UPDATE AV
Ontario Drug Benefit
Formulary/Comparative Drug Index
No. 41
Effective June 27, 2013

SUMMARY OF CHANGES

TABLE OF CONTENTS

New Single Source Drug(s)

DIN	PRODUCT	GENERIC NAME	MFR	DBP
01924559	Dexedrine Spansule 10mg SR Cap	DEXAMPHETAMINE SULFATE	PAL	0.9149
01924567	Dexedrine Spansule 15mg SR Cap	DEXAMPHETAMINE SULFATE	PAL	1.1186

Notes: Patients greater than 6 years of age diagnosed wtih 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 Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02247383	Euro-Lac	667mg/mL	O/L	EUR	0.0145
	(Interchangeable with Cephulac)				
02391473	Mar-Gabapentin	100mg	Cap	MAR	0.1060
02391481	Mar-Gabapentin	300mg	Cap	MAR	0.2578
02391503	Mar-Gabapentin	400mg	Cap	MAR	0.3072
	(Interchangeable with Neurontin)				
02402378	Mint-Sertraline	25mg	Cap	MIN	0.2038
02402394	Mint-Sertraline	50mg	Cap	MIN	0.4000
02402408	Mint-Sertraline	100mg	Cap	MIN	0.4458
	(Interchangeable with Zoloft)				
02399377	PMS-Atorvastatin	10mg	Tab	PMS	0.3138
02399385	PMS-Atorvastatin	20mg	Tab	PMS	0.3922
02399393	PMS-Atorvastatin	40mg	Tab	PMS	0.4216
02399407	PMS-Atorvastatin	80mg	Tab	PMS	0.4216
	(Interchangeable with Lipitor)				
02401665	PMS-Telmisartan-HCTZ	80mg & 12.5mg	Tab	PMS	0.2824
02401673	PMS-Telmisartan-HCTZ	80mg & 25mg	Tab	PMS	0.2824
	(Interchangeable with Micardis Plus)				
02396076	Ran-Topiramate	25mg	Tab	RAN	0.3128
02396084	Ran-Topiramate	100mg	Tab	RAN	0.5929
02396092	Ran-Topiramate	200mg	Tab	RAN	0.8854
	(Interchangeable with Topamax)				

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02395568	Teva-Candesartan/HCTZ	32mg & 12.5mg	Tab	TEV	0.5990
02395576	Teva-Candesartan/HCTZ (Interchangeable with Atacand Plus)	32mg & 25mg	Tab	TEV	0.5990
02343657	Teva-Letrozole (Interchangeable with Femara)	2.5mg	Tab	TEV	1.3780

Reason for Use Code	Clinical Criteria
365	For the treatment of metastatic breast cancer in hormone receptor positive post-menopausal women. LU Authorization Period: Indefinite.
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.
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.

Off Formulary Interchangeable Product(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02398591	Apo-Clopidogrel (Interchangeable with Plavix)	300mg	Tab	APX	9.5447
02365499	Apo-Naratriptan	1mg	Tab	APX	7.7725
02365502	Apo-Naratriptan (Interchangeable with Amerge)	2.5mg	Tab	APX	8.2125
02393484	Apo-Rizatriptan RPD	5mg	Orally Disintegrating Tab	APX	11.1150
02393492	Apo-Rizatriptan RPD (Interchangeable with Maxalt RPD)	10mg	Orally Disintegrating Tab	APX	11.1150
02242177	Co Fluoxetine (Interchangeable with Prozac)	10mg	Cap	COB	1.1773
02401894	Jamp-Fluoxetine (Interchangeable with Prozac)	10mg	Cap	JPC	1.1773
02402289	Jamp-Gabapentin Tablets	600mg	Tab	JPC	1.3045
02402297	Jamp-Gabapentin Tablets (Interchangeable with Neurontin)	800mg	Tab	JPC	1.7393
02403005	Jamp-Levetiracetam	250mg	Tab	JPC	1.1175
02403021	Jamp-Levetiracetam	500mg	Tab	JPC	1.3650
02403048	Jamp-Levetiracetam (Interchangeable with Keppra)	750mg	Tab	JPC	1.9425
02399776	Levetiracetam Tablets	250mg	Tab	ACH	1.1175
02399784	Levetiracetam Tablets	500mg	Tab	ACH	1.3650
02399792	Levetiracetam Tablets (Interchangeable with Keppra)	750mg	Tab	ACH	1.9425
02401657	PMS-Tramadol-Acet (Interchangeable with Tramacet)	37.5mg & 325mg	Tab	PMS	0.6264

