

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 42

Summary of Changes – November 2016

Effective November 30, 2016

**Drug Programs Policy and Strategy Branch
Ontario Public Drug Programs**

Ministry of Health and Long-Term Care

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New Single Source Products

DIN/PIN	PRODUCT NAME, STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02435462	Forxiga 5mg Tab	DAPAGLIFLOZIN*	AZC	2.6200
02435470	Forxiga 10mg Tab	DAPAGLIFLOZIN*	AZC	2.6200

*Dapagliflozin is a Chronic-Use Medication

Therapeutic Note(s)

Added on to metformin for patients:

- Who have inadequate glycemic control on metformin and
- Who have a contraindication or intolerance to a sulfonylurea or
- For whom insulin is not an option.

Added on to a sulfonylurea for patients:

- Who have inadequate glycemic control on a sulfonylurea and
- Who have a contraindication or intolerance to metformin or
- For whom insulin is not an option.

New Multi-Source Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02452308	Jamp-Azithromycin	250mg	Tab	JPC	1.3070
02452324	Mar-Azithromycin	250mg	Tab	MAR	1.3070

(Interchangeable with Zithromax)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02417316	Apo-Ciclesonide	50mcg/Actuation	Metered Dose Nas Sp-120 Dose Pk	APX	19.3350

(Interchangeable with Omnaris)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02454807	Sandoz Diclofenac Ophtha	0.1%	Oph Sol	SDZ	1.7710

(Interchangeable with Voltaren Ophtha)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02454297	Act Escitalopram ODT	10mg	Orally Disintegrating Tab	ACV	1.3199
02454300	Act Escitalopram ODT	20mg	Orally Disintegrating Tab	ACV	1.4052

(Interchangeable Ciprolex Meltz)

New Multi-Source Products (Cont'd...)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02457989	Nat-Oseltamivir	75mg	Cap	NAT	3.1178

(Interchangeable with Tamiflu)

Reason For Use Code and Clinical Criteria

Code 371

For the prophylaxis (max: 75mg daily) of institutionalized individuals during confirmed* outbreaks of Influenza A or Influenza B.

NOTE: Network will limit supply to 6 weeks.

*The outbreak must be confirmed by Public Health.

LU Authorization Period: 1 year.

Code 372

For the treatment (max: 75mg bid) of institutionalized individuals during confirmed* outbreaks due to: Influenza B or, Influenza A (as an alternative to amantadine) or, Influenza A where new cases have developed despite amantadine prophylaxis.

NOTE: Network will limit supply to 5 days.

*The outbreak must be confirmed by Public Health.

LU Authorization Period: 1 year.

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02454645	Valacyclovir	500mg	Tab	SAI	0.8481

(Interchangeable with Valtrex)

Reason For Use Code and Clinical Criteria

Code 159

Herpes zoster in patients 50 years of age or older, up to 72 hours* after appearance of lesions. Dose: 1 gram 3 times/day for 7 days.

*The patient must begin treatment within the time frame specified for the product to be reimbursed. There is no benefit from the therapy begun after this time frame.

NETWORK NOTE: Network will limit supply to 7 days and 42 Tablets.

LU Authorization Period: 1 year.

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02417669	Nat-Alprazolam	2mg	Tab	NAT	0.5508
(Interchangeable with Xanax TS)					

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02398869	Indayo	0.03mg & 0.15mg	Tab-91 Pk	MYL	45.9550
(Interchangeable with Seasonale)					

Addition of Reason For Use Codes

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
02419475	Inflectra	100mg/Vial	Inj Pd Vial Pk	HOS

New Reason For Use Codes and Clinical Criteria in Addition to the Existing Codes

Code 477

For the treatment of ulcerative colitis disease in patients who meet the following criteria:

1. Moderate disease
 - a. Mayo score between 6 and 10 (inclusive) AND
 - b. Endoscopic* subscore of 2 AND
 - c. Failed 2 weeks of oral prednisone at daily doses greater than or equal to 40mg (or a 1 week course of IV equivalent) OR
 - d. Stabilized with 2 weeks oral prednisone at daily doses greater than or equal to 40mg (or 1 week of IV equivalent) but demonstrated that the corticosteroid dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated)

2. Severe disease
 - a. Mayo score greater than 10 AND
 - b. Endoscopy* subscore of greater than or equal to 2 AND
 - c. Failed 2 weeks of oral prednisone at daily doses greater than or equal to 40mg (or 1 week IV equivalent) OR
 - d. Stabilized with 2 weeks oral prednisone at daily doses greater than or equal to 40mg (or 1 week of IV equivalent) but the demonstrated that the corticosteroid dose cannot be tapered despite 3 months of AZA/6MP (or where the use of immunosuppressants is contraindicated)

* The endoscopy procedure must be done within the 12 months prior to initiation of treatment.

The recommended dosing regimen for induction is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks.

