UPDATE AX
Ontario Drug Benefit
Formulary/Comparative Drug Index
No. 41
Effective August 29, 2013

SUMMARY OF CHANGES

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New Single

DIN	PRODUCT	GENERIC NAME	MFR	DBP
02394936	Seebri Breezhaler 50mcg Inh Pd-Cap	GLYCOPYRRONIUM BROMIDE	NOV	1.7700

Note: The dose of Seebri Breezhaler should not exceed 50mcg per day.

02377233	Eliquis 2.5mg Tab	APIXABAN	BQU	1.6000
02397714	Eliquis 5mg Tab	APIXABAN	BQU	1.6000

Reason for Use Code	Clinical Criteria
448	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 25mL/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).

DIN	PRODUCT	GENERIC NAME	MFR	DBP

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Reason for Use Code	Clinical Criteria

Notes:

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

Dosing: the usual recommended dose is 5mg twice daily; a reduced dose of apixaban 2.5mg twice daily is recommended for patients with at least two [2] of the following: age greater than or equal to 80 years old, body weight less than or equal to 60 kg, or serum creatinine greater than or equal to 133 micromole/litre.

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 apixaban product monograph).

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

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

LU Authorization Period: Indefinite.

New Multi-Source Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02408112	Auro-Valsartan HCT	80mg & 12.5mg	Tab	AUR	0.2958
02408120	Auro-Valsartan HCT	160mg & 12.5mg	Tab	AUR	0.2958
02408139	Auro-Valsartan HCT	160mg & 25mg	Tab	AUR	0.2958
02408147	Auro-Valsartan HCT	320mg & 12.5mg	Tab	AUR	0.2912
02408155	Auro-Valsartan HCT (Interchangeable with Diovan HCT)	320mg & 25mg	Tab	AUR	0.2912

02373068	Gd-Latanoprost/Timolol (Interchangeable with Xalacom)	50mcg/mL & 5mg/mL	Oph Sol-2.5mL Pk	GEM	11.0700

Reason for Use Code	Clinical Criteria
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.
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.

02406624	Jamp-Olanzapine ODT	5mg	Rapid Dissolve Tab	JPC	0.8937
02406632	Jamp-Olanzapine ODT	10mg	Rapid Dissolve Tab	JPC	1.7857
02406640	Jamp-Olanzapine ODT (Interchangeable with Zyprexa Zydis)	15mg	Rapid Dissolve Tab	JPC	2.6777

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02397781	Mint-Rosuvastatin	5mg	Tab	MIN	0.3225
02397803	Mint-Rosuvastatin	10mg	Tab	MIN	0.3400
02397811	Mint-Rosuvastatin	20mg	Tab	MIN	0.4250
02397838	Mint-Rosuvastatin	40mg	Tab	MIN	0.4975
	(Interchangeable with Crestor)				
02398370	PMS-Galantamine ER	8mg	ER Cap	PMS	1.2465
02398389	PMS-Galantamine ER	16mg	ER Cap	PMS	1.2465
02398397	PMS-Galantamine ER	24mg	ER Cap	PMS	1.2465
	(Interchangeable with Reminyl ER)				

Reason for Use Code	Clinical Criteria
347	Initial Trial: For patients with mild to moderate Alzheimer's Disease (Mini-Mental State Exam [MMSE] 10-26). Patients will be reimbursed for a period of up to 3 months after which continued treatment must be reassessed. Network note: Maximum duration 3 months. LU Authorization Period: 1 year.
348	Continuation: Further reimbursement will be made available to those patients whose disease has not progressed/deteriorated while on this drug. Patients must continue to have a MMSE score of 10-26. LU Authorization Period: 1 year.

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02402610	Ran-Lansoprazole	15mg	DR Cap	RAN	0.5000
02402629	Ran-Lansoprazole (Interchangeable with Prevacid)	30mg	DR Cap	RAN	0.5000

