UPDATE AZ
Ontario Drug Benefit
Formulary/Comparative Drug Index
No. 41
Effective October 31, 2013

SUMMARY OF CHANGES

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New Single Source Drug(s)

DIN	PRODUCT	GENERIC NAME	MFR	DBP
02373785	NYDA 50% w/w Top Sol-50mL Pk	DIMETHICONE	GPB	22.4200
02320681	Stelara 90mg/mL Inj Sol-Pref Syr Pk	USTEKINUMAB	JAN	4593.1400

Reason for Use Code	Clinical Criteria
419	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. *** 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. **** 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

DIN	PRODUCT	GENERIC NAME	MFR	DBP

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Reason for Use Code	Clinical Criteria

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

Approvals will only allow for standard dosing for Stelara 45mg to be administered at weeks 0, 4 and every 12 weeks thereafter. Alternatively, 90mg may be used in patients with a body weight of over 100 kg. In patients weighing over 100 kg, both the 45mg and 90mg doses were shown to be efficacious. However, 90mg was efficacious in a higher percentage of these patients. If the patient has not responded after 12 weeks of treatment, the physician should consider switching to an alternative biologic agent.

LU Authorization Period: 1 year

DIN	PRODUCT	GENERIC NAME	MFR	DBP
02371081	Xeomin 50 LD50 Units Pd for Inj-Vial Pk	CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A	MEZ	165.0000

Reason for Use Code	Clinical Criteria
130	To reduce the subjective symptoms and objective signs of cervical dystonia (spasmodic torticollis) in adults. LU Authorization Period: 1 Year
412	For the management of focal spasticity, due to stroke or spinal cord injury in adults. LU Authorization Period: 1 Year
421	For the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in adults. LU Authorization Period: 1 Year **Note**: Xeomin should be administered personally by a neurologist or a physician with equivalent post-graduate training and experience with neuromuscular disorders.

New Multi-Source Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02248499	Apo-Quinapril	5mg	Tab	APX	0.6867
02248500	Apo-Quinapril	10mg	Tab	APX	0.6867
02248501	Apo-Quinapril	20mg	Tab	APX	0.6867
02248502	Apo-Quinapril (Interchangeable with Accupril)	40mg	Tab	APX	0.6867
02408767	Apo-Quinapril/HCTZ	10mg & 12.5mg	Tab	APX	0.6865
02408775	Apo-Quinapril/HCTZ	20mg & 12.5mg	Tab	APX	0.6865
02408783	Apo-Quinapril/HCTZ (Interchangeable with Accuretic)	20mg & 25mg	Tab	APX	0.6512
02393824	Apo-Valganciclovir (Interchangeable with Valcyte)	450mg	Tab	APX	17.4093

Reason for Use Code	Clinical Criteria
374	For the treatment of CMV retinitis in patients with AIDS LU Authorization Period: 1 Year.

02408244	Jamp-Losartan HCTZ (Interchangeable with Hyzaar)	50mg & 12.5mg	Tab	JPC	0.3147
02408252	Jamp-Losartan HCTZ (Interchangeable with Hyzaar DS)	100mg & 25mg	Tab	JPC	0.3147
02407671	Sandoz Quetiapine XRT	50mg	ER Tab	SDZ	0.3950
02407698	Sandoz Quetiapine XRT	150mg	ER Tab	SDZ	0.7780
02407701	Sandoz Quetiapine XRT	200mg	ER Tab	SDZ	1.0520
02407728	Sandoz Quetiapine XRT	300mg	ER Tab	SDZ	1.5440
02407736	Sandoz Quetiapine XRT (Interchangeable with Seroquel XR)	400mg	ER Tab	SDZ	2.0960

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
02400022	Teva-Capecitabine	150mg	Tab	TEV	1.3725
02400030	Teva-Capecitabine (Interchangeable with Xeloda)	500mg	Tab	TEV	4.5750