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and whose disease is maintained at Mayo score less than 6 AND who demonstrate at least 50% reduction in the dose of prednisone compared with the starting dose following the first 6 months of treatment with Inflectra or be off corticosteroids after the first year of treatment.

The recommended dosing regimen is 5mg/kg/dose every 8 weeks.

LU Authorization Period: 1 year

Addition of Reason For Use Codes (Cont'd...)

Code 478

For the treatment of moderate to severe (luminal) Crohn's Disease in patients who meet the following criteria:

- HBI (Harvey Bradshaw Index) score greater than or equal to 7; and
- Failed to respond to conventional treatment with a corticosteroid equivalent to a daily dose of prednisone 40mg daily for at least 2 weeks
OR the patient is stabilized on corticosteroid but cannot be tapered to a corticosteroid dose below prednisone 20mg daily or equivalent; and
- Failed to respond to an immunosuppressive agent (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) tried for at least 3 months (or where the use of immunosuppressants is contraindicated).

The recommended dosing regimen is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks. (Note: Higher doses up to 10mg/kg/dose may be considered in patients who have failed to respond to lower doses)

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria and whose disease is maintained with a 50% reduction in the Harvey Bradshaw Index(HBI) from pre-treatment measurement, AND improvement of symptoms (For example: absence of bloody diarrhea, weight is stable or increased), AND the use of corticosteroids and/or other immunosuppressive therapy is reduced, being tapered, or discontinued.

For funding beyond the second year, the patient must continue to demonstrate benefit and if unable to be discontinued on corticosteroids, the physician may wish to consider other funded alternatives.

The recommended dosing regimen is 5mg/kg/dose every 8 weeks.

LU Authorization Period: 1 year

Code 479

For the treatment of fistulizing Crohn's Disease in patients with actively draining perianal or enterocutaneous fistula(e) who meet the following criteria;

Fistula has persisted despite a course of antibiotic therapy (ciprofloxacin and/or metronidazole) and immunosuppressive therapy (azathioprine or 6-mercaptopurine).

The recommended dosing regimen is 5mg/kg/dose at 0, 2 and 6 weeks followed by 5mg/kg/dose every 8 weeks.

Maintenance/Renewal:

Maintenance therapy is funded for patients who meet the Ministry initiation criteria for fistulizing Crohn's disease and who have demonstrated benefit from treatment (e.g. partial resolution of fistulae and symptom improvement.).The recommended dosing regimen is 5mg/kg/dose every 8 weeks.

LU Authorization Period: 1 year

Product DIN Change

CURRENT DIN	NEW DIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
02210355	02450488	Mylan-Verapamil SR	180mg	LA Tab	MYL

Product Brand and Manufacturer Name Changes

DIN/PIN	CURRENT BRAND NAME	CURRENT MFR	NEW BRAND NAME	NEW MFR	STRENGTH	DOSAGE FORM
02308894	Granisetron	AAP	Apo-Granisetron	APX	1mg	Tab

Drug Benefit Price (DBP) Change

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02441020	Apo-Diclofenac Ophthalmic	0.1%	Oph Sol	APX	1.7710

OFI Product Price Change

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	Unit Cost
02441144	Auro-Rizatriptan	6.25mg	Tab	AUR	11.1150

Discontinued Products

(Some products will remain on Formulary for six months to facilitate depletion of supply)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
02285819	Gd-Gabapentin	100mg	Cap	GEM
02254581*	Pegetron Clearclick	80mcg/0.5mL & 200mg/Cap	Inj Pd & 56 Caps Combination Kit	MEK
02254603*	Pegetron Clearclick	100mcg/0.5mL & 200mg/Cap	Inj Pd & 56 Caps Combination Kit	MEK
02254638*	Pegetron Clearclick	120mcg/0.5mL & 200mg/Cap	Inj Pd & 70 Caps Combination Kit	MEK
02254646*	Pegetron Clearclick	150mcg/0.5mL & 200mg/Cap	Inj Pd & 84 Caps Combination Kit	MEK
02246026*	Pegetron	50mcg/0.5mL & 200mg/Cap	Inj Pd & 56 Caps Combination Kit	MEK
02246030*	Pegetron	150mcg/0.5mL & 200mg/Cap	Inj Pd & 84 Caps Combination Kit	MEK
02210355	Mylan-Verapamil SR	180mg	LA Tab	MYL
02210363	Mylan-Verapamil SR	240mg	LA Tab	MYL
02240457	Novo-Nizatidine	150mg	Cap	NOP
02240458	Novo-Nizatidine	300mg	Cap	NOP
02244646	Ratio-Aclavulanate 125F	25mg & 6.25mg/mL	O/L	RPH
02244647	Ratio-Aclavulanate 250F	50mg & 12.5mg/mL	O/L	RPH

*Exceptional Access Program product