Manufacturer Requested Discontinued Drug(s)
Please note that these discontinued products will remain on the formulary until the current stock is depleted.

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02313448	PMS-Atrovastatin	10mg	Tab	PMS
02313456	PMS-Atrovastatin	20mg	Tab	PMS
02313464	PMS-Atrovastatin	40mg	Tab	PMS
02313472	PMS-Atrovastatin	80mg	Tab	PMS
02252570	PMS-Ofloxacin	0.3%	Oph Sol	PMS
02239577	PMS-Tobramycin	0.3%	Oph Sol	PMS

Drug Benefit Price(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02242518	Actonel	5mg	Tab	WAR	1.9200
02239146	Actonel	30mg	Tab	WAR	12.4700
02316838	Actonel	150mg	Tab	WAR	44.7500
01997580	Asacol	400mg	Tab	WAR	0.5520
02267217	Asacol	800mg	Tab	WAR	1.0565
00687456	Viroptic	1%	Oph Sol	THE	3.1293

New Manufacturer Name(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
09857294	Humira	40mg/0.8mL	Inj Sol-Pref Pen Pk	ABV
02258595	Humira	40mg/0.8mL	Inj Sol-Pref Syr Pk	ABV
02243644	Kaletra	80mg/mL & 20mg/mL	O/L	ABV
02312301	Kaletra	100mg & 25mg	Tab	ABV
02285533	Kaletra	200mg & 50mg	Tab	ABV

Not-A-Benefit Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02280213	Avalide	300mg & 25mg	Tab	SAV
00546283	Capoten	25mg	Tab	BQU
02146118	Dilaudid-HP-Plus	20mg/mL	Inj	PFP
02145863	Dilaudid-XP	50mg/mL	Inj-1mL Pk	PFP
00885843	Lotensin	10mg	Tab	NOV
00010480	Tofranil	50mg	Tab	NOV

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

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02239044	Apo-Benzydamine	0.15%	Oral Rinse	APX
00402699	Apo-Carbamazepine	200mg	Tab	APX
00868949	Apo-Clonidine	0.1mg	Tab	APX
00868957	Apo-Clonidine	0.2mg	Tab	APX
02247937	Apo-Hydroxyurea	500mg	Cap	APX
00611158	Apo-Indomethacin	25mg	Cap	APX
00611166	Apo-Indomethacin	50mg	Cap	APX
00842826	Apo-Metoclop	5mg	Tab	APX
00842834	Apo-Metoclop	10mg	Tab	APX
02115514	Desocort	0.05%	Lot	GAC
02115522	Desocort	0.05%	Oint	GAC
00720941	Euglucon	5mg	Tab	PMS
00893773	Gen-Timolol	0.25%	Oph Sol	GEN
02352419	Jamp-Tamsulosin	0.4mg	Cap	JPC
00690244	M.O.S.-60	60mg	Tab	VAL
00611190	Marinol	2.5mg	Cap	SPH
00611204	Marinol	5mg	Cap	SPH
02257378	Mylan-Amilazide	5mg & 50mg	Tab	MYL
00454583	Phenazo	200mg	Tab	VAL

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

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02248732	Apo-Clonidine	0.025mg	Tab	APX
00476722	Pyridium	200mg	Tab	PDA

Limited Use Change(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02378604	Xarelto	15mg	Tab	BAH
02378612	Xarelto	20mg	Tab	BAH