Reason for Use Code	Clinical Criteria
346	For the first-line treatment of patients with metastatic colorectal cancer in whom combination chemotherapy is not recommended. **NOTE**: Not to be used in patients who have failed 5-flurouracil. LU Authorization Period: Indefinite.
360	For the treatment of metastatic breast cancer where patients have progressed after prior chemotherapy. LU Authorization Period: Indefinite.
406	For adjuvant treatment of stage 3 or high risk stage 2* colon cancer in patients who have completed surgery (within three months), who would normally be candidates for adjuvant chemotherapy with 5FU/LV. *high risk stage 2 colon cancer is defined as one of the following: - obstruction, - perforation, - poorly differentiated adenocarcinoma, - inadequate lymph node sampling, - T4 tumour. LU Authorization Period: 6 Months.
409	As part of the CAPOX regimen for the first-line and second-line treatment of metastatic colorectal cancer. LU Authorization Period: Indefinite.
426	In combination with trastuzumab and cisplatin for the treatment of patients with HER2-positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. LU Authorization Period: Indefinite.
427	For the neo-adjuvant treatment of rectal cancer. LU Authorization Period: Indefinite.

Off Formulary Interchangeable Product(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02410745	Apo-Lorazepam Sublingual	0.5mg	SLTab	APX	0.0875
02410753	Apo-Lorazepam Sublingual	1mg	SLTab	APX	0.1100
02410761	Apo-Lorazepam Sublingual (Interchangeable with Ativan Sublingual Tab)	2mg	SLTab	APX	0.1711

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
00021458	Novo-Ferrogluc	300mg	Tab	NOP
02253933	PMS-Ciprofloxacin	0.3%	Oph Sol-5mL Pk	PMS
02240682	PMS-Fluvoxamine	50mg	Tab	PMS
02240683	PMS-Fluvoxamine	100mg	Tab	PMS
00792942	PMS-Oxtriphylline	20mg/mL	O/L	PMS

Drug Benefit Price(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR	DBP
00545031	Apo-Ferrous Gluconate	300mg	Tab	APX	0.0360
02299909	Cubicin	500mg/10mL	Pd for Inj -10mL Vial Pk	SUO	177.0000
02063808	Dipentum	250mg	Cap	UCB	0.5228
02297809	Metrogel	1%	Top Gel	GAC	0.6149
00629324	Novo-Profen	200mg	Tab	NOP	0.0510
02246016	Thyrogen	0.9mg/mL	Inj Pd-2x1.1mg Vial Pk	GZM	1636.4600
02357615	Vimpat	50mg	Tab	UCB	2.4420
02357623	Vimpat	100mg	Tab	UCB	3.4278
02357631	Vimpat	150mg	Tab	UCB	4.5474
02357658	Vimpat	200mg	Tab	UCB	5.6096

New Manufacturer Name(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02230090	Apo-Pentoxifylline	400mg	SR Tab	AAP

Not-A-Benefit Drug(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02410788	Zamine 21 (Interchangeable with Yasmin 21)	3.0mg & 0.03mg	Tab-21 Pk	APX
02410796	Zamine 28 (Interchangeable with Yasmin 28)	3.0mg & 0.03mg	Tab-28 Pk	APX

Therapeutic Note Change(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02301881	Isentress	400mg	Tab	MFC

For use in combination with an optimized regimen, for the treatment of HIV-1 infection in treatment-experienced adult patients who cannot achieve complete viral suppression on multiple prior anti-retroviral regimens
AND who have one of the following:

- HIV-1 strains with documented resistance to at least one drug in each of the major classes of anti-retrovirals: protease inhibitors (PIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors (NRTIs); OR
- serious class-effect intolerance to PIs, NNRTIs and/or NRTIs precluding treatment with that antiretroviral class

- As part of a HIV treatment regimen for treatment-naive adult patients.

Note: For the treatment of HIV/AIDS, the prescriber must be approved for the Facilitated Access mechanism.

Trade Name Change(s)

DIN	BRAND	STRENGTH	DOSAGE FORM	MFR
02230090	Pentoxifylline SR	400mg	SR Tab	APX

New Diabetic Testing Agent(s)

PIN	PRODUCT	MFR	COST/ UNIT	AMT MOH PAYS	AMT PATIENT PAYS
09857454	MyGlucoHealth Test Strips	EHS	0.6851	0.6851	0.0000