mg	Tab	DOLUTEGRAVIR & RILPIVIRINE	VIH	34.8678

Therapeutic Note

As a complete regimen to replace the current antiretroviral (cARV) regimen for the treatment of human immunodeficiency virus (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies per mL).

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

New Single Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02458640	Lixiana	15mg	Tab	EDOXABAN	SEV	2.8400
02458659	Lixiana	30mg	Tab	EDOXABAN	SEV	2.8400
02458667	Lixiana	60mg	Tab	EDOXABAN	SEV	2.8400

Reason For Use Code and Clinical Criteria

Code 444

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) for up to six (6) months.

LU Authorization Period: 6 Months.

Note: The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60mg once daily following initial use of a parenteral anticoagulant for 5 to 10 days. Edoxaban 30 mg once daily is recommended in patients with one or more of the following clinical factors:

a) Moderate renal impairment (creatinine clearance (CrCL) 30-50 mL/min);

b) Low body weight less than or equal to 60 kg, and

c) Concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.

ODB Program coverage for edoxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, Edoxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

For clarity, coverage will not be provided for patients who have already received 6 months of treatment with apixaban or rivaroxaban for the same DVT or PE.

Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

New Single Source Products (Continued)

Code 554

INCLUSION CRITERIA:

At risk patients with non-valvular atrial fibrillation, for the prevention of stroke and systemic embolism AND in whom:

1. Anticoagulation is inadequate following at least a 2-month trial on warfarin;

OR

2. Anticoagulation using warfarin is contraindicated or not possible due to inability to regularly monitor the patient via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

EXCLUSION CRITERIA:

1. Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate less than 30 mL per min);

OR

2. Patients who are greater than or equal to 75 years of age and who do not have documented stable renal function;

OR

3. Patients who have hemodynamically significant rheumatoid valvular heart disease (especially mitral stenosis);

OR

4. Patients who have prosthetic heart valves.

NOTES:

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e., adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).

Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months.

New Single Source Products (Continued)

DOSING:

The usual recommended dose is 60mg once daily for the prevention of stroke and systemic embolisms in patients with nonvalvular atrial fibrillation is 60 mg once daily; a reduced dose of Edoxaban 30 mg once daily is recommended for patients in patients with one or more of the following clinical factors:

a) Moderate renal impairment (creatinine clearance (CrCL) 30-50 mL/min);
b) Low body weight less than or equal to 60 kg, and
c) Concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil.

Duration of therapy should be individualized after careful assessment of the treatment benefit against the individual risk of bleeding.

Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see edoxaban product monograph).

Patients starting edoxaban should have ready access to appropriate medical services to manage a major bleeding event.

There is currently no data to support that edoxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, edoxaban is not recommended for these patient populations.

LU Authorization Period: Indefinite

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02454858	Metoject Subcutaneous	15mg/0.3mL	Inj Sol-Pref Syr	METHOTREXATE SODIUM	MDX	32.7600/syr

New Single Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02457997	IZBA	0.003%	Oph Sol (with Preservative)	TRAVOPROST	NOV	3.9400/mL

Reason For Use Code and Clinical Criteria

Code 171

As first line treatment of elevated intraocular pressure in patients who cannot tolerate an ophthalmic beta-blocking agent or where beta-blocking agents are contraindicated.

LU Authorization Period: Indefinite

Code 172

As second line monotherapy or combination therapy in patients who do not have an adequate intraocular pressure lowering response to ophthalmic beta-blocking agents.

LU Authorization Period: Indefinite

Code 387

For use as adjunctive therapy with an ophthalmic beta-blocking agent in an urgent situation (e.g. patients with a high baseline intraocular pressure) where monotherapy is unlikely to be effective.

LU Authorization Period: Indefinite

New Multi-Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02482576	Sandoz Amoxi-Clav Tablet	500mg & 125mg	Tab	SDZ	0.7555
02482584	Sandoz Amoxi-Clav Tablet	875mg & 125mg	Tab	SDZ	0.5551

(Interchangeable with Clavulin)

Therapeutic Note

Amoxicillin/clavulanic acid is not recommended as first line treatment for acute otitis media and sinusitis. Antibiotic resistance (H. influenzae, M. catarrhalis) due to B-lactamase production has caused only a minority of treatment failures with amoxicillin. Amoxicillin/clavulanic acid is first line treatment for infected bites of cat, dog or human.

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02445808	Auro-Candesartan	16mg	Tab	AUR	0.2281
02445816	Auro-Candesartan	32mg	Tab	AUR	0.2281

(Interchangeable with Atacand)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02474786	Jamp-Enalapril	2.5mg	Tab	JPC	0.1863
02474794	Jamp-Enalapril	5mg	Tab	JPC	0.2203
02474808	Jamp-Enalapril	10mg	Tab	JPC	0.2647
02474816	Jamp-Enalapril	20mg	Tab	JPC	0.3195

(Interchangeable with Vasotec)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02477017	Jamp-Perindopril	4mg	Tab	JPC	0.2042
02477025	Jamp-Perindopril	8mg	Tab	JPC	0.2831

(Interchangeable with Coversyl)

New Multi-Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02476770	Mint-Perindopril	4mg	Tab	MIN	0.2042
02476789	Mint-Perindopril	8mg	Tab	MIN	0.2831

(Interchangeable with Coversyl)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02415305	Apo-Travoprost-Timop	0.004% & 0.5%	Oph Sol	APX	8.8425/mL

(Interchangeable with DuoTrav DIN 02278251)

Reason For Use Code and Clinical Criteria

Code 310

As second-line therapy for patients who do not have an adequate intraocular pressure lowering response to monotherapy with ophthalmic beta-blocking agents.