Reason for Use Code	Clinical Criteria
435	For the prevention of stroke and systemic embolism in at-risk patients who have non-valvular atrial fibrillation (AF) **AND** in whom: 1) Anticoagulation is inadequate following a reasonable trial on warfarin; **OR** 2) Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e., no access to INR testing services at a laboratory, clinic, pharmacy, and at home). **Exclusion Criteria:** Patients who: (a) have impaired renal function (creatinine clearance or estimated glomerular filtration rate less than 30mL/min); **OR** (b) are greater than or equal to 75 years in age without documented stable renal function; **OR** (c) have hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; **OR** (d) have prosthetic heart valves. **Definitions and Clarification:** (a) "documented stable renal function" is defined as creatinine clearance or estimated glomerular filtration rate that maintained for at least 3 months (i.e., 30-49mL/min for 15mg once daily dosing or greater than or equal to 50mL/min for 20mg once daily dosing for at least 3 months). (b) "at-risk patients with atrial fibrillation" are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 score (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1. Continued on the next page:

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR

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Reason for Use Code	Clinical Criteria

Definitions and Clarification:

(c) "inadequate anticoagulation" is defined as INR testing results that are outside of 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).

(d) "a reasonable trial on warfarin" is defined as at least 2 months of therapy.

(e) 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 Xarelto product monograph).

(f) Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

(g) There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so rivaroxaban is not recommended in these populations.

LU Authorization Period: Indefinite

444 For the treatment of deep vein thrombosis (DVT) without symptomatic pulmonary embolism (PE) for up to six (6) months.

LU Authorization Period: 6 months.

Notes:

- The recommended dose of rivaroxaban for patients initiating DVT treatment is 15mg twice daily for 3 weeks, followed by 20mg once daily.
- ODB Program coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban 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.
- Since renal impairment can increase bleeding risk, it is impotant to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02296810	Lucentis	10mg/mL	Inj Sol-0.23mL Vial Pk	NOV

Reason for Use Code	Clinical Criteria
422	For the treatment of patients with new onset (< 3 months) neovascular (wet) age-related macular degeneration (AMD) in a verteporfin PDT (Visudyne)-naïve eye. Initial diagnosis should be confirmed by an appropriate diagnostic procedure and administration should be done by a qualified ophthalmologist experienced in intravitreal injections. Patients receiving concurrent administration of verteporfin PDT (Visudyne) are not eligible for reimbursement. Treatment should be initiated with a loading phase of one injection per month for three consecutive months, followed by a maintenance phase. During the maintenance phase, patients should be monitored for best corrected visual acuity or continued disease activity. If there is clinical or diagnostic evidence of disease activity such as a loss of greater than 5 letters in visual acuity (Early Treatment Diabetic Retinopathy Score (ETDRS) chart or one Snellen line equivalent), Lucentis may be administered. The interval between two doses should not be shorter than one month. LU Authorization Period: 1 year
439	For the treatment of patients with clinically significant diabetic macular edema (DME) for whom laser photocoagulation is also indicated; and a hemoglobin A1c of less than 11%. Treatment to be given monthly and continued until maximum visual acuity is achieved, confirmed by stable visual acuity for three consecutive monthly assessments performed while on Lucentis treatment. Thereafter patients should be monitored monthly for visual acuity. Treatment is resumed with monthly injections when monitoring indicates a loss of visual acuity due to DME and continued until stable visual acuity is reached again for three consecutive monthly assessments. LU Authorization Period: 1 year

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DIN	BRAND	STRENGTH	DOSAGE FORM	MFR

Continued from previous page

Reason for Use Code	Clinical Criteria
445	For the treatment of patients with clinically significant macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). Treatment to be given monthly and continued until maximum visual acuity is achieved, confirmed by stable visual acuity for three consecutive monthly assessments performed while on Lucentis treatment. Thereafter patients should be monitored monthly for visual acuity. Treatment is resumed with monthly injections when monitoring indicates a loss of visual acuity due to macular edema secondary to retinal vein occlusion and contined until stable visual acuity is reached again for three consecutive monthly assessments. LU Authorization Period: 1 year

Trade Name Change(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
09857369	PurAmino A+	5kcal/g	Pd-400g Pk	MJN