UPDATE D
Ontario Drug Benefit
Formulary/Comparative Drug Index
No. 41
Effective December 03, 2008

SUMMARY OF CHANGES

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New Single Source Drug(s)

DIN	PRODUCT	GENERIC NAME	MFR	DBP
02274728	Enbrel 50mg/mL Inj Pref Syr	ETANERCEPT	IMU	364.2800

NOTE: For the treatment of severe 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**.

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.

* 'severe plaque psoriasis' is defined as:
(i) Psoriasis Area and Severity Index (PASI) score of at least 10, and

(ii) Body Surface Area (BSA) involvement of at least 10%, or involvement of the face, hands, feet or genital regions, and

(iii) Dermatology Life Quality Index (DLQI) score of at least 10.

** 'failure, intoleranace or contraindication to adequate trials of standard therapies' is defined as:
(a) 6 month trial of at least 3 topical agents including vitamin D analogues and steroids, and

(b) 6 months trial of phototherapy (unless not accessible), and

(c) 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 a 50% reduction in PASI, and
- at least a 50% reduction in BSA involvement, and
- at least a 5 point reduction in DLQI score

Dosing Approved by Health Canada

Approvals will only allow for standard dosing for Enbrel (Etanercept): the recommended dose is 50mg subcutaneous twice weekly for 12 weeks followed by maintenance therapy at 25-50mg subcutaneous once weekly. The Committee to Evaluate Drugs noted that this is the Manufacturer's recommended dosing regimen, as approved by Health Canada. 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.

02251930	Lantus-(Cartridge) 100U/mL Inj Sol-5x3mL Pk	INSULIN GLARGINE	SAV	85.1700
02245689	Lantus-(Vial) 100U/mL Inj Sol-10mL Vial Pk	INSULIN GLARGINE	SAV	56.7800

DIN	PRODUCT	GENERIC NAME	MFR	DBP
02272504	Raptiva 150mg Inj Pd-Vial Pk	EFALIZUMAB	EMS	411.9225

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* 'severe plaque psoriasis' is defined as:
(i) Psoriasis Area and Severity Index (PASI) score of at least 10, and

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(a) 6 month trial of at least 3 topical agents including vitamin D analogues and steroids, and

(b) 6 months trial of phototherapy (unless not accessible), and

(c) 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 a 50% reduction in PASI, and
- at least a 50% reduction in BSA involvement, and
- at least a 5 point reduction in DLQI score

Dosing Approved by Health Canada

Approvals allow only for standard dosing for Raptiva (Efalizumab). The recommended dose is 0.7mg/kg subcutaneous initially followed by maintenance therapy at 1mg/kg subcutaneous every week. The Committee to Evaluate Drugs noted that this is the Manufacturer's recommended dosing regimen, as approved by Health Canada. 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.

02302063	Rasilez 150mg Tab	ALISKIREN	NOV	1.1400
02302071	Rasilez 300mg Tab	ALISKIREN	NOV	1.1400

NOTE: For patients with moderate hypertension who have not achieved blood pressure targets while on maximally optimized therapy with a thiazide-diuretic AND an Angiotensin Converting Enzyme Inhibitor (ACE-I) or a thiazide-diuretic AND Angiotensin II Receptor Blocker (ARB).