Reason for Use Code	Clinical Criteria
	Gastroesophageal Reflux Disease (GERD)
293	For the treatment of erosive GERD or upper GI malignancy; OR For the treatment of non-erosive GERD after failure of H2-receptor antagonist therapy. Patients with GERD should be reassessed within 6 months after initial treatment with a PPI. The reassessment could include confirmation of need for PPI with endoscopy, a trial of PPI withdrawal, or stepdown therapy to H2-receptor antagonist therapy. **Note:** There is a lack of published evidence to support double-dose PPI therapy in this setting. LU Authorization Period: 1 year
	H. pylori-positive Peptic Ulcers
295	For the treatment of H. pylori-positive peptic ulcers where H. pylori is documented, by serology, urea breath test or endoscopy, for a one-week course in combination with antimicrobial therapy. Retreatment of H. pylori-positive peptic ulcers must be documented by persistent H. pylori infection on urea breath test or endoscopy. Maximum duration: 7 days (for retreatment, a four-week period must elapse since the end of the previous treatment). LU Authorization Period: 1 year
	Confirmed Peptic Ulcers or NSAID-induced Ulcer Prophylaxis:
297	For the treatment of confirmed peptic ulcers and NSAID-induced ulcers; OR For the prophylaxis of NSAID-induced ulcers for patients at increased risk of GI bleeding. **Note:** There is a lack of published evidence to support double-dose PPI therapy in this setting. LU Authorization Period: 1 year
	Other Gastrointestinal Disorders
401	For the treatment of gastroduodenal Crohn's disease, short-gut syndrome, scleroderma, or pancreatitis. **Note:** There is a lack of published evidence to support double-dose PPI therapy in these settings LU Authorization Period: 1 year

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DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP

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Reason for Use Code	Clinical Criteria
402	**Severe Conditions:** For the treatment of severe esophagitis, Zollinger-Ellison syndrome, esophageal stricture, persistent symptoms of GERD or persistent erosive esophagitis, or upon hospital discharge following a gastrointestinal bleed. For patients receiving double-dose therapy, the need to continue treatment at higher doses should be reassessed after eight weeks. For re-treatment at higher doses, a four-week period should have elapsed from the end of the previous treatment. Reassessment could include a procedural assessment of the condition or step-down therapy to lower-dose proton pump inhibitor (PPI) therapy. LU Authorization Period: 1 year

02403064	Ran-Olanzapine	2.5mg	Tab	RAN	0.4493
02403072	Ran-Olanzapine	5mg	Tab	RAN	0.8986
02403080	Ran-Olanzapine	7.5mg	Tab	RAN	1.3479
02403099	Ran-Olanzapine	10mg	Tab	RAN	1.7972
02403102	Ran-Olanzapine (Interchangeable with Zyprexa)	15mg	Tab	RAN	2.6958

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02403617	Ran-Omeprazole DR Cap (Interchangeable with Losec DR Cap)	20mg		RAN	0.4117

Reason for Use Code	Clinical Criteria
	Gastroesophageal Reflux Disease (GERD)
293	For the treatment of erosive GERD or upper GI malignancy; OR For the treatment of non-erosive GERD after failure of H2-receptor antagonist therapy. Patients with GERD should be reassessed within 6 months after initial treatment with a PPI. The reassessment could include confirmation of need for PPI with endoscopy, a trial of PPI withdrawal, or step down therapy to H2-receptor antagonist therapy. **Note:** There is a lack of published evidence to support double-dose PPI therapy in this setting. LU Authorization Period: 1 year
	Confirmed Peptic Ulcers or NSAID-induced Ulcer Prophylaxis:
297	For the treatment of confirmed peptic ulcers and NSAID-induced ulcers; OR For the prophylaxis of NSAID-induced ulcers for patients at increased risk of GI bleeding. **Note:** There is a lack of published evidence to support double-dose PPI therapy in this setting. LU Authorization Period: 1 year
	Other Gastrointestinal Disorders
401	For the treatment of gastroduodenal Crohn's disease, short-gut syndrome, scleroderma, or pancreatitis. **Note:** There is a lack of published evidence to support double-dose PPI therapy in these settings LU Authorization Period: 1 year

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Reason for Use Code	Clinical Criteria
402	**Severe Conditions:** For the treatment of severe esophagitis, Zollinger-Ellison syndrome, esophageal stricture, persistent symptoms of GERD or persistent erosive esophagitis, or upon hospital discharge following a gastrointestinal bleed. For patients receiving double-dose therapy, the need to continue treatment at higher doses should be reassessed after eight weeks. For re-treatment at higher doses, a four-week period should have elapsed from the end of the previous treatment. Reassessment could include a procedural assessment of the condition or step-down therapy to lower-dose proton pump inhibitor (PPI) therapy. LU Authorization Period: 1 year