LU Authorization Period: Indefinite

Code 393

For use as initial therapy in an urgent situation (e.g. patients with a high baseline intraocular pressure) where monotherapy is unlikely to be effective.

LU Authorization Period: Indefinite

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02478900	Auro-Cinacalcet	30mg	Tab	AUR	10.1947
02478919	Auro-Cinacalcet	60mg	Tab	AUR	18.5900
02478943	Auro-Cinacalcet	90mg	Tab	AUR	27.0517

(Interchangeable with Sensipar)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02479451	Auro-Eletriptan	20mg	Tab	AUR	10.0850
02479478	Auro-Eletriptan	40mg	Tab	AUR	10.0850

(Interchangeable with Relpax)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02483610	Fulvestrant Injection	50mg/mL	Inj Sol-5mL Pref Syr Pk	SDZ	495.4600/Syr

(Interchangeable with Faslodex)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02428334	Auro-Gabapentin Tablets	600mg	Tab	AUR	1.3045
02428342	Auro-Gabapentin Tablets	800mg	Tab	AUR	1.7393

(Interchangeable with Neurontin)

New OFI Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02472120	Jamp-Moxifloxacin	0.5%	Oph Sol-3mL Pk (Preservative Free)	JPC	11.2700

(Interchangeable with Vigamox)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02472805	Zoledronic Acid for Injection	4mg/5mL	Inj Sol-5mL Pk (Preservative- Free)	MAR	415.5600

(Interchangeable with Zometa Concentrate)

Changes to Reason For Use Codes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02242145	Cellcept	200mg/mL	Pd for Oral Susp-175mL Pk	HLR

New Reason For Use Code and Clinical Criteria

Code 556

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

LU Authorization Period: Indefinite

Removed Reason For Use Code

Current LU code 190 is removed.

Transition from Limited Use to General Benefits

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02192748	Cellcept	250mg	Cap	HLR
02352559	Apo-Mycophenolate	250mg	Cap	APX
02386399	Jamp-Mycophenolate Capsules	250mg	Cap	JPC
02383780	Mycophenolate Mofetil Capsules	250mg	Cap	ACH
02364883	Novo-Mycophenolate	250mg	Cap	TEV
02320630	Sandoz Mycophenolate Mofetil	250mg	Cap	SDZ
02433680	Van-Mycophenolate	250mg	Cap	VAN

Current LU code 190 is removed.

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02237484	Cellcept	500mg	Tab	HLR
02352567	Apo-Mycophenolate	500mg	Tab	APX
02380382	Jamp-Mycophenolate	500mg	Tab	JPC
02378574	Mycophenolate Mofetil Tablets	500mg	Tab	ACH
02348675	Novo-Mycophenolate	500mg	Tab	TEV
02313855	Sandoz Mycophenolate Mofetil	500mg	Tab	SDZ
02432625	Van-Mycophenolate	500mg	Tab	VAN

Current LU code 190 is removed.

Transition from Exceptional Access Program to General Benefits

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02100606	Multi-12 Injection	N/A	Inj – 2x5mL Vial Pk	SDZ	23.0000/Pk
02242529	Multi 12/K1 Pediatric	N/A	Inj – 4+1mL Vial Pk	SDZ	41.8000/Pk
00781878	Vitamin K1 Inj 1mg/0.5mL USP	1mg/0.5mL	Inj-0.5mL Amp Pk (Preservative Free)	SDZ	5.2950/Amp
00804312	Vitamin K1 Inj 10mg/mL USP	10mg/mL	Inj-1mL Amp Pk (Preservative Free)	SDZ	6.0000/Amp

Manufacturer Name Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Current Mfr	New Mfr
01945939	Anusol Ointment	0.5%	Oint	JAJ	CDC

Product Brand and Manufacturer Name Changes

DIN/PIN	Current Brand Name	Current Mfr	New Brand Name	New Mfr	Strength	Dosage Form
01997602	Dantrium	JHP	Dantrium Capsules	EPI	25mg	Cap

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, 2019). 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
02417316	Apo-Ciclesonide	50mcg/Actuation	Metered Dose Nas Sp-120 Dose Pk	APX
02367866	Apo-Candesartan/HCTZ	16mg & 12.5mg	Tab	APX
02395126	Apo-Candesartan/HCTZ	32mg & 12.5mg	Tab	APX
02395134	Apo-Candesartan/HCTZ	32mg & 25mg	Tab	APX

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02253429*	Pegasys RBV	0.5mL Pref Syr & 42 Tabs	Combination Pk	HLR
09857418*	Pegasys RBV	0.5mL Pref Syr & 28 Tabs	Combination Pk	HLR
09857420*	Pegasys RBV	0.5mL Pref Syr & 35 Tabs	Combination Pk	HLR
09857421*	Pegasys RBV	0.5mL 4 Pref Syr Pk & 196 Tabs	Combination Pk	HLR
09857506*	Pegasys RBV ProClick Autoinjector	180mcg/0.5mL & 200mg x 28 Tabs	Combination Pk	HLR
09857507*	Pegasys RBV ProClick Autoinjector	180mcg/0.5mL & 200mg x 35 Tabs	Combination Pk	HLR
09857509*	Pegasys RBV ProClick Autoinjector	180mcg/0.5mL & 200mg x 42 Tabs	Combination Pk	HLR
09857510*	Pegasys RBV ProClick Autoinjector	4X180mcg/0.5mL & 200mgX196 Tabs	Combination Pk	HLR
02230087	Novo-Theophyl SR	300mg	LA Tab	NOP
00461008**	Theo-Dur	300mg	LA Tab	AZC
02097176	Ratio-Ipratropium UDV	125mcg/mL	Inh Sol-2mL UDV Pk	RPH

* Exceptional Access Program (EAP) Product

** Not-a-Benefit (NAB)


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