New Multi-Source Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02313901	Apo-Quetiapine	25mg	Tab	APX	0.2470
02313928	Apo-Quetiapine	100mg	Tab	APX	0.6590
02313936	Apo-Quetiapine	200mg	Tab	APX	1.3234
02313944	Apo-Quetiapine	300mg	Tab	APX	1.9313
	(Interchangeable with Seroquel)				
02316080	Co Quetiapine	25mg	Tab	COB	0.2470
02316099	Co Quetiapine	100mg	Tab	COB	0.6590
02316110	Co Quetiapine	200mg	Tab	COB	1.3233
02316129	Co Quetiapine	300mg	Tab	COB	1.9312
	(Interchangeable with Seroquel)				
02307804	Gen-Quetiapine	25mg	Tab	GEN	0.2470
02307812	Gen-Quetiapine	100mg	Tab	GEN	0.6590
02307839	Gen-Quetiapine	200mg	Tab	GEN	1.3234
02307847	Gen-Quetiapine	300mg	Tab	GEN	1.9313
	(Interchangeable with Seroquel)				
02284235	Novo-Quetiapine	25mg	Tab	NOP	0.2470
02284243	Novo-Quetiapine	100mg	Tab	NOP	0.6590
02284278	Novo-Quetiapine	200mg	Tab	NOP	1.3234
02284286	Novo-Quetiapine	300mg	Tab	NOP	1.9313
	(Interchangeable with Seroquel)				
02296551	PMS-Quetiapine	25mg	Tab	PMS	0.2470
02296578	PMS-Quetiapine	100mg	Tab	PMS	0.6590
02296594	PMS-Quetiapine	200mg	Tab	PMS	1.3234
02296608	PMS-Quetiapine	300mg	Tab	PMS	1.9313
	(Interchangeable with Seroquel)				
02303426	Sandoz Cefprozil	125mg/5mL	Oral Susp	SDZ	0.0791
02303434	Sandoz Cefprozil	250mg/5mL	Oral Susp	SDZ	0.1581
	(Interchangeable with Cefzil)				

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02296446	Sandoz Omeprazole Cap (Interchangeable with Losec DR Tab DIN # 02190915)	20mg		SDZ	1.1000
09857314	Sandoz Omeprazole (Interchangeable with Losec Cap DIN # 00846503)	20mg	Cap	SDZ	1.1000

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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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

02313995	Sandoz Quetiapine	25mg	Tab	SDZ	0.2470
02314002	Sandoz Quetiapine	100mg	Tab	SDZ	0.6590
02314010	Sandoz Quetiapine	200mg	Tab	SDZ	1.3233
02314029	Sandoz Quetiapine (Interchangeable with Seroquel)	300mg	Tab	SDZ	1.9312

Exceptional Access Product(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02282097	Orencia	250mg/Vial	Inj Pd-Vial Pk	BQU	440.0000

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
02231502	PMS-Diclofenac	25mg	Ent Tab	PMS
02231503	PMS-Diclofenac	50mg	Ent Tab	PMS
00846341	Sibelium	5mg	Cap	PMS

Drug Benefit Price(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02315866	Apo-Alfuzosin	10mg	Prolong-Rel Tab	APX	0.4966
02284227	Nexavar	200mg	Tab	BAY	45.0625

Off Formulary Interchangeable Product(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02246859	Apo-Feno-Super (Interchangeable with Lipidil Supra)	100mg	Tab	APX	0.7875
02309556	Novo-Cyproterone/Ethinyl Estradiol (Interchangeable with Diane-35)	2mg & 0.035mg	Tab-21 Pk	NOP	23.3394
02284251	Novo-Quetiapine (Interchangeable with Seroquel)	150mg	Tab	NOP	1.3518
02308444	Piperacillin & Tazobactam for Injection	2g & 250mg	Inj Pd-Vial Pk	APX	10.1300
02308452	Piperacillin & Tazobactam for Injection	3g & 375mg	Inj Pd-Vial Pk	APX	15.2000
02308460	Piperacillin & Tazobactam for Injection (Interchangeable with Tazocin)	4g & 500mg	Inj Pd-Vial Pk	APX	20.2700
02240334	Ratio-Tryptophan	500mg	Cap	RPH	0.4987
02240333	Ratio-Tryptophan	500mg	Tab	RPH	0.4987
02237250	Ratio-Tryptophan (Interchangeable with Tryptan)	1g	Tab	RPH	0.8978
02242686	Taro-Warfarin (Interchangeable with Coumadin)	6mg	Tab	TAR	0.2805

New Nutrition Product(s)

PIN	PRODUCT	MFR	COST/ PKG	AMT MOH PAYS	AMT PATIENT PAYS
A. COMPLETE POLYMERIC, 3. FIBRE CONTAINING					
09857310	Jevity 1.5 Cal 1.5kcal/mL Liq-1000mL Pk	ABB	11.5200	11.5200	0.0000
09857312	Jevity 1.5 Cal 1.5kcal/mL Liq-1500mL Pk	ABB	17.2800	17.2800	0.0000