02397099	Ran-Quetiapine	25mg	Tab	RAN	0.1235
02397102	Ran-Quetiapine	100mg	Tab	RAN	0.3295
02397110	Ran-Quetiapine	200mg	Tab	RAN	0.6617
02397129	Ran-Quetiapine (Interchangeable with Seroquel)	300mg	Tab	RAN	0.9656

Off Formulary Interchangeable Product(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02406659	Jamp-Olanzapine ODT (Interchangeable with Zyprexa Zydis)	20mg	Rapid Dissolve Tab	JPC	7.5977
02406969	Jamp-Zopiclone Tablets (Interchangeable with Imovane)	5mg	Tab	JPC	0.2231
02393069	Mint-Sildenafil	25mg	Tab	MIN	8.2900
02393077	Mint-Sildenafil	50mg	Tab	MIN	8.8475
02393085	Mint-Sildenafil (Interchangeable with Viagra)	100mg	Tab	MIN	9.2000
02396106	Ran-Levetiracetam	250mg	Tab	RAN	1.1175
02396114	Ran-Levetiracetam	500mg	Tab	RAN	1.3650
02396122	Ran-Levetiracetam (Interchangeable with Keppra)	750mg	Tab	RAN	1.9425
02358077	Ran-Nabilone (Interchangeable with Cesamet)	0.25mg	Cap	RAN	1.3962

Drug Benefit Price(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02342138	PMS-Ramipril-HCTZ	2.5mg & 12.5mg	Tab	PMS	0.2093
02342146	PMS-Ramipril-HCTZ	5mg & 12.5mg	Tab	PMS	0.2069
02342162	PMS-Ramipril-HCTZ	5mg & 25mg	Tab	PMS	0.2069
02342154	PMS-Ramipril-HCTZ	10mg & 12.5mg	Tab	PMS	0.2633
02342170	PMS-Ramipril-HCTZ	10mg & 25mg	Tab	PMS	0.2633
02395444	Teva-Quetiapine XR	50mg	ER Tab	TEV	0.3950
02395452	Teva-Quetiapine XR	150mg	ER Tab	TEV	0.7780
02395460	Teva-Quetiapine XR	200mg	ER Tab	TEV	1.0520
02395479	Teva-Quetiapine XR	300mg	ER Tab	TEV	1.5440
02395487	Teva-Quetiapine XR	400mg	ER Tab	TEV	2.0960

New Manufacturer Name(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
00860689	Apo-Clorazepate	3.75mg	Cap	AAP
00860700	Apo-Clorazepate	7.5mg	Cap	AAP
00860697	Apo-Clorazepate	15mg	Cap	AAP
00808563	Apo-Triazo	0.125mg	Tab	AAP
00808571	Apo-Triazo	0.25mg	Tab	AAP
02248472	BenzaClin	1% & 5%	Top Gel	VAL
02097249	Cardizem CD	120mg	LA Cap	VAL
02097257	Cardizem CD	180mg	LA Cap	VAL
02097265	Cardizem CD	240mg	LA Cap	VAL
02097273	Cardizem CD	300mg	LA Cap	VAL
00029246	Delatestryl	1000mg/5mL Oily	Inj Sol-5mL Pk	VAL
02247238	Elidel	1%	Cr	VAL
02273217	Enablex	7.5mg	ER Tab	MEU
02273225	Enablex	15mg	ER Tab	MEU
02272903	Linessa 21	3 Phase	Tabs-21 Pk	MEK
02257238	Linessa 28	3 Phase	Tabs-28 Pk	MEK
09857292	Resultz	50%	Top Sol-120mL Pk	MEF
02279592	Resultz	50%	Top Sol-240mL Pk	MEF
02275090	Wellbutrin XL	150mg	Tab	VAL
02275104	Wellbutrin XL	300mg	Tab	VAL

Not-A-Benefit

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02401185	Lutera 21	100mcg & 20mcg	Tab 21-Pk	COB
02401207	Lutera 28	100mcg & 20mcg	Tab 28-Pk	COB
	(Interchangeable with Alesse)			

Trade Name Change(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02248472	BenzaClin Topical Gel	1% & 5%	Top Gel	SAV
00860689	Clorazepate	3.75mg	Cap	APX
00860700	Clorazepate	7.5mg	Cap	APX
00860697	Clorazepate	15mg	Cap	APX
00808563	Triazolam	0.125mg	Tab	APX
00808571	Triazolam	0.25mg	Tab	APX